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Cluster randomised controlled trial on the effects of long-term home-based exercise for patients with chronic obstructive pulmonary disease with recent exacerbation: research protocol of the *COPDtoParis* Project

Anna Lei Stoustrup ,[1,2] Lars Pilegaard Thomsen,[3] Jane Andreasen,[4,5,6] Thorvaldur S Palsson,[7,8] Ulla Møller Weinreich [1,8]

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For numbered affiliations see end of article.

Correspondence to
Mrs Anna Lei Stoustrup; a.stoustrup@rn.dk

ABSTRACT

Background Chronic obstructive pulmonary disease (COPD) is a highly prevalent respiratory disease associated with significant health decline and economic burdens. Pulmonary rehabilitation is an effective intervention, but securing adherence to exercise is difficult, particularly for frail and disabled patients, challenged by leaving their home. Home-based exercise is an emerging alternative for persons with COPD, but long-term adherence is unclear. This study aims to investigate the effects, experiences and acceptability of long-term home-based cycling for patients with COPD post exacerbation.

Methods and analyses This cluster randomised controlled trial will recruit hospitalised patients with COPD following hospitalisation following exacerbation of COPD. Participants will be referred to acute rehabilitation for 8 weeks at discharge. After rehabilitation, participants are randomised in clusters of five into 1 year of home-based cycling with the goal of cycling from Aalborg to Paris, or into the control group, who will receive standard care. Data will be collected at baseline, postrehabilitation/intervention initiation, at 6 and 12 months. Primary outcome is physical performance, while secondary outcomes include daily activity levels, lung function, mobility, frailty, symptom severity, health-related quality of life, survival rates and readmissions. A qualitative substudy will uncover experiences from participants. Daily activity levels will be measured using leg-mounted triaxial accelerometers. Other parameters will be tested with physical tests, questionnaires and interviews. The study aims to include 50 patients, with 25 participants in each group. A cost-effectiveness analysis will assess the impact on disease prevention and hospitalisation.

Ethics and dissemination This study, approved by The North Denmark Region Committee on Health Research Ethics (N-20230008) and compliant with the Helsinki Declaration, includes annual safety and progress reporting of potential adverse events. Results will be disseminated through peer-reviewed publications, conference presentations and community outreach to ensure accessibility to participants, healthcare professionals and the public.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Little is known about the long-term effects of home-based exercise following an exacerbation of chronic obstructive pulmonary disease (COPD).

WHAT THIS STUDY ADDS

⇒ This study evaluates long-term, home-based cycling for patients with COPD, focusing on adherence, symptoms, mobility, quality of life and survival.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings could guide recommendations for home-based exercise programmes for persons with COPD.

Trial registration number NCT06235502 and Northern Jutland trial register (F2023-066).

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is the most prevalent respiratory disease globally and is associated with increased risk of early death, frequent hospitalisations and increasing expenses for society and patients.[1] Expenses relate primarily to exacerbation events where 60% of patients in Denmark with COPD hospitalised with an exacerbation are readmitted within a year.[2]

Early initiation of pulmonary rehabilitation (PR) following an acute exacerbation can lead to significant improvements in health-related quality of life (HRQoL) and a reduction in hospital readmissions.[3] Participating in PR and exercise is an important measure in the management of COPD, aiming at improving patients' quality of life, symptoms

and functionality, as well as reducing anxiety and depression, exacerbations, hospital admissions and mortality rates.[3 4] Furthermore, attending PR can significantly enhance the HRQoL and reduce dyspnoea, which is one of the predominant symptoms limiting daily activities in these patients.[5–7] The literature also indicates that the long-term maintenance of benefits derived from PR is crucial for sustaining improvements in physical and psychological health. While initial participation in PR yields significant benefits, the challenge lies in ensuring ongoing engagement and adherence to health-enhancing behaviours post rehabilitation.[8]

Despite the benefits of PR, participation and adherence to exercise and rehabilitation can be challenging for patients with COPD; especially the more frail and disabled patients, who refrain from leaving their home.[9–11] Patients with advanced COPD, who experience exacerbations, report several obstacles to engage in regular exercise, for example, impact of COPD symptoms, pain and discomfort during intense exercise, distance to rehabilitation, accessibility, challenges related to transport and parking, symptoms from other comorbidities, weather conditions and so on.[10 12] Furthermore, lack of social support and peer support significantly affect adherence to exercise for patients with COPD.[11]

The implementation of PR programmes has evolved to include various modalities, such as home-based and telehealth approaches, which help address barriers related to accessibility and adherence, while providing an alternative to traditional center-based rehabilitation. Although these approaches have demonstrated feasibility and acceptability among patients with COPD, providing a comprehensive approach that includes exercise training, education and psychosocial support,[13 14] their effectiveness in maintaining long-term improvement is still an area of ongoing research. The maintenance of benefits derived from PR in patients with COPD remains uncertain, particularly in the context of patients recovering from acute exacerbations of COPD.[15] However, home-based exercise has shown to be a viable alternative exercise format for patients with COPD for improving exercise tolerance, mobility, walking distance, HRQoL, decreasing disabilities and improving COPD symptoms such as dyspnoea.[16–19] However, long-term adherence to participating in home-based exercise is sparsely studied.

Cycling has, by the American and British Thoracic Societies, been described as an effective part of (PR), improving lower limb muscle function as well as exercise performance, dyspnoea and quality of life in patients with COPD, including those recovering from acute exacerbations.[3 20 21] The cycle allows for controlled and adjustable exercise intensity, which can be tailored to the individual capabilities of patients, making it a suitable option for those with varying levels of disease severity.[22] The use of cycle ergometers in home-based exercise settings has shown promise, allowing patients to engage in regular exercise without the need for frequent visits to rehabilitation centres. This is particularly advantageous for patients who may face challenges in accessing traditional rehabilitation facilities.[23 24] Considering that cycling is a familiar activity for people in Denmark and is deemed a safe and comprehensible exercise equipment, this was chosen as the home-based exercise modality. We hope that our study will contribute valuable insights into this area, particularly regarding the long-term adherence to exercise training and the specific needs of patients recovering from acute exacerbations.

Several studies have determined physical activity levels of patients with COPD following an exercise programme and found a positive correlation between exercise and an increase in physical activity.[25] However, these studies measure activity through questionnaires or/and with wrist-mounted pedometers, which has been shown to measure activity imprecisely, especially in patients with COPD who tend to walk less rigorously and rhythmically. Leg-mounted, triaxial accelerometers for measuring PA has by recent studies shown to be a valid and reliable measurement.[26 27]

We used the Standard Protocol Items: Recommendations for Interventional Trials checklist when writing our report.[28]

OBJECTIVES OF THE STUDY

The primary objective of this study is to investigate the effect of long-term home-based cycling on lower limb function between intervention and control group:

- physical performance in patients with COPD with recent admission for exacerbation of COPD.

Furthermore, following secondary objectives between intervention and control groups are:

- to investigate effects on lung function, symptom severity of COPD and HRQoL;
- to investigate the short-term effects of early rehabilitation on daily activity levels;
- to investigate the effects that long-term home-based rehabilitation has on daily activity levels;
- to capture participants' perceptions, barriers, enablers and experiences with participating in—and adhering to home-based cycling through repeated semistructured group interviews;
- to assess the effects of long-term, home-based telerehabilitation on disease—and hospitalisation prevention through a cost-effectiveness analysis within a year through survival rates and readmissions within a year.

The aim of this study protocol is to clarify the rationale, methods, outcomes and analysis of COPDtoParis. This study protocol will serve as a reference for future publications on data from this study.

METHODS, PARTICIPANTS AND ANALYSES

Study design

This study is designed as a single-centre, parallel-group cluster randomised controlled trial (RCT) conducted at Aalborg University Hospital. Patients diagnosed with

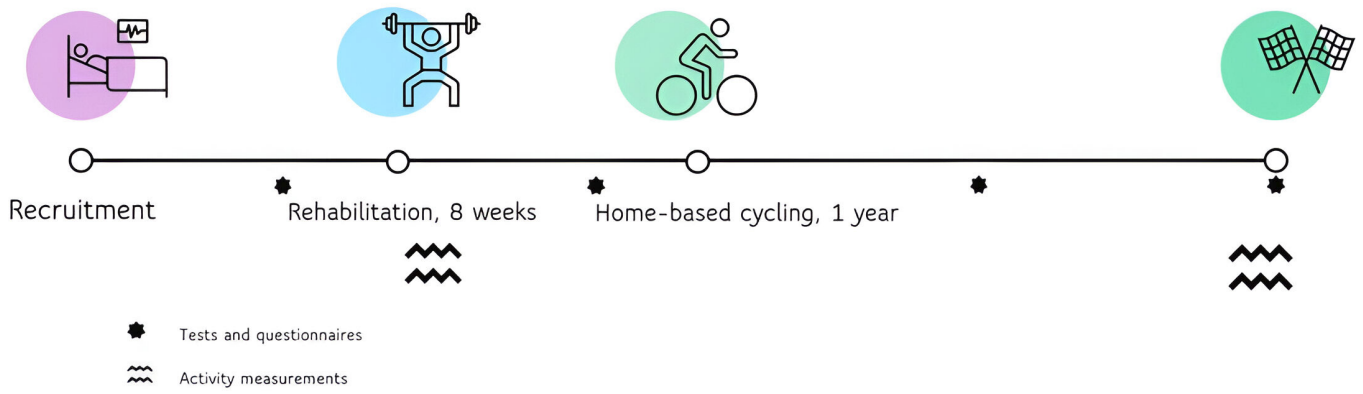

Figure 1 Overview of recruitment, acute rehabilitation, home-based exercise and completion. Tests and questionnaires are marked at baseline, 6 weeks, 6 months and 12 months. Activity measurements are marked at baseline, and at completion.

acute exacerbation of COPD will be recruited during their hospitalisation. Following discharge, all participants will undergo municipality-based 'acute rehabilitation' (Almen Genoptræningsplan) as mandated by Danish legislation, typically lasting around two times a week for 8 weeks.[29] After completing this rehabilitation period, participants will be allocated to the intervention or control group through cluster randomisation, with clusters consisting of teams of patients who have completed the acute rehabilitation period. These clusters will be randomly assigned to the intervention—or control group using computer-generated sequences concealed in envelopes. Each cluster, consisting of five participants, will be randomised as a whole, to ensure that all participants within a cluster receive the same allocation. A total number of 10 clusters will be included in this trial.

The intervention group will commence 1 year of home-based cycling as described below, and the control group will receive standard care as described below. Data will be collected during home visits at baseline, after 6 weeks, after 6 months and after 12 months of home-based cycling, as shown in figure 1.

The study has begun inclusion of participants as of 13 October 2023. Recruitment will conclude after inclusion of 50 participants. The study will finalise when the last participant has reached 12 months of home-based cycling.

Patient and public involvement statement

The development of the COPDtoParis intervention involved patients and the public throughout. It was inspired by interest of a patient with COPD in cycling for a greater cause while watching Team Rynkeby cycling from Aalborg to Paris. Patients contributed to the iterative design of the intervention through pilot testing and interviews. They selected the exercise bikes and helped design the 4MVideo app for virtual cycling. Physiotherapists from the municipality reported on patient inclusion and referrals. Patients assessed the intervention's burden through short interviews, offering feedback on time commitment and feasibility, highlighting the need to minimise participant strives. Even those who declined participation were interviewed to gain their insights and motives for declining. Municipal physiotherapists handled postdischarge rehabilitation. Results will be shared via email with participants (where consent was provided) (consent form online supplemental appendix 1), and publicised through conferences, articles and social media.

Patient engagement was central to ensuring the study's relevance and acceptability for patients with COPD.

Intervention

Participants in the intervention group will engage in home-based cycling in teams. On exercise bikes connected to a tablet, participants push forward virtual bike routes from Aalborg to Paris in the 4Mvideo app (4Mvideo ApS, Kongens Lyngby, Denmark). During cycling, participants will be able to communicate with others participating in the programme using the tablet to recreate a team experience. The route from Aalborg to Paris has been filmed by the local cycling team, 'Team Rynkeby', and the participants will reach Paris within 6 weeks. The videos have been divided into 42 stages, one for each day of the 7 weeks, every video approximately 20 min long. The app and the cycle are adjusted by physiotherapists to fit the exercise capacity of the individual participant, enabling participants at different physical capacities to cycle the same stages together. The team members can follow their own—and each other's progress through a virtual map. The participants are encouraged to cycle every day but can do so, when they choose during the day. They are contacted semiweekly by telephone by physiotherapists to assess whether they need assistance. The progress of each cyclist is visible to the research assistant. After the trip to Paris, new cycling routes will be available for the participants of the intervention group to partake in the following months. The cycle and tablet will be available for a total of 12 months.

Control group

Participants who are randomised to the control group will receive standard care and/or an individual solution which includes either continuing exercise by the municipality or receiving a standardised home-based work-out programme for patients with exacerbation of COPD.

Randomisation

Cluster randomisation, as described in the section 'Study design', which is used as the intervention is group based and hence patients need to be randomised to the same arm at the same time. An automatic adaptive randomisation allocation will be used to ensure 1:1 balance between the interventions—and control groups, by adjusting the probability of each arm according to the previous allocations. This process will adjust the allocation probabilities based on previous assignments to minimise bias.

The randomisation process is performed by a dedicated research assistant, who will play a pivotal role in the execution of the study. They will ensure that the allocation is concealed from the research team involved in participant recruitment and data collection. The assistant is also responsible for the installation of exercise equipment, mounting of activity measurement devices and administration of questionnaires, thus ensuring the blinding of the research team involved in physical testing and data analysis. The statisticians analysing the data will be blinded to the group assignments during the statistical analysis phase. This will be ensured by coding the data in such a way that the group labels are not disclosed until the final analysis is complete. The participants are not blinded.

Eligibility criteria

Patients will be considered eligible to participate in this study if they meet following criteria:

- Adults >18 years old.
- Hospital admission with COPD exacerbation with pre-existing COPD diagnosis.
- Citizens of Aalborg Municipality.
- Able to provide informed consent.
- Accepting referral to rehabilitation.

Patients will be excluded if they are diagnosed with:

- Terminal illness.
- Unstable heart disease, that is, ischaemic heart disease and cardiac rhythm disorders.
- Other conditions preventing participating in virtual cycling, that is, leg amputation, blindness, or regimens and earlier or upcoming surgeries preventing seated position.
- Are unable to understand basic oral and written information in Danish.

Outcomes

For all participants in the study, the following information will be registered from the digital patient record:

Demographics

- Sex.
- Age.
- Civil status.
- Smoking status and tobacco history.
- Working status.
- Body mass index.
- Comorbidities.
- Hospital contact and readmissions.
- Mortality.

Primary outcome

The primary outcome of this RCT is the five-repetition sit-to-stand test (5RSTS), which is a validated measure of physical performance, functional lower limb strength and endurance in patients with COPD.[30]

Secondary outcomes

Lung function (forced expiratory volume with a mobile, hand-operated spirometer (CareFusion, Jaeger, San Diego, USA)), dyspnoea (modified Medical Research Council Dyspnoea Scale (mMRC)), daily functioning (Canadian Occupational Performance Measure), disease-specific health status (St. George's Respiratory Questionnaire and the COPD Assessment Test), generic health status (EuroQol 5-Dimensions 5-Level (EQ-5D-5L)), frailty assessment (Tilburg Frailty Indicator and the Clinical Frailty Scale), lower limb capacity (including balance) will be assessed with the 30-s sit-to-stand test and short physical performance battery, and mobility patterns (UAB Study Of Aging Life-Space Assessment (LSA-DK)) (see table 1). All questionnaires are validated in Danish and are validated for patients with COPD and/or chronically ill patients. Furthermore, another secondary outcome is the changes in daily activity levels. Triaxial accelerometers for measuring physical activity (*SENS*, SENS Innovation ApS, Copenhagen, Denmark) will be mounted onto participants' knees and will measure activity continuously for 6 weeks at initiation and through the last 6 weeks of the intervention. Activity data will be stratified into specific activity categories: sedentary, walking and cycling, with outcomes being reported as the total time (in minutes) spent in each activity per day.

Interviews are performed in the setting of the participants' home. The semistructured interviews are conducted by a research assistant with experience in performing interviews as to ensure blinding of the research team.

Sample size

In this trial, we aimed to evaluate the effectiveness of our intervention using the 5RSTS as a primary outcome measure in persons with COPD. The minimum clinically important difference (MCID) for the 5STS has been established at 1.7 repetitions by Jones *et al*.[30] For the purpose of this study, we estimate a sample size of 50 participants, which allows for a balanced distribution

Table 1 Overview of measurements per home visit

	Baseline	Six weeks	Six months	Twelve months
Primary outcome				
Physical performance: 5 repetition sit-to-stand test (5RSTS)	X	X	X	X
Secondary outcomes				
Daily activity levels	X			X
Semistructured interviews			X	
Lung function: forced expiratory volume (FEV1)	X	X	X	X
Mobility: 6-min walking test (6MWT)	X	X	X	X
Strength and endurance: 30-s sit-to-stand test	X	X	X	X
Lower limb capacity: short physical performance battery (SPPB)	X	X	X	X
Dyspnoea: modified Medical Research Council Dyspnoea Scale (mMRC)	X	X	X	X
Daily functioning: Canadian Occupational Performance Measure (COPM)	X	X	X	X
Disease-specific health status: St. George's Respiratory Questionnaire (SGRQ)	X	X	X	X
Chronic obstructive pulmonary disease (COPD) Assessment Test (CAT)	X	X	X	X
Generic health status: EuroQol 5-Dimensions 5-Level (EQ-5D-5L)	X	X	X	X
Frailty assessment: Tilburg Frailty Indicator (TFI)	X	X	X	X
Frailty assessment: Clinical Frailty Scale (CFS)	X	X	X	X
Mobility patterns: Life-Space Assessment (LSA-DK)	X	X	X	X

Overview of measurements during the study, primary and secondary. Daily activity levels are measured during 'acute rehabilitation' and again after 12 months of home-based exercise for both groups. Interviews are planned for the intervention group after approximately 6 months of cycling. All other tests are performed home based by a research assistant at baseline, after 6 weeks, 6 months and 12 months for both groups.

between the intervention and control groups, accounting for a dropout rate of 20%. This sample size is sufficient to detect clinically meaningful differences while accounting for potential dropouts and variability in the data. The power analysis conducted for this study indicates that with an assumed SD of two repetitions, the effect size (ES) calculated based on the MCID of 1.7 is approximately 0.85, which corresponds to a large ES according to Cohen's (1988) conventions.

Recruitment

Recruitment and enrolment are handled by trained physiotherapists. Newly admitted patients with diagnosis of exacerbation of COPD will be identified daily by screening patient lists at the Emergency Department and the Department of Lung Medicine. Patients who meet the inclusion criteria and none of the exclusions criteria will be approached by the principal investigator. Potential participants are provided with oral and written information and are given at least 24 hours before consent is obtained (consent form (online supplemental appendix 1)). Participants can at all times withdraw consent to participate and will be discontinued in the event of medical or cognitive conditions that inhibit the participant from safely exercising. After consenting, participants are referred to acute rehabilitation, in Danish context referred to as 'general rehabilitation',[31] which will commence on discharge from the hospital.

Data management and statistical analysis

Data will be protected according to current Danish legislation. Data will be stored electronically on Aalborg University Hospital's secure server in accordance with the General Data Protection Regulation. Each participant is allotted a unique sample identification number. After study completion, data will be stored pseudonymised. Referable information and data collected within the scope of this study are not passed on to other parties. Data will be stored for 10 years. The final dataset is accessible by primary investigators only.

For data analysis, SPSS V.29 (IBM, Chicago, USA) or R Studio V.3.6.0+ (Posit, Boston, USA) will be employed. Missing data are expected to be minimised due to physical tests and questionnaires being administered in the participants' home. Handling of missing data will be carried out according to the guidelines of the questionnaires

in question or last value carried forward by imputation. A priori, a two-sided level of significance will be set at p<0.05.

Data will be evaluated with descriptive statistics and analysis of variance with repeated measures. Group comparisons will be done on the different parameters with logistic regression analysis correcting for baseline data such as gender, age, lung function and mMRC score. Effect of the intervention at 6 and 12 months will be evaluated in a two-way analysis of variance with repeated measures. Data gathered from the participants' case files in the 12 months of intervention will be analysed with regression analysis, corrected for characteristics such as age and number of hospitalisations 12 months prior to admission.

Cost-effectiveness will be assessed through a cost-utility analysis, where healthcare sector costs and quality-adjusted life-years (QALYs) will be the primary outcomes.[32] QALYs will be calculated using the EQ-5D-3L utility values, and the analysis will follow the 12-month duration of the clinical trial. Costs will be calculated based on resource use (hospital admissions, primary care visits and home-based cycling intervention) using 2024 Danish Consumer Price Index values. Intervention costs will include cycling equipment, setup and maintenance. Patients who die during the study period will be given an EQ-5D-5L index value of zero, equalling the health state for death. This analysis will be conducted from a healthcare sector perspective, focusing on disease-specific costs.

Data from interviews will be coded and analysed based on emerging themes using NVivo (Lumivero, Melbourne, Australia), V.14.23.0. All interviews are recorded and transcribed verbatim. A phenomenological-hermeneutic methodology inspired by Ricoeur's theory of interpretation[33] was chosen for analysis of the data, previously used for investigation patients' experiences with care after acute exacerbation of COPD.[34] Analysis is performed by two or more coders who perform thorough and iterative read-throughs marking emerging statements. The findings are then presented before participants to validate the findings. Data are reported by the Consolidated criteria for Reporting Qualitative research 32-item checklist for interviews and focus groups.[35]

Ethics and dissemination

This study and appurtenant participant information materials, recruitment documents and participant consent form (online supplemental appendix 1) are approved by The North Denmark Region Committee on Health Research Ethics (N-20230008) and in compliance with the Helsinki Declaration.[1] Safety and progress reports are made annually. These reports include progress and registration of potential adverse events. The study is registered at ClinicalTrials.gov (NCT06235502) and in the Region of Northern Jutland trial register (study number F2023-066). The study results will be communicated through peer-reviewed publications, presentations at relevant conferences, social media and community engagement initiatives. The dissemination plan will ensure that findings are accessible to participants, healthcare professionals and the public, thereby maximising the impact of the research on COPD management.

DISCUSSION

This study aims to provide knowledge on the long-term effects of home-based exercise for patients with COPD newly discharged after an exacerbation of COPD in terms of, not only physical outcomes, but also related to quality of life, activity levels, mobility and challenges in their everyday life, hereunder problematic activities of daily life. The qualitative and quantitative information gained in this study will further the understanding of barriers and facilitators for improving long-term adherence in exercise for patients with COPD. The relevance, strengths and limitations will be discussed in the following.

Clinical relevance

Results from this study on the long-term effects of a home-based cycle exercise will contribute to the existing body of knowledge in the rehabilitation of patients with COPD newly discharged after an exacerbation of COPD. The existing Danish recommendations and possibilities for rehabilitating this group of patients are characterised by shorter and more intensive exercising,[36] which might deter patients and leave them without an exercise option after rehabilitation. Worryingly, some might not even start exercising.[10] Despite existing knowledge on the necessity of exercise for this patient group on the one side and the perceived barriers for engaging in regular exercise (eg, too intense and inaccessible exercise options) introduces a gap between available knowledge and successful implementation after an exacerbation of COPD. This warrants an investigation of innovative ways of supporting adherence to regular exercise after discharge for these patients.

Comprehensive, structured and intense exercise for patients with COPD have for a long time been defined as important and significant[3 25 37]; however, the subject of investigating long-term, home-based exercise is yet to be described. Findings from this study will build on the emerging body of knowledge on moderately intense home-based exercise of chronically ill patients.[38 39]

Change in primary outcome measure

Initially, the primary outcome for this study was to assess the exercise capacity using the 6-min walk test. However, during the initial recruitment phase, walking proved to be a significant challenge for the participants of the study, primarily due to fatigue, walking limitations and the physical demands of the test. As a result, it was decided to revise the primary outcome measure to the 5RSTS test, which is also feasible to administer in a home-based setting. This change in outcome corresponds with the goal of improving the feasibility and inclusivity of

COPDtoParis, while still ensuring the measurement of meaningful and clinically relevant functional outcomes in persons with COPD.

Strengths

This study has a comprehensive approach to the effects that attending a long-term exercise offer might have on the patients' life and health status. The long-term design of this study is a clear strength as it will provide insights into the lived experiences of patients with COPD. The focus on life-space mobility, problematic activities of daily living (ADLs) and HRQoL will reveal the biopsychosocial effects on the participants, and thus the effects are not limited to physiological outcomes.

The online team element of the home-based cycling combines the technological advances that may be necessary to accommodate the increase in home-dwelling individuals living with chronic illness for several years. The qualitative elements of this study will likewise provide an in-depth understanding of the experiences and acceptability elements the experiences of virtual group training instead of attending similar exercise sessions in traditional on-site exercise settings.

It is challenging to secure continuity in the care pathways when patients move between sectors. A strength of this proposed study is that participants are recruited when hospitalised and then prospectively followed post discharge through municipality-based rehabilitation and subsequently transferring to home-based exercise.

The study uses three-dimensional activity monitoring devices to detect changes in activity type and intensity down to 5 s intervals. Pedometers have previously proven difficult to use in patients with COPD where steps are small and gait uneven; Sens have proven useable in patients with COPD.[40] The leg-mounted, three-dimensional device provides a reliable and valid investigation of the activity levels of the participants. The device can distinguish between activities such as walking, cycling and sedentary behaviour, and the data will allow for detailed analysis of time spent in different activities throughout the day, for the first time providing insights into the daily activities of this group of patients. The decision to assess physical activity over a 6-week period, rather than the more common 7-day measurement, is grounded in the need for a comprehensive understanding of physical activity patterns and their variability over time. This extended monitoring period allows for the capture of changes in activity over time. Physical activity is inherently variable, influenced by numerous factors such as weather, social engagements and individual health status. A 6-week assessment provides a broader temporal context, allowing for the identification of trends and. Studies have shown that longer monitoring periods can yield more representative data regarding habitual physical activity levels, particularly in populations with chronic conditions like COPD, where daily activity may fluctuate significantly due to health status or exacerbations.[41 42]

The randomised, controlled and single-blinded design provides a systematic and controlled assessment of the effects of the intervention by limiting observer bias. To further minimise bias, testing and mounting equipment are performed by a research assistant.

Limitations

This study will have some predictable limitations. First, a pilot study was conducted before finalising the protocol which revealed some significant challenges in terms of acceptability. Following a hospitalisation due to COPD, patients may not have the mental or physical capacity to accept referral to rehabilitation due to illness and functional decline after hospitalisation. Furthermore, the number of patients who meet the inclusion criteria is relatively small. This is a premise when studying a group of patients, who are characterised by being severely comorbid and thus experience difficulty in participating in exercise,[2] and thus, recruitment is expected to be time consuming. Related to this, several confounders in the clinical outcomes of the group, related to comorbidities, are expectable.

During the development of intervention, participants did express some burden related to the time-consuming task of filling out multiple questionnaires. The burden of participating is accommodated by limiting the number of questionnaires. Furthermore, the questionnaires will be administered at the patients' homes at their convenience to minimise the burden and risk of refusing participation in the study. Nevertheless, the more symptomatic patients might still refuse participation, which might lead to overestimation of health status, functioning and quality of life for the study population.

The practical and economical limitations related to availability of study equipment, drop-outs and loss to follow-up can be expected. Moreover, the duration of the study period may result in participants refraining from participating in additional visits, dying from comorbidities, or withdrawn accept, thus leading to missing data. Lastly, it is possible that the regular interaction between the study team and the intervention group may motivate participants to exercise more rigorously than they would otherwise. This potential bias of being observed should be addressed in future articles based on the data from this study. However, the long duration of the study is expected to prevent short-term effects of observation bias.

Author affiliations
[1]Department of Respiratory Diseases, Aalborg University Hospital, Aalborg, Denmark
[2]Department of Clinical Medicine, Aalborg University, The Faculty of Medicine, Aalborg, Denmark
[3]Department of Health Science and Technology, Aalborg University, Aalborg, Denmark
[4]Public Health and Epidemiology Department of Health Science and Technology, Aalborg University, Aalborg, Denmark
[5]Aalborg Health and Rehabilitation Center, Aalborg, Aalborg Municipality, Denmark

[6]Department of Health Science and Technology, The Faculty of Medicine, Aalborg University, Aalborg, Denmark
[7]Department of Physiotherapy and Occupational Therapy, Aalborg University Hospital, Aalborg, Denmark
[8]Department of Clinical Medicine, Aalborg University, Aalborg, Denmark

Contributors ALS: conceptualisation, formal analysis, writing - original draft, visualisation. LPT, JA, TSP, and UMW: conceptualisation, methodology, supervision, writing – review and editing. ALS is responsible for the overall content as guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval This study involves human participants and was approved by The North Denmark Region Committee on Health Research Ethics (N-20230008). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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ORCID iDs
Anna Lei Stoustrup http://orcid.org/0009-0004-6039-1223
Ulla Møller Weinreich http://orcid.org/0000-0003-1975-3654

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