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Effects of a COPD self-management support intervention: a randomized controlled trial

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Background: This study examines the effects of the COPD-specific health promoting self-management intervention "Better living with COPD" on different self-management-related domains, self-efficacy, and sense of coherence (SOC).

Methods: In a randomized controlled design, 182 people with COPD were allocated to either an intervention group (offered Better living with COPD in addition to usual care) or a control group (usual care). Self-management-related domains were measured by the Health Education Impact Questionnaire (heiQ) before and after intervention. Self-efficacy was measured by the General Self-Efficacy Scale (GSE) and SOC was measured by the 13-item Sense of Coherence Scale (SOC-13). Effects were assessed by ANCOVA, using intention-to-treat (ITT) analysis and per-protocol analysis (PPA).

Results: The PPA and the ITT analysis showed significant positive changes on Constructive attitudes and approaches (heiQ) (ITT: P=0.0069; PPA: P=0.0021) and Skill and technique acquisition (heiQ) (ITT: P=0.0405; PPA: P=0.0356). Self-monitoring and insight (heiQ) showed significant positive change in the PPA (P=0.0494). No significant changes were found on the other self-management domains (heiQ), self-efficacy (GSE), or SOC (SOC-13).

Conclusion: Better living with COPD had a significant positive short-term effect on some self-management-related domains, and could be an intervention contributing to the support of self-management in people with COPD. However, further work is needed to establish the clinical relevance of the findings and to evaluate the long-term effects.

Keywords: constructive attitudes and approaches, Health Education Impact Questionnaire (heiQ), self-efficacy, self-monitoring and insight, sense of coherence, skill and technique acquisition

Introduction

COPD is characterized by persistent airflow limitation and respiratory symptoms, due to abnormalities in airways and/or the alveolus, and is a leading cause of mortality and morbidity worldwide.[1,2] The disease is common, preventable, and treatable,[2] and individuals living with COPD must make daily decisions regarding their own care; thus, self-management is an essential part of living with COPD[3,4] and essential for the health care system's efficiency and effectiveness.[5] Still, previous studies suggest that individuals' management of COPD is often far from optimal.[6–8]

Various self-management support interventions (SMIs) have been developed to facilitate adequate self-management of COPD.[9,10] However, agreement on the definition of SMIs has previously been lacking,[11] although their multifaceted nature and emphasis on enhancing people's active roles and responsibilities have been highlighted.[12] Recent guidelines state that SMIs for people with COPD are "structured but personalized and often multi-component interventions, with goals of motivating, engaging and supporting

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the participants to positively adapt their behavior(s) and develop skills to better manage their disease".[13,14] SMIs should provide information,[12] elicit personalized goals, formulate appropriate strategies, and focus on intrinsic processes (eg, motivation, resource utilization, coping, and self-efficacy),[11,13–15] and mental health.[10] Furthermore, behavior change techniques are recommended to elicit participants' motivation, confidence, and competence.[14]

Recent systematic reviews and meta-analyses of randomized controlled trials of COPD-specific multicomponent SMIs in primary care show positive effects of SMIs, such as a reduced number of unscheduled physician visits[16] and COPD-related hospital admissions,[9,12,17] reduced emotional distress,[16,17] improved health-related quality of life (HRQoL),[9] and increased self-efficacy.[16] Two other systematic and integrative reviews[18,19] reported less dyspnea,[18] changed health care utilization,[18,19] and improved HRQoL in people who have undergone SMIs.[18,19] However, some studies included in the reviews[12,16–19] contain supervised exercises. This exceeds support levels coherent with SMIs in COPD[11] and makes it difficult to distinguish between the effects of the SMI and those of the exercise component. Furthermore, SMIs can have a specified salutogenic orientation and/or use motivational interviewing (MI) techniques. A study by Benzo et al[20] concludes that the use of MI may increase a person's commitment and engagement in self-management and be feasible for people living with COPD, and evidence from related health care settings indicates that the use of a salutogenic orientation may be feasible and effective.[21]

Few studies have examined the effects of COPD-specific SMIs on self-management-related abilities or behavior. One study's effects include improved skill and technique acquisition, improved self-monitoring and insight, and more constructive attitudes and approaches.[22] Studies have also found better adherence to inhalation treatment and techniques,[23] increased smoking cessation,[24] improved knowledge of COPD,[23–25] improved identification and treatment of exacerbations,[23] and improved activation for self-management[22] in those who have undergone COPD-specific SMIs.

The importance of integrating SMIs in the primary care setting has been increasingly accentuated.[3,26] In this study, we have developed a structured and salutogenic oriented health-promoting COPD-specific SMI, named Better living with COPD,[27] for implementation in local municipal health services. Our hypothesis is that Better living with COPD would improve different self-management-related domains, general self-efficacy, and sense of coherence (SOC).

Material and methods

Design and participants

This randomized controlled trial (ClinicalTrials.gov identification: NCT02479841) examines the effects of Better living with COPD on eight self-management-related domains (primary outcomes), general self-efficacy and SOC (secondary outcomes) in a parallel design, with a baseline measure (before randomization) and a follow-up measure 1–2 weeks after the intervention period. We expected that different self-management-related domains would be improved, but general self-efficacy and SOC are rather stable personal characteristics,[29–31] therefore it is possible that the time frame (a few weeks after the intervention period) might be too short to see changes in general self-efficacy and SOC.

Participants with COPD from eleven municipalities on the west coast of Norway were recruited from a hospital register with the following inclusion criteria: registered ICD-10 code J44.0, 1, 8, or 9 after January 1, 2010; age ≥18 years; confirmed COPD grade II–IV, according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD);[32] and the ability to read and speak Norwegian. Exclusion criteria were substantial cognitive impairment reported in a medical journal (eg, severe dementia, severe Alzheimer's disease), substantial alcohol and/or drug abuse, or a life expectancy <12 months due to comorbidity. Evaluation of fulfillment of inclusion and exclusion criteria was conducted by a research nurse and a lung specialist in collaboration.

The Health Education Impact Questionnaire (heiQ) was considered the primary outcome, and a sample power for a two-sample *t*-test (individual randomization), with a suggested effect size of 0.50 (Cohen's *d*), a significance level of 0.05, and 80% power, together with an allowed 20% attrition rate, resulted in the inclusion of a minimum of 154 participants.

Allocation, randomization, and procedures

The allocation ratio was 1:1. Included participants were given a running number (based on the alphabetical order of last names), and then the numbers were randomized by a statistician (using MATLAB[33]) with no access to the participant list. However, the geographically varying recruitment for a group intervention led to challenges with the allocation. Based on previous research,[34] the minimum group size was set to five participants, and as an attrition of 20% was expected, this indicates that at a minimum of six participants were to be allocated to each group. In municipalities with fewer than 12 registered participants, it was therefore not possible to establish two groups, and we decided to allocate one group to either intervention or control. In the larger

municipalities, participants were allocated individually to the groups. The participants were randomly assigned to groups of ten within the municipality, and then the groups were randomized to either intervention or control, whereas participants from municipalities with only one group were randomized to either intervention or control at the municipality level. In total, 61 participants from six municipalities were randomized at the municipality level, whereas 121 participants were individually randomized. Of the 182 study participants, 92 were randomized to an intervention group and 90 to a control group. Those randomized to an intervention group were offered Better living with COPD in addition to usual care, whereas those randomized to a control group received usual care, although they were informed that they would be offered the intervention ~6 months later.

Participants were recruited between February and June 2015. Questionnaires including demographic and clinical characteristics were measured at baseline (inclusion), whereas the self-management-related domains, general self-efficacy, and SOC were measured at baseline and follow-up. The questionnaires were sent by post, and one reminder was sent out after ~3 weeks in cases with no response.

All participants received an information letter about the study before agreeing to participate and were informed of their allocation in a separate letter after randomization. The study was approved by the Regional Committee of Medical Research Ethics (reference no 2013/1741), and all participants gave written informed consent.

Intervention

The SMI, Better living with COPD, aimed to increase the participants' consciousness of their potential, their internal and external resources and their abilities to use them, and thus to improve their self-management capabilities in the context of everyday living. A salutogenic orientation was incorporated into the group conversations. This orientation included a focus on SOC; understanding, manageability, and meaningfulness, and on emphasizing health as a continuum, the person's history, the understanding of tension and strain as potentially health promoting, resources for health, and active adaption,[34,35] as described by Langeland et al.[36,37] MI,[38–40] congruent with improvement in self-efficacy,[41,42] enhanced activation for self-management,[42] and a salutogenic approach,[43] was used as a communication technique.

The intervention consists of weekly 2-hour-long group conversations over 11 weeks.[44] The face-to-face conversations took place in meeting locations in the participants' home municipalities. The sessions started with participants discussing their everyday life experiences. The next part was related to topics initiated by conversations based on reflected notes (homework) related to those topics, voluntarily prepared by the participants. Themes such as problem solving, goal setting, symptoms, social challenges, physical activity, nutrition, medication, smoking cessation, exacerbations, and psychological issues were covered.[27] A small booklet with information and advice about physical activity, nutrition, dyspnea, and health care resources was handed out during the SMI[45] in addition to a general COPD action plan draft.[46] Each session followed a similar structure,[27,36] albeit customized according to group dynamics and participants' needs. From this, the intervention was delivered as planned, but with some variation due to differences in group dynamics.

All group sessions were planned to be moderated by two moderators. The main moderator was a registered nurse (RN) with special competence in COPD care,[47] salutogenesis, self-efficacy, and MI. In addition, the main moderator had initial training in the intervention and had previously co-moderated Better living with COPD with the first author. An RN and/or a physiotherapist from the participant's home municipality participated as co-moderator.

Usual care

The Norwegian guidelines for care and treatment of people with COPD include specific criteria regarding frequency of visits to a general practitioner, smoking cessation, physiotherapy, nutritional advice, and pulmonary rehabilitation.[48] Although it is possible that "usual care" varies between municipalities,[49,50] the Norwegian health care system is mainly based on public funding and a principle of universal access regardless of residential area.[51] Therefore, no precautions were taken in this study to ensure equality in usual care.

Measures

Demographic and clinical characteristics

Age and sex were obtained from the hospital register, whereas education, cohabitation, comorbidity, and years diagnosed with COPD were self-reported.

Lung function

For participants with spirometry conducted according to international standards[52,53] less than 12 months prior to enrollment, data on post-bronchodilator FVC and FEV_1 were obtained from medical records. For participants with the last spirometry registered more than 12 months prior to enrollment, a new spirometry was conducted according to international standards.[52,53] To calculate FEV_1 percentage

predicted (FEV_1% predicted), Norwegian reference values were used.[54] COPD disease severity was classified using GOLD criteria[2]: moderate (II), severe (III), or very severe (IV), defined as $FEV_1/FVC < 0.7$ and FEV_1% 50%–79% (II), FEV_1% 30%–49% (III), or FEV_1% <30% (IV).[2]

Modified Medical Research Council (mMRC) Dyspnoea Scale

The mMRC[48,55] Dyspnoea Scale was used to measure dyspnea. This measure asks people to rate dyspnea by choosing the statement best describing when dyspnea occurs. Different statements describing decreasing levels of physical activity that may precipitate shortness of breath are presented on a five-point scale (range 0–4), with higher scores indicating more severe dyspnea.[2,55] The mMRC Dyspnoea Scale has shown satisfactory reliability and validity.[56–58]

COPD Assessment Test (CAT)

To measure COPD symptom burden, the CAT[59] was used. The CAT consists of eight items (cough, phlegm, chest tightness, breathlessness, activities, confidence, sleep, and energy) rated on a 0–5 scale. The total score range is 0–40, with a higher score indicating a higher symptom burden.[59–61] The CAT has shown satisfactory reliability and validity.[59,60,62,63]

Self-management

HeiQ, version 2.0,[28,64] was used to measure eight self-management-related domains: 1) Positive and active engagement in life; 2) Health directed activities; 3) Skill and technique acquisition; 4) Constructive attitudes and approaches; 5) Self-monitoring and insight; 6) Health service navigation; 7) Social integration and support; and 8) Emotional distress. HeiQ comprises 40 items, scored on a Likert scale ranging from 1 (strongly disagree) to 4 (strongly agree).[28,64] Domain scores are calculated by adding the score of items within scales and dividing by the number of items; consequently, all domain scores range between 1 and 4. Higher scores indicate higher levels of self-management ability for all domains, except for the Emotional distress domain, where a higher score indicates more emotional distress. This generic questionnaire has shown satisfactory validity and reliability across diverse settings,[28,64–67] and has been used in studies including people with COPD.[22,68,69] Cronbach's alpha ranged from 0.63 (Health service navigation) to 0.90 (Emotional distress).

General Self-Efficacy Scale (GSE)

The GSE was used to measure self-efficacy. The GSE is a ten-item scale designed to assess perceived general self-efficacy.[70–72] Each item is scored on a Likert scale ranging from 1 (not at all true) to 4 (exactly true), generating a sum score ranging from 10 to 40. Higher scores indicate higher self-efficacy.[70,71] Up to two responses (20%) were allowed to be missing and were replaced by the mean value of the person's valid scores.[73] The GSE has been used in studies including people with COPD,[73,74] and has shown satisfactory reliability and validity.[30,70,71,73,75]

Sense of Coherence Scale-13 (SOC-13)

SOC was measured using the SOC-13.[29] The SOC-13 is a 13-item short form of the original 29-item Orientation to Life Questionnaire.[29] Each item is rated on a seven-point Likert scale, where the most common anchor points are "never" and "very often".[29] The items cover comprehensibility (five items), manageability (four items), and meaningfulness (four items), generating a total sum score ranging from 13 to 91. Higher scores indicate stronger SOC.[70] The SOC-13 has satisfactory reliability and validity,[76–80] and has been used in previous COPD studies.[81,82] In this study, missing data were substituted separately for individuals who answered at least 75% of the items for each component.

Data handling and statistical analysis

Missing data were a problem in the collected data. We used the observed data for all descriptive analyses. For the inference, we used multiple imputation with 50 imputed data sets.[83] The imputation was based on information about heiQ, age, sex, education, FEV_1% predicted, GSE, and SOC-13. Data were blinded during the analyses, ie, the groups were labeled with non-identifying terms.

Descriptive statistics were used to characterize the sample. The SMI effect on each heiQ domain, GSE, and SOC-13 was assessed by an analysis of covariance (ANCOVA), ie, a linear model for the follow-up measurement of each outcome depending on intervention type and adjusted for its baseline measure. All models were estimated using intention-to-treat (ITT) analysis and per-protocol analysis (PPA). The ITT analysis was conducted for all available data, while inclusion in the PPA required participants to follow the protocol sufficiently; ie, we included in the PPA all participants who had participated in more than half of the group conversations. The general significance level was set to 0.05. All descriptive computations were conducted using SPSS 24 (IBM Corp., Armonk, NY, USA), whereas the imputation and inference (ANCOVA) were carried out using R 3.4[84] with the package mice 2.46.[85]

Results

Participants' characteristics

Of the 649 people invited to participate, 225 (34.7%) consented (baseline). Of these, 43 were excluded; ten were

allocated to a pilot study and 33 either withdrew from further participation before randomization or responded post-randomization (Figure 1). Consequently, 182 participants were included in this study. The attrition rate was 22.2% in the control group and 31.5% in the intervention group (ITT).

Participants' characteristics at baseline are shown in Table 1. Self-monitoring and insight (heiQ) had the highest mean ± SD score at 3.03±0.35, whereas Health directed activities (heiQ) had the lowest mean score at 2.63±0.63. The mean score for Emotional distress (heiQ) was 2.38±0.62, and the mean scores for self-efficacy (GSE) and SOC (SOC-13) were 25.97±6.42 and 64.59±9.64, respectively.

Effects of Better living with COPD

As shown in Table 2, both PPA and ITT analysis showed significant positive changes on Constructive attitudes and approaches (heiQ) (PPA: P=0.0021, d=0.38; ITT: P=0.0069, d=0.32) and Skill and technique acquisition (heiQ) (PPA: P=0.0405, d=0.17; ITT: P=0.0356, d=0.17). While the estimated effect on Constructive attitudes and approaches (heiQ) was slightly higher using the PPA [mean change difference (95% CI) PPA: 0.16 (0.03 to 0.30) vs ITT: 0.14 (0.00 to 0.27)], the effect on Skill and technique acquisition (heiQ) [PPA: 0.06 (–0.07 to 0.19); ITT: 0.06 (–0.06 to 0.19)] was similar for both. In addition, the PPA indicated a significant positive change in self-monitoring and insight

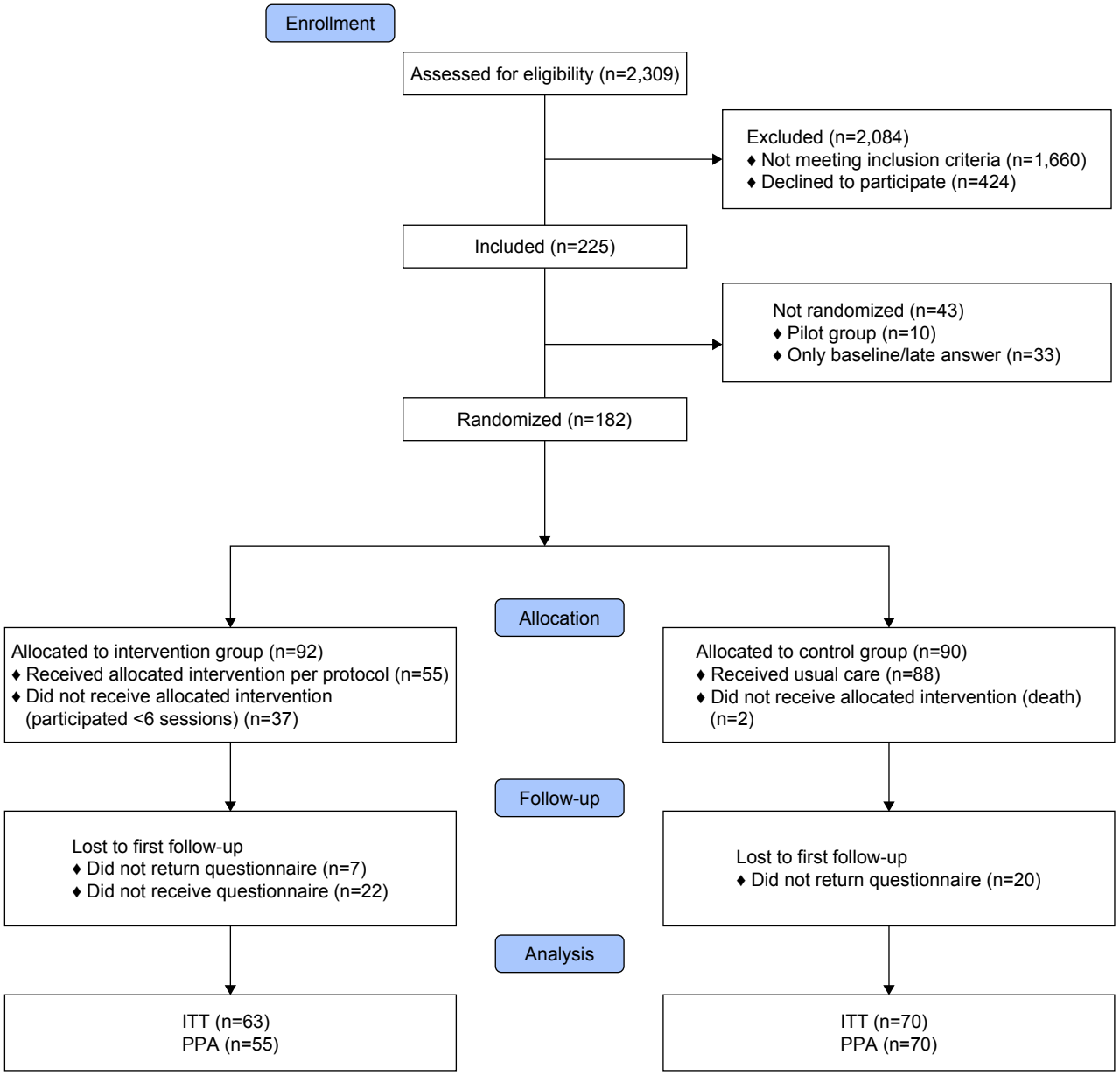

Figure 1 Overview of recruitment, allocation, and randomization.
Abbreviations: ITT, intention to treat; PPA, per-protocol analysis.

Table 1 Characteristics of participants at baseline

	Randomized (N=182)[j]	Intervention (N=92)[j]	Control (N=90)[j]
	Value	Value	Value
Age (years)	68.93±8.58	68.53±8.16	69.34±9.02
Sex, male	111 (61.0)	54 (58.7)	57 (63.3)
Education			
Primary school	57 (32.2)	29 (31.9)	28 (32.6)
High school/university	120 (67.8)	62 (68.1)	58 (67.4)
Cohabitation, living alone[a]	54 (30.0)	27 (29.3)	27 (30.7)
Other chronic disease[b]	170 (96.6)	87 (95.6)	83 (97.6)
Comorbidity[c]	2.51±1.87	2.68±1.91	2.33±1.82
FEV_1% predicted	45.03±15.31	45.22±14.44	44.84±16.23
GOLD[d] grade			
GOLD II	73 (40.1)	35 (38.0)	38 (42.2)
GOLD III	73 (40.1)	42 (45.7)	31 (34.4)
GOLD IV	36 (19.8)	15 (16.3)	21 (23.3)
Years diagnosed with COPD	8.83±5.87	9.20±6.25	8.47±5.49
CAT[e] score	19.09±7.35	18.68±7.15	19.51±7.58
mMRC[f] score	1.82±1.09	1.88±1.06	1.76±1.12
mMRC grade 0	20 (11.6)	7 (7.9)	13 (15.5)
mMRC grade 1	51 (29.5)	29 (32.6)	22 (26.2)
mMRC grade 2	51 (29.5)	27 (30.3)	24 (28.6)
mMRC grade 3	42 (24.3)	20 (22.5)	22 (26.2)
mMRC grade 4	9 (5.2)	6 (6.7)	3 (3.6)
Self-management domains[g]			
Positive and active engagement in life	2.92±0.44	2.96±0.41	2.88±0.46
Health directed activities	2.63±0.63	2.63±0.68	2.64±0.58
Skill and technique acquisition	2.70±0.44	2.73±0.45	2.68±0.43
Constructive attitudes and approaches	2.89±0.44	2.90±0.40	2.88±0.48
Self-monitoring and insight	3.03±0.35	3.06±0.35	3.00±0.35
Health service navigation	2.87±0.38	2.93±0.38	2.82±0.38
Social integration and support	2.80±0.44	2.83±0.41	2.77±0.48
Emotional distress	2.38±0.62	2.41±0.62	2.34±0.63
GSE,[h] total score	25.97±6.42	26.92±6.16	24.96±6.57
SOC-13,[i] total score	64.59±9.64	65.10±9.64	64.06±9.66

Notes: Data are shown as mean ± SD or n (%). [a]Cohabitation: living alone; living with someone. [b]Other chronic disease: yes; no. [c]Comorbidity: rated between 0 (no comorbidities) and 16 based on a list of common comorbidities. [d]GOLD, grading of lung function; mild (I), moderate (II), severe (III), or very severe (IV), defined as FEV_1/FVC <0.7 and FEV_1% ≥80% (I), FEV_1% 50%–79% (II), FEV_1% 30%–49% (III), or FEV_1% <30% (IV). [e]CAT: score range: 0–40. [f]mMRC: score range: 0–4. [g]Domains of the heiQ: score range: 1–4. [h]GSE: score range: 10–40. [i]SOC-13: score range: 13–91. [j]N=182, N=92, and N=90 are the largest N values; for some variables the N is lower.

Abbreviations: CAT, COPD Assessment Test; GOLD, Global Initiative for Chronic Obstructive Pulmonary Disease; GSE, General Self-Efficacy Scale; heiQ, Health Education Impact Questionnaire; mMRC, modified Medical Research Council Dyspnoea Scale; SOC-13, 13-item Sense of Coherence Scale.

(heiQ) [P=0.0494, d=0.15, mean change difference (95% CI): 0.05 (−0.07 to 0.18)], although this was not significant in the ITT analysis (Table 2). The changes found in the other self-management domains were insignificant (P≥0.0944), as were the changes in general self-efficacy (GSE) and SOC (SOC-13) (P≥0.1814).

Discussion

Better living with COPD had a significant positive effect on Constructive attitudes and approaches in both PPA and ITT analysis. Constructive attitudes and approaches covers the important shift in how people view the impact of their condition on their lives, positive attitude, and sense of control and empowerment.[28,64] Our finding is supported by a longitudinal study that found improvement in Constructive attitudes and approaches after a similar group-based SMI.[22] Together, these findings suggest that participation in SMIs could improve Constructive attitudes and approaches for people with COPD. Although the effect size is larger in the PPA (d=0.38), the ITT analysis (d=0.32) better reflects the clinical effect.[86,87] An effect size of 0.32 is considered small, according to Cohen,[88] but is higher than the estimated benchmark effect sizes for change in Constructive attitudes and approaches, varying from 0.19 to 0.21.[67] The salutogenic orientation of Better Living with COPD could be one explanation for the positive effect on Constructive attitudes and approaches. A salutogenic orientation focuses on health as a continuum, the person's history, active adaption, and salutary factors, and stressors are

Table 2 Effects of better living with COPD (primary outcomes) evaluated by PPA and ITT analysis, ANCOVA: means from baseline and follow-up, mean change difference and effect size

Self-management domains		PPA[c]								ITT							
		Control		Intervention		Mean change difference[b]				Control		Intervention		Mean change difference[b]			
		N	Mean ± SD[a]	N	Mean ± SD[a]	Mean	95% CI	*d*	*P*-value[d]	N	Mean ± SD[a]	N	Mean ± SD[a]	Mean	95% CI	*d*	*P*-value[d]
Positive and active engagement in life	Baseline	68	2.87±0.47	54	2.94±0.40					86	2.88±0.46	91	2.96±0.41				
	Follow-up	68	2.91±0.49	54	3.00±0.32	0.02	−0.13 to 0.17	0.04	0.3634	68	2.91±0.47	60	2.97±0.33	0.00	−0.14 to 0.14	0.00	0.5543
Health directed activities	Baseline	67	2.60±0.54	54	2.53±0.71					85	2.64±0.58	91	2.63±0.68				
	Follow-up	69	2.67±0.53	54	2.68±0.59	0.13	−0.04 to 0.30	0.27	0.3154	69	2.67±0.53	60	2.70±0.59	0.11	−0.05 to 0.28	0.25	0.3225
Skill and technique acquisition	Baseline	68	2.68±0.45	54	2.78±0.44					86	2.68±0.43	90	2.73±0.45				
	Follow-up	67	**2.70±0.35**	55	**2.85±0.40**	**0.06**	**−0.07 to 0.19**	**0.17**	**0.0405**	67	**2.70±0.35**	61	**2.85±0.38**	**0.06**	**−0.06 to 0.19**	**0.17**	**0.0356**
Constructive attitudes and approaches	Baseline	68	2.88±0.46	54	2.93±0.43					86	2.88±0.48	90	2.90±0.40				
	Follow-up	67	**2.87±0.41**	54	**3.09±0.39**	**0.16**	**0.03 to 0.30**	**0.38**	**0.0021**	67	**2.87±0.41**	61	**3.07±0.41**	**0.14**	**0.00 to 0.27**	**0.32**	**0.0069**
Self-monitoring and insight	Baseline	69	2.97±0.34	54	3.05±0.33					87	3.00±0.35	91	3.06±0.35				
	Follow-up	69	**2.98±0.32**	**55**	**3.11±0.27**	**0.05**	**−0.07 to 0.18**	**0.15**	**0.0494**	69	2.98±0.32	61	3.09±0.27	0.02	−0.10 to 0.15	0.07	0.0944
Health service navigation	Baseline	68	2.79±0.37	54	2.92±0.35					86	2.82±0.38	91	2.93±0.38				
	Follow-up	67	2.86±0.39	55	3.00±0.37	−0.00	−0.14 to 0.13	−0.01	0.3606	67	2.86±0.39	62	3.00±0.38	0.00	−0.13 to 0.13	0.00	0.3635
Social integration and support	Baseline	69	2.79±0.48	53	2.80±0.42					87	2.77±0.48	89	2.83±0.41				
	Follow-up	67	2.78±0.46	55	2.82±0.46	0.02	−0.11 to 0.16	0.06	0.5623	67	2.78±0.46	61	2.82±0.45	0.02	−0.11 to 0.14	0.05	0.5840
Emotional distress	Baseline	68	2.32±0.60	54	2.30±0.61					86	2.34±0.63	90	2.41±0.62				
	Follow-up	67	2.29±0.56	55	2.31±0.70	−0.04	−0.22 to 0.14	−0.08	0.8809	67	2.29±0.56	61	2.32±0.71	−0.03	−0.20 to 0.14	−0.06	0.8914

Notes: [a]Means are presented from the data, therefore all participants (the total intervention and control groups) who provided data are included in the ITT description of means, including those with responses at only baseline or follow-up. [b]Mean change difference in both PPA and ITT is from the data; therefore, for both PPA and ITT only those with responses at both baseline and follow-up are represented. [c]Included in PPA were those who participated in more than half of the sessions on Better living with COPD. [d]*P*-value is from the ANCOVA based on multiple imputation (50 imputed data sets based on information on heiQ, education, FEV_1%, GSE, and SOC). A *P*-value <0.05 was considered statistically significant and is marked in bold.

Abbreviations: ANCOVA, analysis of covariance; *d*, Cohen's d; GSE, general self-efficacy; heiQ, Health Education Impact Questionnaire; ITT, intention-to-treat; PPA, per-protocol analysis; SOC, sense of coherence.

seen as possibly salutary,[29,36,37,89] and may have contributed to a shift in participants' attitudes and approaches.

Better living with COPD also had a positive effect on Skill and technique acquisition, significant in both PPA and ITT analysis. The Skill and technique acquisition scale captures knowledge-based skills and techniques related to managing disease-related symptoms and health problems, including the use of particular aids,[28] and our finding is supported by Turner et al.[22] Inhalation techniques are important skills and techniques related to medication adherence in COPD.[13,90] However, incorrect inhalation techniques are common,[13,91,92] and inhalation techniques were therefore specifically addressed as a topic in one group session. As a result of this, a surprising finding was the small effect size (d=0.17) in Skill and technique acquisitions. One possible explanation may be related to the group-based intervention. Previous research suggests that repeating education and teach-back approaches are recommended,[93–95] but in Better living with COPD, inhalation techniques were specifically addressed at one group session, and a teach-back approach was not mandatory for participants. Another possible explanation could be that inhalation techniques were not what participants had in mind when responding to the generic items in the Skill and technique acquisition scale.[28]

Furthermore, a significant positive effect of Better living with COPD was also found in the PPA for Self-monitoring and insight (P=0.0494). This is in accordance with the findings in the longitudinal study by Turner et al.[22] Still, the effect size in this study (d=0.15) was smaller than the estimated benchmark effect sizes for change in this domain in chronic diseases in general.[67] Also, the benchmark sizes presented for changes in heiQ scores are not benchmark sized for clinical relevance.[67] Therefore, the clinical relevance of the improvements found on Self-monitoring and insight, as well as on the Constructive attitudes and approaches and Skill and technique acquisition domains, is uncertain.

No significant effects were found on Positive and active engagement in life, Health directed activities, Health service navigation, Social integration and support, or Emotional distress. Previous randomized controlled studies including participants with chronic conditions have reported effects of various SMIs on one or more of these domains.[96–98] However, differences between the SMIs, the context, and the participants make direct comparisons difficult, and possible explanations for our findings are multiple. For example, in accordance with models clarifying COPD-specific SMIs,[11] Better living with COPD did not include supervised physical training. However, previous studies on pulmonary rehabilitation programs found the frequency and duration of supervised training to be crucial to increasing physical activity levels,[99] and items related to physical activity are included in the Health directed activities domain of heiQ.[28] Our findings could therefore suggest that support of some self-management-related domains could be better met by means additional to the ones included in Better living with COPD (eg, supervised physical training and individual teach-back methods).

In addition, the changes found in general self-efficacy and SOC were insignificant. The self-management-related domains are described as proximal outcomes of SMIs,[28] but because self-efficacy and SOC are relatively stable personal characteristics,[29–31] change may need time to develop. This is in line with descriptions of general self-efficacy and SOC as more distal outcomes of SMIs.[28] The post-intervention scores were measured shortly after the intervention period, and it is possible that the time frame was too short to detect developing changes in these characteristics. Further work including long-term evaluations is warranted.

Some methodological remarks should be mentioned. Three different nurses were the main group moderators and participants were actively involved in the conversations, leading to possible differences in group dynamics. Although group moderators had education before the SMI, their experience with a specific salutogenic orientation varied, and none had previous experience using MI in group contexts. This may have introduced additional variance, possibly reflecting variance in a real-life clinical implementation, but the effects may have been weaker than with experienced group moderators. The response rate was low, although similar to another study of self-management (cross-sectional),[100] but slightly lower than the response rate in another comparable study with inclusion criteria from a hospital register using postal mail.[101] A low response rate may increase the risk of volunteer bias. The baseline measurement was performed before randomization, but since participants could not be further blinded, desirability bias could account for some changes in the intervention group. Knowledge of group assignment may affect participants' responses to outcome measures and their behavior in the trial.[102] Yet, this bias may have been reduced by the control group's expectation of being offered the intervention after the study and possible activation following their knowledge of future SMI participation. Being informed that they would be offered the intervention after ~6 months could have had an impact on participants' experience of the usual care provided.[103] In addition, this study only explored short-term effects possibly affected by

positive experiences in the group conversations. Long-term effects as well as prognostic or predictive factors are yet to be investigated. It is also possible that we had easier access to participants through hospital registers, and inclusion may differ in clinical practice. Previous studies suggest that SMIs may be hampered by challenges faced in real-world clinical settings, such as referrers' lack of enthusiasm.[104]

One study limitation is that the follow-up measurements were limited because of a clerical error, where 22 intervention group participants did not receive follow-up questionnaires (Figure 1) after leaving the groups. This introduced unnecessary missing data in the ITT analysis. Unfortunately, we lack sufficient information to determine whether this affected the results, although there were no significant differences between these 22 and other participants at baseline on any of the self-management-related domains. This error also made it difficult to evaluate the attrition rate for those allocated to an intervention group, but the attrition rate was slightly higher (22.2%) than the estimated 20% for those allocated to a control group. In addition, we had to adapt the randomization procedure because of unexpectedly few participants in smaller municipalities, leading to a lower power than planned and a potential for introducing confounding variables owing to possible differences in services between the municipalities. The first author's participation in the SMIs could also raise methodological issues.

Conclusion

No randomized controlled studies have previously evaluated the effects of a salutogenic oriented SMI for people with COPD on the eight self-management-related domains, self-efficacy, and SOC specified in this study, and this study significantly adds to the knowledge of effects of disease-specific and health-promoting SMIs in COPD. Better living with COPD had significant positive effects on some self-management-related domains (Constructive attitudes and approaches, Skills and technique acquisition, and Self-monitoring and insight), whereas no significant effects were found on the other domains, general self-efficacy, and SOC. Therefore, Better living with COPD may serve as one of several means of self-management support, but further work is necessary to establish possible long-term effects of Better living with COPD on the specified domains and to evaluate possible long-term effects on SOC and self-efficacy.

Data sharing statement

Participant data (sociodemographic variables [age, sex, and GOLD grade] and the eight heiQ domains) used in the analysis in this study, together with a complementary specification of the intervention, "Better living with COPD" (in Norwegian), can be obtained on direct request to the corresponding author.

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Disclosure

The authors report no conflicts of interest in this work.

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