

# Chronic disease self-management and exercise in COPD as pulmonary rehabilitation: a randomized controlled trial

Helen L Cameron-Tucker<sup>1</sup>  
 Richard Wood-Baker<sup>1</sup>  
 Christine Owen<sup>2</sup>  
 Lyn Joseph<sup>3</sup>  
 E Haydn Walters<sup>1</sup>

<sup>1</sup>Centre of Research Excellence for Chronic Respiratory Disease and Lung Aging, School of Medicine, University of Tasmania, Hobart, TAS, Australia; <sup>2</sup>Faculty of Education, University of Tasmania, Hobart, TAS, Australia; <sup>3</sup>Department of Respiratory Medicine, Royal Hobart Hospital, Hobart, TAS, Australia

**Purpose:** Both exercise and self-management are advocated in pulmonary rehabilitation for people with chronic obstructive pulmonary disease (COPD). The widely used 6-week, group-based Chronic Disease Self-Management Program (CDSMP) increases self-reported exercise, despite supervised exercise not being a program component. This has been little explored in COPD. Whether adding supervised exercise to the CDSMP would add benefit is unknown. We investigated the CDSMP in COPD, with and without a formal supervised exercise component, to address this question.

**Patients and methods:** Adult outpatients with COPD were randomized to the CDSMP with or without one hour of weekly supervised exercise over 6 weeks. The primary outcome measure was 6-minute walk test distance (6MWD). Secondary outcomes included self-reported exercise, exercise stage of change, exercise self-efficacy, breathlessness, quality of life, and self-management behaviors. Within- and between-group differences were analyzed on an intention-to-treat basis.

**Results:** Of 84 subjects recruited, 15 withdrew. 6MWD increased similarly in both groups: CDSMP-plus-exercise (intervention group) by  $18.6 \pm 46.2$  m; CDSMP-alone (control group) by  $20.0 \pm 46.2$  m. There was no significant difference for any secondary outcome.

**Conclusion:** The CDSMP produced a small statistically significant increase in 6MWD. The addition of a single supervised exercise session did not further increase exercise capacity. Our findings confirm the efficacy of a behaviorally based intervention in COPD, but this would seem to be less than expected from conventional exercise-based pulmonary rehabilitation, raising the question of how, if at all, the small gains observed in this study may be augmented.

**Keywords:** supervised exercise, physical capacity, 6-minute walk distance

## Introduction

Developing self-management skills is now seen as a standard component of pulmonary rehabilitation (PR) programs.<sup>1-3</sup> Indeed, PR is considered an integral component of managing chronic obstructive pulmonary disease (COPD), a progressive disabling respiratory and systemic condition.<sup>4</sup> Guidelines also recommend that PR should include a detailed assessment, exercise, education, and psychosocial support.<sup>1,2</sup>

Exercise in PR has demonstrated improvements in physical capacity, health-related quality of life, dyspnea, and fatigue.<sup>5</sup> Recommendations have stipulated at least three exercise sessions weekly, two of which are to be preferably supervised.<sup>6</sup> However, the supporting evidence for this degree of supervised exercise is limited<sup>7</sup> and was subsequently contradicted by others who provided only once-weekly exercise supervision.<sup>8-11</sup> These later studies question the conventionally recommended degree

Correspondence: Helen L Cameron-Tucker  
 School of Medicine, University of Tasmania,  
 Medical Science I Building, Private Bag 23,  
 Hobart, TAS 7000, Australia  
 Tel +61 3 6226 4893  
 Fax +61 3 6226 7704  
 Email cameronh@utas.edu.au

of exercise supervision. The frequency of supervised exercise sessions has relevance to our study. As we will explain in the Materials and methods section, our intervention was once-weekly supervised exercise added to a self-management program, which we offered as a combined PR approach.

Condition-specific education in PR has traditionally been delivered in a didactic format and has not demonstrated additional benefit in terms of physical or exercise capacity.<sup>2,12–14</sup> Consequently, exercise, not education, has become the cornerstone of PR. However, the benefits of the traditional format for PR, especially on physical capacity and exercise behavior, wane over time.<sup>15,16</sup> This has led to an emphasis on behavioral strategies in PR as a potential means of maintaining the acute gains,<sup>3,16</sup> but this is little tested.

Indeed, self-management interventions, underpinned by health psychology principles, have been seen as an alternative to the conventional PR approach. Such programs are seen particularly as strategies for improving health behaviors, such as regular exercise, and integrating them into daily life. Chronic disease self-management is defined as a process that facilitates an individual's confidence and capability to engage in health-promoting behaviors in order to deal with the impact of their condition on all aspects of their health – namely, a sense of self, physical, emotional, social, and medical domains so as to maximize function and quality of life.<sup>17,18</sup> Self-management education or training is recognized as needing to be interactive, to facilitate not only the acquisition of health behavior knowledge but its implementation, by fostering the self-management skills

of collaborative goal-setting with associated action plans, problem solving, and decision-making.<sup>13</sup> However, with the exception of increased uptake of a symptom-based action plan to manage COPD exacerbations (ie, self-management of symptoms),<sup>19</sup> and some decrease in hospitalization rates,<sup>20</sup> the evidence for the efficacy of holistic COPD-specific self-management approaches, while popular and continuing to increase in practice, has been limited.<sup>20–25</sup>

However, in more general chronic disease situations, statistically sustained significant improvements in health care utilization, health status, and health behaviors such as self-reported exercise have been reported for participants who attended the Stanford Chronic Disease Self-Management Program (CDSMP).<sup>26</sup> The CDSMP, either provided at a medical center or community-based, is a generic, 6-week, group-based self-management education approach led by two trained leaders.<sup>26</sup> Such benefits were subsequently supported in a review of self-management approaches<sup>27</sup> and have been widely implemented, as indeed is the case in our institution. The CDSMP includes educational information delivered in a lecturette style and supplemented by a companion book. The topics cover generic health information, the basis of which is comparable to that relating to health behaviors in conventional PR (Table 1). Some condition-specific information is included in the companion book. The interactive format of the CDSMP deliberately fosters self-efficacy (“confidence”) to manage one's health condition through mastery (practicing skills through setting action plans), vicarious experiences (role modelling and peer support), social persuasion

**Table 1** Comparison of program content

<b>CDSMP program content</b>	<b>PR program content (Team member delivering the lecture)</b>
Condition-specific information in the companion book	Heart and lungs: structure and function in relation to chronic heart and lung conditions (physiotherapist)
Symptom management: shortness of breath, breathing exercises	Monitoring and responding to symptoms: relaxation, breathing exercises, managing breathlessness
Muscle relaxation	
Endurance exercise (discussion)	Beginning an exercise program (physiotherapist)
Cognitive symptom management	
Symptom management: anger, fear, frustration, depression, fatigue, pain	Living with heart and lung conditions: emotional and social impact, communication (social worker)
Communication skills	
Advance directives for health care	
Working with and informing the health care team	
Medication usage: generic advice, specific information in companion book	Medications and delivery devices: condition-specific (pharmacist)
Healthy eating	Nutrition (dietician)
Specific suggestions in the companion book	Activity modification (occupational therapist)
How to set action plans and problem solve	Not formally addressed

**Notes:** 1) The CDSMP course content is presented in comparison with PR and not as the content of the six individual CDSMP sessions. PR is shown as presented in the six sessions with the presenting health professional at our center. 2) Supervised exercise preceded the educational component of PR. The CDSMP has no supervised exercise component.

**Abbreviations:** CDSMP, Chronic Disease Self-Management Program; PR, pulmonary rehabilitation.

(encouragement via guided feedback), and reinterpretation of symptoms (exploring different explanations of symptoms).<sup>28</sup> Unlike PR, the CDSMP is not designed to include supervised exercise, yet has been reported to increase self-reported exercise<sup>26,29</sup> and decrease dyspnea.<sup>29</sup> Any added benefit of formally adding supervised exercise to the CDSMP has not been reported, especially in COPD.

Thus, with an increasing worldwide focus on self-management of chronic conditions, the opinion of hospital management at our institution was that the rehabilitation needs of the target population might be most effectively met through the CDSMP rather than conventional PR. A small pilot of the CDSMP for people with COPD compared with our traditional PR<sup>30</sup> found that the CDSMP alone improved physical capacity by 30 m, measured by the 6-minute walk distance (6MWD).<sup>31</sup> However, with supervised exercise considered an essential component of PR and the benefits of such exercise for people with COPD established,<sup>5</sup> we felt that it was incumbent on us to investigate more fully the likely benefits of the CDSMP approach on exercise capacity, specifically in COPD patients, as well as on more subjective endpoints in this context. We wished to establish whether supervised exercise in addition to the CDSMP would have added benefit compared with the CDSMP alone. This would be a step to informing us of whether the CDSMP with supervised exercise, or without, might offer an alternative to more traditional PR.

## Materials and methods

### Study design

This was a parallel group, randomized clinical trial aiming to investigate both the efficacy of the CDSMP itself in COPD and, more particularly, the addition of supervised exercise to the CDSMP on physical capacity measured by the 6MWD. The trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12610000781044).

In our pilot study already mentioned, which had included a similar population of people with COPD, we found the mean baseline 6MWD to be 365 m, with a standard deviation of 74 m.<sup>30</sup> The acknowledged minimal clinical important difference (MCID) at that time was reported as 54 m.<sup>32</sup> To achieve this difference in exercise capacity, for power of 0.8 and level of significance of 0.05, using a two-sided *t*-test for our primary outcome of 6MWD, we calculated that the current study would require 31 participants in each arm to allow demonstration of superiority for the active intervention by this amount. Allowing for the 25% dropout rate seen in the

pilot, we estimated a total of 78 participants needed to be recruited, with 1:1 randomization to the exercise intervention arm of the CDSMP plus a single supervised exercise session versus the CDSMP alone.

Randomization used a random numbers table with allocation stored in opaque sealed envelopes until completion of baseline data measurement. Participants were assigned a depersonalized identification number, to provide blinding during data analyses. However, a double-blind clinical trial was not possible, as there was no appropriate dummy for the exercise component, and the whole population attended the CDSMP together.

### Study subjects

Participants were recruited from patients referred by clinicians to PR at the Royal Hobart Hospital, a tertiary, university-affiliated, public hospital. Participants gave written informed consent. Ethical approval was granted by the Tasmanian Human Research Ethics Committee (H0008105).

Referring staff were aware that our rehabilitation service was intending to trial the addition of formal exercise to the CDSMP. Inclusion criteria included being over age 18 years, agreeable to attend supervised exercise as well as the CDSMP as randomized, a firm diagnosis of COPD, and there being at least 2 months since an acute exacerbation. Exclusion criteria were cognitive impairment, inability to provide informed consent or complete a self-administered questionnaire, previous CDSMP or PR attendance within the past 2 years, and standard contraindications to exercise.<sup>33</sup>

### Detail of interventions

The intervention group underwent 6 weeks of a 1-hour, weekly, supervised group exercise session of aerobic and strengthening exercises for upper and lower limbs, individualized for each participant, in the same week as the 6-week CDSMP. We were able to offer only this 1-hour supervised exercise session per week due to operational constraints. However, this approach has been supported by others.<sup>8,11</sup> Participants were offered a choice of attending the supervised exercise session either in the morning prior to the CDSMP or later in the week. The first exercise session took place in the week of the first CDSMP session. In collaboration with the physiotherapist-investigator, an individualized exercise regime was determined with each participant. A physiotherapy assistant trained in exercise supervision and not otherwise involved in the study supervised the actual exercise sessions, with the physiotherapist available for consultation if needed. Exercise intensity in the intervention group was determined by using the modified Borg Rating of Perceived

Exertion (RPE) Scale (0–10; 10= maximum).<sup>34</sup> A minimum of moderate intensity (RPE =3) exercise was aimed for, according to recommended exercise guidelines,<sup>35</sup> and a maximum intensity of strong (RPE =5).

As it was not possible for us to offer separate CDSMP sessions for intervention and control participants, they attended the CDSMP together, each receiving the same encouragement and information about following a home exercise regime. To avoid contamination, the intervention group was requested not to discuss experience of supervised exercise with controls. Controls, receiving the CDSMP alone, were offered supervised exercise on completion of their study participation.

The participants attended the 6-week group-based CDSMP, with sessions of 2.5 hours duration offered once per week, facilitated by the respiratory nurse and the physiotherapist–investigator who had both undertaken leader training. The sessions were interactive with lecturates, problem solving, brain storming, action planning, and reporting-back activities. There were up to 12 participants per cohort. A comparison of the CDSMP lecture topics with those previously delivered in PR education is shown in Table 1.

## Outcome measures and data analyses

Outcomes were assessed in the week prior to and the week following completion of the interventions. It was deemed more ethical to first determine whether or not a significant and clinically meaningful change resulted for the intervention in the short-term before extending the study to longer-term follow-up.

The primary outcome was physical capacity measured by the 6MWD<sup>31</sup> and was assessed by an assistant not connected with the trial, affording some degree of objectivity at that point. Secondary outcomes, more directed to the likely efficacy outcomes of the CDSMP, are detailed in Table 2.<sup>31,35–41</sup> We selected the Short-Form 36 Questionnaire, version 2 (SF-36) as the quality-of-life measure to account for the impact of comorbidities. It has been deemed as responsive as the COPD-specific Saint George's Respiratory Questionnaire<sup>42</sup> at detecting even small changes in people with COPD.<sup>43</sup>

Data were analyzed on an intention-to-treat basis, using the statistical software package SPSS (SPSS, Chicago, IL, USA), version 15. The data analyst was blinded to participant allocation until all analyses were completed. Missing variables were replaced by carrying forward the last item measured, and for missing cases, the baseline data was carried forward to the post-data. The exception was for the CHAMPS (Community Healthy Activities Model Program for Seniors)

self-report of physical activity, whereby all missing data were scored as zero.<sup>39</sup>

Results are reported as medians with ranges or means with standard deviations, depending on distribution of data points. Differences in outcomes were compared using Student's *t*-tests for parametric data and Mann–Whitney *U* tests for nonparametric data. Differences in proportions were tested using chi-squared tests. Significance for the primary outcome was set at a *P*-value <0.05. Due to the large number of secondary outcomes, significance levels for these were calculated using a highly conservative Bonferroni correction (*P*<0.003).<sup>44</sup>

## Results

### Participants

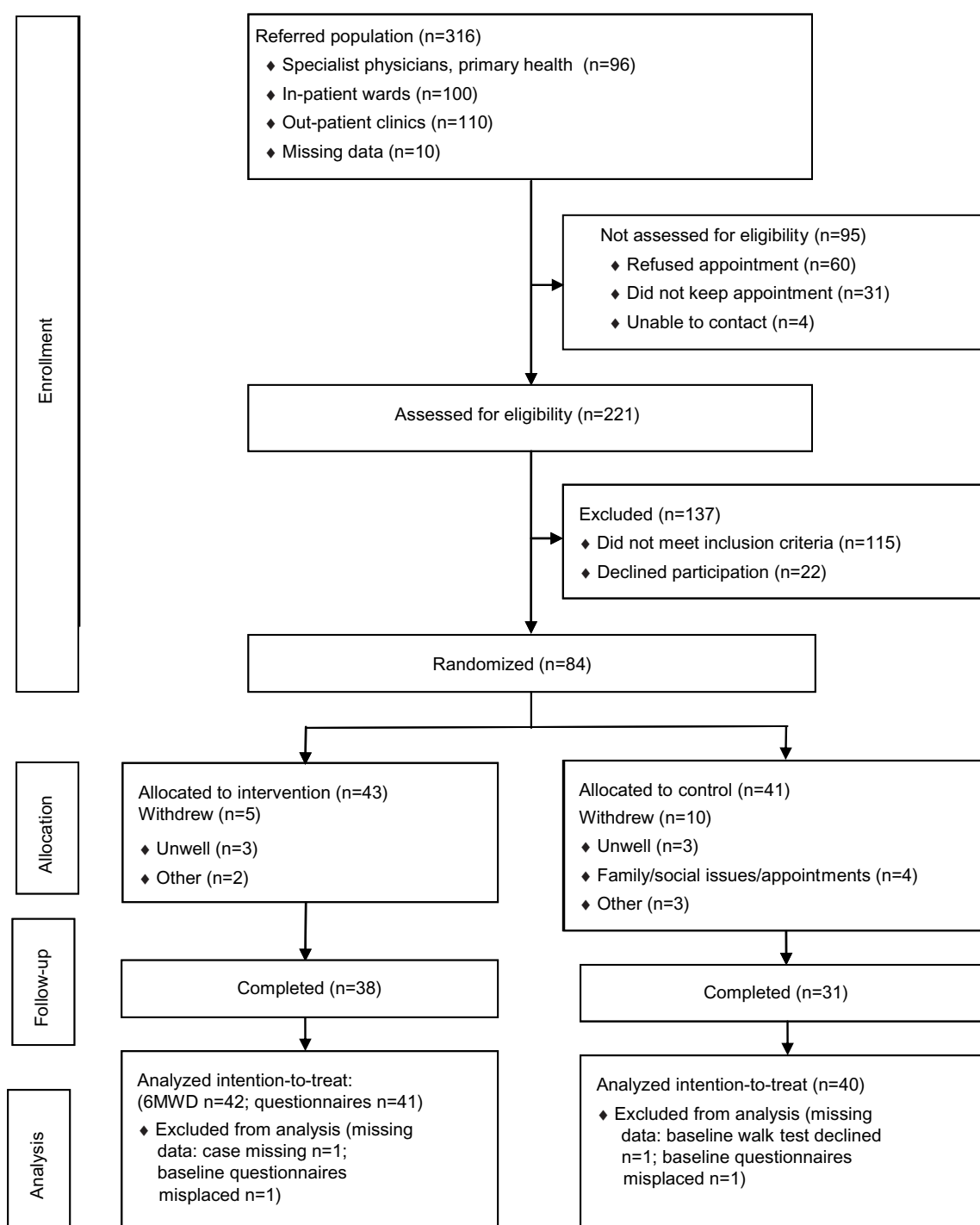
There were 316 potential participants referred for PR (Figure 1), with similar proportions from the private sector (30%), public inpatient service (32%), and public outpatient clinics (35%). The referral source was not recorded in 3%. Overall, attendance at screening was 70% (*n*=221). Of those not screened, the majority declined an appointment, while many others failed to keep their appointment (Figure 1). Those referred from the hospital wards were least likely, whereas those referred from the private sector were most likely, to attend a screening appointment (*P*<0.001). Of those deemed eligible at screening visit, 21% refused further involvement. Participants attended a median of five sessions of the CDSMP, and where appropriate, of the supervised exercise sessions.

There were 15 withdrawals (five intervention and ten controls) due to illness, family issues, or medical appointments. Data were missing for four participants: one could not cooperate, feeling “overwhelmed” by the process and subsequently withdrew permission for their data to be used; one could not complete the baseline walking test due to increasing breathlessness, and for two, baseline questionnaires were misplaced.

Participant characteristics are depicted in Table 3. The groups did not differ significantly in any baseline demographic measure. Outcome variables at baseline were similar, with no statistically significant differences between groups (Table 4). The 15 withdrawals had no baseline differences compared with completers, defined as those attending at least one CDSMP session and both data collections.

### Primary outcome

There were statistically significant increases in 6MWD in both groups, of around 20 m on average (Table 5). However, there



**Figure 1** Flowchart showing participant's progress through the study.

**Abbreviation:** 6MWD, 6-minute walk test distance.

was no statistically significant difference between the groups. The number of participants in each group who reached the MCID of 54 m was similar, 22% in the CDSMP-plus-exercise group and 23% in the CDSMP-only group.

The associations between the changes in 6MWT distance and the selected variables of age, sex, education, breathlessness, exercise duration, and frequency, SF-36 physical and mental

component summaries, exercise self-efficacy, and body mass index were weak; all Pearson's correlation coefficients were less than 0.3, and none reached statistical significance. Severity and frequency of breathlessness were selected rather than COPD grade, as the latter had missing data. The strongest correlations with the change in 6MWD were frequency of moderate exercise ( $r=-0.188$ ,  $P=0.066$ ), and exercise self-efficacy ( $r=0.140$ ,



**Table 2** Outcomes and measures**Primary outcome and measure**Physical capacity, measured by the 6MWD, a field walking test<sup>31</sup>**Secondary outcomes and measures**

Outcome	Measure
Self-reported exercise	CHAMPS Activities Questionnaire for Older Adults <sup>39*</sup>
Self-efficacy for exercise	Exercise: Self-Efficacy measure <sup>37*</sup>
Exercise participation criteria (achieving minimum recommended level of daily exercise)	Achieving weekly exercise <sup>35,36</sup> "Regular Exercise is any planned physical activity (eg, brisk walking, aerobics, bicycling, swimming, line-dancing, tennis, doing formal exercises etc.) performed to increase or maintain health and physical fitness. Such exercise should be performed on all or at least 5 days of the week to accumulate 30 minutes or more per day. Exercise does not have to be painful to be effective but should be done at a moderate level that increases your breathing rate and makes you feel warmer. Do you exercise regularly according to the definition above? Yes/No"
Stage of change for exercise	Exercise: Stages of Change – Short Form questionnaire <sup>36*</sup>
SOB	10 cm VAS <sup>38</sup>
Self-management behaviors	Flinders University PIH Scale <sup>40*</sup>
HRQoL	SF-36v2 Generic Health Survey <sup>41*</sup>

**Note:** \*Permission obtained for instrument use.**Abbreviations:** 6MWD, 6-minute walk test distance; CHAMPS, Community Healthy Activities Model Program for Seniors; HRQoL, health-related quality of life; PIH, Partners in Health; SF-36v2, Short Form 36 version 2; SOB, shortness of breath; VAS, visual analog scale.

$P=0.132$ ), although neither were statistically significant. When entered in a multivariable linear regression model, the frequency of moderate exercise ( $\beta=-0.257$ ,  $P=0.048$ ) and exercise self-efficacy ( $\beta=0.220$ ,  $P=0.089$ ) explained only 7.9% of the variance in the change in 6MWD.

**Secondary outcomes**

Both groups increased similarly in the frequency of moderate exercise, achieving 3 days per week, and showed

small increases in physical function, "role physical", and exercise self-efficacy ("confidence" to exercise), but none of these intragroup changes reached statistical significance. There were no statistically significant differences between the groups in these changes for any secondary outcome measure (Table 5). However, only the intervention group had a statistically significant increase, but only of 1 hour per week, in the duration of moderate intensity self-reported exercise ( $P=0.002$ ).

**Table 3** Participant characteristics

Variable	Participants (n=84)	I: CDSMP + exercise (n=43)	C: CDSMP-only (n=41)	P-value I versus C
Female	39 (46%)	20 (47%)	19 (46%)	0.99
Age, years	65.8±9.35	64.5±9.13	67.1±9.41	0.19
Married	50 (60%)	25 (58%)	25 (61%)	0.97
Education: to year 8	21 (26%)	12 (29%)	9 (23%)	0.53
to year 10	37 (45%)	20 (48%)	17 (43%)	
to year 12	24 (29%)	10 (24%)	14 (35%)	
Self-reported comorbidities: present	22 (26%)	9 (21%)	13 (33%)	0.35
Referral source: primary health or private practice	37 (44%)	18 (42%)	19 (46%)	0.80
Public hospital wards	19 (23%)	11 (26%)	8 (20%)	
Public outpatient clinics	28 (33%)	14 (32%)	14 (34%)	
Socioeconomic status: below State median	43 (54%)	21 (53%)	22 (55%)	1.00
Body mass index, kg/m <sup>2</sup>	29.0±7.07	28.4±7.63	29.7±6.50	0.44
COPD severity:				
Mild (60%–80%)	20 (29%)	8 (22%)	12 (38%)	0.23
Moderate (40%–59%)	16 (23%)	11 (30%)	5 (15.6%)	
Severe (<40%)	33 (48%)	18 (49%)	15 (47%)	

**Notes:** Data are reported as either raw number (percent) within study group status and as means ± standard deviations. The  $P$ -values are from Student's  $t$ -tests or chi-squared analyses. Level of significance was set at  $P<0.05$ . COPD severity classified according to COPD-X Plan Australian and New Zealand management guidelines for COPD.<sup>50</sup>**Abbreviations:** C, control; CDSMP, Chronic Disease Self-Management Program; COPD, chronic obstructive pulmonary disease; I, intervention.

**Table 4** Intervention versus control group: baseline outcome variables

Variable	Intervention (CDSMP + exercise)	Control (CDSMP-only)	P-value
<b>Primary outcome</b>	<b>(n=42)</b>	<b>(n=40)</b>	
6MWD, m	351.6±122.9	353.0±97.4	0.953
<b>Secondary outcomes</b>	<b>(n=41)</b>	<b>(n=40)</b>	
All exercise: duration, hours per week	5.250 (0.00–26.00)	9.250 (0.00–52.25)	0.011
All exercise: frequency, times per week	9.0 (0.0–49.0)	13.5 (0.0–59.0)	0.126
Moderate exercise: duration, hours	0.500 (0.00–19.50)	1.500 (0.00–10.25)	0.171
Moderate exercise: frequency, times per week	2.0 (0.0–20.0)	2.0 (0.0–23.0)	0.491
Exercise self-efficacy, scale 0–5	2.7±1.1	2.8±1.0	0.763
Self-management behaviors, scale 0–8	6.1±1.1	6.2±1.0	0.492
Shortness of breath: severity, cm	7.1±2.3	6.8±2.4	0.592
Shortness of breath: frequency, cm	6.9±2.6	6.4±2.6	0.330
SF-36v2 Physical Function	29.26±8.99	28.99±8.04	0.886
SF-36v2 Role Physical	31.95±10.37	32.12±9.42	0.938
SF-36v2 Bodily Pain	45.64±11.68	45.09±11.49	0.832
SF-36v2 General Health	30.30±9.88	32.41±8.96	0.317
SF-36v2 Vitality	41.74±9.19	40.77±9.69	0.648
SF-36v2 Social Function	42.75±13.19	39.94±11.37	0.309
SF-36v2 Role Emotional	36.25±16.10	37.22±15.28	0.782
SF-36v2 Mental Health	47.67±11.66	46.21±10.68	0.557
SF-36v2 Physical Component Summary	31.53±8.19	31.97±7.247	0.796
SF-36v2 Mental Health Component Summary	46.74±12.85	45.53±12.17	0.664
Achieving exercise criteria: Yes	11 (26.8%)	6 (15.0%)	0.301
No	30 (73.2%)	34 (85.0%)	
Stage of change for exercise: Precontemplation	4 (9.8%)	6 (15.0%)	0.789
Contemplation	14 (34.1%)	17 (42.5%)	
Preparation	9 (22.0%)	7 (17.5%)	
Action	6 (14.6%)	5 (12.5%)	
Maintenance	8 (19.5%)	5 (12.5%)	

**Notes:** Data are reported as either raw number (percent) within study group, as mean  $\pm$  standard deviation, or as median with range. The P-values are from Student's t-tests, Mann-Whitney U tests or chi-squared analyses, with level of significance  $P < 0.05$  for 6MWT and  $P < 0.003$  for secondary outcomes, following a Bonferroni correction.

**Abbreviations:** 6MWD, 6-minute walk test distance; CDSMP, Chronic Disease Self-Management Program; SF-36v2, Short Form 36 version 2.

## Discussion

## Summary of results

This is the first study to investigate the effect of the CDSMP itself on physical capacity in COPD, and whether limited supervised exercise produces additional benefit. This is important, because current formats of PR with an emphasis on lecture-style education and multiple weekly, health professional-supervised exercise sessions is costly, reaches only up to 50% of those to whom it is offered,<sup>3</sup> and has waning effects over time.<sup>3</sup> Wider-reaching, more cost-effective and sustainable alternatives are needed.

We found a statistically significant mean increase in 6MWD for both groups, but no extra benefit for the supervised exercise component, apart from some evidence for an increase in the mean duration of moderate self-reported exercise by 1 hour in the intervention group. However, this probably reflected just what participants had received in the intervention itself. There was also an increase in “role

physical” of the SF-36 for both groups, although this lost statistical significance following the Bonferroni adjustment.

## 6MWD

Our study is the first on the CDSMP, when used for COPD self-management, to report in the literature a statistically significant increase in 6MWD for a self-management intervention alone (our control group). All participants in our study received a behaviorally-based educational and self-management skills training intervention (CDSMP), in contrast to other studies where controls have typically been assigned to usual medical care<sup>7,8,20,21</sup> or usual activities only.<sup>9</sup>

However, the mean increase in 6MWD achieved by both groups was small and might be regarded as of borderline clinical significance. Although the direction of change is consistent with an updated systematic review<sup>5</sup> and other randomized controlled studies,<sup>8,9</sup> it does not approach the previously reported MCID of 54 m (95% confidence interval [CI] 37–71 m).<sup>32</sup>

**Table 5** Change in outcomes: CDSMP + exercise versus CDSMP-only

Variable	CDSMP + exercise (intervention)			CDSMP-only (control)			Change		
	Baseline	Post	P-value	Baseline	Post	P-value	CDSMP + exercise	CDSMP-only	P-value
6MWD, m	351.6±122.9	370.2±128.2	<b>0.013</b>	353.0±97.4	373.0±97.7	<b>0.017</b>	18.6±46.2	20.0±50.6	0.90
Moderate exercise duration, hours (pw)	0.50 (0.0–19.5)	1.75 (0.0–30.8)	<b>0.002</b>	1.50 (0.0–10.3)	1.38 (0.0–15.8)	0.350	1.00 (–5.8–14.0)	0.000 (–9.8–10.3)	0.230
Moderate exercise frequency, times (pw)	2.0 (0.0–20.0)	3.0 (0.0–22.0)	<b>0.007</b>	2.0 (0.0–23.0)	3.0 (0.0–22.0)	0.290	1.0 (–8.0–11.0)	0.5 (–23.0–16.0)	0.766
Exercise self-efficacy, scale 0–5	2.7±1.1	2.9±1.1	0.354	2.8±1.0	3.0±1.0	0.290	0.2±1.1	0.2±1.1	0.892
Self-management behaviors, scale 0–8	6.1±1.1	6.3±0.8	<b>0.037</b>	6.2±1.0	6.4±1.0	<b>0.076</b>	0.3±0.8	0.2±0.7	0.698
Shortness of breath severity, cm	7.1±2.3	6.3±2.5	0.032	6.8±2.4	6.8±2.3	0.989	–0.8±2.4	0.0±2.3	0.118
Stage of change									
Precontemplation	4 (10%)	3 (7%)	NS	6 (15%)	4 (10%)	NS	NS	NS	NS
Contemplation	14 (34%)	10 (24%)		17 (43%)	13 (33%)				
Preparation	9 (22%)	4 (10%)		7 (18%)	6 (15%)				
Action	6 (15%)	15 (36%)		5 (12%)	9 (22%)				
Maintenance	8 (19%)	9 (23%)		5 (12%)	8 (20.0%)				
Achieving weekly exercise criteria: Yes	11 (27%)	22 (54%)	<b>0.066</b>	6 (15%)	18 (45%)	<b>0.013</b>	19 (47%)	22 (55%)	NS
SF-36v2 domains below									
Physical function	29.3±9.0	30.7±9.0	<b>0.076</b>	29.0±8.0	30.4±8.2	0.254	1.5±5.2	1.4±7.8	0.963
Role physical	32.0±10.4	34.3±10.3	<b>0.033</b>	32.1±9.4	35.1±9.8	<b>0.038</b>	2.4±6.9	2.9±8.0	0.752
Bodily pain	45.6±11.7	47.7±11.0	0.206	45.1±11.5	44.7±11.5	0.621	2.1±10.3	–0.6±7.9	0.191
General health	30.3±9.9	31.2±8.6	0.467	32.4±9.0	31.8±10.1	0.580	0.9±8.2	–0.6±6.8	0.361
Vitality	41.7±9.2	43.0±9.0	0.382	40.8±9.7	43.7±8.1	<b>0.032</b>	1.2±8.8	3.0±8.5	0.366
Social function	42.8±13.2	43.3±10.9	0.777	40.0±11.4	43.2±11.1	<b>0.050</b>	0.5±11.9	3.8±10.2	0.271
Role emotional	36.3±16.1	38.0±15.8	0.282	37.2±15.3	39.1±13.7	0.358	1.7±10.0	2.9±12.5	0.956
Mental health	47.7±11.7	47.9±10.0	0.849	46.2±10.7	47.7±10.1	0.428	0.2±6.4	1.3±10.0	0.567
Physical component summary	31.5±8.2	33.5±7.3	<b>0.026</b>	32.0±7.2	32.7±8.4	0.506	2.0±5.6	0.7±6.6	0.340
Mental component summary	46.7±12.9	47.2±11.3	0.707	45.5±12.2	47.9±10.4	0.205	0.4±7.1	2.9±11.7	0.362

**Notes:** Data are reported as either raw number (percentage) within study group status, or as mean ± standard deviation or median with range. The P-values are from Student's *t*-tests, Mann–Whitney *U*-tests or chi-squared analyses, with level of significance  $P < 0.05$  for the primary outcome and  $P < 0.003$  for the secondary outcomes, following a Bonferroni adjustment. P-values in bold are those which were below or approximated a P-value of 0.05.

**Abbreviations:** 6MWD, 6-minute walk test distance; CDSMP, Chronic Disease Self-Management Program; NS, not significant as there were insufficient data to report significance; SF-36v2, Short Form 36 version 2; pw, per week.

On the other hand, our results do approach the more recently reported MCID of 25 m (95% CI 20–61 m),<sup>45</sup> and others have also reported an MCID of 26±2 m in people with severe COPD following PR.<sup>46</sup> Such small improvement may have particular relevance for severe COPD, and in our study, half of the participants were severely affected in this way. The 20 m change we observed is also within the lower limit of the CI observed by Holland et al.<sup>45</sup>

Other groups have also tried to reduce the PR frequency of weekly exercise component. These studies are relevant to our research, as we could offer only 1 weekly session of supervised exercise, in contrast to current recommendations.<sup>1,3</sup> Thus, Singh et al<sup>9</sup> compared twice-daily home-based walking recorded in a log and monitored once-weekly over 4

weeks with usual activities and found a significant increase in 6MWD for the intervention group but not the control group (54.2±26.7 m versus 6.7±10.3 m,  $P < 0.001$ ). Finnerty et al<sup>8</sup> compared education, plus once-weekly supervised exercise, plus an unsupervised home exercise program of 5 days per week over 6 weeks with usual care and reported a median increase in 6MWD of 51 m (range 20–81 m) in the intervention group. These studies contrast with the limited earlier evidence<sup>7,47</sup> on which the recommendation of at least twice-weekly supervised exercise sessions is based. Furthermore, no significant difference between once weekly or twice weekly exercisers for the incremental shuttle walking test was demonstrated in a recent randomized controlled trial.<sup>11</sup> Others included a structured home exercise program to supervised



exercise, also finding no additional benefit of two supervised sessions to the incremental shuttle walking test distance.<sup>10</sup> These later studies of weekly versus twice-weekly supervised exercise point to uncertainty over the optimal frequency and mode of supervision required to increase physical capacity. They suggest that once-weekly exercise supervision with a structured home exercise program may be as good as more intensive regimes. To an extent, that is what we have tested, with negative results.

## Self-reported exercise

In contrast with our study, others have reported a significant increase in self-reported exercise immediately following the CDSMP alone for people with chronic conditions, including COPD.<sup>48</sup> One explanation could be that the measure of self-reported exercise we used is more comprehensive than the Stanford measure<sup>49</sup> used previously. Thus, our study is the first CDSMP-related study to focus on COPD and the amount of moderate exercise which is required for optimal health benefits.<sup>35</sup> Disappointingly, our results indicate that the CDSMP alone is of limited benefit for meeting the minimum recommendations of exercising in the community for 30 minutes on each of at least 5 days per week. Furthermore, the single supervised exercise session did not add anything in this regard either.

## Study limitations and implications for future research

While a major strength of our study was its execution in “real world” clinical practice, utilizing existing resources, this also imposed some limitations. Firstly, due to ethical considerations, we were unable to include a second control group who did not receive any rehabilitation-type intervention. Secondly, it would have been informative to have a group in a twice-weekly or three-times-weekly supervised exercise schedule to determine whether this more exacting approach to exercise would add to the effects of the CDSMP. While this more intense exercise has its advocates,<sup>6</sup> such an approach is highly resource-intensive; most other similar centers would have been unable to achieve this. Therefore, the effect of adding more than one supervised exercise session to the CDSMP is unknown, or indeed whether there are optimal numbers of weekly exercise sessions. This may be another area worthy of future research. However, even if more sessions are better, resource limitation will always be a major factor for generalizability within many health centers. Thirdly, participants were recruited from referrals to a hospital-based program that may differ from

those who might self-refer to community-based CDSMPs. Nevertheless, our study reflects the usual practice for Australian PR, thus enhancing local generalizability. Fourthly, due to resource limitations, we were unable to offer separate sessions for CDSMP-exercise and CDSMP-only groups. While participants were requested not to discuss the exercise experience, vicarious “contamination” of the control group by the active intervention cannot be excluded. Fifthly, the leaders in this study were health professionals rather than peer leaders as is typical for other CDSMPs. Nevertheless, a recently published systematic review concluded that there were few differences between peer-led or health professional-led self-management programs,<sup>27</sup> suggesting this was unlikely to be a source of bias. Sixthly, we did not stratify randomization according to COPD severity. Although this did not vary a great deal, it may have yielded information as to a differential effect of the intervention and would be a consideration for future research. Finally, the CDSMP does not include a structured home exercise program, since under the license agreement, we were precluded from doing so.

## Conclusion

In conclusion, participants with COPD attending a CDSMP can expect a small increase in their physical capacity, but there seems little point in adding a single supervised exercise session. Either there needs to be a more intensive conventional exercise program as advocated in guidelines, or new ways need to be investigated for successfully fostering adequate amounts of home or community-based exercise which meet current recommendations for optimizing health benefits. Before completely abandoning the CDSMP plus limited supervised exercise approach, we are currently undertaking such a trial using an additional community-based mentoring component.

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