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ORIGINAL RESEARCH

Taking Charge After Acute Exacerbation of Chronic Obstructive Pulmonary Disease: A Randomized Controlled Feasibility Trial of a Psychologically Informed Self-Management Intervention

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Purpose: Few interventions improve outcomes for people with Chronic Obstructive Pulmonary Disease (COPD), particularly higher risk groups such as those admitted to hospital with an acute exacerbation of COPD (AECOPD). The aim of the study was to test the feasibility and acceptability of a modified version of the Take Charge program in people after AECOPD and to determine the potential to improve self-reported limitations, health-related quality of life and reduce future hospitalizations.

Patients and Methods: A prospective, parallel group randomized trial with blinded endpoint assessment. Participants had been discharged from hospital with a diagnosis of AECOPD and were randomized to receive either a single 60–90 minute session of "Take Charge for COPD" from a trained facilitator in their own home or usual care. Take Charge is a "talking therapy" that encourages a sense of purpose, autonomy, mastery, and connectedness with others. The primary outcome was the rate of moderate or severe episodes of AECOPD in the subsequent 12 months.

Results: Fifty-six people were randomized (study target 60): predominantly European (71%), female (61%), older (mean [SD] age 70 [11] years), and non-smokers (89%). Charlson Comorbidity Index mean (SD) score was 2.3 (1.6) indicating mild to moderate comorbidity severity. There were 85 moderate or severe AECOPD episodes in the 12 months after the index admission for the Take Charge participants and 84 episodes in the control group (relative rate 0.93; 95% confidence interval (CI) 0.69 to 1.26). COPD Clinical Questionnaire (CCQ) scores were significantly lower (better) in the Take Charge group (mean difference −1.26; 95% CI −2.06 to −0.45).

Conclusion: The Take Charge intervention proved feasible with a population of people recently discharged from hospital with AECOPD. The direction of change in the primary outcome and some secondary outcomes suggest that an adequately powered study is justified.

Keywords: COPD, self-management, Take Charge, randomized controlled trial

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is an important world-wide cause of death, disability and reduced quality of life.[1] Acute exacerbations of COPD (AECOPD) are a common reason for hospital admission and predict both recurrent hospital admission and death: 18–39% of patients admitted with AECOPD are readmitted within 3 months,[2] while up to 73% may be readmitted within one year.[3,4] The only interventions shown to reduce mortality and disease progression from COPD are smoking cessation and vaccination against influenza and pneumococcus,[5] although selected

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patients with severe COPD may also gain improved life expectancy from oxygen therapy, lung volume reduction surgery or lung transplantation.[5,6]

There is high-quality evidence that pulmonary rehabilitation produces moderately large and clinically significant improvements in health-related quality of life (HRQoL) and exercise capacity for people with COPD.[7–9] Early pulmonary rehabilitation may also reduce readmission rates after AECOPD.[8] However, availability and uptake of pulmonary rehabilitation is low. Less than 2% of people with COPD have access to pulmonary rehabilitation globally,[10] including in New Zealand,[11,12] the country of origin for this study. In addition to pulmonary rehabilitation, self-management interventions for COPD that include an exacerbation action plan have been associated with improvements in HRQoL and lower probability of respiratory-related hospital admissions.[13] However, alternative or additional effective strategies to manage AECOPD are urgently required.

Previously, we and others have advocated for investigations of psychological interventions for COPD.[14] Indeed, we have hypothesized that the positive benefits of pulmonary rehabilitation may not solely, or even primarily, arise from a physiological response to exercise.[14] Psychological interventions that emphasise self-determination, autonomy, and hope may be crucial for helping people with COPD regain control of their health and wellbeing, particularly after an episode of AECOPD. "Take Charge" is one such intervention. Although originally tested and shown to be effective as an intervention for people with stroke,[15,16] Take Charge is not stroke-specific and is easily adapted for other health conditions.

The aim of the study was to test the feasibility and acceptability of a modified version of the Take Charge program in people after AECOPD and to determine the potential to improve self-reported limitations, health-related quality of life and reduce future hospitalizations. We undertook a randomized feasibility study to adapt and test such an intervention, known to be effective for people following acute stroke, in AECOPD, and to collect baseline and outcome data to plan a larger effectiveness study.

Materials and Methods

Study Design

This was a prospective, parallel group randomized trial with blinded endpoint assessment with one active and one control intervention, conducted between 1 December 2017 and 30 November 2019. The study was conducted according to the Declaration of Helsinki and was approved by a Health and Disability Ethics Committee: Reference: 17/CEN/122. All participants gave written informed consent and the trial had prospective registration with the Australia New Zealand Clinical Trials Registry: ACTRN12617000952347.

Participants

Participants were adults (≥18 years) with a clinical diagnosis of COPD admitted to hospital with a diagnosis of AECOPD. Exclusions were comorbid conditions with significantly limited 12-month survival such as advanced cancer or unstable heart conditions, or active psychiatric disorders. Baseline data were collected after participant recruitment but before group allocation, and included age, gender, ethnicity, smoking history, height, weight, body mass index, and comorbidities using the Charlson Comorbidity Index.[17]

Setting

The trial was conducted in a single tertiary hospital in Wellington, New Zealand, that serves a population of 900,000 people.

Interventions

Participants in the intervention group received a single 60 to 90 minute "Take Charge Session" (TCS), delivered to people in their homes following discharge from hospital for AECOPD and targeted to be delivered within two weeks of discharge. The TCS consisted of a face-to-face session with a trained facilitator using an illustrated booklet that the person with COPD kept. Components of the session were: 1) a non-directed exploration of what aspects of life and which

people were most important for the person, 2) hopes and fears for the future and 3) an individualized assessment of areas where they could make progress and set personal goals, ie, self-directed rehabilitation. This assessment was documented by the participant in the booklet, using headings such as: physical, social, emotional, information needs, financial, and health promotion. Participants could add to, or amend, the booklet at any time. Throughout the TCS, the participants and their families were encouraged to "take charge" of their recovery process. The TCS booklet was retained by the person with COPD, to be used as they saw fit, and they were not required to share it with any health professionals. All facilitators completed a five-day training program prior to starting the study and ongoing training during the study. There were regular feedback sessions between the facilitators and the principal investigator.

Participants in the control group received "usual care" for COPD after hospital discharge, plus a pamphlet about COPD with general information about management of common problems. Participants in both the intervention and control group were given information about how to be referred to pulmonary rehabilitation.

Randomization and Blinding

Participants were randomized to the Take Charge intervention or control group in a 1:1 ratio by third-party methods, ie, central administration of randomization. The randomization sequence, which was generated using block randomization via www.randomization.com was concealed from investigators involved in participant recruitment, baseline and outcome data collection. Participants were recruited in the hospital before discharge, as the preferred method, or by phone after discharge.

Outcomes

The primary outcome was the frequency of moderate to severe acute exacerbations of chronic obstructive pulmonary disease (AECOPD) within 12 months of the index hospital admission. Moderate AECOPD was defined as requiring treatment with oral corticosteroids or antibiotics with no hospitalization, and severe AECOPD as requiring admission to hospital.

Secondary outcomes included Physical Component Summary and Mental Component Summary of the Short Form 36,[18] Clinical COPD Questionnaire,[19] and the Hospital Anxiety and Depression Scale.[20] We recorded mortality at 12 months plus attendance (at least one session) and completion (more than 70% of sessions attended) of pulmonary rehabilitation within 6 months of the index admission.

Statistical Methods and Analysis

The rates of exacerbations per year, and relative rate of exacerbations, were estimated by Poisson regression, with the count of exacerbations as response variable and the logarithm of the observation time (in years) as an offset. A model was fitted comparing the randomized treatments but also, as specified in the funding application, an "intercept-only" model was used to estimate the overall rate of exacerbations. Sample size estimates, using Poisson regression models, are shown for detecting specified relative rates of exacerbation based on the point estimate and confidence limits for the overall rate of exacerbations. Continuous variables were summarized by mean and standard deviation (SD) and were compared by t-tests. Categorical variables were compared by estimating relative risks using an exact method and the Fisher's test. A sample size of 55 has 80% power to rule out a lower 95% confidence limit for an AECOPD rate of less than 1 (should it in fact be 2) and we aimed to recruit 60 participants. SAS version 9.4 was used for analysis.

Results

Summaries of the baseline characteristics of the study participants are presented in Table 1. The flow of the 56 participants during the 12-month study is presented in Figure 1.

Primary outcome data (rates of AECOPD) were collected for all participants. Although the target for intervention delivery was two weeks after hospital discharge, the actual delivery was a mean (SD) 34 (23) days from hospital discharge. The main reason given was that the participants needed more time to settle back into home life after hospital discharge.

Table 1 Baseline Characteristics

Continuous Variables		**All N=56 mean (SD)**	**Take Charge N=28 mean (SD)**	**Control N=28 mean (SD)**
Age (years)		70 (11)	70 (12)	69 (10)
Pack years		22 (39)	11 (39)	11 (39)
Body mass index (kg/m^2)		25 (10)	24 (10)	26 (9)
Charlson Comorbidity Index; lower is less comorbidity		2.3 (1.6)	2.4 (1.5)	2.2 (1.7)
Categorical variables		**N/56 (%)**	**N/28 (%)**	**N/28 (%)**
Ethnicity	European/ Other	40 (71)	17 (61)	23 (82)
	Māori	11 (20)	9 (32)	2 (7)
	Pacific	5 (9)	2 (7)	3 (11)
Current Smoker		6 (11)	2 (7)	4 (14)
Receiving domiciliary oxygen		11 (22)	2 (8)	9 (35)
Admissions or ED presentation for AECOPD last 12 months				
One or more events (%)		15 (26)	3 (11)	12 (43)
Mean number of events (SD)		0.7 (1.3)	0.2 (0.5)	1.3 (1.6)
		N/51 (%)	**N/25 (%)**	**N/26 (%)**
Previously enrolled in pulmonary rehabilitation program n (%)		33 (65)	16 (64)	17 (65)

Abbreviation: SD, standard deviation.

Five of 56 (8.9%) study participants died within a year of their index hospital admission (4 in the control group; 1 in the "Take Charge" intervention group). Cause of death was not collected as part of this study.

Primary and secondary outcome data are presented in Table 2 and Table 3 respectively. The overall rate of moderate to severe exacerbations per year was a little over three per year (Table 2) and based on this and the confidence interval for the estimate of rate a set of sample size estimates have been calculated to detect nominated relative rate reductions (Table 4). For the whole study population, 61 severe AECOPD events were recorded (Control 29, Take Charge 32), and 108 moderate AECOPD events were recorded (Control 55, Take Charge 53). The relative rate of all AECOPD for Take Charge vs control was 0.93 (95% CI 0.69 to 1.26) (Table 5). As anticipated, the study was underpowered to detect a likely important relative rate reduction with the intervention (Table 4).

Discussion

These results show that it is possible to recruit participants to a study of a primarily psychological intervention early after discharge from hospital with AECOPD. The approach was generally acceptable to people with COPD. Participants engaged well with the intervention when it was delivered. There was no difficulty adapting the intervention, as used in the randomized trials for people with stroke, for people with COPD.

Almost 30% of those screened for the study agreed to participate. We randomized 56 participants against a target of 60 participants in one year (93% of target), recruiting from a single moderate-sized tertiary hospital (300 beds). However, there was considerable attrition. In addition to the five who died within 12 months of the index admission, a further six withdrew from data collection before 12 months, five more did not respond to efforts to contact them, and seven were too unwell to contribute to data collection at the 12-month time point, all of whom subsequently died, most in the next 1–2 months. This left 33 participants contributing to the self-reported data collection at 12 months, only 59% of those randomized. This reflects the severity of illness for people with AECOPD who present to hospital. In a future study, if the

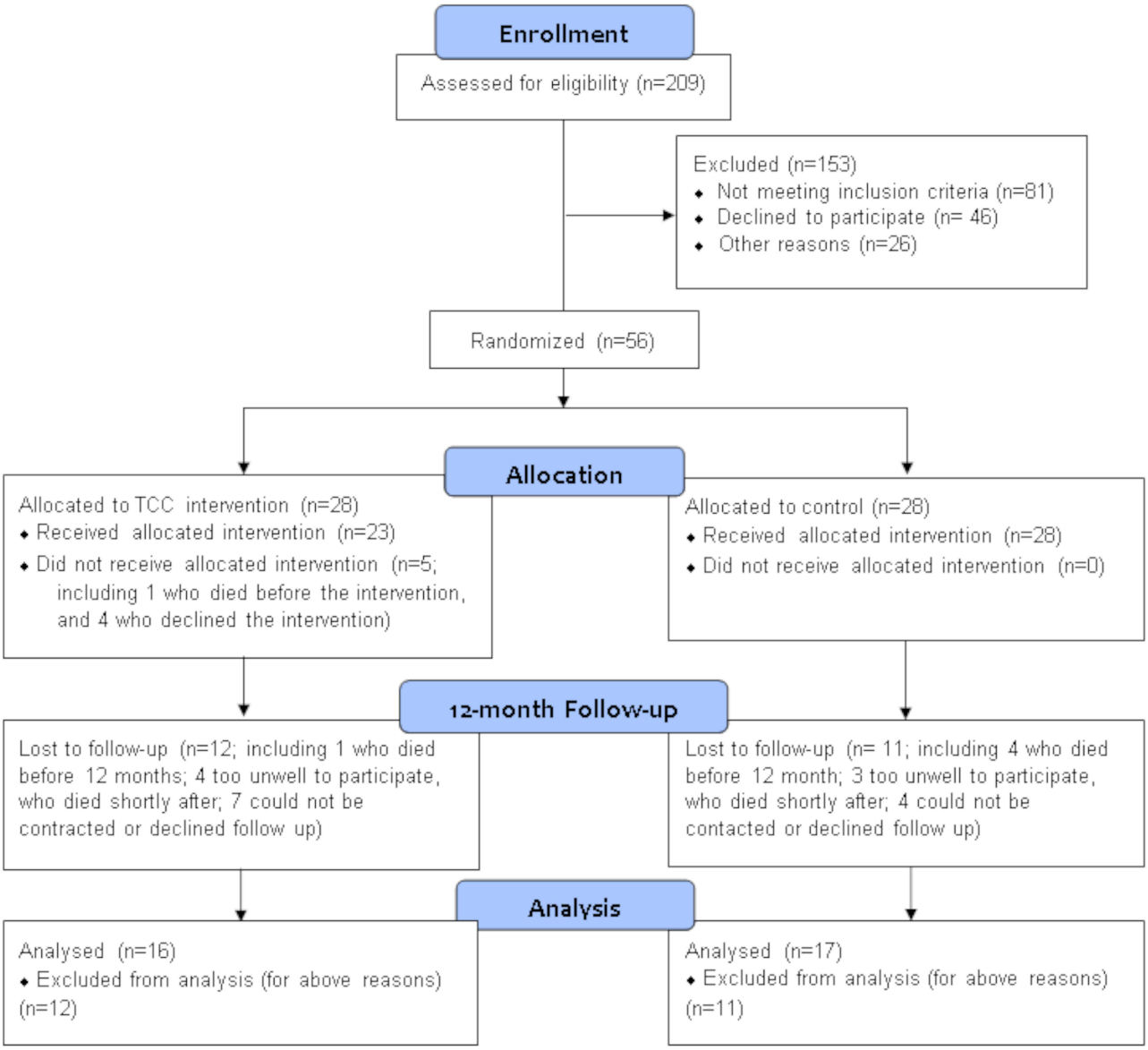

Figure 1 CONSORT Flow Diagram.

same population was studied, setting the primary outcome at six rather than 12 months would increase the amount of data available, especially if a self-report measure (rather than death or exacerbation rate) was the primary outcome. There may also be value in exploring the application of the Take Charge intervention with a group of people with less severe COPD.

There was no significant difference between the groups for the primary outcome of AECOPD exacerbations. This study was not powered for this endpoint. Our results could inform the design of an adequately powered study to investigate the effect of Take Charge on rates of AECOPD. For example, our study shows that 240 participants would be required, in a two-armed clinical trial, to detect a 20% relative reduction in the rate of moderate to severe exacerbations, with 80% power, given a control rate of around three exacerbations in a year following an index hospital admission of AECOPD (Table 4).

Any differences in secondary outcome variables need to be interpreted with caution because of Type I error inflation induced by multiple variable testing and the uncertain effect of missing data for the secondary outcome variables. We also did not collect data on the participants' treatment characteristics, such as inhaled steroid and vaccine use, which may have influenced outcomes. As this was a feasibility study and as treatment approaches to AECOPD in the participating hospital are well established, we

Table 2 Primary Outcome (AECOPD) at 12 Months Following Index Admission by Randomized Treatment (Includes All Participants Randomized)

Variable	All	Control	Take Charge
AECOPD	**Mean (SD)**		
Total	3.02 (2.79)	3.00 (3.02)	3.04 (2.59)
Hospital only	1.09 (1.61)	1.04 (1.35)	1.14 (1.86)
Non-hospital only	1.93 (2.57)	1.96 (2.85)	1.89 (2.31)
Time			
Days	342.0 (72.87)	328.04 (98.39)	356 (26.51)
Years	0.94 (0.2)	0.90 (0.27)	0.98 (0.07)
Count divided by years of observation			
All	3.15 (3.06)	3.13 (3.37)	3.16 (2.78)
Hospital only	1.10 (1.61)	1.05 (1.35)	1.15 (1.86)
Non-hospital only	2.04 (2.88)	2.08 (3.18)	2.01 (2.59)

Abbreviations: AECOPD, acute exacerbation of chronic obstructive pulmonary disease; SD, standard deviation.

Table 3 Secondary Outcomes (Quality of Life, Anxiety, Depression, Adverse Events, Uptake of Pulmonary Rehabilitation) at 12 Months Following Index Admission by Randomized Treatment

Continuous Variables				
	Take Charge (N=16)	**Control (N=17)**	**Take Change Minus Control**	**P**
	Mean (SD)	**Mean (SD)**	**Difference (95% CI)**	
CCQ	1.65 (0.87)	2.91 (1.33)	−1.26 (−2.06 to −0.45)	0.003
HADS Depression	4.81 (2.32)	4.47 (2.74)	0.34 (−1.47 to 2.15)	0.70
HADS Anxiety	4.63 (3.70)	6.35 (4.64)	−1.73 (−4.72 to 1.26)	0.25
SF36-PCS	43.3 (5.8)	42.0 (10.0)	1.4 (−4.5 to 7.2)	0.64
SF36-MCS	44.1 (10.5)	36.7 (14.6)	7.4 (−1.7 to 16.4)	0.11
Categorical variables – Deaths and acute exacerbations				
	Take Charge N/28 (%)	**Control N/28 (%)**	**Take Charge versus Control Relative risk (95% CI)**	**P**
Death by 12 months	1 (3.6)	4 (14.3)	0.25 (0.01 to 1.74)	0.35
At least one AECOPD	24 (85.7)	22 (78.6)	1.09 (0.83 to 1.50)	0.73
Categorical variables – Uptake of pulmonary rehabilitation				
	Take Charge N/15 (%)	**Control N/18 (%)**	**Take Charge versus Control Relative risk (95% CI)**	**P**
Attend at least one session	11 (73.3)	13 (72.2)	1.02 (0.60 to 1.67)	>0.99
Completed programme	5 (33.3)	8 (44.4)	0.75 (0.25 to 1.82)	0.72

Abbreviations: CCQ, Chronic COPD Questionnaire; CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; SF36-MCS, Short Form 36 - Mental Component Summary; SF36-PCS, Short Form 36 - Physical Component Summary; SD, standard deviation.

Table 4 Sample Size Calculations

		Total Sample Size in a Two-Armed Trial		
		Control Rate of Moderate to Severe Exacerbations Per Year		
Relative Rate to Detect	**Power**	**2.77**	**3.22**	**3.74**
0.66	0.8	66	56	48
0.66	0.9	90	78	66
0.70	0.8	86	74	64
0.70	0.9	118	102	88
0.75	0.8	126	108	94
0.75	0.9	174	150	130
0.80	0.8	202	174	150
0.80	0.9	280	240	208

Table 5 Rates of All AECOPD from Poisson Regression Models

	Relative Rate (95% CI)	**P**
Take charge versus control	0.93 (0.69 to 1.26)	0.65
	Rate (95% CI)	
Take charge	3.11 (2.52 to 3.85)	
Control	3.34 (2.70 to 4.13)	
All combined	3.22 (2.77 to 3.74)	

Abbreviation: CI, confidence interval.

opted to reduce the information burden on participants by not collecting these data. However, treatment characteristics should be accounted for in the analysis of any fully powered RCT of the Take Charge intervention.

Overall, point estimates favored Take Charge with a striking difference in the CCQ at 12 months (mean difference −1.26; 95% CI −2.06 to −0.45; p = 0.003). The MCID for the CCQ is 0.4 points.[19] By way of comparison, a randomized trial of smoking cessation using varenicline (n = 504) in current smokers with COPD showed the mean change difference from baseline to 12 months of the CCQ between continuous abstainers and continuous smokers was 0.9 points.[21] In another randomized trial (n = 233), an individualized action plan for exacerbations of COPD resulted in a mean 0.4 point decrease (improvement) in the total CCQ score for the intervention group compared to control at six months.[22] Regardless of the possible impact of the Take Charge intervention on AECOPD rates, these data present a compelling reason to conduct a future fully powered clinical trial given the potential to improve the quality of life of people with COPD via a relatively low-cost intervention. If a definitive trial is positive, the implication would be to shift practice to include the Take Charge intervention as part of routine recommendations for people with COPD, placing greater emphasis on the empowerment of people with COPD to lead their own healthcare management.

Conclusion

It is feasible to deliver the Take Charge intervention for people discharged home after an exacerbation of COPD. An adequately powered RCT of Take Charge for people admitted to hospital with AECOPD is justified to definitively test effectiveness.

Data Sharing Statement

Individual deidentified participant data from this study is permanently stored and available at Harvard Dataverse: https://doi.org/10.7910/DVN/GKH6X6.

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Disclosure

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