Aalborg Universitet

AALBORG UNIVERSITY
DENMARK

Optimizing individual benefits of pulmonary rehabilitation including a multifaceted dietary intervention – A single-arm feasibility study

Beck, A. M.; Geisler, L.; Mikkelsen, S. L.; Rasmussen, H. H.; Jørgensen, B. G.; Bach-Dahl, C.; Holst, M.

Published in:
Clinical Nutrition Open Science

DOI (link to publication from Publisher):
10.1016/j.nutos.2023.10.006

Creative Commons License
CC BY-NC-ND 4.0

Publication date:
2023

Document Version
Publisher's PDF, also known as Version of record

Link to publication from Aalborg University

Citation for published version (APA):
Beck, A. M., Geisler, L., Mikkelsen, S. L., Rasmussen, H. H., Jørgensen, B. G., Bach-Dahl, C., & Holst, M. (2023). Optimizing individual benefits of pulmonary rehabilitation including a multifaceted dietary intervention – A single-arm feasibility study. *Clinical Nutrition Open Science*, *52*, 96-109. Advance online publication. https://doi.org/10.1016/j.nutos.2023.10.006

General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal -

Take down policy
If you believe that this document breaches copyright please contact us at vbn@aub.aau.dk providing details, and we will remove access to the work immediately and investigate your claim.

Clinical Nutrition Open Science 52 (2023) 96–109

Contents lists available at ScienceDirect

Clinical Nutrition Open Science

journal homepage: www.clinicalnutritionopenscience.com

Original Article

Optimizing individual benefits of pulmonary rehabilitation including a multifaceted dietary intervention – A single-arm feasibility study

A.M. Beck [a, *], L. Geisler [b], S.L. Mikkelsen [b], H.H. Rasmussen [b], B.G. Jørgensen [c], C. Bach-Dal [d], M. Holst [b]

[a] Research Unit for Dieticians and Nutrition Research, Herlev Hospital, Borgmester Ib Juuls Vej 1, 20th Floor, DK-2730 Herlev, Denmark
[b] Center of Nutrition and Intestinal Failure, Aalborg University Hospital, Søndre Skovvej 5, DK-9000 Aalborg, Denmark
[c] Health Promotion and Prevention, Frederikshavn Kommune, Nytorv 1, DK-9900 Frederikshavn, Denmark
[d] Health Care Consulting, Stampevej 4, Hørsholm DK-2970, Denmark

ARTICLE INFO

Article history:
Received 10 June 2023
Accepted 18 October 2023
Available online 21 October 2023

Keyword:
COPD
Nutrition intervention
Chronic diseases
Pulmonary rehabilitation
Physical activity

SUMMARY

Introduction: Few studies have examined the effectiveness of nutrition interventions in municipal COPD rehabilitation programs. The objectives of this study were to examine the feasibility of implementation in practice (primary) and the feasibility of study methods and potential effectiveness (secondary) of a multidisciplinary dietary intervention offered to patients who start municipal rehabilitations program.

Methods: This study was a single arm intervention study with a pre-post design. Participant were recruited from five different municipal rehabilitation centers and received three individualized dietary counselling's. The primary outcome was retention, compliance to the intervention and complement of data collection. Secondary outcomes included changes in dietary intake, body composition and physical function. Analysis of the primary and secondary outcomes was primarily based on descriptive statistics.

Results: In total, 111 (77%) of 145 eligible patients from five different municipalities consented to participate. Of them 99 (89%) completed. Before the intervention 67 (63%) of the participants had 75% or more of their requirement of energy covered, and 48 (45%) had 75% or more of their protein requirements covered. At the end of the intervention, 76 (77%) of the participants had 75% or more coverage of energy

* Corresponding author.
E-mail address: anne.marie.beck@regionh.dk (A.M. Beck).

https://doi.org/10.1016/j.nutos.2023.10.006
2667-2685/© 2023 The Authors. Published by Elsevier Ltd on behalf of European Society for Clinical Nutrition and Metabolism. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

requirements and 80 (83%) had 75% or more coverage of their protein requirements. In general, the level of completeness was high.
Conclusion: We found recruitment to be feasible, a high rate of retention, a high compliance to the intervention and high completeness of the data collection.

© 2023 The Authors. Published by Elsevier Ltd on behalf of European Society for Clinical Nutrition and Metabolism. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Introduction

Chronic obstructive pulmonary disease (COPD) has been known throughout the past decades. Approximately 50,000 Danish patients suffer from severe and very severe COPD, defined by having a reduction of forced expiratory volume in one second (FEV1) below 50% of the predicted value [1,2]. Approximately 25,000 hospital admissions each year are caused by COPD as main diagnosis, and many Danish patients with severe COPD have more than one hospitalization every year due to exacerbations [1,3]. The development of the disease is significantly dependent on lifestyle factors [4].

Rehabilitation programs (RP), including physical exercise, are recommended for COPD-patients with a dyspnea score corresponding to a disease severity of MRC 2 or higher (inability to keep track of peers in even terrain). In the Danish COPD RP, physical exercise is a main component, aiming to improve physical function and reduce shortness of breath [5,6]. Annually 4,500 COPD-patients participate in RP throughout Denmark.

Malnutrition is common in COPD and is associated with significantly increased mortality and impaired quality of life [7,8]Studies of body composition in COPD show, that both fat mass and fat free mass are decreased. Muscle wasting is common, and this wasting may be of great importance as muscle fatigue may predispose to respiratory failure and further functional decrease [9–12].

Systematic reviews have demonstrated that nutritional interventions in COPD patients have a positive impact on several outcomes, including energy and protein intake, length of stay (LOS) and hospital readmissions as well as other nutritional and patient-centered outcomes [7,13,14]. This beneficial effect seems to be further improved when combined with exercise [8,15].

In order to achieve the highest benefit of the exercise rehabilitation, the participants need to be in energy and protein balance; otherwise, they may risk a (further) loss of weight, muscle mass and function [7,9,14–16]. A sufficient intake of protein seems of utmost significance in this context [7,16–18]. In a former study among patients referred to PR it was however shown that most of the patients did not achieve a healthy diet and further, one third of the patients indicated no specific interest in their own nutritional status or intake and were not aware of the significance of their diet [8]. In a study of 79 patients from the group behind the present article, we documented that almost 50% of the patients had insufficient intake of protein and energy, when they entered a RP. In addition, we found a significant positive association between protein intake and functional capacity [16] Lack of strength to participate in the exercise rehabilitation, due to insufficient dietary intake, might be one explanation to the high drop-out rates seen in pulmonary rehabilitation [19].

In our former study we found that 80% of the participants suffered from concomitant diseases such as cardiovascular diseases, diabetes mellitus, musculoskeletal or rheumatoid diseases, cancers, or others [16]. One third suffered from eating obstacles, and the most profound nutrition impact symptoms (NIS) were: a reduced appetite, not having the strength to eat very much, large meals evoking shortness of breath and dysphagia. These findings indicate the need for an individual multidisciplinary intervention, which should preferably start before the pulmonary exercise rehabilitation is initiated. Today this is not the case in Denmark, where limited time in PR is spent on nutritional care, compared to the time spent on the physical exercise [20].

About 23% of all COPD-patients drop out of pulmonary rehabilitation [19]. The many challenges for the COPD-patients due to comorbidities, poor functional level, and insufficient dietary intake, might be

one explanation to the high drop-out rates seen in pulmonary rehabilitation, which makes it difficult to design an intervention, where the patients complete. Further, most of the studies looking at the benefit of nutrition in relation to PR took place several years ago and hence might not reflect the current praxis [21]. In addition, it seems like the focus has been on provision of oral nutritional supplements (ONS) to COPD-patients participating in PR, and to our knowledge only a few studies has included dietary counselling [13,22]. Hence sufficient and updated methodological evidence about the design, planning, and justification of a trial among COPD patients is lacking, and feasibility studies may be beneficial to investigate where improvements need to be made to the design and conduct of relevant trials.

The aim of this study therefore was to examine the feasibility of implementation in practice (primary) and the feasibility of study methods and potential effectiveness (secondary) of a multidisciplinary dietary intervention offered to patients who start municipal rehabilitations program to be used in future practices and studies.

Methods

This study was a single arm feasibility intervention study with a pre-post design, measuring the outcomes at baseline and again at the end of the ten weeks intervention period. The results were reported according to the guidelines for non-randomized pilot and feasibility studies [23].

Participants

Danish municipalities who had participated in our former studies [16,20] were asked to participate in the present study. Of these, four municipality health care centers agreed. Three of these were situated in the Northern Jutland, so to secure a more even distribution of municipalities an additional municipality health care center from the eastern part of Denmark was invited to participate. The five health care centers included consecutive COPD-patients referred to pulmonary rehabilitation. All patients enrolled in pulmonary rehabilitation (PR) during a specified time-period were approached and invited to participate in the study, by the primary contact person, which in all communities was the COPD-nurse. There were no other inclusion criteria.

Exclusion criteria were alcohol abuse, severe psychiatric disorders, or non-willingness to participate.

The recruitment took place in the period September 2020 to May 2021 and was planned according to the start of new PR groups in the municipalities. The COPD-nurse provided oral and written information about the project. Interested patients then signed the written informed consent. After this, the baseline data were collected by the nurse, by use of questionnaires used in our former study [16]. Further, the patients had their body composition and physical strength assessed. In addition, the patients were provided with a dietary record and instructed how to fill this in before the first appointment to the individual dietary counselling. Finally, the nurse booked the first appointment with the nutrition expert.

Baseline characteristics

After inclusion, and before the start of the exercise rehabilitation, the COPD-nurse collected the following background information: Age, gender, education level, work status, living status, type of exercise rehabilitation and other kinds of pulmonary rehabilitation prescribed, smoking and alcohol status, comorbidities (e.g., ischemic heart disease, diabetes, musculoskeletal and rheumatic diseases, cancer), and use of home care, home nursing and meals-on-wheels.

Intervention

The content of the multidisciplinary intervention was developed in close collaboration with health care staff from the participating health care centers. Before the study the length of the exercise rehabilitation differed but for comparison, this was standardized to ten weeks for all centers.

The individual dietary counselling consisted of three individualized nutritional guidance sessions with the patient, before the start of the exercise rehabilitation, approximately half-way and at the end of the exercise rehabilitation.

The individual dietary counselling was provided by nutrition experts, already affiliated with the community and PR.

The nutrition experts received standardized material to support the individual dietary counselling including different hand-out nutritional information material, a scheme for a dietary plan, supportive material regarding assessment of energy, protein and fluid intake and requirement, and Danish guidelines for dietary counselling provided to older adults.

In addition, the nutrition experts were provided with a questionnaire to assess NIS at the second meeting. At the first and third meeting information about NIS was obtained from the dietary record, - see below. In connection to the assessment of NIS, there were suggestions for multidisciplinary contacts/appointments if problems were observed (see also below).

Finally, the nutrition experts received an algorithm to assist in the decision of whether oral nutritional supplements (ONS) were needed. If this was the case ONS was provided to the patients for free. Every individual dietary counselling had a duration of between 45 minutes to an hour.

Flow chart of the rehabilitation program including the individual dietary counselling is seen in Figure 1.

Outcomes

Feasibility of study methods

Feasibility of recruitment were assessed in terms of the percentage of participants who accepted the invitation to participate.

Feasibility of the intervention was assessed in terms of the percentage if participants finished the 10 weeks intervention period (retention). In a former study including dietary counselling provided to COPD patients attending PR, the percentage who completed the intervention was 80% [22] so this was the percentage expected in this study as well.

To assess representativeness a comparison between completers and non-completers were performed.

Feasibility of the intervention was also evaluated in relation to the percentage of participants who achieved an intake of energy and protein above 75% of their requirement. Nutritional studies performed among COPD patients attending PR has not used this an outcome before [21]. However, in a recent Danish nutritional intervention study using individual dietary counselling three times, 93%

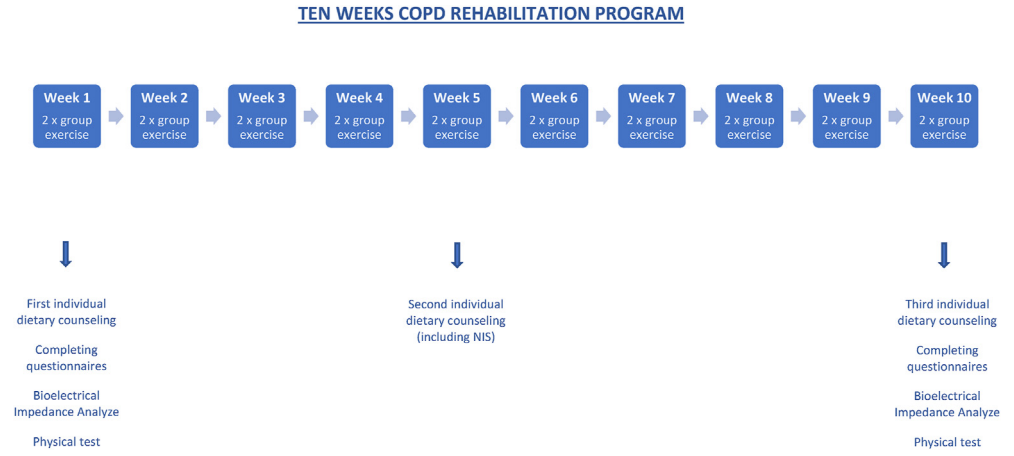

Figure 1. Flow chart of the rehabilitation program.

reached this goal for energy and 73% for protein [24]. Hence, this was the percentage expected in this study as well.

In addition to these assessments of feasibility, the compliance to the other outcome assessments was also documented, see details below. Data completeness of ≥80 % was required for an outcome to be considered for a definitive trial [25].

Other outcomes

Data were collected at baseline, and at the end of the PR period by the COPD-nurses, dietitians and by a research assistant. Data collection was made at the PR-municipal center, except for some post-measurements that were made in participants home due to risk of COVID-19 contamination. All data collectors received standardized written procedures for the collection of data, which were presented and discussed at a kick-off meeting to secure uniform data collection.

Questionnaires

Dietary intake

To get valid data about the intake of protein and energy a total of four days of dietary registration is needed [26]. The participants were therefore provided with a three-days dietary record and instructed by the local contact person or the nutrition expert on how to fill it in at home. At the first appointment with the nutrition expert an additional 24-h dietary recall was made. In addition to the 24-h recall, the nutrition expert also went through the patient registered dietary record together with the patient, to check for missing information (e.g., regarding fat content of milk, cheese, and meat, and use of in-between meals). This method was the same as used in the former study [16].

Subsequently, dietary records were entered in the "Vitakost.dk" dietary data program by a research assistant. The program allows detailed calculation of the content of the food's distribution of nutrients according to estimated portion size. The results of the calculation were assessed against the individual energy requirement. The total four days food intake was then used to assess whether the intake of energy and protein was above or below 75% of the estimated requirements [27]. Requirements for the individual with BMI 18.5–25 were based on information of weight as a pragmatic cut-off of energy 25 kcal/kg/d and protein 1.1 g/kg/d [15,28,29]. Requirements were regulated for obesity (BMI> 30) and underweight patients (BMI< 18.5) according to the recommendations from the Danish National Health Authority [30]. The amount of dietary record delivered and returned in completed form were documented.

Nutritional impact symptoms

The prevalence of different NIS was assessed as part of the dietary registration, at baseline and end of RP. Furthermore, NIS data were also gathered at the second dietary counselling. A total of 16 items were scored including nausea, constipation, mouth sores, chewing and swallowing problems, early satiety, pain, depression, and fatigue. Measures were none (0), green [1–3] over yellow [4–7] to red [8–10], where 10 relates to worst thinkable symptoms that reduces food intake [31]. In connection with the questionnaire there were suggestions for whom to contact if problems were observed, e.g., an occupational therapist in the case of chewing and swallowing problems. The number of dietary records with information about NIS from the patient were documented at baseline and at the end of intervention and compared to the possible amount.

Risk of sarcopenia

Risk of sarcopenia was assessed by means of A Simple Questionnaire to Rapidly Diagnose Sarcopenia (SARC-F). This is a questionnaire consisting of 5 questions to screen for sarcopenia. For every question there are three possible answers: 'none' giving a score of 0, 'some' giving a score of 1, and 'a lot/unable/with help' giving a score of 2. Thus, a total score of 0–10 can be achieved, where a score ≥ 4 represent risk of 'sarcopenia' [32,33]. The percentage of participants where a score could be calculated at baseline and at 10 weeks were documented.

Severity of COPD

Severity of COPD was evaluated by questions on whether in Prednisolone maintenance treatment.

In addition, self-reported dyspnea was assessed by means of the modified Medical Research Council (mMRC) dyspnea scale, range 1–5 [34].

The percentage of patients where these data were collected at baseline and at week 10 were documented.

Measurements

Body composition

Height was measured or self-reported if patients had their height measured within the past year. Body composition was measured by means of Bioelectrical Impedance Analysis (BIA) (InBody 230). Data were gathered regarding body weight; muscle mass, total fat mass, total lean body mass (LBM); LBM in arms, LBM in legs, LBM in torso, and total body water (TBW). Patients were encouraged to fully fast for two hours and avoid physical activity for eight hours prior to the measurement. Furthermore, patients were asked to empty their bladder just before measurement.

The baseline and post-intervention measurements took place at the same time of the day. Patients with pacemakers and metallic implants were excluded from the BIA measurement.

The percentage of patients offered this measurement at baseline and 10 weeks follow-up were documented.

Lung function

Lung function was measured by means of FEV1 [35]. If a recent measurement was available in the medical records, this result was used. The percentage of patients where these data were available at baseline were documented.

Physical function

To measure physical function, the patients performed a 30-second chair-stand test (30-s CST), and a six-minute walking test (6MWT).

Regarding 30-s CST, participants were asked to fold their arms across their chest and to stand up and sit down on a chair, as many times as possible for 30 seconds [36]. The seat should be a height of at least 43 cm. The score was the total number of times the person managed to stand within 30 seconds. Initially, the patients were shown the test in a slow tempo (stand-sit), to demonstrate the technique. Number of stand ups were recorded and divided according to the prevalence below 9, 9 to 11 and above 11 repetitions using the criteria developed for the healthy oldest old [36,37].

The 6MWT was performed at sight according to standards from the Pulmonary Rehabilitation Toolkit, and evaluated for walking distance <350 meters, between 350 and 450 meters and >450 meter [38].

The percentage of patients offered these measurements and completing these at baseline and 10 weeks follow-up were documented.

Statistical analysis

All collected data was entered in REDCap (Research Electronic Data Capture) hosted by Aalborg University Hospital, and exported to the Statistical Software Program, STATA, version 17. All statistical analyses were performed in STATA. The feasibility outcomes were reported descriptively and narratively. For the clinical endpoints only descriptive statistics, mean (standard deviation) for continuous outcomes and raw count (%) for categorical outcomes were reported.

If all participants did not reply to the given question, the number of replies is reported in the results. *P*-values of less than 0.05 are considered statistically significant.

Ethical considerations

Prior to inclusion, the patients were given written and oral information about the study. The participants were informed that they could withdraw from participation at any time during the study. The study was conducted according to the Helsinki Declaration of 2002. The study was put forward to the local ethic committee of Region North Denmark, who concluded that the project could be performed as described. The study was approved by The Danish Data Protection Agency (number 2020–017).

Results

Participants and feasibility of recruitment

One-hundred-and-forty-five COPD-patients were invited to participate in the study, and feasibility of recruitments was found as a total of 111 (77%) COPD patients from five different municipalities started (see Figure 2). Two did not want to participate due to the risk of COVID 19, 22 patients thought it was unmanageable, one patient passed to cancer rehabilitation, one had earlier completed a dietitian course, one patient was engaged in a dietitian course elsewhere, one patient could not get more time off from work and four patients just rejected without a reason.

The baseline characteristics of the participants can be found in table 1. Of the population, 88% suffered from concomitant diseases such as cardiovascular diseases, diabetes mellitus, musculoskeletal or rheumatoid diseases, cancers, mental illness, or others. Few participants (11%) had never smoked. Pulmonary Function (FEV1) was widely distributed in the patients, but almost all patients (96%) had a FEV1 below 80% of the predicted value. Most patients (98%) had moderate or severe dyspnea rated on the MRC dyspnea scale. Only a few of the participants (6%) received permanent treatment with Prednisolone.

Feasibility of study methods

Feasibility of the intervention was assessed in terms of the percentage if participants (retention) finished the 10 weeks intervention period: Of the 111 COPD-patients who started, 99 (89%) completed. This is a drop-out rate of 11%. The patients dropped out due to hospitalizations and fear of COVID-19.

Regarding the representativeness a comparison between completers and non-completers showed that those who dropped out of the study were younger, with higher weight, muscle mass, had better lung function and a higher prevalence of diabetes. Details can be found in Appendix table 1.

Feasibility of the intervention was also evaluated in relation to the percentage of participants who achieved an intake of energy and protein above 75% of their requirement. Before the intervention 68% of the patients, who completed the intervention, had coverage of 75% or more of their requirement on energy intake, and 45% had coverage of 75% or more of their requirement on protein intake. At the end of the intervention 78% of these patients had 75% or more coverage of energy requirement and 84% had 75% or more coverage of their protein requirement.

In addition to these assessments of feasibility, the compliance to the other outcome assessments was also documented. The result of these can be found in Table 2. In addition, a flowchart of the intervention and compliance to other outcome assessments is shown in Figure 2. In general, the level of completeness was high.

Discussion

In this study we aimed to develop, test, and evaluate a multidisciplinary dietary intervention offered to patients who start a RP including pulmonary exercise rehabilitation and to investigate the feasibility of the recruitment, retention and provision of a dietary intervention offered to COPD-patients.

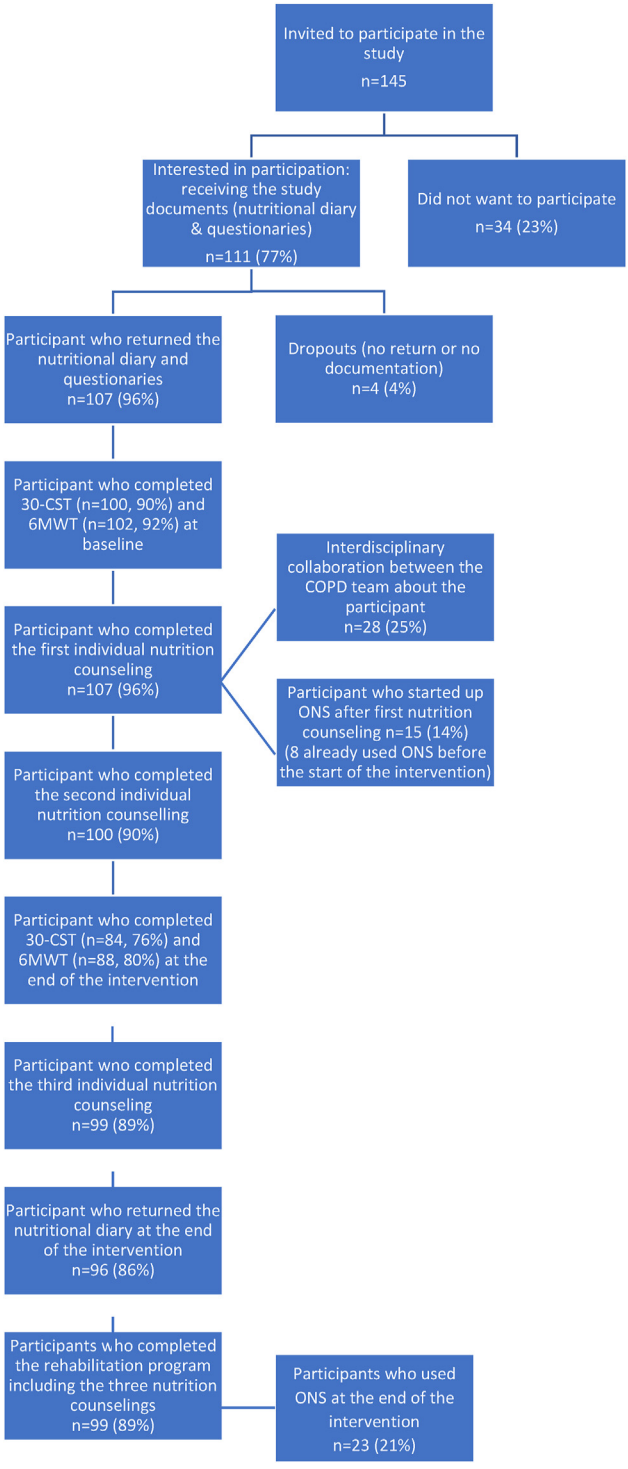

Figure 2. Flowchart of the participants and compliance to outcome assessments.

Table 1
Baseline characteristics of included participants

Included participants	Characteristics
Gender (female), n (%) (n=111)	52.0 (46.9)
Age, mean (SD) (n=111)	70.8 (±8.7)
Smoking habits (n=110)	
Actual smokers, n (%)	24 (21.8)
Former smokers, n (%)	74 (66.3)
Never smokers, n (%)	12 (10.9)
Drinking habits (n=101)	
Never drink alcohol, n (%)	32 (28.8)
Units per week, for those who reports drinking alcohol (n= 69), mean (SD)	7.6 (±10.3)
BMI kg/m2, mean (SD) (n=110)	28 (±5.9)
Below 20, n (%)	10 (9.1)
20–24.9, n (%)	22 [20]
25–29.9, n (%)	42 (38.2)
30–34.9, n (%)	20 (18.2)
>35, n (%)	16 (14.6)
Comorbidities	
Cardiovascular disease, n (%)	44 (39.6)
Diabetic, n (%)	14 (12.6)
Musculoskeletal and rheumatic diseases, n (%)	33 (29.7)
Cancer, n (%)	17 (15.3)
Mental illness, n (%)	15 (13.5)
Other comorbidities than the above, n (%)	33 (29.7)
No comorbidities, n (%)	13 (11.7)
Prednisone (n=109)	
Continuous treatment, n (%)	7 (6.4)
Short treatment within the last year, n (%)	24 (22)
None, n (%)	78 (71.6)
Lung function FEV1 mean L/s (SD) (n=82)	54.5 (±17.8)
<30, n (%)	10 (12.2)
30-49, n (%)	22 (26.8)
50-79, n (%)	43 (52.4)
≥80, n (%)	7 (8.5)
Medical Research Council (MRC) dyspnea scale (n=98)	
1. Breathless with strenuous exercise (Mild), n (%)	2 (2)
2. Short of breath when hurrying on the level of walking of a slight hill (Moderate), n (%)	32 (32.7)
3. Walks slower than people of the same age on the level or stops for breath while walking at own pace on the level (Moderate), n (%)	42 (42.9)
4. Stops for breath after walking 100 meters (Severe), n (%)	19 (19.4)
5. Too breathless to leave the house or breathless when dressing (Severe), n (%)	3 (3.1)

Table 2
Number and percentage of the patients (n=99), who completed the intervention where data for different outcomes were available

Outcome assessed	At baseline	At the end of intervention
All NIS data in dietary records, n (%)	87 (88)	83 (84)
Risk of sarcopenia score, n (%)	99 (100)	99 (100)
Prednisolone maintenance treatment, n (%)	97 (98)	97 (98)
Medical Research Council dyspnea scale, n (%)	82 (83)	82 (83)
Patient questionnaire completed, n (%)	97 (98)	92 (93)
Body composition measurement, n (%)	92 (93)	92 (93)
Lung function data, n (%)	87 (88)	-

In this study 77% of the patients accepted the invitation to participate. This is equal to what has been seen in another study, where attendance to pulmonary rehabilitation was assessed and 79% accepted to participate [19]. In the study by Fischer and co-authors no intervention was provided, and the participants were only asked to provide answers to questionnaires which might be considered much less challenging than the intervention and outcome assessments in our study. Further, these authors found that 23% of the COPD-patients dropped out of pulmonary rehabilitation [19]. In contrast we had a high rate of retention, despite the COVID-19 pandemic, and the drop-out rate in our study was only 11%. The low drop-out rate may be because the participants feel obligation to stay in the rehabilitation program knowing they are part of a research project. However, in a former study also including dietary counselling provided to COPD-patients attending PR, the percentage who completed the intervention was 80% [22] and hence lower than in our study.

Another explanation for the high compliance in our study might therefore be the single-arm design, where all participants are invited to receive the same intervention. Regarding the social aspects of the group RP, this might have influenced the firm participation. This aspect needs to be taken into consideration when defining a future RCT and determining the number of participants and design, where a cluster randomization might be beneficial, although the evidence grading is lower.

Feasibility of the intervention was also evaluated in relation to the percentage of participants who achieved an intake of energy and protein above 75% of their requirement.

At the end of the intervention 78% of the participants had 75 % or more coverage of energy requirement and 84% had 75% or more coverage of their protein requirement. Former nutritional studies among COPD-patients attending PR have not used this as an outcome [21], but another study using individual dietary counselling three times as in our study has used this. They found a comparable result, i.e., that, respectively, 93% and 73% reached an energy and protein intake of 75% or more of coverage [39]. Hence an intervention consisting of three dietary counselling, seems to be sufficient to reach the goal for energy and protein intake for most patients. Still, some participants might need some additional counselling. This could be in the form of telephone consultations, which has also proven to be effective [40].

In addition to these assessments of feasibility, the compliance to the other outcome assessments was also documented. Data completeness of $\geq$80 % was required for an outcome to be considered for a definitive trial [25]. All the outcomes used in the present study might therefore be considered for a future RCT. One explanation for the high completeness rate might be that almost all the outcomes chosen has been used by us in our former studies among this patient group [16,20] and hence found feasible. Also, several of the methods are already used by the municipalities in their present COPD rehabilitation and were therefore well-known to the COPD-nurses who assisted with the data collection. Since the COPD-nurse was also involved in the successful recruitment it seems very relevant to include the assistance of the local COPD-nurses in a future RCT. Finally, in three of the participating municipalities all included participants were handed out the questionaries at a joint meeting of all participants, where the professionals of COPD-rehabilitation (nutrition expert, COPD-nurse, etc.) also joined, and were able to help if the participant had any questions about the questionary. Here they were also handed out the nutritional diary and were instructed in how to fill it out and booked an individual appointment with the nutritional expert. Due to the different organization of the PR in Danish municipalities this set-up might not be possible in a randomized design, which should be taken into consideration when planning a future RCT.

The primary aim of the present study was to assess the feasibility of the recruitment, retention and provision of a dietary intervention offered to COPD-patients. As such we did not perform a power calculation. This must be done in a future RCT, and hence the primary outcome needs to be decided. Based on the data collected in the present study we now have information about e.g., the mean score difference and 95% confidence intervals for mean difference for a huge number of outcomes, including patient reported outcome measures. Also, we know from both the present study and our former study [16], that COPD-patients starting rehabilitation has an insufficient intake of especially protein according to their requirement and also that this can be optimized by a multifaceted dietary intervention.

This can help us deciding the primary outcome and assist in the power calculation. Still, we have to be aware of the impact of the COVID-19 pandemic on many of these outcomes.

Conclusion

In the present study we developed, tested, and evaluated a multidisciplinary dietary intervention offered to COPD-patients who started a rehabilitation program and found the recruitment to be feasible, a high rate of retention, a high compliance to the intervention and high completeness of the data collection.

Clinical messages

Nutrition intervention is feasibility in COPD rehabilitation and a high percentage of the COPD patients achieved the goal for energy and protein intake.

Recruitment to a nutrition intervention is feasibility, there is a high rate of retention, and there is high compliance to the dietary counselling.

Author contribution

Lea Geisler: Data collection, formal analysis, editing.

Anne Marie Beck: Conceptualization, methodology, validation, writing and editing– original draft, project administration.

Henrik Højgaard Rasmussen: Conceptualization, methodology, review and editing.

Birte Grønbeck Jørgensen: Conceptualization, review and editing.

Charlotte Bach-Dal: Conceptualization, data collection, review and editing.

Mette Holst: Conceptualization, methodology, validation, editing, project administration.

Funding support

This study was supported by the national association of municipalities and the health cartel. Grant registration number A244.

Declaration of competing interest

The Authors declare that there is no conflict of interest'.

Acknowledgements

The authors would like to thank patients and staff at the five municipality rehabilitation programs for their efforts and positive attitude towards this study. Furthermore, we would like to thank Fresenius-Kabi for supporting the study with ONS to provide to patients for free.

Appendix 1. Table. Comparison of participants who, respectively, completed the study and dropped out.

	Completed	Dropout	*P*-value
Sex (n=99,12)			0.321
Male	51	8	
Female	48	4	
Age, year (n=99,12)	71.4±8.4	65.8±9.9	0.037*
Body weight kg (n=99,12)	79.4±19.1	93.1±21.1	0.022*
Muscle Mass, kg (n=96,12)	31.2±10.0	38.2±16.0	0.035*
Total fat mass, % (n=96,12)	34.7±9.9	37.6±6.4	0.334
Quality of life, EQ-5D-5L, VAS (n=96,10)	61.6±17.1	50.7±21.1	0.063
30seconds-Chair Stand test (n=94,6)	10.8±2.9	11.8±2.9	0.406
6 minutes walking test (n=96,6)	374.6±128.8	413.7±83.1	0.466
Smoking (n=98,12)			0.401
Actual smokers	20	4	
Former smokers	68	6	
Never smokers	10	2	
Prednisone (n=99,10)			0.885
No treatment	71	7	
Continuous treatment, n (%)	6	1	
Short treatment within the last year, n (%)	22	2	
BMI, kg/m^2 (n=98,12)	27.6±6.0	31.0±4.8	0.070
BMI groups (n=98,11)			0.294
<20	10	0	
20–24.9	21	1	
25–29.9	38	4	
30–34.9	16	4	
≥35	13	3	
Lung function FEV1 (n=77,5)	53.3±17.6	72.7±8.5	0.017*
Lung function grp (n=77,5)			0.040*
<30, n (%)	10	0	
30-49, n (%)	22	0	
50-80, n (%)	40	3	
>80, n (%)	5	2	
Medical Research Council (MRC) dyspnea scale (n=93,5)			0.708
1. Breathless with strenuous exercise (Mild)	2	0	
2. Short of breath when hurrying on the level of walking of a slight hill (Moderate)	30	2	
3. Walks slower than people of the same age on the level or stops for breath while walking at own pace on the level (Moderate)	41	1	
4. Stops for breath after walking 100 meters (Severe)	17	2	
5. Too breathless to leave the house or breathless when dressing (Severe)	3	0	
Comorbidities (n=99,12)			
Cardiovascular disease, yes	40	4	0.636
Diabetic, yes	9	5	<0.001*
Musculoskeletal and rheumatic diseases, yes	28	5	0.338
Cancer, yes	15	2	0.891
Mental illness, yes	12	3	0.218
Other comorbidities than the above, yes	30	3	0.704
No comorbidities, yes	13	0	0.182

References

[1] Lange P, Marrot JL, Dahl M, Ingebrigtsen TS, Vestbo J, Nordestgaard BG. Substantial need for early diagnosis, rehabilitation and treatment of chronic obstructive pulmonary disease. 2012.

[2] Lange P, Tøttenborg SS, Sorknæs AD, Andersen JS, Søgaard M, Nielsen H, et al. Danish register of chronic obstructive pulmonary disease. In: Clinical epidemiology, vol. 8. Dove Medical Press Ltd; 2016. p. 673–8.

[3] Bilde L, Rud Svenning A, Dollerup J, Bække Borgeskov H, Lange P. The cost of treating patients with COPD in Denmark - A population study of COPD patients compared with non-COPD controls. Respir Med 2007 Mar;101(3):539–46.

[4] Gea J, Casadevall C, Pascual S, Orozco-Levi Mauricio, Barreiro E. Clinical management of chronic obstructive pulmonary disease patients with muscle dysfunction. In: Journal of thoracic disease, vol. 8. AME Publishing Company; 2016. p. 3379–400.

[5] Carone M, Patessio A, Ambrosino N, Baiardi P, Balbi B, Balzano G, et al. Efficacy of pulmonary rehabilitation in chronic respiratory failure (CRF) due to chronic obstructive pulmonary disease (COPD): The Maugeri Study. Respir Med 2007; 101(12):2447–53.
[6] Mccarthy B, Casey D, Devane D, Murphy K, Murphy E, Lacasse Y. Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database of Systematic Reviews 2015;2015(2).
[7] Collins PF, Stratton RJ, Elia M. Nutritional support in chronic obstructive pulmonary disease: A systematic review and meta-analysis. American Journal of Clinical Nutrition 2012;95:1385–95.
[8] ter Beek L, van der Vaart H, Wempe JB, Dzialendzik AO, Roodenburg JLN, van der Schans CP, et al. Dietary resilience in patients with severe COPD at the start of a pulmonary rehabilitation program. International Journal of COPD 2018 Apr 23; 13:1317–24.
[9] Dubé BP, Laveneziana P. Effects of aging and comorbidities on nutritional status and muscle dysfunction in patients with COPD. In: Journal of thoracic disease, vol. 10. AME Publishing Company; 2018. S1355–66.
[10] Anker SD, John M, Pedersen PU, Raguso C, Cicoira M, Dardai E, et al. ESPEN Guidelines on Enteral Nutrition: Cardiology and Pulmonology. Clinical Nutrition 2006 Apr;25(2):311–8.
[11] Ingadottir AR, Beck AM, Baldwin C, Weekes CE, Geirsdottir OG, Ramel A, et al. Two components of the new ESPEN diagnostic criteria for malnutrition are independent predictors of lung function in hospitalized patients with chronic obstructive pulmonary disease (COPD). Clinical Nutrition 2018 Aug 1;37(4):1323–31.
[12] Schols AMWJ, Gosker HR. The pathophysiology of cachexia in chronic obstructive pulmonary disease. Curr Opin Support Palliat Care 2009 Dec;3(4):282–7.
[13] van Beers M, Rutten-van Mölken MPMH, van de Bool C, Boland M, Kremers SPJ, Franssen FME, et al. Clinical outcome and cost-effectiveness of a 1-year nutritional intervention programme in COPD patients with low muscle mass: The randomized controlled NUTRAIN trial. Clinical Nutrition 2020 Feb 1;39(2):405–13.
[14] Deutz NE, Ziegler TR, Matheson EM, Matarese LE, Tappenden KA, Baggs GE, et al. Reduced mortality risk in malnourished hospitalized older adult patients with COPD treated with a specialized oral nutritional supplement: Sub-group analysis of the NOURISH study. Clinical Nutrition 2021 Mar 1;40(3):1388–95.
[15] van de Bool C, Rutten EPA, van Helvoort A, Franssen FME, Wouters EFM, Schols AMWJ. A randomized clinical trial investigating the efficacy of targeted nutrition as adjunct to exercise training in COPD. J Cachexia Sarcopenia Muscle 2017 Oct 1;8(5):748–58.
[16] Holst M, Beck AM, Rasmussen HH, Lange P. Insufficient intake of energy and protein is related to physical functional capacity among COPD patients referred to municipality based pulmonary rehabilitation. Clin Nutr ESPEN 2019 Apr 1;30: 35–41.
[17] Peden CJ, Stephens T, Martin G, Kahan BC, Thomson A, Rivett K, et al. Effectiveness of a national quality improvement programme to improve survival after emergency abdominal surgery (EPOCH): a stepped-wedge cluster-randomised trial. The Lancet 2019 Jun 1;393(10187):2213–21.
[18] Nguyen HT, Collins PF, Pavey TG, Nguyen NV, Pham TD, Gallegos DL. Nutritional status, dietary intake, and health-related quality of life in outpatients with COPD. International Journal of COPD 2019;14:215–26.
[19] Fischer MJ, Scharloo M, Abbink JJ, van 't Hul AJ, van Ranst D, Rudolphus A, et al. Drop-out and attendance in pulmonary rehabilitation: The role of clinical and psychosocial variables. Respir Med 2009 Oct;103(10):1564–71.
[20] Jørgensen BG, Beck AM, Rasmussen HH, Lange P, Bach-Dahl C, Holst M. Ernæringsindsats blandt KOL-patienter i kommunal rehabilitering – er der forbedringspotentiale? Diætisten [Internet] 2019;159:24–6.
[21] Aldhahir AM, Rajeh AMA, Aldabayan YS, Drammeh S, Subbu V, Alqahtani JS, et al. Nutritional supplementation during pulmonary rehabilitation in COPD: A systematic review. In: Chronic respiratory disease, vol. 17. SAGE Publications Ltd; 2020.
[22] van Wetering CR, Hoogendoorn M, Broekhuizen R, Geraerts-Keeris GJW, de Munck DRAJ, Rutten-van Mölken MPMH, et al. Efficacy and Costs of Nutritional Rehabilitation in Muscle-Wasted Patients With Chronic Obstructive Pulmonary Disease in a Community-Based Setting: A Prespecified Subgroup Analysis of the INTERCOM Trial. J Am Med Dir Assoc 2010;11(3): 179–87.
[23] Lancaster GA, Thabane L. Guidelines for reporting non-randomised pilot and feasibility studies. Pilot Feasibility Stud 2019; 5(1):1–6.
[24] Cramon MØ, Raben I, Beck AM, Andersen JR. Individual nutritional intervention for prevention of readmission among geriatric patients—a randomized controlled pilot trial. Pilot Feasibility Stud 2021 Dec 1;7(1).
[25] Schulz KF, Grimes DA. Sample size calculations in randomised trials: mandatory and mystical, vol. 365. Lancet: Elsevier B. V.; 2005. p. 1348–53.
[26] Nelson M, Black AE, Morris JECTJ. Between- and within-subject variation in nutrient intake from infancy to old age: estimating the number of days required to rank dietary intakes with desired precision. Am J Clin Nutr 1989;50:155–67.
[27] Kondrup J, Johansen N, Plum LM, Bak L, Larsen HI, Martinsen A, et al. Incidence of nutritional risk and causes of inadequate nutritional care in hospitals. Clinical Nutrition 2002;21(6):461–8.
[28] Deutz NEP, Bauer JM, Barazzoni R, Biolo G, Boirie Y, Bosy-Westphal A, et al. Protein intake and exercise for optimal muscle function with aging: Recommendations from the ESPEN Expert Group. Clinical Nutrition 2014 Dec 1;33(6):929–36.
[29] Gomes F, Schuetz P, Bounoure L, Austin P, Ballesteros-Pomar M, Cederholm T, et al. ESPEN guidelines on nutritional support for polymorbid internal medicine patients. Clinical Nutrition 2018 Feb 1;37(1):336–53.
[30] The Danish Health Authority. A guide for doctors , nurses , healthcare assistants , auxiliary nurses and Screening and treatment of patients at nutritional risk. 2008.
[31] Holst M, Rasmussen HH, Bruun KS, Otten RE, Geisler L. Nutritional Risk in Pulmonology Outpatients and Health Professionals` Perspectives on Nutritional Practice. Journal of Nursing Studies and Patient Care 2019;1(1):1–7.
[32] Malmstrom TK, Miller DK, Simonsick EM, Ferrucci L, Morley JE, Sarc-F. A symptom score to predict persons with sarcopenia at risk for poor functional outcomes. J Cachexia Sarcopenia Muscle 2016;7(1):28–36.
[33] Gade J, Beck AM, Rønholt F, Andersen HE, Munk T, Vinther A. Validation of the Danish SARC-F in Hospitalized, Geriatric Medical Patients. Journal of Nutrition, Health and Aging 2020;24(10):1120–7.
[34] Williams N. The MRC breathlessness scale, vol. 67. Oxford, England: Occupational medicine; 2017. p. 496–7.

[35] Doherty DE. A review of the role of FEV1 in the COPD paradigm. COPD: Journal of Chronic Obstructive Pulmonary Disease 2008;5(5):310–8.
[36] Rikli RE, Jones CJ. Development and validation of criterion-referenced clinically relevant fitness standards for maintaining physical independence in later years. Gerontologist 2013 Apr;53(2):255–67.
[37] Vaidya T, Chambellan A, de Bisschop C. Sit-to-stand tests for COPD: A literature review. In: Respiratory medicine, vol. 128. W.B. Saunders Ltd; 2017. p. 70–7.
[38] Dale M. Media: Review – Pulmonary Rehabilitation Toolkit: a physiotherapist's perspective. J Physiother 2018;64(4):275–6.
[39] Munk T, Svendsen JA, Knudsen AW, Østergaard TB, Thomsen T, Olesen SS, et al. A multimodal nutritional intervention after discharge improves quality of life and physical function in older patients – a randomized controlled trial. Clinical Nutrition 2021;40(11):5500–10.
[40] Marx W, Kelly JT, Crichton M, Craven D, Collins J, Mackay H, et al. Is telehealth effective in managing malnutrition in community-dwelling older adults? A systematic review and meta-analysis. Maturitas 2018;111(January):31–46.