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ORIGINAL RESEARCH

A feasible lifestyle program for early intervention in patients with chronic obstructive pulmonary disease (COPD): a pilot study in primary care

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Abstract

Aim: To evaluate the feasibility of a lifestyle program for early intervention in patients with COPD in a primary care population.

Methods: The study was performed in a Primary Health Care Centre in Western Sweden. During a four-week period, all smokers between 40-70 years of age were invited to answer a questionnaire and to perform spirometry. The intervention program included a specially designed smoking cessation program and programs for physical activity and diet.

Results: 84 smokers were included. 42% fulfilled the criteria for COPD. All of the COPD patients were in GOLD stage I and II. Among the COPD subjects, 38% were underweight and 56% had a low fat-free mass – both together indicating malnutrition and the need for nutritional treatment. By the end of the intervention program, 47% of the COPD patients had stopped smoking.

Conclusions: The intervention program was feasible and effective with a very high smoking cessation rate.

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The full version of this paper, with online Appendix, is available at www.thepcrj.org

Introduction

Chronic obstructive pulmonary disease (COPD) is a major health problem worldwide. In 2020, the World Health Organisation predicts that it will be the third most common cause of death.[1] Swedish studies have shown that about 8% of the population over the age of 46 have COPD, but only about 40% of these have a known diagnosis.[2] Most COPD patients in Sweden are cared for in the primary health care system. In a recently published study from Finland, general practitioners (GPs) handled 38% of all exacerbations of COPD.[3]

Access to spirometry is increasing in primary care. In Sweden, about 90% of the Primary Health Care Centres (PHCCs) provide spirometry testing.[4] National and international studies, however, demonstrate that COPD is under-diagnosed,[5] and it is reported that primary care physicians seldom use spirometry to diagnose COPD amongst smokers or people with respiratory symptoms.[6] In fact, COPD may not always be associated with symptoms; in a study on male middle-aged smokers, Geijer and co-workers found that mild COPD was not related to the presence of symptoms.[7]

In Sweden, smoking is the major risk factor for COPD. A report from the National Lung Health Education Program in

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the USA recommends that smokers over 45 years of age should undergo spirometry irrespective of the presence of symptoms.[8] It is possible to identify COPD patients in primary care using active spirometry screening.[5,9] However, it is not clear what benefit is achieved by such screening; a recent review reported a lack of intervention studies evaluating spirometry screening in relation to smoking cessation programs.[10] Nevertheless, in The Lung Health Study,[11] middle-aged heavy smokers with mild COPD showed good results in terms of smoking cessation following a complex stop-smoking program. There is a need for smoking cessation methods suitable for use in primary care.

Nutritional status among COPD patients has been well studied in secondary care, especially among patients with severe COPD. However, studies in primary care with milder COPD patients are scarce.

Positive results have been shown for special nurse-led management for COPD patients in primary care.[12] A recently published study from the Netherlands concluded that a structured model for COPD care involving different disciplines improved both the care process itself as well as some patient outcomes both for COPD and asthma.[13]

The aim of this study, therefore, was to evaluate the feasibility of a lifestyle program for early intervention in patients with COPD in a primary care population. Lifestyle changes included a program for smoking cessation, dietary counselling, and physical training by special trained staff. The effectiveness of the smoking cessation program was evaluated separately.

Materials and methods

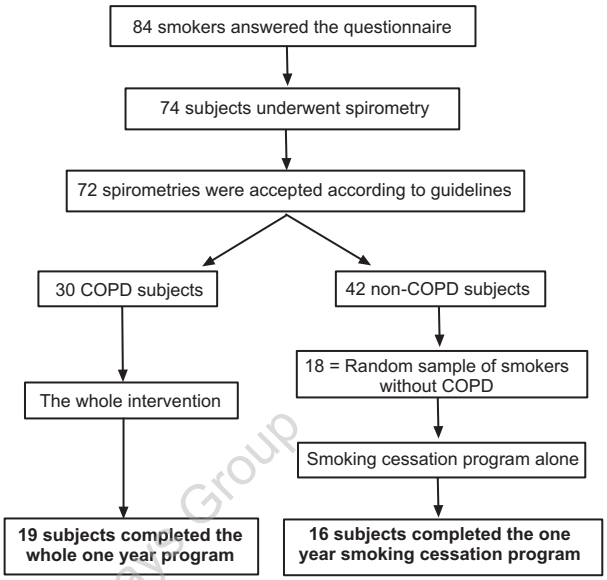
Design and setting

This was a prospective intervention study performed in a PHCC in Western Sweden. The centre had access to spirometers and three specialist COPD-trained nurses educated in spirometry and smoking cessation procedures.

Screening procedure

Over a four-week period, all smokers between 40-70 years of age (of both sexes) who attended the PHCC, irrespective of the reason, were invited to take part in the study. They were asked to complete a short questionnaire with items on smoking habits, medications, respiratory symptoms, allergies, occupational history and nutritional status. They were then invited to a standardised spirometry examination performed according to American Thoracic Society (ATS) guidelines.[14] COPD was defined according to the national guidelines [www.slmf.se/kol] which are very similar to the Global initiative on Obstructive Lung Disease (GOLD) guidelines [www.goldcopd.com] – i.e., FEV_1/FVC or VC <0.7, not normalised after inhalation of a β_2-agonist, and in subjects over 65 years of age FEV_1/FVC or VC <0.65.

Figure 1. The number of subjects participating in the study.



Study population

Among the 84 smokers who answered the questionnaire, 74 people accepted the invitation to undergo spirometry. Of these, 72 spirometry tracings were acceptable according to ATS criteria. The number of subjects in the study is illustrated in Figure 1. Smokers who fulfilled the criteria for COPD were included in the intervention part. To evaluate if the smoking cessation model was a suitable clinical method for primary health care, a random group of smokers (18 out of 42) without COPD was also included. Nineteen (63%) of the COPD patients completed the whole intervention program. The most common causes of dropout were lack of time for attending. Other causes were moving from the area and other serious diseases.

Intervention program

Included subjects were evaluated before and after one year of the program with respect to lung function, different symptoms, health-related quality of life, and smoking cessation rate verified by exhaled carbon monoxide (CO). The intervention program included a specially designed smoking cessation program and counseling programs on physical activity and diet.

Questionnaires

Airway symptoms and health-related quality of life were evaluated with the St George´s Respiratory Questionnaire (SGRQ) and the Clinical COPD Questionnaire (CCQ).[15] SGRQ has a validated Swedish version. CCQ is a short questionnaire developed for primary care use; it contains ten questions, distributed into the different domains of "symptoms", "functional state" and "mental state".

Depressive symptoms were registered by the Prime-MD

questionnaire.[16] The occurrence of incontinence was registered with five short standardised questions.

Nutritional status

Nutritional status was evaluated with a nutrition screening form and measurement of Body Mass Index (BMI). In all COPD patients, arm muscle circumference (AMC) and Fat-Free Mass (FFM) were calculated. AMC was calculated as the circumference of the arm and "triceps skin fold", i.e. panniculus on the back of the brachium.[17] To calculate FFM further anthropometric measurements were taken of "biceps skin fold" (panniculus on the front of the brachium), "sub scapula skin fold" (panniculus below the scapula) and "supra iliac skin fold" (panniculus over the iliac). Skinfold thickness was measured by using the Harpenden skinfold caliper (Baty International, UK). Together with information about age, sex, height and weight, FFM was calculated using Durnin and Womersley's equations.[18] The FFMI (fat-free mass index) was calculated as FFM (kg) divided by body height^2 (m). Based on previous studies on COPD patients, subjects were considered as malnourished using the following cut-off levels: BMI ≤21, FFMI ≤15 (females) and ≤16 (males).[19]

Dietary assessment

A dietician collected dietary intake data from the subjects by using the 7- day food record method. The quantities of food eaten were described in household measures as the number of units consumed (cups, glasses, spoons, number of slices, pieces, decilitres). Dietary analyses were performed with the software Dietist XP (Food & Nutrition data Ltd, Bromma, Sweden) which was based on data from the Swedish National Food Administration.

Physical activity

All patients were instructed by a physiotherapist in breathing exercises and breathing technique according to their different needs. The Bronchitis aid tube (BA-tube) was used both for transportation of phlegm and as a breathing exercise.

All COPD patients were offered individual treatment by a dietician and a physiotherapist at one visit. Furthermore, group educational sessions with dietary advice and physical activity were performed twice.

Smoking cessation

The model for smoking cessation was based on a validated model recommended for primary care (see Appendix 1 at www.thepcrj.org).[20] Smoking cessation was verified by measuring CO in exhaled air with a CO measuring device (EC50 Smokerlyzer) where the cut off level for being smoke free was 6 parts per million (ppm).[21]

Statistics

Descriptive statistics were used for prevalence data. For comparison between groups, Fisher's exact test was used for dichotomous variables, two sample t-test for normal distributed and Mann-Whitney test for non-normal continuous variables. Effects after the intervention program

Table 1. Background characteristics of the subjects.

		Questionnaire				Spirometry			
		All	Male	Female	p-value	All	COPD	Non COPD	p-value
Answered the questionnaires	N	84	32	51	-	72	30	42	-
Mean age	Years	55	57	56	0.55	56	58	55	0.05
Pack years	Years	28	31	27	0.22	27	31	27	0.27
Educational level-low	%	43.9	43.8	43.1	0.57	46.6	51.6	46.3	0.35
Educational level-middle	%	48.8	53.1	45.1	0.31	45.2	41.9	48.8	0.44
Educational level-high		7.3	3.1	7.8	0.36	5.5	6.5	4.9	0.56
Employed	%	51.4	65.6	49.0	0.10	52.1	51.6	51.2	0.58
Have had occupational exposures of vapors, gases, dust or smoke	%	37.3	63.3	20.0	<0.001	6.4	48.1	30.0	0.11
Airway symptoms as seeking cause	%	13.0	16.7	12.5	0.42	13.2	21.4	7.3	0.09
Reporting chronic bronchitis	%	18.8	25.8	14.9	0.18	19.1	20.7	17.5	0.49
Respiratory medication	%	20.5	6.3	28.0	0.01	20.8	22.6	19.0	0.47
Reported atopic manifestations	%	28.8	37.5	20.0	0.07	29.2	40.0	20.9	0.07
Former attempt to stop smoking	%	75.3	71.9	74.0	0.51	75	73.3	76.7	0.47
BMI	Kg/m^2	26.8	28.0	26.2	0.16	26.9	25.8	27.5	0.19
CCQ total		1.24	1.38	1.15	0.28	1.25	1.42	1.11	0.17

COPD=Chronic Obstructive Pulmonary Disease, BMI=Body Mass Index, CCQ=Clinical COPD Questionnaire

Table 2. Spirometry results.

		ALL	COPD	Non COPD	p-value
Correctly performed spirometries	n %	72	30 42	42 58	-
Male	n %	24	15 61	9 39	
Female	n %	48	15 31	33 69	
FEV_1	l	2.54	2.36	2.67	0.06
FVC	l	3.49	3.79	3.38	0.04
GOLDstage I (FEV_1 ≥80%)	%		57		-
GOLDstage II (FEV_1 50-79%)	%		43		-
GOLDstage III (FEV_1 30-49%)	%		0		-
GOLDstage IV (FEV_1 <30%)	%		0		-

COPD=Chronic obstructive pulmonary disease; GOLD=Global initiative of Obstructive Lung Disease (GOLD) guidelines; FEV_1=Forced expiratory volume in one second; FVC=Forced volume capacity

Table 3. Nutrition values of the COPD patients who completed a 7 –day food record. Dietary data represents the daily energy and nutrient intake.

		All n=16 mean (SD)	Female n=11mean (SD)	Male n=5 Mean (SD)	Recommendations
Age	years	62 (4)	64 (5)	63 (4)	
BMI	kg/m^2	24.9 (5.2)	25.2 (5.5)	24.2 (5.2)	BMI 22-29 [19]
FFMI	kg/m^2	16.2 (3)	15.5 (2.8)	17.6 (3.7)	Female FFMI >15 [19] Male FFMI >16
FEV_1	l	2.18	1.95	2.68	-
FVC	l	3.59	3.35	4.09	-
Energy	kcal	1726 (352)	1647 (312)	1901 (406)	2.200 kcal [22]
Fat	E %	37 (7)	37 (6)	36 (9)	30 [22] , 45 [29]
Carbohydrate	E %	44 (6)	45(5)	41 (8)	55 [22] , 35-45 [29]
Protein	E %	17 (3)	16 (2)	18 (3)	15 [22] , 18-20 [29]
Calcium	mg/day	767 (193)	744 (207)	816 (170)	800 mg [22]
Vitamin C	mg/day	96 (47)	104 (51)	78 (36)	75 mg [22]
Carotene	µg/day	1.8 (1.3)	2,1 (1,4)	1 (1)	-
Vitamin D	µg/day		All 5.8 (2.2)	All 8.0 (2.0)	
<60 years ≥61 years		5.9 (2.3) 6.8 (2.4)	5.8 (2.5) 6.0 (2.1)	7.0 (0.0) 8.0 (2.5)	<60 years = 7,5µg [22] ≥61 years = 10 µg [22]
Vitamin E	mg α-Te	7.0 (1.0)	7.0 (1.0)	7.2 (2.0)	Female = 8 mg [22] Male = 10 mg [22]
Fruit & vegetables	g/day	303 (168)	343 (156)	214 (173)	≥ 500 [22]

BMI=Body Mass Index; Reference value for COPD: BMI ≤ 21=underweight, BMI ≥30=overweight [19, 29]; FFMI=Fat Free Mass Index; Reference value for COPD. Values below these could indicate the need of nutritional treatment [19]; E%=Proportion of energy intake in percent

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compared to before were calculated with Paired samples t-test and Wilcoxon rang sum test. Correlations were tested with Spearman and Person correlation tests.

Ethical approval

The study was approved by The Ethics Committee at the University of Gothenburg.

Results

During the four-week screening period, 746 patients 40-70 years of aged attended the PHCC. The total number of persons listed at the PHCC aged 40-70 at that time was 4669. It was not possible to calculate the number of smokers among these persons, but using the overall prevalence of smokers in Sweden (about 14%, see http://www.fhi.se/templates/Page_12664.aspx) the numbers of smokers aged 40-70 in the PHCC area should be about 653 (0.14 x 4669) and the number of smokers attending the PHCC during the screening period should therefore be about 104 (0.14 x 746). The questionnaire was answered by 84 smokers (61% women and 39% men), corresponding to approximately 81% (84/104) of the total smokers aged 40-70 in the PHCC.

The background characteristics are presented in Table 1. A significantly higher proportion of females used respiratory medication and a higher proportion of males reported chronic bronchitis as compared with females (non significant). No significant difference was found between the groups (COPD/non-COPD) with respect to occupational exposure for dust or smoke. However, males were significantly more exposed than females.

Among the COPD patients, 20% reported depressive complaints of any kind and 10% reported trouble with urinary leakage. A statistically significant correlation was found between CCQ and SGRQ (r_{xy}=0,56; p<0.01).

The spirometry results are presented in Table 2. 42% of the screened subjects fulfilled the criteria for COPD. All of the COPD patients were in GOLD stage I and II. A minority of

Table 4. Subjects participating in the intervention program. Baseline and outcome measures after one year intervention.

		COPD	Non-COPD	p-value
Baseline:	N	19	16	
Mean age	years	54	62	0.001
Educational level – low	%	42.1	33.3	0.74
Pack years	years	31.1	30.8	0.96
After one year: Stopped smoking	n %	9 47.4	3 18.8	0.77
Pharmacological treatment for smoking cessation	n %	3 15.8	13 72.2	0.001
CO	n ppm	18 9.1	13 14.5	0.66
ΔBMI	n kg/m²	19 -0.48		
ΔFEV_1	n l	19 -0.07	16 -0.03	0.69
ΔFVC	n l	19 -0.22	16 -0.05	0.23
ΔCCQ	n	18 -0.18	16 -0.24	0.82

		COPD			Non-COPD		
		Stop smoking*	Smokers*	p-value	Stop smoking*	Smokers*	p-value
ΔBMI	n Kg/m²	9 -1.77	10 -0.69	0.21	-	-	-
ΔFEV_1	n l	9 -0.05	10 -0.07	0.08	3 0.13	13 -0.04	0.91
ΔFVC	n l	9 -0.17	10 -0.27	0.44	3 -0.06	13 -0.04	0.09
ΔCCQ	n	8 -0.31	10 -0.07	0.003	2 -0.15	11 -0.25	0.16

Δ=difference between baseline values and results after one year intervention; *= after one years´ intervention

them reported airway symptoms as the primary cause for seeking help (21%). There were more males compared to females with COPD (61% vs 31%, p=0.05).

Of the COPD patients, 22 attended the nutrition and physical program. Sixteen of these filled out a 7-day food record. The nutritional data is presented in Table 3. Six subjects (38%) had a BMI ≤21 and nine subjects (56%) had a FFMI below the reference values. Three subjects (18%) had a BMI >30. Eleven subjects (68%) had a calcium intake below Swedish nutritional recommendations and 14 (87%) had vitamin D intake below these recommendations. Furthermore, the intake of fruit and vegetables was below the recommendations in 15 (93%) of the subjects.[22]

The intervention results are presented in Table 4. At the end of the intervention program, 47% of the COPD patients had stopped smoking. The corresponding result amongst the smokers without COPD was three subjects (19%). There was a significantly less proportion of COPD patients using pharmacological treatment during the smoking cessation program as compared with non-COPD subjects. In the COPD group, those who had succeeded with the smoking cessation after one year had significantly improved their CCQ score, indicating a higher health-related quality of life, as compared with those who continued to smoke. There was no significant difference in SGRQ scores between the two groups.

The time spent with the COPD patients during the intervention period was estimated. The nurse spent about 230 minutes/patient, dealing with the questionnaires, spirometries, measurements of CO in exhaled air and BMI, research protocols and the smoking cessation program. The GP spent 60 minutes/patient including two visits lasting 30 minutes each. The dietician and the physiotherapist spent one hour individually/patient and then together gave two 30-minute group sessions with the patients. The time spent with the COPD patients included all visits during one year, including emergency visits due to exacerbations.

Discussion

The lifestyle program seems to be feasible and effective with a very high smoking cessation rate. The health-related quality of life was also higher among those who had succeeded with smoking cessation after one year. The nutrition data suggest that underweight and malnutrition can develop early in COPD disease. The spirometry screening procedures found a rather high proportion of smokers with COPD indicating that COPD is a common disease among smokers in a primary care population.

The spirometry screening was linked to a structured program for smoking cessation. The smoking cessation rate was higher in the COPD group and this suggests that the diagnosis itself is a motivating factor as in previous studies – Stratelis and coworkers[23] found a higher smoking cessation rate among smokers who had spirometry-diagnosed COPD compared with other smokers, and similar findings have been reported in a British study.[24] These data reinforce the importance of performing spirometry in smokers.

As early COPD can be asymptomatic,[7] spirometry is the only way to detect the disease. All COPD patients found in this study were in the early stages of the disease (GOLD stages I and II), when stopping smoking is effective in preventing further rapid decline in lung function.

There was a significant gender difference, where males were more likely to have COPD. This may be explained by a higher occupational exposure to dust and smoke among males. However, gender was not considered as a covariate in the analyses due to the small number of subjects included.

A significant correlation was found between the SGRQ and CCQ scores. This is interesting, since the SGRQ is thought to be the "gold standard" in COPD research. The CCQ is more convenient as it contains less items. A significant improvement in CCQ but not in SGRQ was found among those who had quit smoking after one year. These findings are similar to those reported by van der Molen *et al*,[15] indicating that CCQ has a higher responsiveness than SGRQ.

Malnutrition is common in COPD patients and increases with the degree of illness; this can start to develop in the early stage of the disease. Among the COPD subjects, 38% were underweight and 56% had a low FFM, together indicating malnutrition and need of nutritional treatment. Underweight and low FFM in COPD has previously been linked to reduced quality of life and muscle strength, the risk of development of osteoporosis, and increased mortality.[25]

There are several methods available for measurements of body composition and FFM such as skinfold anthropometry (SFA), bioelectrical-impedance (BIA) and dual energy X-ray absorptiometry (DEXA). We used SFA as a rather simple and inexpensive method suitable for every PHCC. Previous methodological studies on body composition measurement in COPD show that the results are fairly similar but SFA measurements may overestimate the FFM values compared with the other methods.[26] If this is true, it would strengthen the indication of malnutrition found in this study among the COPD patients.

Osteoporosis is a multifactorial disease and several risk factors are present in COPD subjects. In our study, the dietary intake of calcium and vitamin D was found to be below recommended levels; this is a risk factor – especially in combination with low body weight and low FFMI – for development of osteoporosis in COPD. The subjects in our study had a fruit and vegetable consumption below the recommendation of 500g per day. Similar results have been found in previous studies on smokers, where a lower consumption of fruits and vegetables compared to non-

smokers was reported.[27] Previous studies have also shown a positive association between a high consumption of fruits and vegetables and lung function.[28]

The nurse spent about 230 minutes/patient including time dealing with questionnaires, spirometries, measuring CO in exhaled air and BMI, research protocols and the smoking cessation program. Is this a lot of time? In comparison, the smoking cessation program alone at the Sahlgrens´ Hospital, Gothenburg, Sweden requires 270 minutes of therapist/patient time. The time spent with the GP was similar to what is recommended in the Swedish national guidelines.[29]

In conclusion, the lifestyle program seems to be feasible and effective with a very high smoking cessation rate. Health-related quality of life was higher among those who had succeeded with smoking cessation after one year. The nutrition data suggest that underweight and malnutrition can develop early in COPD. This was a pilot study; the results are therefore based on a small number of subjects, must be interpreted with caution, and should be verified in a larger study which includes a control group.

Conflict of interest declarations

The authors declare no conflict of interest.

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Appendix 1 Smoking cessation program:

Visit 1

- A Guide for interviewing the patient about tobacco habits was used (former attempts to give up smoking, social status and physical and mental health).
- Fagerströms´ test for nicotine dependence where the subject has to answer eight different questions and every question scores from 0-2 and then adds up (30).

- Five motivational questions were posed:
  - How interested are you in give up smoking? Score 0-10.
  - How important is it for you to give up smoking? Score 0-10
  - What can give you a higher score on that scale?
  - How certain are you to succeed if you make up your mind to give up smoking?
  - What kind of problems do you have due to your smoking?

- A "Cross of ambivalence" where four different domains are penetrated. What is positive with giving up smoking and what is positive with continuing to smoke? What is negative with giving up smoking and what is negative with continuing to smoke?

- Two different forms were distributed to be filled out at home:
  - Registration of tobacco use during twenty-four hours (what time, occupation, what kind of feeling when smoking)
  - Investigation of high risk situations followed by the patient giving suggestions of strategies to avoid these situations
- Carbon monoxide (CO) measurement in exhaled air
- The subject decided a day of smoking stop

Follow-up by phone

- A telephone call the day before smoking stop
- A telephone call the day after smoking stop
- A telephone call once a week in three weeks
- After three weeks, a telephone call once every second week until Visit 2 at three months.

The telephone calls followed a structured schedule with standardized questions regarding smoking status, present plan/strategy and motivation.

Visit 2 after three months

- Assess if smoke free
- CO measurement in exhaled air
- Evaluating and discussing the forms filled out at home
- Ask the motivational questions (see above)

Visit 3 after twelve months

- Assess if smoke free
- CO measurement in exhaled air
- Spirometry

The subjects could be offered pharmacological treatment, either in the form of different Nicotine Replacement Treatments (NRTs) or bupropion during the program.