

Clinical and cost-effectiveness of SPACE for COPD delivered as a pulmonary rehabilitation maintenance programme: a randomised controlled trial

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Original research

Clinical and cost-effectiveness of SPACE for COPD delivered as a pulmonary rehabilitation maintenance programme: a randomised controlled trial

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ABSTRACT

Introduction The benefits of pulmonary rehabilitation (PR) decline after 6–12 months. Previous studies of maintenance in the literature have been labour-intensive and concentrated on secondary care healthcare utilisation only. We aimed to investigate whether Self-management Programme of Activity, Coping and Education (SPACE) for chronic obstructive pulmonary disease (COPD), a light-touch self-management programme, was clinically and cost-effective following PR.

Methods We conducted a prospective, multicentre, assessor-blind randomised controlled trial. Patients with COPD were randomised 1:1 to usual care (control) or SPACE. The intervention included a home-based manual and four facilitated group sessions, delivered over 12 months. Primary outcome: Endurance Shuttle Walking Test at 12 months. Secondary outcomes: maximal exercise capacity, mood, patient activation, physical activity, healthcare costs and health-related quality-of-life (HRQoL).

Results 116 participants were recruited (October 2019–June 2022). Baseline characteristics: SPACE (65% male, aged 71.8 years, median Medical Research Council (MRC) 3, mean pack years 41.1, mean body mass index (BMI) 29.1), control (51% male, aged 71.8 years, median MRC 3, mean pack years 44.5, mean BMI 28.3). SPACE completion rate=83% and intervention fidelity (assessed via checklist) was excellent. No statistically significant differences at 12 months for primary and secondary outcomes. Economic analysis at 12 months shows a positive HRQoL difference between groups of 0.0871 quality adjusted life years (QALY) and reduced National Health Service (NHS) costs of £139 per participant, driven primarily by a reduction in general practitioner visits in favour of SPACE.

Conclusions Endurance exercise tolerance was maintained in both groups. The programme improved HRQoL at 12 months in the intervention group (above control) and was cost-effective, driven by reduced primary care costs.

INTRODUCTION

Pulmonary rehabilitation (PR) is a programme of exercise and self-management education for patients with chronic obstructive pulmonary

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ There is currently a lack of evidence to support formal maintenance programmes following pulmonary rehabilitation (PR) and previous studies have been labour-intensive, with a focus on secondary care healthcare use only.

WHAT THIS STUDY ADDS

⇒ This study used a light-touch self-management approach to PR maintenance and took a holistic review of clinical and cost effectiveness.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The programme did not improve endurance exercise tolerance above usual care but was cost-effective and may therefore be a valuable programme to implement.

disease (COPD). There is evidence that it is highly effective in improving both physical and mental function.^{1 2} It may also reduce healthcare/patient costs^{3 4} and provide a mortality benefit in those able to complete a programme.⁵ PR programmes are typically provided for 6–8 weeks in the UK, in line with international guidance.¹ However, the important benefits derived from the intervention are not sustained if patients do not continue to engage in lifestyle change.⁶ Patients often return for repeat programmes, particularly around the time of a disease exacerbation.⁷

A number of factors may affect someone's ability to maintain exercise capacity and health-related quality of life (HRQoL) gains in the long term, including.⁸ From a psychological point of view, focus groups have identified a theme of 'abandonment' following PR⁹ with a desire for ongoing support from both peers and healthcare professionals (HCPs).^{8 10}

Several structured maintenance programmes, defined as 'ongoing supervised exercise at a lower frequency than that delivered in the PR programme itself',¹¹ have been described in the literature to facilitate maintaining the benefits of PR. The American Thoracic Society (ATS) and British Thoracic Society (BTS) have both independently reviewed the



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maintenance literature to inform their recent guidance.^{12 13} The ATS used data from two published systematic reviews^{14 15} and found that many maintenance programmes were resource and labour-intensive (eg, involving frequent in-person visits/phone calls). Furthermore, there was inconsistent evidence that maintenance PR improved exercise capacity/HRQoL at 6–12 months following the initial programme. The balance of effects tended to favour maintenance compared with control (usual care); however, the number of studies was small, and the interventions were heterogeneous in terms of duration, setting and level of supervision.¹² Both suggested a research gap exists around the optimal frequency, duration, content and level of supervision for unsupervised/supervised PR maintenance programmes, with a call to examine the cost-effectiveness of these programmes.^{12 13}

With reference to the recognised research gap on optimal content of PR maintenance programmes, patients' motivational and behaviour change strategies play a major role in maintenance but are seldom examined in maintenance studies.^{14 15} The latest ATS guidelines¹² advocate that future research of maintenance PR should be underpinned by behaviour change techniques.⁶ This led us to consider if the SPACE for COPD (Self-management Programme of Activity, Coping and Education) would be clinically and cost-effective as a maintenance programme. SPACE for COPD was codeveloped by patients and HCPs in Leicester, UK as a 4 stage manual.¹⁶ The programme uses motivational interviewing techniques to support behaviour change.¹⁷ The development and underpinning theory of the SPACE for COPD maintenance programme has been described elsewhere¹⁸; in brief, the aim of the programme is to retain the expected benefits of PR as well as increasing patients' motivation and addressing the feelings of abandonment following traditional PR. We will particularly focus on exacerbation and mood management, as well as promoting regular exercise in our programme. By developing this post-PR intervention, we aim to preserve physical and mental well-being, potentially reducing the likelihood of healthcare attendances'. The programme has been extensively studied prior to this trial in a number of populations and settings.^{19–23} The programme is 'lighter touch,' in terms of staff and resources, in comparison to other maintenance strategies described in the literature.

In terms of the call to examine the cost-effectiveness of PR maintenance programmes, previous studies have concentrated on healthcare costs from the hospital perspective,^{14 15 24} with very little data on primary care resource use.¹⁵ Maintenance PR did not reduce the risk of respiratory- or all-cause hospital admissions when data was pooled from four randomised controlled trials (RCTs¹²). One study (an observational, data-linkage design of 11 standardised PR programmes) suggested that PR significantly reduced hospital days and emergency department visits at 12-month post-programme.²⁴

The aim of this trial was to compare the effectiveness and cost-effectiveness of the SPACE for COPD maintenance programme compared with usual care, with the Endurance Shuttle Walk Test (ESWT) as the primary outcome measure.

METHODS

Trial reporting

This study was registered at <https://doi.org/10.1186/ISRCTN30110012>. The full trial methods are available in the published protocol paper¹⁸ in accordance with <https://authors.bmj.com/policies/trial-registration/> and are reported in this manuscript according to Consolidated Standards of Reporting Trials (CONSORT) guidelines for RCTs.²⁵

Trial design and setting

The trial was a prospective, two-centre, RCT, assessor-blind trial of SPACE FOR COPD maintenance programme vs usual care. Recruitment occurred at two UK centres in Leicester and London. Both programmes were delivered according to standardised guidance from the BTS at the time⁷ and were equitable in terms of content delivered, equipment/resource, venues, class sizes and staff supervision.

The trial recruited in part during the COVID-19 pandemic (March 2020–June 2021). During this time, face-to-face rehabilitation and research visits were stopped to protect vulnerable respiratory patients from the virus. This led to important modifications to the trial, including: loss to follow-up for outcomes requiring in-person attendance, providing some of the intervention sessions online/individually rather than groups and extending the recruitment/study end dates by 12 months (original end date was 30 September 2022, actual end date was 30 September 2023). These modifications were planned, reviewed and approved by the Trial Steering Committee.

Participants were randomised using a web-based programme (<https://authors.bmj.com/policies/trial-registration/>), 1:1 to either usual care (control) or the SPACE FOR COPD maintenance programme (intervention). Randomisation codes were blocked per site. It was not possible to blind participants due to the nature of the intervention.

Participants attended three visits: PR discharge (baseline), 6 and 12 months following PR discharge. Where possible, routinely collected data from the initial PR programme discharge assessment were used as baseline data.

Participants

Eligibility criteria

- ▶ Completed PR (75% of sessions completed and attended discharge assessment) within the last 4 weeks (PR must meet standards defined by the BTS⁷).
- ▶ Clinical diagnosis of COPD (forced expiratory volume in 1 s/forced vital capacity ratio less than 0.70 and symptoms typical of COPD (eg, breathlessness and cough).
- ▶ Eighteen years and older.

Exclusion criteria

- ▶ Have a significant disability which limits the daily physical activity.
- ▶ Unable to read (to the level of an 8 year old) and/or write English due to the nature of the manual.

Eligibility criteria for HCPs

HCPs involved in delivering the intervention were respiratory physiotherapists, therapy assistants/technical instructors, respiratory nurses or health psychologists with experience in delivering PR. They all attended a 1-day training course (supplemented with a written facilitator manual and DVD tutorials to take away) to learn the structure of the group sessions, the SPACE for COPD manual and motivational interviewing skills. Training was facilitated by a health psychologist and the group of facilitators had regular contact to troubleshoot any issues with intervention delivery.

Procedure

Usual care (control group)

The control group received best usual care in line with UK guidance.⁷ In both centres, this consisted of standard written maintenance advice on PR discharge about continuing to exercise

and a referral to a local community exercise scheme as desired.⁷ Those attending exercise schemes/gyms and leisure centres were captured via healthcare use self-report questionnaires.

SPACE for COPD maintenance programme (intervention group)

Participants in the intervention group received best usual care plus the SPACE for COPD maintenance programme, comprising the SPACE for COPD manual, SMART goal setting sheets and four in-person, group-based maintenance sessions evenly spaced over the 12-month intervention period. Groups included 5–10 patients and were facilitated by 2 HCPs (nurses, physiotherapists and health psychologists). Group sessions lasted for 2 hours. Due to the COVID-19 pandemic, some sessions were delivered on a 1:1 basis or via telephone/video conference. The four sessions were delivered using a motivational interviewing approach to identify barriers and facilitators to maintenance, expressing empathy, supporting self-efficacy and ‘rolling with resistance.’ The underpinning theory for the programme, mapped to the Practical Reviews in Self-Management Support taxonomy and the topics for each session, is outlined in the protocol.¹⁸ Participants were asked to focus on their goals between each session, at home.

Outcome measures

Blinded outcomes were assessed at the three time points in both groups. During periods of lockdown due to the COVID-19 pandemic, efforts were made to collect outcome measures remotely (eg, questionnaires completed by telephone/post).

Primary outcome: Endurance exercise tolerance: ESWT (time in seconds).²⁶

Secondary clinical outcomes were:

- ▶ Maximal exercise capacity: Incremental Shuttle Walk Test distance (metres).²⁷
- ▶ HRQoL: EuroQoL-5 Dimensions-5 Levels questionnaire (EQ-5D-5L score).²⁸
- ▶ Anxiety and Depression: Hospital Anxiety and Depression Scale.²⁹
- ▶ Symptoms: COPD Assessment Test (CAT score).³⁰
- ▶ Patient Activation: Patient Activation Measure (PAM score and level).³¹

Cost-effectiveness

National Health Service (NHS) resource use (hospital and general practitioner (GP) services), personal expenditure and societal costs were collected from patient self-report questionnaires (dirum.org) and hospital records; the cost of the maintenance programme was estimated. NHS resource use was compared with difference in EQ-5D-5L index values from baseline (quality adjusted life years (QALY)) to provide a preliminary cost-effectiveness analysis. A full economic analysis, described elsewhere,³² will be reported separately.

Qualitative study

Semistructured interviews with patients and staff focus groups were used to explore participants’ and staff experience of the intervention, including barriers and facilitators to implementation. Audio recordings were transcribed verbatim and analysed using Framework Analysis.³³ Qualitative study findings will be reported separately.

Adherence to and fidelity of the intervention

Attendance was recorded for the intervention sessions with 75% (3/4 sessions attended) defined as a ‘completion.’ Intervention

fidelity checklists were completed for a sample of sessions at each site to assess content and delivery (at least one session was observed per cohort, per site). Intervention delivery and content covered was assessed using the checklist, facilitators from Leicester assessed the London site and vice versa.

Statistical analysis

A generalised linear mixed model (GLMM) was fitted for the primary outcome ESWT and the secondary outcomes. Independent variables in the GLMM were baseline ESWT, group (intervention or control), time point (baseline, visit 2 and visit 3—categorical), site (1 or 2). An interaction term group*time point was included in the GLMM, and a random intercept was included for each subject. Missing data for the primary and secondary outcomes was imputed using a Bayesian framework. GLMMs were fitted to both outcomes with and without imputation (please see online supplement S1, Additional GLMM analysis, for more details). All analyses were performed using R V.4.3.1 (Posit PBC (formerly RStudio), Boston, USA) on the ALICE HPC system at University of Leicester by Statistician (author MR). GLMMs were fitted using lmer³⁴ from the lme4 library; imputation was performed using the JointAI³⁵ library. An estimate of cost-effectiveness was undertaken from an NHS perspective; uncertainties in cost and outcomes data were incorporated into a sensitivity analysis.^{36 37} Missing values (predominantly due to the COVID-19 pandemic restrictions) were imputed using Bayesian Mixed Model with confounders.

Sample size

The power calculation (for a continuous outcome superiority trial) was based on the primary outcome measure. We required 116 patients for an 80% chance of finding a 184 s (SD: 282 s) difference in the ESWT time between groups at 12 months (at the 5% level). This number included expected attrition of 20%. This value is the between-group difference reported in the original primary care SPACE FOR COPD study¹⁹ and is similar to the suggested minimum important difference (MID) range for this outcome (174–279 s).³⁸ Further details on sample size calculation can be found in online supplemental material S1.

RESULTS

Study flow and baseline characteristics

The number of participants assessed for eligibility at PR discharge was 677 and of these, 116 were randomised (59 control group and 57 intervention group) between October 2019 and June 2022. For full participant flow through the trial, please see the CONSORT diagram (figure 1). 408 did not meet the inclusion criteria; these were primarily people who had completed PR but without having a COPD diagnosis or because their initial PR was not in person due to pandemic restrictions. 104 refused to take part. Baseline characteristics are shown in table 1. The median Medical Research Council (MRC) grade of the study population was 3; eight participants were from non-White ethnic backgrounds (7%) and nine were receiving home oxygen (8%).

Primary outcome: ESWT

The GLMM imputed data are shown in table 2. There was no statistically significant difference between groups at the three time points (figure 2). Based on the results of the GLMM, exercise tolerance as measured by the ESWT was maintained in both groups, that is, ESWT did not vary significantly over time in either group.

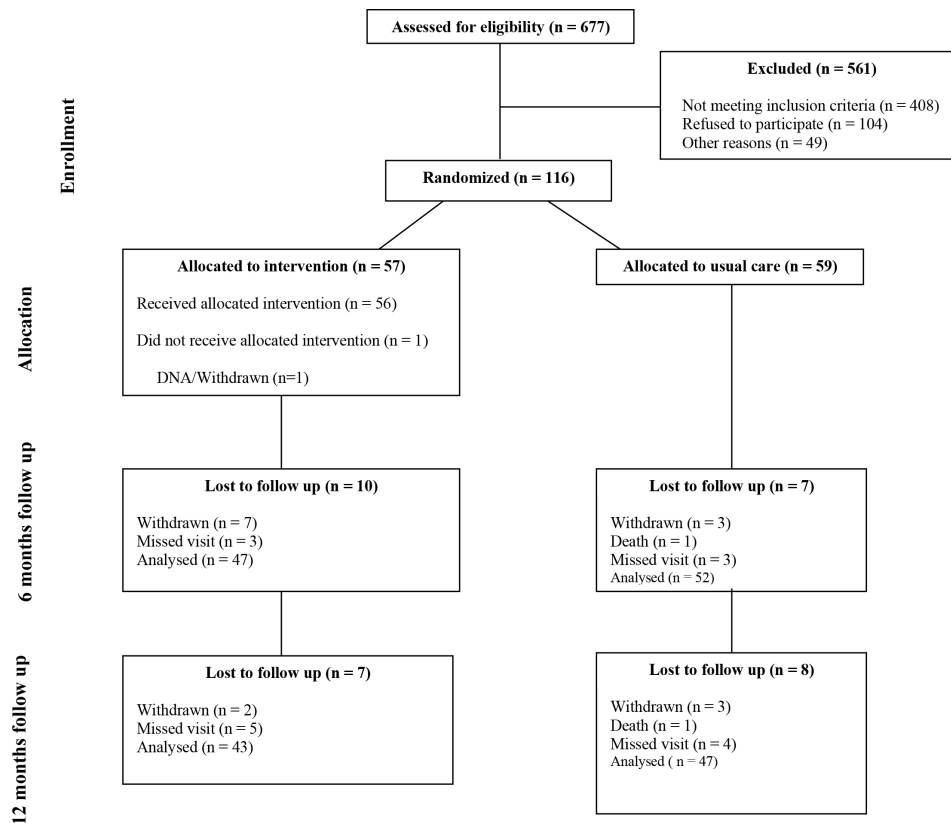


Figure 1 CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials.

Secondary outcomes

HRQoL (as measured by EQ-5D-5L index values) did not differ significantly between trial groups at baseline and 6 months. However, at 12 months the intervention group retained a significantly higher value compared with controls (table 3). The mean difference at 12 m was -0.0871 QALYs (95% CI $(-0.1712$ to $-0.0029)$).

Cost effectiveness

NHS service use per participant over 12 months was lower in the intervention group compared with controls; this was primarily driven by fewer GP visits in the intervention group. Prescription costs to the NHS were also slightly lower in the SPACE group. Overall mean healthcare costs in the intervention arm were £139 lower per patient than for usual care (table 4). Since the patients receiving SPACE for COPD intervention have both lower NHS costs and also better health outcomes, the pathway with PR maintenance added is dominant.

Intervention fidelity and adherence

The majority of patients (83%) in the intervention group attended at least 3/4 sessions and full content was delivered in 100% of sessions where fidelity checks took place. Due to COVID-19 pandemic restrictions, some of the sessions were delivered by telephone/virtually, and some were done individually; this therefore limited the group-based delivery of 50% of the sessions (online supplemental table S3—intervention fidelity).

Supplementary material

A summary of the GLMM with baseline ESWT included as a covariate is presented in table 1 in section S4 of the online supplemental material. When compared with the model presented in

table 2, we find that there is no change in the results for the main effects and interaction terms, all remaining non-significant.

The groups were well matched at baseline; we found no differences in baseline values between completers vs dropouts across a range of variables considered as potential confounders (see online supplemental material S5—completers vs drop-outs baseline characteristics). The full baseline characteristics of intervention versus control groups are shown in online supplement S6.

Online supplement S7 displays the GLMM for the EST fitted on un-imputed data.

DISCUSSION

Key findings

To our knowledge, this is the first study to attempt to address both clinical and cost effectiveness of the chosen PR maintenance programme in relation to full primary and secondary care costs.

Endurance exercise tolerance, as measured by the ESWT, was maintained in both groups. However, there was no statistically significant difference between groups at 12 months for the primary outcome. At 12 months, although HRQoL declined in both groups, the SPACE group retained a significantly higher HRQoL compared with the control group. For context, the suggested MID for EQ-5D-5L utility values in COPD is estimated to be around 0.051, with a range from 0.037 to 0.063.³⁹ The other secondary clinical outcomes (maximal exercise tolerance, symptoms, patient activation, anxiety and depression) did not differ significantly between groups at 6/12 months. Intervention completion and fidelity were excellent with all content being delivered.

Thus, the trial did not record significant differences in any outcome measure, other than HRQoL at 12 months. Even

Table 1 Baseline characteristics

Characteristic	Intervention (n=57)	Control (n=59)	P value*
ESWT	426 (155, 829)	360 (204, 606)	0.9
Age (years)	73 (62, 78)	71 (64, 76)	0.4
Pack years (years)	38 (25, 48)	40 (30, 53)	0.3
BMI (kg/m ²)	27.9 (24.4, 32.9)	27.7 (23.1, 33.1)	0.6
FEV ₁ (% predicted)	48 (35, 65)	60 (41, 69)	0.3
MRC Score			0.9
1	3 (5.3%)	2 (3.6%)	
2	24 (42%)	27 (48%)	
3	21 (37%)	17 (30%)	
4	7 (12%)	8 (14%)	
5	2 (3.5%)	2 (3.6%)	
Ethnicity			0.010
Any other White background	0 (0%)	2 (3.5%)	
Asian or Asian British Indian	0 (0%)	4 (7.0%)	
Asian or Asian British Pakistani	1 (1.7%)	0 (0%)	
Mixed White and Black Caribbean	0 (0%)	1 (1.8%)	
White British	56 (95%)	50 (88%)	
White Irish	2 (3.4%)	0 (0%)	
Home oxygen			0.6
Missing	0 (0%)	1 (1.8%)	
No	55 (93%)	51 (89%)	
Yes	4 (6.8%)	5 (8.8%)	

Data are median (IQR).
 *Wilcoxon rank sum test; Fisher's exact test; Wilcoxon rank sum exact test.
 BMI, body mass index; ESWT, Endurance Shuttle Walk Test; FEV₁, forced expiratory volume in 1 s; MRC, Medical Research Council.

so, because the intervention reduced NHS costs and it did not adversely affect the main outcome measure, it can still be considered cost-effective. Such paradoxical conclusions are not uncommon in RCTs.⁴⁰ Indeed, the systematic review by Jenkins *et al*¹⁵ points to a potential benefit of maintenance PR on healthcare use, but not other clinical outcomes. Previous trials of maintenance PR have recently been summarised.¹⁴ For people with COPD, inconsistent evidence exists that maintenance PR improves exercise capacity and HRQoL at 6–12 months. The balance of effects tends to favour maintenance PR, but the number of studies is small and heterogeneity of trial and

intervention designs currently poses challenges for interpretation. The evidence for PR maintenance is therefore limited and the recently updated BTS and ATS statements do not support the routine offer of formalised maintenance programmes in COPD, with common sense advice given around promoting regular exercise after a PR programme. Where resources are limited, the guidance suggests that the initial PR programme should be prioritised.^{12 13} It may be that for this trial, participants had the added benefit of disease self-management and awareness of their symptoms to manage exacerbations. It is possible that patients viewed the four study visits as replacements for their primary care visits. These outcomes may be difficult to quantify with the chosen outcome measures but have been demonstrated within the cost-effectiveness analysis and the qualitative data to a certain extent (reported elsewhere). Despite that, the PAM, a tool that assesses an individual's knowledge, skills and confidence to manage their own health and care, was not different between groups.

Strengths, limitations and implications for clinical practice

This was a fully powered, mixed-method, assessor-blind RCT, with embedded economic analysis. Looking at power retrospectively with a total of 84 subjects the power to detect a 184s (SD: 282s) difference in the ESWT time between groups at 12 months at 5% significance level is 85%. To our knowledge, this is the first exploration of cost-effectiveness and patient and staff views to optimise any future programme roll-out. The findings of the full cost-utility analysis and qualitative study will be reported separately.

Table 2 Results for GLMM ESWT (seconds) with imputation

Model term	Estimate	P value	LL 95% CI	UL 95% CI
(Intercept)	195.47	0.00	117.64	273.30
Visit 2	27.53	0.48	-49.70	104.77
Visit 3	-6.99	0.86	-84.23	70.24
Baseline ESWT	0.59	0.00	0.51	0.66
Intervention	19.93	0.64	-64.34	104.19
Site 2	-6.27	0.83	-64.04	51.50
Visit 2: Intervention	-90.16	0.11	-200.34	20.03
Visit 3: Intervention	-29.84	0.59	-140.02	80.35

Further GLMM analysis is provided in online supplemental file 1 to look at the suitability of the linear relationship.
 ESWT, Endurance Shuttle Walk Test; GLMM, generalised linear mixed model; LL, lower limit; UL, upper limit.

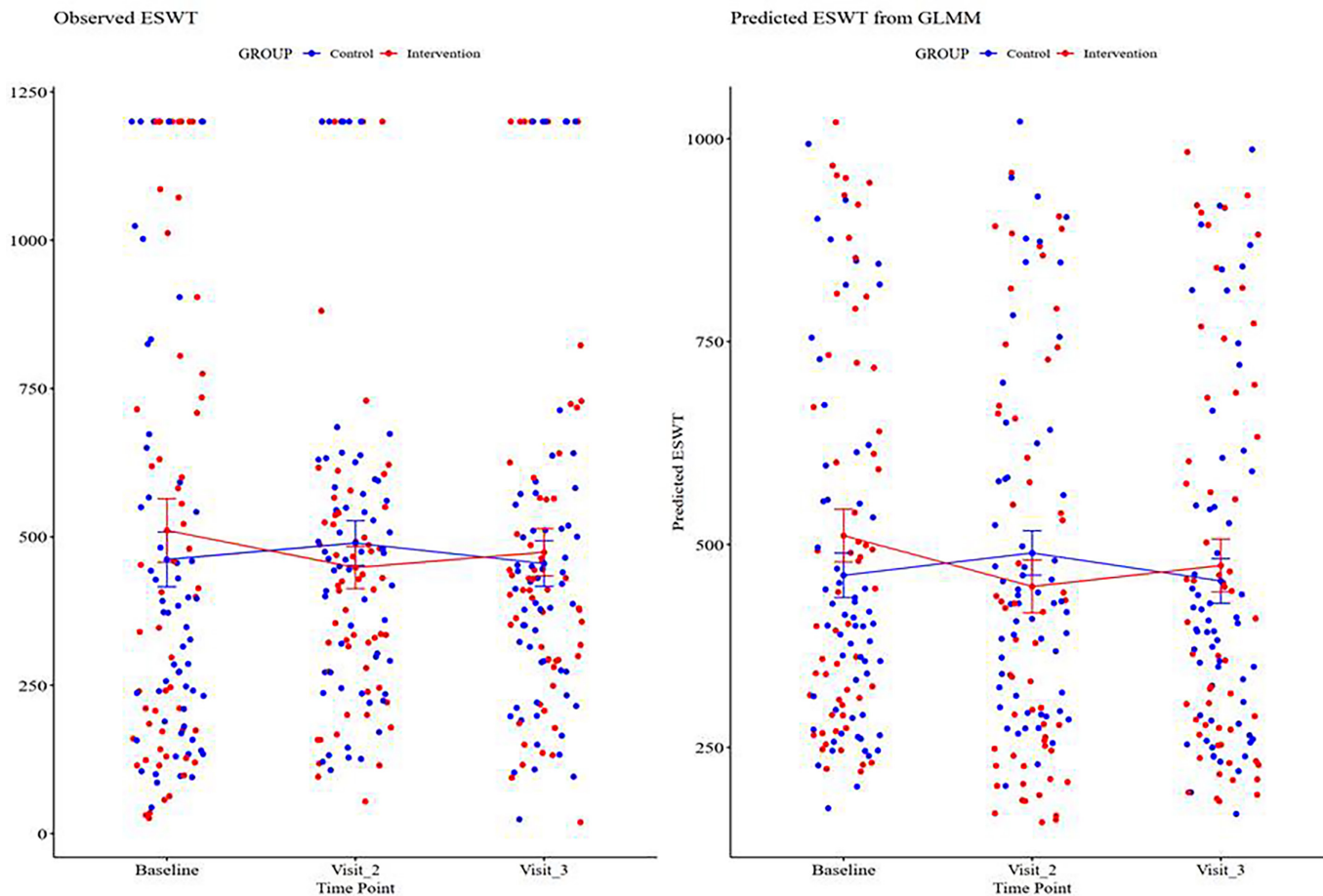


Figure 2 Primary outcome ESWT over time in both groups. Error bars represent lower and upper values for the IQR. ESWT, Endurance Shuttle Walk Test; GLMM, generalised linear mixed model.

The SPACE maintenance programme used in this trial was ‘lighter touch’ compared with many structured maintenance programmes described in the literature. This is therefore less resource intensive to deliver, with the focus on self-management dependent on patient concordance. Intervention completion and delivery of content was excellent.

In terms of limitations, approximately 100 people declined to take part. This was for a variety of reasons, including: not interested, already happy with current state/exercise level, too busy (work/family commitments). For those ineligible, this was predominately because they had other respiratory conditions (non-COPD), had not received their initial PR face to face due to the COVID-19 pandemic or were not recruited within 4 weeks of PR discharge. This information is potentially important for future roll-out.

The trial was delivered pre, during and post-COVID-19 pandemic. This had a profound effect on recruitment, trial methods, intervention delivery and data collection during national lockdown periods as described in the paper (considering the CONSORT-CONSERVE checklist).⁴¹ The primary outcome, ESWT, was a physical measure that had to be collected in person. As such, we had to account for several missing data points in our analysis. We acknowledge that the level of missingness for the ESWT is substantial at 6 and 12 months and that this may impact on the reliability of the multiple imputation and hence the reliability of the estimates for the GLMM. For the intervention, it was intended to be delivered in groups; however, some sessions were delivered one to one due to COVID restrictions. Therefore, the group-based problem solving was not possible. This affected intervention fidelity. Also, it was an artificial environment for the trial to take place in as there were periodic restrictions on

Table 3 Mean utilities derived from the EQ-5D-5L

	Intervention (n=57)	Control (n=59)	Mean difference (95% CI) (usual care–intervention)
Baseline	0.7964 (0.0240)	0.7434 (0.0274)	–0.0530 (–0.1253 to 0.0194)
6 months	0.7538 (0.0226)	0.7061 (0.0291)	–0.0476 (–0.1209 to 0.0257)
12 months	0.7609 (0.0348)	0.6738 (0.0348)	–0.0871 (–0.1712 to –0.0029)*

There were no differences between groups at 6/12 months for the other secondary outcomes (online supplemental table S2) secondary outcomes.

Index values (SE).

*p=0.04

EQ-5D-5L, EuroQol 5 Dimensions 5 Levels.

Table 4 NHS costs

Cost per participant	Intervention (n=57)	Control (n=59)
Intervention cost	£18 293.80	£0.00
NHS services*	£56 344.26	£85 033.62
Prescription cost to NHS	£45 045.00	£47 092.50
Total NHS cost	£119 683.06	£132 126.12
Cost per participant	£2099.70	£2239.43
Difference in costs	−139.72	

*Hospital and GP services.
GP, general practitioner; NHS, National Health Service.

physical activity time outside, gym access and exercise on referral schemes.

The intervention did not include ongoing supervised exercise, despite endurance exercise capacity being the primary outcome measure. As the ESWT distance was maintained in both groups, we must consider selection bias of the population. In that, this was a self-selecting population who had already completed PR. Therefore, by definition, they are already engaged in being active and potentially invested in the research. It may be that the control group altered their behaviour during the study period. We did set out to collect physical activity (accelerometry) data from both groups to account for this; however, we were not able to collect enough valid physical activity data to make meaningful conclusions (predominantly due to the pandemic restrictions in terms of sending non-single use equipment into the home or patients not wearing for a minimum of 4 hours per day). Also, while we did look at SMART goal setting sheets and the manual as a group in each intervention session, we did not formally record engagement with these materials. In terms of those accessing exercise schemes/gyms and leisure centres in the maintenance period, we know from the full economic analysis that the societal cost of community exercise schemes was £2020 in the intervention group and £820 in the control group (to be reported elsewhere).

A further limitation is that mainly White British participants were recruited to the trial; therefore, the results may not be generalisable to the entire COPD population. That said, we believe our data is reflective of national audit data, where 82.5% of patients assessed for PR were White British.⁴²

Future work

The trial, undertaken during COVID, signals the potential for emerging digital innovations to provide transformative change in sustaining health and reducing NHS costs for people with COPD (ie, due to the hybrid nature of the intervention delivery with a range of face-to-face and remote options). There is some evidence to suggest that the use of an app following PR helps to maintain physical activity and improve symptoms in patients with COPD at 6 months.⁴³ Learning from the current study could also be extended to other long-term conditions.

We plan to use secondary data analysis to explore the differences recorded in the primary outcome measure (ESWT) and HRQoL over 12 months. Further data analysis will consider the likely cost of different modes of delivery and the impact on cost-effectiveness.

Other data available include pre-PR data for the ESWT, ISWT and CAT for the Leicester site only. This will allow us to explore if changes made in the initial programme have any bearing on maintenance success.

In general, future research should determine the optimal frequency of maintenance PR, the optimal content and level/type of supervision required. There is also a need to determine the effects

of maintenance PR for individuals with chronic respiratory diseases other than COPD.¹²

CONCLUSIONS

The SPACE for COPD maintenance programme improved quality of life and was cost-effective when delivered over 12 months. However, the primary outcome, endurance walking time, was not different between control and intervention groups. The light-touch approach, with a focus on self-management, is a potentially effective model for future roll-out in research studies and clinical services. This work has been published in part as a conference abstract.⁴⁴

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