The effect of a simple intervention on the health status in patients with COPD: a randomized controlled trial

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ANR: 152017

Running head: Efficacy of an intervention for COPD patients

Numbers of words in manuscript: 4115

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Tilburg, 2009

Abstract

Objective: To assess the effects of a simple motivation intervention on the HS in patients with COPD and to investigate whether the intervention leads to more supplementary treatment at a pulmonary outpatient clinic.

Methods: In this randomized control trial, the sub domains of HS were measured by completing the Nijmegen Clinical Screening Instrument (NCSI) at baseline and at six-months follow-up. The patients who scored in the abnormal range on the NCSI at baseline were allocated to an intervention group or an usual care group. The intervention consisted of discussing the results of the NCSI, graphically expressed on a patient profile chart (PPC), and was carried out by a pulmonary nurse three months after the initial assessment.

Results: One hundred and fifty-four of the 303 participants were randomized into the intervention group and usual care group. The number of patients completing both assessments were 59 and 62 respectively. At six-month follow-up, the intervention group reported significantly less problems with respect to Fatigue in comparison with the usual care group (Wilks' lambda= 0.96, $F(1,119)= 5.00$, $p= 0.03$, ES= 0.04). However, this improvement appeared not to be clinically relevant. In addition, the intervention group received significantly more supplementary treatment ($\chi^2(3)= 10.01$; $p= 0.019$).

Conclusions: The intervention resulted in diverse treatment referrals by the pulmonary nurse and lead to significantly higher rates of supplementary treatment. This suggests that the NCSI and the intervention can be helpful in identifying the problems in HS and can contribute to more patient-tailored care. However, after six months, the intervention had only a limited effect on patients' HS.

Keywords: COPD, health status, usual care, motivation intervention, randomized controlled trial.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is defined as 'a disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of lungs to noxious particles or gases' [1]. COPD leads to persistent symptoms of dyspnoea, cough, sputum production, and tiredness [2]. COPD constitutes a major public health problem, and is currently the fourth leading cause of chronic morbidity and mortality in the world [3]. It has a major impact on the utilization of health care resources [4]. Further increases in the prevalence and mortality of the disease can be predicted in the coming decades because of socio-demographic factors as ageing and cigarette smoking patterns [2].

Health Status (HS) is severely affected in patients with COPD [5-8]. Recently, there has been a growing body of research concerning endpoints that are assessed directly by patients [5,9]. HS is one of these widely applied patient-reported health outcomes [5-7,9,10]. For example, HS is used as an index for the clinical significance of a treatment effect [7,11]. However, there is no consensus about the definition of HS. The concepts of HS, health-related quality of life, quality of life, complaints, and functional impairment are often used interchangeably [3,7,10,12-14]. Nevertheless, most general theories in the lung literature define HS as an overall concept consisting of four conceptually distinct main domains: physiological functioning, complaints, functional impairment in daily life, and quality of life [3,7,9]. One framework goes a step further by postulating that the four domains of HS consist of 15 independent sub domains [3]. This implies that integral assessment of HS requires measuring all sub domains. To the best of our knowledge, this is the only framework that also composed a battery of instruments to measure all these sub domains of HS [3, 25]. Therefore, this framework will be used.

The majority of patients with COPD experience problems in HS [6,7], but are poorly motivated to adopt adequate health behaviours [15,16]. An important factor contributing to this problem is the way usual care is organised for patients with COPD [21,2]. Traditionally, usual care is characterized by a predominant medical focus and less emphasis is placed upon the patient's complaints, functional impairments in daily life or quality of life [8,17]. However, numerous studies have shown that physiological functioning is relatively independent from these domains [6,7,9,17,18]. As a consequence, the assessment of physiological processes does not provide a complete picture of patients with COPD [3,5,7,9,19]. Similarly, treatment exclusively directed at improving physiological functioning will have little effect on the patient's complaints, functional impairments in daily life or quality of life. Other problems characterizing the usual care for COPD patients are the phenomena doctor delay and patient delay [20]. Patients do not present their problems to their physician because of poor recognition of their symptoms [7] or because they attribute their symptoms to their smoking habit and ageing (patient delay) [21]. Moreover, physicians underestimate the symptoms and fail to diagnose the disease, sometimes until it has progressed considerably (doctor delay) [20-22] As a result, serious problems in complaints, functional impairments or quality of life are identified in a later stage, both by patients and doctors, and consequently are left untreated until then. For many patients, this may lead to deterioration in the domains of HS [20,21,23]. To reduce the future burden of the disease for patients, physicians and society, early identification and intervention is important [24].

To ensure early identification of HS problems, an instrument is needed that helps the physician to identify these problems. Until recently, no instrument existed that identified impairments in all domains of HS and was suitable for clinical practice. To overcome this problem, the Nijmegen Clinical Screening Instrument (NCSI) was developed [25]. The NCSI is an evidence-based battery of instruments that provides a detailed assessment of all the sub

domains of HS in patients with COPD. It has adequate psychometric properties [25] and is short and simple enough to warrant use in usual care.

Second, an intervention is needed that helps patients to get insight into the factors that elucidate their problems in HS and to motivate them to adopt more adequate health behaviours. In the past decade, this notion has been increasingly acknowledged as witnessed by the increasing development of self-management programs [26,27]. Similarly, in rehabilitation programs active cooperation and participation of patients are seen as key factors in successful management [20,28]. Therefore, a simple intervention, which consists of discussing the results of the NCSI with the patient and partner, was developed. This intervention can be performed by a pulmonary nurse.

During the last three years, the NCSI and intervention have been used at the outpatient clinic of the University Centre for Chronic Illnesses of the Radboud University Nijmegen Medical Centre. The aim of this randomized controlled trial is to investigate the efficacy of this intervention. First, the effect of the intervention on patients' HS is examined. It is hypothesized that the intervention leads to less reported problems on the HS sub domains after six months when compared to patients who receive usual care. In addition, the effect of the intervention on the rates of supplementary treatment is investigated. It is expected that after six months, the intervention has lead to more supplementary treatment as compared to patients who receive usual care.

Methods

Participants

Patients were recruited from the University Centre for Chronic Illnesses and the Department of Pulmonary Disease of the Radboud University Nijmegen Medical Centre from May 2007 to March 2009. Outpatient charts were screened for eligibility. Patients were eligible if they met the following criteria: (1) diagnosed as having COPD according to the GOLD criteria [2] by their pulmonary physician, (2) understood Dutch sufficiently to answer the questionnaires, (3) did not participate in a pulmonary rehabilitation program or other research project in the previous 6 months, and (4) did not fill in an NCSI in the previous 6 months. Eligible patients were given a brochure by their pulmonary physician and asked if they would grant permission to be contacted by an investigator. During the phone call, more information about the study was given and patients were asked to participate. Written informed consent was given by the participants. The local Ethics Committee approved this study.

Instruments

The Nijmegen Clinical Screening Instrument

All patients received the NCSI, an evidence-based battery of instruments that provides a detailed assessment of HS in patients with COPD. It measures eleven sub domains of physiological functioning, complaints, functional impairment, and quality of life. The NCSI consists of subscales of the following questionnaires: Physical Activity Rating Scale Dyspnoea Global - Dyspnoea Activity and Global Dyspnoea Burden [29], Dyspnoea Emotions Questionnaire - Frustration and Anxiety [3], Checklist Individual Strength - fatigue [29], Beck Depression Inventory Primary Care [30], Satisfaction with Life Scale - Satisfaction Physical, Satisfaction Future, Satisfaction Spouse and Satisfaction Social [31], Quality of Life for Respiratory Illness Questionnaires - General Activities [32], and Sickness

Impact Profile - Home Management and Ambulation [33]. Besides sociodemographic variables (sex, age, education, personal situation, work situation), clinical variables (comorbidity, previous and current treatments, hospitalization) and smoking status were recorded.

Questionnaire completion was performed by the Test Organizer, a computerized questionnaire system developed by the Department of Medical Psychology and the Department of Instrumental Services of the Radboud University Nijmegen Medical Centre [3]. The structure of the questionnaires is similar to the paper-and-pencil versions. It is impossible for participants to skip items, and both scoring and data storage is automated. The questionnaires took approximately 20 minutes to complete. A test assistant was available when participants required further instructions. The Test Organiser integrated the assessment of NSCI and the measurements of lung function.

To provide a graphical presentation of the scores of an individual patient in each HS-domain, the Test Organiser can produce a Patient Profile Chart (PPC). During previous research, data of two control groups were used to determine cut-off scores for each domain to indicate normal functioning (coloured in green), clinically relevant problems (red) or an intermediate area between normal and problematic functioning (orange) [25]. The score range for clinically relevant problems was determined by patients with COPD participating in a clinical multidisciplinary pulmonary rehabilitation program at the University Centre for Chronic Illnesses of the Radboud University Nijmegen Medical Centre, who experienced clinically relevant problems in multiple areas of HS. The score range of normal functioning was determined by a control group of healthy subjects, who were screened for absence of COPD or asthma. The two groups were matched on age and gender.

The intervention by a pulmonary nurse

The patients in the additional care group received an intervention by a pulmonary nurse, which consisted of discussing the PPC with the patient and partner. In total, the simple intervention took about 30 minutes. The pulmonary nurse first explained how to read the PPC and then discussed each result with the patient. The patient and partner were frequently asked if they recognised the results in themselves. When the problems on the several sub domains of a patient's HS were identified by means of the PPC and the pulmonary nurse had an idea of the motivation and capability of a patient to adopt more adequate health behaviours, the type of treatment to be prescribed could be determined. This treatment advice could range from a quit-smoking intervention, a simple rehabilitation program for mild to moderate problems to a more intensive rehabilitation program for serious problems.

The advantage of this method is that it highlights the severity and the type of problems patients may experience. Besides that, it elucidates the factors underlying the problems in patients' HS. The intervention aims to increase the awareness of the severity of the problem and to increase the commitment of the patient with the conclusions obtained from the PPC. It is believed that this method can help patients to overcome natural defence reactions such as denial, trivialization or resistance. The PPC has many advantages. First of all, the results are presented graphically, which may have a greater impact than words and increases awareness of the problems. Second, the results are the responses collected directly from the patient himself, which can increase commitment and motivation. Third, the communication technique used is characterized by making the patient an active participant in the interpretation of the results as much as possible, which also may increase commitment. The patient takes the PPC home and is encouraged to discuss results and conclusions with the partner, who is therefore acting as a co-therapist.

Design

The time path of this study is shown in Figure 1.

* Insert Figure 1 about here *

The baseline measurement (T0) consisted of the completion of the NCSI and a supplementary lung function test. Three independent psychologists interpreted the results obtained from the PPC and decided if the patients scored in the normal or abnormal range on the domains of HS. The patients who scored in the abnormal range were randomly divided into two groups:

- The usual care group: patients who received their usual care
- The intervention group: patients who received the intervention of the pulmonary nurse

The usual care group received their usual care from their pulmonary physician, which could include further referral. The intervention group received the intervention of the pulmonary nurse approximately three months after T0 in addition to their usual care. Based upon the results of the PPC, the pulmonary nurse could refer them for supplementary treatment. After six months (T1), the patients of both groups completed the NCSI and a lung function test for the second time. During T1, the NCSI explicitly stressed the experienced complaints, functional impairments, and quality of life in the previous six months. Furthermore, changes in demographic and clinical variables were recorded. The intervention group filled in an additional question regarding levels of satisfaction with the intervention by the pulmonary nurse.

Data analysis

A flow chart was computed to describe the inclusion procedure. Frequencies were used to summarize the demographical and clinical characteristics of the included patients and the

different types of treatments prescribed. Baseline differences between the usual care and the intervention group were measured with independent t-tests for continuous variables, and chi-square tests for dichotomous variables. Due to randomisation, no differences in baseline characteristics were expected.

General linear model analyses for repeated measurements were used to examine the course of HS scores for both groups at baseline and six-month follow-up. Partial eta squared (effect size) was derived from the general linear model. According to Cohen's definition, an effect size between 0.01 and 0.06 is considered small, while effect sizes between 0.06 and 0.13 and greater than 0.14 are considered moderate and strong sizes respectively [34]. Multiple statistical comparisons were corrected with Bonferroni's method. The differences between the HS scores at baseline and six-month follow-up (deltas) were calculated and used with chi-square tests to determine clinical relevant improvements.

To examine the difference in rates of supplementary treatment between both groups at six-month follow-up, chi-square tests were used. The inter-rater reliability of the interpretation of the PPC was measured and appeared to be good (Cohen's kappa= 0.80) [35]. All analyses were performed using the Statistical Package for Social Sciences (SPSS) 16.0. The p-value was set at 0.05 to determine statistical significance.

Results

The screening of outpatient charts resulted in 1061 eligible patients. The inclusion flow chart is displayed in Figure 2.

* Insert Figure 2 about here *

In total, 482 patients were asked to participate. Twenty-nine percent (n= 303) of the eligible patients agreed to participate in this study. There were diverse reasons for non-participation; some patients felt they could neither afford the time nor the effort to participate, others felt it would be too exhausting physically or had no transport possibilities.

After interpretation of the PPC, fifty percent (n= 154) of the patients were scoring in the abnormal range. These patients could be randomized between the usual care group and the intervention group. The demographic and clinical characteristics of these included patients are presented in Table 1.

* Insert Table 1 about here *

No significant baseline differences between the usual care group and the intervention group were found. During the trial period, two patients died in the usual care group and one patient died in the intervention group.

The results of the ANOVA for repeated measurements are shown in Tables 2 and 3.

Insert Tables 2 and 3 here

A significant effect of time was found on the HS sub domains Subjective Impairment (Wilks' lambda= 0.97, F(1,118)= 4.21, p= 0.04, ES= 0.03), Subjective Complaints (Wilks' lambda= 0.93, F(1,119)= 9.61, p= 0.002, ES= 0.08) and Fatigue (Wilks' lambda= 0.94, F(1,119)= 7.00, p= 0.01, ES= 0.06). For both groups, the scores on these domains tended to decrease, which implies less reported problems in these domains at six-month follow-up. With regard to the sub domain Fatigue, there was a significant interaction effect for group by time (Wilks' lambda= 0.96, F(1,119)= 5.00, p= 0.03, ES= 0.04; see Figure 3) indicating that there were significantly less fatigue problems in the intervention group than in the usual care group after six months. However, the effect sizes and observed power values were small.

Insert Figure 3 about here

At six months, the mean fatigue scores were still above the established cut-off scores for severe fatigued (see Table 2) [29]. Of the patients in the intervention group, 33.3 percent (n= 26) showed a clinically relevant improvement of at least 10 points in fatigue after six months. In comparison with the usual care group, this was not a significant difference ($\chi^2(3)= 2.92$; p= 0.41).

The treatment advices of the pulmonary nurse were diverse, ranging from a rehabilitation program to a consultation from a dietician or psychologist. Some patients were referred to more than one treatment. Eighty-six percent (n= 57) patients followed the advice completely or partly and started a treatment, whereas 10 percent (n= 7) did not follow the advice. At baseline, there were no significant differences in the amount of treatment between the two groups (p= 0.297). However, at six-month follow-up, the intervention group received significantly more supplementary treatment than the usual care group ($\chi^2(3)= 10.01$; p= 0.019; see Table 4).

Insert Table 4 about here

Of the patients who not received treatment at baseline but started a treatment at six-month follow-up, 82.4 percent (n= 14) consisted of patients from the intervention group. Similarly, of the patients who continued to have no treatment, 62.5 percent (n= 25) consisted of patients from the usual care group. From the patients who received the intervention, 93 percent (n= 47) reported moderate to high levels of satisfaction with the intervention by the pulmonary nurse.

Discussion

The aim of this randomized control trial was to examine the effect of a simple motivation intervention on the HS of patients with COPD. In addition, the effect of the intervention on the amount of supplementary treatment was investigated. As such, this study aimed to improve the way usual care for patients with COPD is organised. By developing an intervention that could help patients to gain insight into the factors that elucidate their problems in HS and to motivate them to adopt more adequate health behaviours, further deterioration of their HS could be minimised.

With regards to HS, this randomized control trial only demonstrated an effect of the intervention on the sub domain Fatigue, with the intervention group reporting significantly less fatigue problems in comparison with the usual care group. However, this improvement was not clinically relevant and the fatigue levels experienced by patients from both groups appeared to remain severe. On the sub domains Subjective Impairment and Subjective Complaints both groups improved, but this can be probably be explained by multiple testing [36]. For all HS domains, the effect sizes and observed power values appeared to be small.

These findings are in accordance with results from previous studies, where the COPD programs merely demonstrate equivalence to usual care [26,37,38]. Indeed, Steuten et al. conclude in their review that "the innovators behind chronic care programs for COPD patients keep struggling to articulate the value of their chronic care programs to patients, care providers and payers in terms of proof rather than belief" [37]. Compared to other studies [39], the intervention was possibly too short of duration to demonstrate an effect on HS. More intensive pulmonary rehabilitation programs seem more effective in COPD [40,41]. For instance, the clinically relevant improvement of fatigue is clear after pulmonary rehabilitation programs [41-43]. COPD patients describe their fatigue as a feeling of general tiredness that

occurs on a daily basis and is intermittently present throughout the day [44]. Considering this, a more intensive approach seems more effective.

Similarly, previous research has shown that it is difficult to promote adequate health behaviour [16,45]. In the literature, program components including patient education, self-management, nutritional support and respiratory muscle training seem beneficial in promoting health behaviour change [39,41]. Which exact components are essential remain uncertain but a more intensive program instead of a simple motivation intervention seems required.

However, when looked at the guideline for health behaviour counselling, which includes individually targeted goal setting and the assessment of a patients motivation, potential barriers and supporting factors [46], the intervention of this study contains some important aspects. For instance, the intervention gives the pulmonary nurse the possibility to explore, together with the patient, the factors underlying the problems in patients' HS, and formulate individual treatment goals by shared decision-making. Furthermore, patient passivity, which is the norm in medical consultations [47], may be overcome. This is important as COPD patients, generally older people with serious illnesses, may be among those who participate least in medical consultations [47].

Furthermore, the clinical experience of the pulmonary nurses is that the NCSI and intervention raises patients' insight and contributes to a good work relationship. Indeed, the majority of patients in this study reported moderate to high levels of satisfaction with the intervention. Although the satisfaction scores tend to be negatively skewed because of the tendency to answer more positively on questions about satisfaction, this remains a high percentage [48]. The importance of this finding is supported by previous research suggesting that the interaction with the health care provider is an important factor in the patient's adherence to treatment regimes [43]. Similarly, a recent meta analysis concludes that

resources devoted to improve the communication between physician and patient are worth investing in [49].

Chronic care programs for patients with COPD are increasingly implemented in daily health care [50]. Generally, the aim of these programs is to improve processes and outcomes of care whilst making more efficient use of scarce health care resources [37]. In light of this, the NCSI and intervention can be promising clinical instruments as they ensure early identification and intervention. At baseline, 50 percent of the participants appeared to have problems in different areas of HS.

In addition, the many diverse referrals to supplementary treatment by the pulmonary nurse suggest that the NCSI and the intervention can not only be helpful in identifying problems in the domains of HS, but can also contribute to more patient-tailored care. It is known that the impact of COPD on a patients' life can be substantial but different for each patient [27] and that treatment should be individually-tailored [46,51]. Moreover, after six months, the intervention lead to significantly more supplementary treatment in the intervention group than in the usual care group. This suggests that the intervention may influence the motivation of patients to change their health behaviour. The main reasons for patients not following supplementary treatment appeared to be for practical issues, such as transport difficulties or physical comorbidity rather than motivation. However, it is difficult to define the exact contribution of the intervention to the motivation of patients. Future research should add a motivation scale to assess whether the intervention can influence the motivation of patients to adopt more adequate health behaviours. Nevertheless, the given individual-tailored supplementary treatment could possibly lead to improvements on the domains of HS on the long term. Future research should take a follow-up measurement into account to investigate the effect of the intervention on HS after twelve months or after completion of treatment. In general, it is important to study whether the intervention actually

translates into significant and sustained behavioural changes on the long term [37]. For instance, in absence of a maintenance program, the positive effects of pulmonary rehabilitation on patients' HS diminish with time [43].

Some methodological issues of this study need to be addressed. The selection of instruments for the NCSI is based on a theory-driven and empirically validated framework measuring HS, developed during previous research [3]. However, this framework should not be considered as the final reflection of HS. Therefore, the NCSI may not be the final and most exhaustive assessment battery to measure HS [3]. Nevertheless, the instruments of the NCSI are selected by means of evidence-based testing, rather than selecting the most commonly used instruments.

Second, patients participating in this study were volunteers. This is not unique to intervention studies [52]. However, previous published studies involving interventions have found that on average 50% of eligible out-patients participate [53]. In this study, the drop-out rate was higher. The main reasons for not including all eligible patients in this study were patients not showing up at their appointment and comorbidity that was in the opinion of the physician too severe to enable participation. It could be possible that these patients would be the most susceptible for the benefits of the intervention and that this selection bias may have contributed to the limited effect of the intervention on HS. Unfortunately, the demographic characteristics of this group are unknown. Besides that, only the patients who scored in the abnormal range of the NCSI at baseline were included in this study. As a result, the appropriateness of generalising the findings may be questioned.

Studies examining the efficacy for COPD intervention represent a wide range of efforts. Those studies that reported some positive effects, used changes in health care use as outcome parameters [39]. For example, the evidence around hospital readmission is equivocal [8,26,42]. Future studies assessing the effect of this intervention should also take

these parameters into account. Also the costs of this intervention deserves further exploration as the relative costs of various interventions modes for patients, clinicians and health care system are not clear [39].

In conclusion, the intervention resulted in diverse treatment referrals by the pulmonary nurse and lead to significantly higher rates of supplementary treatment when compared with usual care. This suggests that the NCSI and the intervention can be helpful in identifying the problems in HS and can contribute to more patient-tailored care. However, after six months, the intervention had only a limited effect on patients' HS. To improve patients' HS, a more intensive approach seems more effective.

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Table 1: Baseline characteristics of the patients with COPD in the usual care and intervention group

	Usual care group (N)	*Intervention group (N)*	*P-value (2-tailed)*
Demographic variables			
Age in years[a]	67.58 ± 10.03	66.86 ± 10.63	0.67
Gender male (%)	46 (60.5%)	51 (65.4%)	0.53
Education level (%)			0.59
Low	41 (53.9%)	39 (50.0%)	
Medium	24 (31.6%)	25 (32.1%)	
High	11 (14.5%)	14 (17.9%)	
Personal situation (%)			0.52
Married	58 (76.3%)	52 (66.7%)	
Divorced	4 (5.3%)	6 (7.7%)	
Widowhood	6 (7.9%)	11 (14.1%)	
Single	9 (10.5%)	9 (11.5%)	
Smoking (%)			0.65
Yes	13 (17.1%)	18 (23.1%)	
No, quit	52 (68.4%)	49 (62.8%)	
No, never	11 (14.5%)	11 (14.1%)	
Clinical variables			
COPD diagnosis (%)			0.79
GOLD stage 1	9 (11.8%)	9 (11.5%)	
GOLD stage 2	31 (40.8%)	38 (48.7%)	
GOLD stage 3	30 (39.5%)	26 (33.3%)	
GOLD stage 4	6 (7.9%)	5 (9.4%)	
Self-reported comorbidity (%)	68 (89.5%)	64 (82.1%)	0.19
Pulmonary function			
Fev_1[a] %	53.5 ± 17.59	56.6 ± 18.79	0.29
RV[a]	2.36 ± 0.66	2.38 ± 0.85	0.86
TLC[a]	5.69 ± 1.30	5.80 ± 1.52	0.63
Body Mass Index[a]	26.70 ± 4.60	26.81 ± 5.18	0.89

[a]Data are expressed as mean ± SD.

Abbreviations: Fev_1% = forced expiratory volume percent predicted, RV = residual volume, TLC = total lung capacity.

Table 2: The descriptive statistics of the sub domains of HS of the patients with COPD in the usual care group and the intervention group at baseline and six-month follow-up

		Usual care group			**Intervention group**		
Domains of Health Status		*N*	*Mean**	*Std deviation*	*N*	*Mean*	*Std deviation*
Airflow	T0	59	93.37	18.71	62	92.75	18.85
	T1	59	95.36	18.74	62	93.19	20.18
Body Composition	T0	58	26.66	4.61	62	26.57	4.92
	T1	58	26.77	4.77	62	26.69	4.81
Static Lung Volume	T0	32	297.60	51.45	32	309.60	65.33
	T1	38	296.94	54.94	38	312.13	73.24
Quality of Life	T0	62	26.59	13.77	59	27.22	13.74
	T1	62	28.86	15.75	59	26.20	15.63
Health Related Quality of Life	T0	62	7.23	1.66	59	7.42	1.58
	T1	62	7.24	1.84	59	7.00	1.85
Satisfaction Relations	T0	60	5.53	1.99	57	5.37	2.14
	T1	60	5.50	2.00	57	5.07	1.95
Subjective Impairment	T0	61	15.21	5.17	59	15.49	4.89
	T1	61	14.97	4.51	59	13.75	5.61
Behavioral Impairment	T0	62	26.28	16.74	59	23.54	14.57
	T1	62	24.33	14.56	59	23.01	14.22
Subjective Complaints	T0	62	12.29	4.05	59	12.51	2.89
	T1	62	11.76	4.38	59	10.47	3.83
Dyspnea Emotions	T0	62	12.26	3.96	59	12.12	3.88
	T1	62	12.02	3.49	59	11.69	3.95
Fatigue	T0	62	40.32	9.28	59	40.63	8.29
	T1	62	39.92	9.37	59	35.80	9.38

* with lower scores meaning less reported problems on that sub domain of HS.

Table 3: The results of the ANOVA for repeated measurements on the sub domains of HS

Domains of Health Status		df	F	p-value	Partial Eta Squared	Observed Power
Air flow	Time	1	2.97	0.09	0.02	0.40
	Group	1	0.17	0.68	0.00	0.07
	Time * Group	1	1.23	0.27	0.01	0.20
Body Composition	Time	1	0.81	0.37	0.01	0.15
	Group	1	0.01	0.92	0.00	0.05
	Time * Group	1	0.00	0.98	0.00	0.05
Static Lung Volumes	Time	1	0.05	0.83	0.00	0.06
	Group	1	0.90	0.35	0.01	0.15
	Time * Group	1	0.14	0.71	0.00	0.07
Quality of Life	Time	1	0.30	0.59	0.00	0.08
	Group	1	0.17	0.68	0.00	0.07
	Time * Group	1	2.06	0.15	0.02	0.27
Health Related Quality of	Time	1	1.08	0.30	0.01	0.18
Life	Group	1	0.01	0.93	0.00	0.05
	Time * Group	1	1.26	0.26	0.01	0.20
Satisfaction Relations	Time	1	0.69	0.41	0.06	0.13
	Group	1	0.89	0.35	0.08	0.16
	Time * Group	1	0.44	0.51	0.04	0.10
Subjective Impairment	Time	1	4.21	0.04*****	0.03	0.53
	Group	1	0.36	0.55	0.00	0.09
	Time * Group	1	2.39	0.13	0.02	0.34
Behavioral Impairment	Time	1	0.93	0.34	0.01	0.16
	Group	1	0.40	0.40	0.01	0.13
	Time * Group	1	0.31	0.58	0.00	0.09
Subjective Complaints	Time	1	9.61	0.002*	0.08	0.87
	Group	1	0.90	0.35	0.01	0.16
	Time * Group	1	34.09	0.07	0.03	0.44
Dyspnea Emotions	Time	1	0.97	0.33	0.01	0.16
	Group	1	0.14	0.71	0.00	0.01
	Time * Group	1	0.07	0.79	0.00	0.06
Fatigue	Time	1	7.00	0.01*****	0.06	0.75
	Group	1	2.07	0.15	0.02	0.30
	Time * Group	1	5.00	0.03*****	0.04	0.60

*Significant at $p \leq 0.05$

Table 4: The course of treatment between the usual care group and the intervention group at six-month follow-up.

T0	**T1**	**Usual care group *(n)***	**Intervention group *(n)***	Total (100%)	**p-value**
Treatment	Treatment	27 (52.9%)	24 (47.1%)	51	
	No treatment	7 (58.3%)	5 (41.7%)	12	
No treatment	Treatment	3 (17.6%)	14 (82.4%)	17	
	No treatment	25 (62.5%)	15 (37.5%)	40	
Total		62	58	120	0.019*

*Significant at $p \leq 0.05$

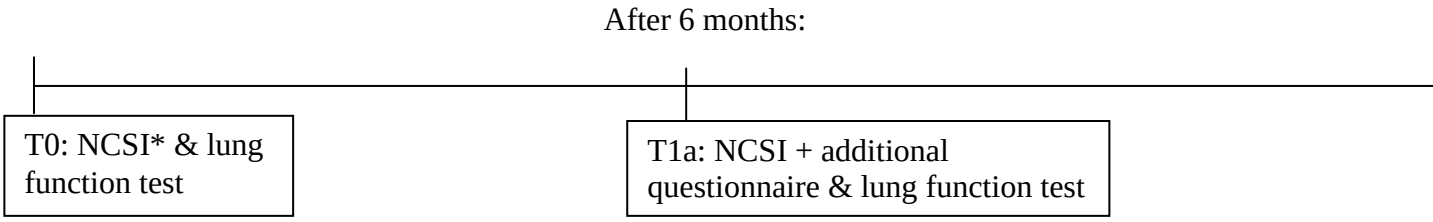
Figure legends

Figure 1: Time path of the usual care group and the intervention group

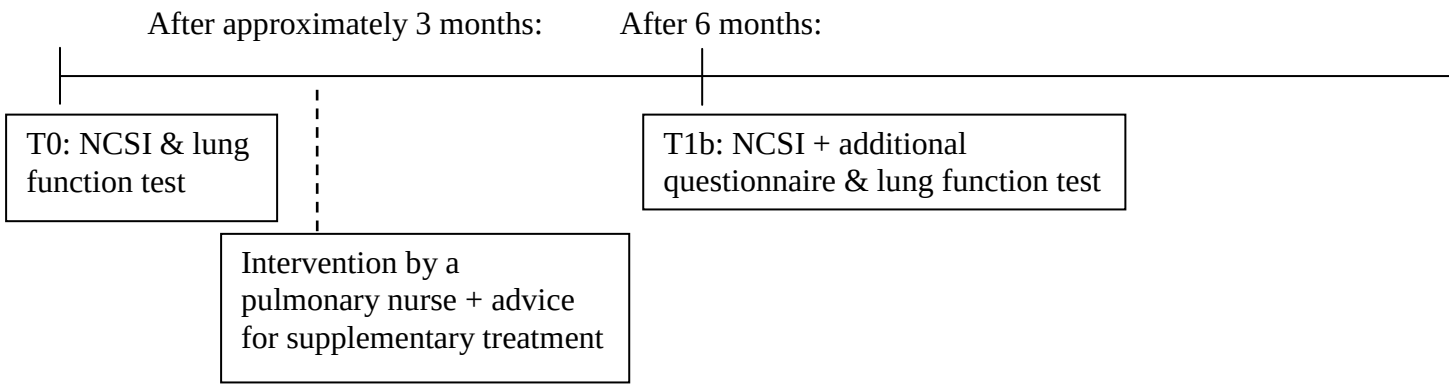
Figure 2: The inclusion flow chart

Figure 3: Mean Fatigue scores across six months for the usual care group and the intervention group

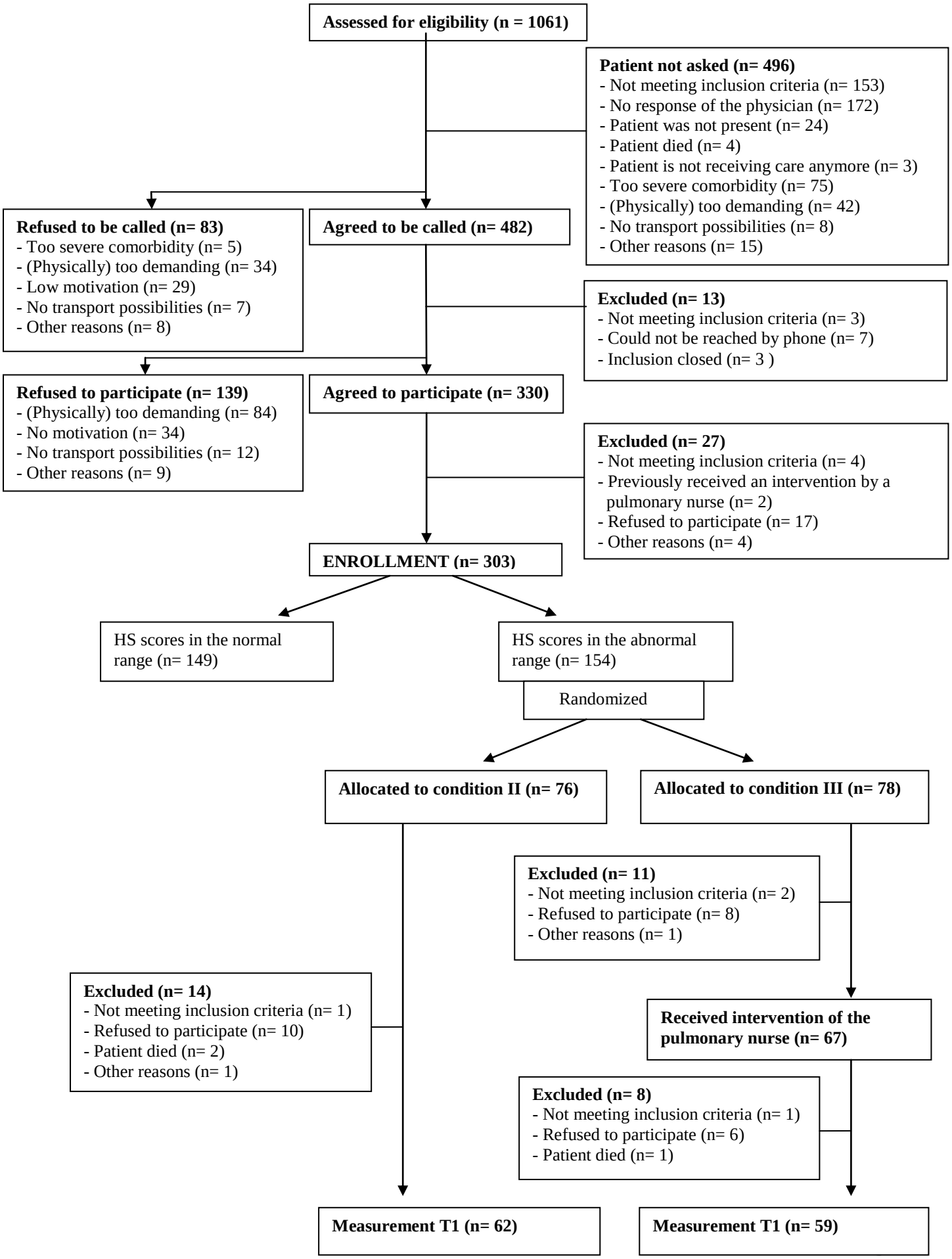
The usual care group

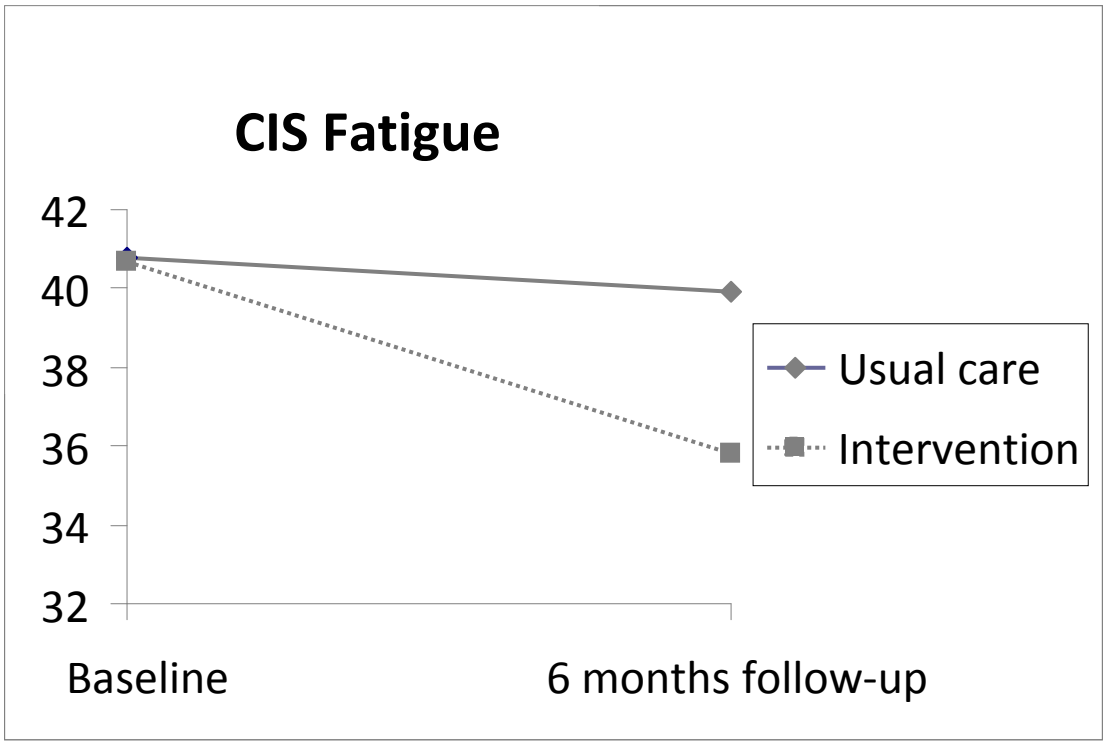


The intervention group



*The NCSI is an instrument that measures several domains of Health Status


Assessed for eligibility (n = 1061)
Patient not asked (n= 496)
- Not meeting inclusion criteria (n= 153)
- No response of the physician (n= 172)
- Patient was not present (n= 24)
- Patient died (n= 4)
- Patient is not receiving care anymore (n= 3)
- Too severe comorbidity (n= 75)
- (Physically) too demanding (n= 42)
- No transport possibilities (n= 8)
- Other reasons (n= 15)
Refused to be called (n= 83)
- Too severe comorbidity (n= 5)
- (Physically) too demanding (n= 34)
- Low motivation (n= 29)
- No transport possibilities (n= 7)
- Other reasons (n= 8)
Agreed to be called (n= 482)
Excluded (n= 13)
- Not meeting inclusion criteria (n= 3)
- Could not be reached by phone (n= 7)
- Inclusion closed (n= 3)
Refused to participate (n= 139)
- (Physically) too demanding (n= 84)
- No motivation (n= 34)
- No transport possibilities (n= 12)
- Other reasons (n= 9)
Agreed to participate (n= 330)
Excluded (n= 27)
- Not meeting inclusion criteria (n= 4)
- Previously received an intervention by a pulmonary nurse (n= 2)
- Refused to participate (n= 17)
- Other reasons (n= 4)
ENROLLMENT (n= 303)
HS scores in the normal range (n= 149)
HS scores in the abnormal range (n= 154)
Randomized
Allocated to condition II (n= 76)
Allocated to condition III (n= 78)
Excluded (n= 11)
- Not meeting inclusion criteria (n= 2)
- Refused to participate (n= 8)
- Other reasons (n= 1)
Excluded (n= 14)
- Not meeting inclusion criteria (n= 1)
- Refused to participate (n= 10)
- Patient died (n= 2)
- Other reasons (n= 1)
Received intervention of the pulmonary nurse (n= 67)
Excluded (n= 8)
- Not meeting inclusion criteria (n= 1)
- Refused to participate (n= 6)
- Patient died (n= 1)
Measurement T1 (n= 62)
Measurement T1 (n= 59)


CIS Fatigue
42
40
38
36
34
32
Baseline
6 months follow-up
Usual care
Intervention