**Patient self-management in primary care patients with mild COPD - a randomised controlled trial of telephone health coaching**

Kate Jolly, Manbinder S Sidhu, Catherine A Hewitt, Peter A Coventry, Amanda Daley, Rachel Jordan, Carl Heneghan, Sally Singh, Natalie Ives, Peymane Adab, Susan Jowett, Jinu Varghese, David Nunan, Khaled Ahmed, Lee Dowson, David Fitzmaurice

Kate Jolly1\*
\* Corresponding author

Professor of Public Health & Primary Care
Email: c.b.jolly@bham.ac.uk

Manbinder S Sidhu2

Lecturer in Social Science Applied to Health
Email: ms964@le.ac.uk

Catherine A Hewitt3

Medical Statistician

Email: c.a.hewitt@bham.ac.uk

Peter A Coventry4
Senior Lecturer in Health Services Research

Email: peter.coventry@york.ac.uk

Amanda Daley5
Professor of Behavioural Medicine

Email: a.daley@lboro.ac.uk

Rachel Jordan1
Senior Lecturer in Public Health, Epidemiology & Biostatistics

Email: r.jordan@bham.ac.uk

Carl Heneghan6
Professor of Evidence-Based Medicine

Email: carl.heneghan@phc.ox.ac.uk

Sally Singh7
Head of Pulmonary/Cardiac Rehabilitation

Email: sally.singh@uhl-tr.nhs.uk

Natalie Ives3

Statistics team Leader

Email: n.j.ives@bham.ac.uk

Peymane Adab1
Professor of Chronic Disease Epidemiology and Public Health

Email: p.adab@bham.ac.uk

Sue Jowett1,8
Reader in Health Economics

Email: s.jowett@bham.ac.uk

Jinu Varghese9
Lecturer in Nursing

Email: j.varghese@bham.ac.uk

David Nunan6
Senior Research Fellow

Email: david.nunan@phc.ox.ac.uk

Khaled Ahmed1

Trial coordinator

Email: K.Ahmed.1@bham.ac.uk

Lee Dowson10
Consultant in Respiratory Medicine

Email: leedowson@nhs.net

David Fitzmaurice11
Professor of Cardiorespiratory Primary Care

Email: D.Fitzmaurice@warwick.ac.uk

1 Institute of Applied Health Research, University of Birmingham, Birmingham, UK

2 Department of Health Sciences, University of Leicester, Leicester, UK

3 Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK

4 Department of Health Sciences, University of York, York, UK

5 School of Sport, Exercise and Health Sciences, Loughborough University, Loughborough, UK

6 Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK

7 Centre for Exercise and Rehabilitation Science, Biomedical Research Centre (Respiratory), University Hospitals of Leicester NHS Trust, Glenfield Hospital, Leicester UK

8 Research Institute for Primary Care & Health Sciences, Keele University, Keele, UK

9 School of Education Research, University of Birmingham, Birmingham, UK

10 Royal Wolverhampton NHS Trust, New Cross Hospital, Wolverhampton Road, Wolverhampton WV10 0QP, UK

11 Warwick Primary Care, University of Warwick, Warwick, UK

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**Abstract**

**Objective:** To evaluate the effectiveness of nurse-led telephone health coaching to encourage self-management in a primary care population with mild symptoms of COPD.

**Design:** Pragmatic, multi-centre randomised controlled trial.

**Setting:** 71 general practices in four areas of England.

**Participants:** 577 people, with MRC dyspnoea grade 1 or 2, recruited from primary care COPD registers with spirometry confirmed diagnosis, were randomised to the intervention (n=289) or usual care (n=288).

**Interventions:** Nurse-delivered telephone health coaching intervention, underpinned by Social Cognitive Theory, promoting: accessing smoking cessation services, increasing physical activity, medication management and action planning (4 sessions over 11 weeks; postal information at weeks 16 and 24). Nurses received two days of training. The usual care group received a leaflet about COPD.

**Main outcome measures:** The primary outcome was health related quality of life at 12 months using the short version of the St Georges Respiratory Questionnaire (SGRQ-C).

**Results:** The intervention was delivered with good fidelity: 86% of scheduled calls were delivered; 75% of participants received all four calls. 92% participants were followed-up at six months and 89% at 12 months. There was no difference in SGRQ-C total score at 12 months (mean difference -1.3, 95%CI -3.6 to 0.9; p=0.2). Compared to usual care participants, at six months follow-up, the intervention group reported significantly greater physical activity, more had received a care plan (44% v 30%), rescue packs of antibiotics (37% v 29%) and inhaler technique check (68% v 55%). There were no differences in other secondary outcomes (dyspnoea, smoking cessation, anxiety, depression, self-efficacy, objectively measured physical activity).

**Conclusions**

A novel telephone health coaching intervention to promote behaviour change in primary care patients with mild symptoms of dyspnoea did lead to changes in self-management activities, but did not improve health related quality of life.

**Trial registration**

Current controlled trials ISRCTN 06710391

**Keywords**

COPD, self-management, physical activity, randomised controlled trial, health coaching,

**Background**

Chronic diseases, such as chronic obstructive pulmonary disease (COPD), are a major cause of death and disability in high income countries and of rising importance in low and middle income countries.[1] Owing to their high prevalence and chronicity, current international policy focuses on the need to support patients to self-manage their conditions.[2] Most interventions designed to support self-management have been targeted at people with more severe disease who are likely to be motivated to change behaviour, and where there is the most opportunity for symptomatic improvement. However, more recent efforts have aimed to prevent onset or slow progression early in the disease course, in order to reduce the burden and costs of treating more advanced disease later. This prevention paradigm has only recently been adopted in COPD, with calls for interventions to reduce risk in people with early disease.[3]

The growing number of people at risk of developing long-term conditions and the high prevalence of early disease, means an accessible and low resource approach needs to be taken to support self-management. One such approach is to use interactive telephone health coaching, with the coach and patient working together to identify barriers to behaviour change and finding ways to overcome them. Key techniques include modelling behaviour, goal setting and empowering the patient to improve their health status.[4] Telephone health coaching has shown potential benefits on self-efficacy, health behaviour and health status in a rapid review of trials in long-term conditions.[5]

COPD is a common respiratory condition with an estimated 65 million people worldwide with moderate or severe disease;[1] like most chronic diseases, it causes a significant burden on health services and society and is a leading cause of death in most countries.[6, 7] Interventions to support self-management interventions in people with COPD have been shown to be effective in improving health related quality of life and in reducing hospital admissions among COPD patients,[8, 9] but trials have largely recruited people from secondary care and excluded those with mild disease.[9] However, people with mild dyspnoea represent 38-54% of diagnosed patients in primary care[10, 11] and with case-finding initiatives this is likely to increase.[12]

Many components of self-management interventions could promote better health and prevent disease progression in the early stages of COPD. Smoking is a major cause of COPD, and smoking cessation has been shown to be beneficial in maintaining better lung function and in slowing disease progression across all severity levels.[13, 14] Reduced physical activity level is an independent risk factor for exacerbations, hospitalisation and mortality among those with COPD[15, 16] and occurs even in the early stages of disease.[17] Inhaler treatments have well established efficacy in reducing exacerbations and admissions amongst patients with moderate and severe lung function, and growing evidence of effectiveness in improving clinical outcomes and reducing decline in lung function among people with more mild impairment.[18, 19] Any intervention that improves medication adherence and inhaler technique, which is frequently poor,[20] is thus likely to improve outcomes for patients. Sixty percent of primary care COPD patients report exacerbations of their disease,[10] which are associated with more rapid decline in lung function.[14] Interventions that aim to reduce the severity of exacerbations include prompting early recognition of symptoms and rapid use of antibiotics and/or corticosteroids either through seeking a primary care appointment or use of a self-treatment rescue medication pack.

We evaluated telephone health coaching in people with mildly symptomatic COPD to explore the effectiveness of supporting self-management activities in this group of patients. We hypothesised that a nurse delivered telephone health coaching intervention to support self-management, compared with usual primary care, would lead to improved COPD health related quality of life at 12 months follow-up and improve physical activity, smoking cessation and self-management behaviours, psychological health and self-efficacy.

**Methods**

**Design**

Patient self-management for COPD (PSM COPD) was a pragmatic multi-centre phase III randomised controlled trial (RCT) of a telephone health coaching intervention to support self-management compared with usual care for people with COPD with mild dyspnoea. Details of the study protocol have been published elsewhere.[21] We followed the CONSORT guidelines for reporting RCTs of non-pharmacological treatments to report this study.[22] Following publication of the protocol in the ISRCTN clinical trial registry at the feasibility study phase, we changed the inclusion criterion for post-bronchodilator spirometry from below the lower limit of normal to forced expiratory volume in one second (FEV1)/forced vital capacity (FVC)<0.7, which is that recommended by the Global Initiative for Obstructive Lung Disease (GOLD).[6] We also included some additional subgroup analyses to those in the published protocol[21] (baseline FEV1 predicted [≥80/<80) and degree of limitation of activities in the St Georges Respiratory Questionnaire (SGRQ)). We embedded a sub-study that investigated participant recruitment materials. In this sub-study, general practices were randomised to send out either the standard participant information leaflet or a participant information leaflet which contained an additional web-address and QR (Quick Response) code to give access to web-based materials including podcasts about taking part in research in general and in the PSM-COPD trial in particular.[23] This did not alter any other trial processes.

**Participants**

Participants were recruited from 71 general practices within England located in Birmingham and West-Midlands South; Greater Manchester; North West Midlands and Oxfordshire/Gloucestershire. Patients aged 18 years or over were identified as eligible if they were (i) on the practice COPD register, thus had respiratory symptoms consistent with COPD; (ii) reported mild dyspnoea (MRC grades 1 (only breathless on strenuous exercise) or 2 (only get short of breath when hurrying on level ground or up a slight hill) on baseline assessment; (iii) had an FEV1/FVC<0.7 after post-bronchodilator spirometry (consistent with current UK guidance)[24] at the baseline assessment. If there was a contraindication or the person was unable or refused spirometry, a spirometry result reported from hospital within the last 18 months was used. General Practitioners (GPs) were asked to exclude patients who they considered to be inappropriate for the research team to invite to take part (e.g. terminal disease, severe psychiatric disorder). Potentially eligible patients were then sent a letter of invitation, information brochure and patient information leaflet from their GP, with a reply slip to the research team which included the MRC dyspnoea scale. If the MRC dyspnoea score was available on the COPD register, then only patients with recorded grade 1 or 2 were invited, if this was not available, then all were invited.

**Baseline assessment**

Those who expressed an interest in the study were telephoned by a researcher and invited to a recruitment assessment at their practice, undertaken by a research nurse or trained researcher. Patients who attended baseline assessments were given the opportunity to discuss the study. Following informed consent, post-bronchodilator spirometry was undertaken, height and weight were measured and the patient was asked to complete a baseline questionnaire pack. This questionnaire pack included questions on patient demographics and the measures for the primary and secondary outcomes. A GENEactiv accelerometer was fitted on their non-dominant wrist, which they were asked to return by post in a pre-paid envelope after 7 days of continuous wear.

**Intervention and usual care**

This was a pragmatic trial with no constraints on GPs’ management of the participants in either group.

The usual care group received a standard information leaflet about self-management of COPD.[25] The 13 page leaflet gave a definition of COPD, a detailed description of associated symptoms, how the illness can be managed with the use of inhalers, how to treat exacerbations, and details of other resources (e.g. British Lung Foundation, Smokefree-NHS Choices).

The intervention consisted of nurse delivered telephone health coaching with supporting written documents, a pedometer and self-monitoring diary. This aimed to support self-management in relation to smoking cessation; increase in physical activity; correct inhaler technique and medication adherence, and for those with recurrent exacerbations an increase in confidence in identifying an exacerbation early in order to commence rescue medication (antibiotics or steroids).

The intervention was underpinned by Social Cognitive Theory,[26] and included education, monitoring and assessment of progress, and taught skills with the aim of increasing self-efficacy.[27, 28] We incorporated best evidence for the promotion of physical activity (tailored, ongoing support, duration 6 months, use of pedometer).[29-32]The intervention, components are detailed in web appendix 1. The first telephone coaching session at one week post randomisation aimed to last 35-60 minutes (determined by the number of issues requiring discussion, such as current smoking), followed by three 15-20 minute telephone contacts at weeks three, seven and 11 with individually tailored written supportive materials following each telephone call (e.g. summary of goals agreed, physical activity diary, contact details for local services, information leaflet showing correct inhaler technique). This was followed by standard written prompts/information at 16 and 24 weeks.

Nurses attended two days of training and practiced telephone coaching sessions with the research team. The telephone consultations were protocolised with the nurses following a proforma to guide the consultation. After each telephone call, the nurses briefly summarised the content of the call and any actions agreed; a sample of telephone consultations were recorded with the participants consent and reviewed by one researcher to explore compliance with the content of the intervention.

**Randomisation and masking**

Participants who had given informed consent and completed all the baseline measures were individually randomised in a 1:1 ratio to the intervention or usual care group stratified by centre. The allocation was made using a web-based programme hosted by the Primary Care Clinical Research and Trials Unit (PC-CRTU), University of Birmingham. Centre specific randomisation lists were produced by a statistician at the trials unit. The four recruitment centres were Birmingham and West-Midlands South; Greater Manchester; North West Midlands and Oxfordshire/Gloucestershire. Only the PC-CRTU had access to the allocation sequence. Participants were informed of their allocation at the end of the recruitment appointment; they were not masked to treatment allocation. Data were entered onto the study database by researchers at the University of Birmingham who were masked to treatment allocation.

**Outcome assessment**

We measured outcomes by postal questionnaire at six months to determine short–term change to the end of the intervention and at 12 months to determine whether any change was sustained. At 12 months, accelerometers were posted to participants with a follow-up telephone call to explain how to start the recording. They were asked to wear the accelerometers continuously for seven days and then to return them by post. Non-responders were telephoned and given the option of completing the questionnaire over the telephone.

**Outcomes**

The primary outcome measure was health related quality of life at 12 months from randomisation measured using the St Georges Respiratory Questionnaire (SGRQ-C).[33] Scores range from 0 to 100, with higher scores indicating greater impairment of quality of life.

Secondary outcomes were the SGRQ-C at 6 months, and the MRC dyspnoea scale,[34] self-reported physical activity (using the International Physical Activity Questionnaire (IPAQ)),[35] psychological morbidity (using the Hospital Anxiety and Depression Scale (HADS)),[36] self-efficacy for managing their COPD and undertaking physical activity (using the Stanford self-efficacy scale),[28] and health state utility using the EuroQoL 5 Dimensions 5 Levels (EQ-5D-5L)[37] at 6 and 12 months post-randomisation. Smoking cessation rates and physical activity measured using GENEactiv accelerometers were assessed at 12 months. Pre-specified exploratory outcomes were self-reported self-management activities (related to smoking cessation, medication adherence, care plans etc.) and health care utilisation at 6 and 12 months. An economic evaluation has also been undertaken, but will be reported elsewhere.

Adverse events were reported by intervention participants during telephone calls and from the 6 and 12 month follow-up questionnaires; they were independently assessed by two independent clinicians.

**Statistical justification for sample size**

The sample size was determined to detect a significant difference in the SGRQ-C at one year. To have 80% power to detect a difference of 4 points (the minimal clinically significant difference)[38] from a baseline total score value of 39,[39] with a standard deviation (SD) of 15 at the 5% level of significance requires 445 evaluable participants. Allowing for an attrition rate of 20% at 12 months, we needed 556 participants (278 per group).

The power to detect differences in self-reported physical activity and in smoking cessation rates are detailed in the protocol paper.[21]

**Analysis**

All data were analysed by intention to treat. The main analyses compared primary and secondary outcome measures between treatment groups at 12 months post-randomisation to assess the long term effect of the self-management intervention. Data were also analysed at 6 months to assess the short term change.

The primary outcome (SGRQ-C) and other continuous secondary outcome measures were analysed using a linear regression model. Ordered categorical secondary outcome measures (e.g. MRC dyspnoea scale) were analysed using an ordinal logistic regression model. All primary and secondary analyses were adjusted for baseline values and centre. Differences between treatment groups were summarised using suitable effect estimates (e.g. mean difference, odds ratio) with 95% confidence intervals (CI). A 5% statistical significance level was used.

Exploratory outcome measures were not analysed using statistical modelling except for the count data. Binary/categorical outcome measures were analysed using Chi-squared or Fisher’s exact test and continuous measures were analysed using t-tests or a non-parametric equivalent (e.g. Wilcoxon rank test). Measures of count were analysed using a Poisson regression model or negative binomial model as appropriate to obtain an incidence rate ratio (IRR). Models included an adjustment for baseline values and centre and an offset term for length of follow-up.

A number of sensitivity analyses were performed for the SGRQ-C. These included (i) a per-protocol analysis which included only those participants who received all 4 telephone calls in the intervention group and excluded the one patient in the usual care group who received the intervention by mistake; (ii) an analysis to assess the effect of missing data, with patients with missing 12 month SGRQ-C scores being simulated by regression imputation using baseline data, with baseline score, age, gender, MRC score and treatment group used as predictors to impute missing scores. All participants were included in this analysis unless they had died by 12 months or both the baseline and 12 month SGRQ-C scores were missing; and (iii) an analysis which excluded participants where the 12 month SGRQ-C questionnaires were returned either early (>1 month prior to the assessment due date) or late (>65 days post the assessment due date).

Subgroup analyses to explore the effects of the intervention in different patient subgroups were undertaken for the primary outcome (SGRQ-C total score only). The subgroups, pre-specified in the statistical analysis plan included participant characteristics (age, gender, ethnicity, smoking status, baseline MRC dyspnoea score and number of co-morbidities), active engagers with the intervention (through increased physical activity, uptake of smoking cessation support or checking of inhaler technique), baseline level of physical activity (from both the IPAQ and the accelerometer data), baseline health related quality of life (SGRQ-C), baseline self-efficacy (Stanford) and baseline depression and anxiety (from HADS). Two post-hoc subgroup analyses were also undertaken for baseline FEV1 predicted (≥80/<80) and degree of limitation of activities in the SGRQ-C. A treatment group by subgroup interaction parameter was included in the linear regression model to assess whether there were any differences in the treatment effect across the different strata. Differences between treatment groups within subgroups were only examined if the interaction parameters were statistically significant (p<0.05).

Details of the data available for the accelerometery analyses are provided in web appendix 2.

**Patient involvement**

The study was supported by a COPD patient advisory group which provided input to a programme of research on COPD. The group met on a regular basis and one was a member of the trial management group for the duration of the study. The group commented on the initial design of the study, the burden of the trial assessment process, participant facing materials and on the content and material to support the intervention. Additionally, a lay representative was a member of the Trial Steering Group. At the end of the study the group commented on the findings and contributed to the dissemination plan.

**Results**

We sent a screening questionnaire and invitation leaflet to 5279 people on the COPD registers of 71 general practices; 2066 responded with an interest in the study, but 920 were excluded as they had an MRC dyspnoea scale of 3 or more. We screened 728 people at their GP surgery between 18th March 2014 and 5th February 2015; 577 were eligible and randomised to telephone health coaching (n=289) or usual care (n=288) (figure 1). In total, 531 (92%) of participants provided data at 6 months and 516 (89%) at 12 months follow-up. There was imbalance in the follow-up rates between the intervention (82.7%; 37 withdrawals) and usual care (96.2%; 7 withdrawals) groups at 12 months, largely due to participants who wished to withdraw from the intervention also withdrawing from further follow-up. Of the 37 participants who withdrew from the intervention group, 4 withdrew before receiving any intervention and 16 withdrew during the intervention; 8 cited illness and 10 cited intervention-related factors ranging from it being too demanding to insufficiently so. Seventeen participants withdrew after the 6 months follow-up. Participants who withdrew from the study did not differ in characteristics to the full sample.

The characteristics of the participants are shown in Table 1. Participants were predominantly white; 63% were male; mean age 70.4 years; 23% were current smokers and only 19% were in paid employment. Participants had mild disease: mean FEV1 was 71.6% predicted, 193 (33%) were GOLD stage 1 and 309 (54%) GOLD stage 2; 165 (28.6%) reported MRC level I dyspnoea and 270 (47%) reported medication for an exacerbation in the previous 12 months. The mean SGRQ-C total score was 28.7. The study groups were generally well balanced in terms of participant characteristics, although there was a higher proportion of current smokers in the intervention group. The usual care group reported a higher level of self-reported moderate and vigorous activity, but this was not reflected in the accelerometry data at baseline. The accelerometry data for all participants showed that participants did a median of 31 minutes of moderate or vigorous activity in bouts of at least 10 minutes daily [IQR 0, 160]. Participants who did not provide data at 12 months were more likely to be in GOLD stage 3, to be smokers, had lower levels of self-reported physical activity and to live alone than responders.

**Table 1: Baseline characteristics of participants**

|  | **Telephone PSM****(N=289)** | **Usual Care****(N=288)** |
| --- | --- | --- |
| Mean (SD) age in years | 70.7 (8.8) | 70.2 (7.8) |
| Age ≥65 years | 221 (76%) | 231 (80%) |
| Male | 183 (63%) | 183 (64%) |
| White ethnic group | 283 (98%) | 284 (99%) |
| Median [IQR] Age Completed Full Time Education1 | 15 [15-16] | 15 [15-16] |
| Highest Level of Qualification |  |  |
|  No Formal Education | 128 (44%) | 135 (47%) |
|  GCSE, CSE, O Level Equivalent | 58 (20%) | 63 (22%) |
|  A-Level/AS Level or Equivalent | 27 (9%) | 24 (8%) |
|  Degree Level or Higher | 35 (12%) | 41 (14%) |
|  Other | 40 (14%) | 23 (8%) |
|  Missing | 1 (<1%) | 2 (1%) |
| Lives Alone | 83 (29%) | 69 (24%) |
| Employment Status2 |  |  |
|  Paid Work | 58 (20%) | 53 (18%) |
|  Unemployed/Looking for Work | 3 (1%) | 5 (2%) |
|  Retired from Paid Work | 216 (75%) | 214 (74%) |
|  Looking After Family/Home | 8 (3%) | 9 (3%) |
|  Unable to Work Due to Health Problems | 8 (3%) | 7 (2%) |
|  Other | 5 (2%) | 9 (3%) |
| **Clinical characteristics** |  |  |
| Current smoker | 75 (26%) | 55 (19%) |
| Mean (SD) BMI (kg/m²) | 27.1 (4.4) | 27.4 (4.9) |
| MRC Dyspnoea Scale |  |  |
|  Level 1 | 89 (31%) | 76 (26%) |
|  Level 2 | 200 (69%) | 212 (74%) |
| Mean (SD) FEV1 Predicted (%) | 71.2 (18.9) | 72.1 (18.7) |
| FEV1 Predicted (%) |  |  |
|  <30 | 1 (<1%) | 2 (1%) |
|  30-49 | 39 (13%) | 33 (11%) |
|  50-79 | 160 (55%) | 149 (52%) |
|  ≥80 | 89 (31%) | 104 (36%) |
| Co-Morbidities |  |  |
|  Cancer | 34 (12%) | 37 (13%) |
|  Diabetes | 32 (11%) | 36 (13%) |
|  High Blood Pressure | 135 (47%) | 123 (43%) |
|  Coronary Heart Disease | 34 (12%) | 44 (15%) |
|  Heart Failure | 15 (5%) | 10 (3%) |
|  Stroke/Mini-Stroke | 16 (6%) | 25 (9%) |
|  Asthma | 98 (34%) | 100 (35%) |
|  Tuberculosis | 6 (2%) | 10 (3%) |
|  Osteoarthritis | 46 (16%) | 56 (19%) |
|  Rheumatoid Arthritis | 22 (8%) | 25 (9%) |
|  Osteoporosis | 13 (5%) | 20 (7%) |
|  Depression | 44 (15%) | 57 (20%) |
|  Other Condition | 37 (13%) | 52 (18%) |
| Medication taken regularly for lung problems |  |  |
|  Beta-2 Agonist | 201 (70%) | 197 (68%) |
|  Inhaled Steroid | 27 (9%) | 39 (14%) |
|  Atrovent/Spiriva | 109 (38%) | 117 (41%) |
|  Seretide | 88 (30%) | 92 (32%) |
|  Symbicort | 33 (11%) | 21 (7%) |
|  Uniphylline/Aminophylline Tablets | 7 (2%) | 6 (2%) |
|  Steroid Tablets | 5 (2%) | 9 (3%) |
| Antibiotic and/or Steroid Course in past 12 Months | 135 (47%) | 135 (47%) |
| **Health related quality of life** |  |  |
|  Mean (SD) SGRQ-C Total Score | 27.8 (14.6) | 29.5 (14.5)  |
|  Mean (SD) SGRQ-C Symptoms Score | 48.5 (21.7) | 47.9 (20.7) |
|  Mean (SD) SGRQ-C Activity Score | 36.3 (21.0) | 38.7 (21.3) |
|  Mean (SD) SGRQ-C Impact Score | 15.4 (13.4) | 17.6 (13.9) |
|  Mean (SD) EQ-5D-5L | 0.90 (0.13) | 0.89 (0.13) |
| **Anxiety and Depression using HADS** |  |  |
|  Mean (SD) anxiety subscale score | 3.8 (3.4) | 4.3 (3.8) |
|  Mean (SD) depression subscale score | 2.9 (2.6) | 3.1 (2.8) |
| **Physical activity** |  |  |
|  Mean (SD) minutes of MVPA/week by accelerometry | 372.1 (305.1) | 379.1 (282.9) |
|  Mean (SD) moderate MET minutes/week using IPAQ | 766.4 (1253.9) | 941.5 (1437.6) |
|  Mean (SD) vigorous MET minutes /week using IPAQ | 809.4 (1771.5) | 910.2 (1997.4) |
| **Self-Efficacy** |  |  |
| Mean (SD) Stanford Self Efficacy Score | 8.3 (1.6) | 8.0 (1.7) |

1 One Subject in the Telephone PSM Group Never Went to School.

2 Not mutually exclusive, participants could tick all that applied.

**Intervention delivery**

The dose and coverage of intervention delivery was high: 86.4% (999/1156) of the scheduled calls were delivered and 218 (75.4%) of participants received all four calls. The average duration of calls was 39.2 minutes (SD 10.7) for the first call, then 23.8 (SD 9.2), 21.4 (SD 8.6) and 20.6 minutes (SD 8.7) for the second, third and final calls respectively. Nurses briefly noted content and duration of each telephone coaching session. Most calls were delivered by the same nurse, although sometimes this was not possible due to illness or leave. Smoking was discussed in a third of sessions, physical activity in over 99%, inhaler technique in 90% and action planning in 88% of all calls. SMART goals were set in 57% of calls for physical activity, in 11% for smoking cessation and in 9% for inhaler technique to be checked.

**Primary outcome**

At 12 months, there was no significant difference in the total SGRQ-C score (mean difference -1.3, 95% confidence interval -3.6 to 0.9; p=0.2), although the direction favoured the intervention group. The mean difference in the SGRQ-C activity score was of borderline significance favouring the intervention group (-3.2, 95% confidence interval -6.3 to 0.0; p=0.05). There was no significant difference between groups for the SGRQ-C symptoms or impact scores (table 2).

**Table 2: Comparison of primary and secondary outcomes**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Baseline** | **6 months** | **12 months** |
|  | **Telephone PSM**mean (sd) | **Usual Care**mean (sd) | **Telephone PSM**mean (sd) | **Usual Care**mean (sd) | **Mean difference (95% CI)** | **p-****value** | **Telephone PSM**mean (sd) | **Usual Care**mean (sd) | **Mean difference (95% CI)** | **p-****value** |
| **Health related Quality of Life** |  |  |  |  |  |  |  |  |
|  SGRQ-C total1 | N=27727.8 (14.6) | N=27229.5 (14.5) | N=22228.6 (17.1) | N=23730.5 (16.7) | -0.3(-2.3 to 1.7) | 0.8 | N=21727.9 (15.7) | N=25630.9 (17.0) | -1.3(-3.6 to 0.9) | 0.2 |
|  SGRQ-C symptom1 | N=28448.5 (21.7) | N=27947.9 (20.7) | N=24149.5 (22.6) | N=26649.2 (21.4) | -0.04 (-2.9 to 2.8) | 1.0 | N=23049.3 (21.4) | N=27350.1 (22.6) | -1.9 (-4.9 to 1.1) | 0.2 |
|  SGRQ-C activity1 | N=28136.3 (21.0) | N=27938.7 (21.3) | N=22936.0 (22.7) | N=25237.9 (23.9) | 0.4 (-2.3 to 3.2) | 0.8 | N=22433.7 (21.1) | N=26039.2 (24.4) | -3.2 (-6.3 to 0.0) | 0.05 |
|  SGRQ-C impact1 | N=28615.4 (13.4) | N=28017.6 (13.9) | N=23316.9 (16.3) | N=25519.0 (15.5) | -0.7 (-2.8 to 1.4) | 0.5 | N=22516.5 (15.2) | N=26119.3 (15.6) | -1.1 (-3.3 to 1.1) | 0.3 |
|  EQ-5D-5L2 | N=2850.90 (0.13) | N=2800.89 (0.13) | N=2440.88 (0.16) | N=2720.87 (0.14) | 0.01 (-0.01 to 0.03) | 0.3 | N=2350.87 (0.14) | N=2700.86 (0.17) | 0.01 (-0.01 to 0.03) | 0.4 |
| **Anxiety and Depression** |  |  |  |  |  |  |  |  |
|  HADS anxiety subscale score1 | N=2863.8 (3.4) | N=2854.3 (3.8) | N=2433.8 (3.8) | N=2794.5 (4.0) | -0.3 (-0.8 to 0.2) | 0.2 | N=2274.0 (3.8) | N=2674.7 (4.0) | -0.06 (-0.6 to 0.4) | 0.8 |
|  HADS depression subscale score1 | N=2872.9 (2.6) | N=2853.1 (2.8) | N=2443.1 (3.0) | N=2793.5 (3.1) | -0.2 (-0.6 to 0.1) | 0.2 | N=2283.3 (3.3) | N=2703.8 (3.4) | -0.1 (-0.6 to 0.4) | 0.6 |
| **Self-Efficacy** |  |  |  |  |  |  |  |  |
|  Stanford Self Efficacy Score2 | N=2878.3 (1.6) | N=2848.0 (1.7) | N=2478.1 (1.7) | N=2757.8 (1.8) | 0.2 (-0.07 to 0.4) | 0.2 | N=2288.1 (1.6) | N=2727.7 (1.8) | 0.1 (-0.1 to 0.4) | 0.3 |
| **Physical Activity (accelerometry)** |  |  |  |  |  |  |  |  |
|  MVPA minutes/week2 | N=263372.1 (305.1) | N=259379.1 (282.9) | - | - | - | - | N=179346.5 (276.6) | N=232315.5 (256.1) | 11.8 (-21.1 to 44.8) | 0.5 |
| **Physical Activity (IPAQ)** |  |  |  |  |  |  |  |  |
|  Total MET minutes/week2 | N=2303242.2 (3284.2) | N=2363265.8 (3480.6) | N=2023786.0 (3685.7) | N=2372920.6 (3195.0) | 924.7(318.3 to 1531.1) | 0.003 | N=1913214.3 (3578.4) | N=2232738.1 (3249.9) | 410.0(-235.7 to 1055.7) | 0.2 |
|  Walking MET minutes/week2 | N=2491496.0 (1324.6) | N=2531371.0 (1249.0) | N=2161728.8 (1390.6) | N=2481404.2 (1244.0) | 283.4(55.2 to 511.6) | 0.02 | N=2001588.5 (1386.7) | N=2341362.7 (1318.2) | 161.5(-86.2 to 409.3) | 0.2 |
|  Moderate MET minutes/week2  | N=267766.4 (1253.9) | N=265941.5 (1437.6) | N=236950.8 (1399.7)  | N=268732.9 (1208.2)  | 233.9(10.6 to 457.1) | 0.04 | N=218765.9 (1256.4)  | N=261628.6 (1164.8)  | 130.1(-83.9 to 344.0) | 0.2 |
|  Vigorous MET minutes /week2  | N=271809.4 (1771.5) | N=282910.2 (1997.4) | N=2291050.5 (2212.7)  | N=270728.7 (1656.6)  | 335.8(23.2 to 648.4) | 0.04 | N=218864.4 (1994.3)  | N=264705.3 (1674.0)  | 160.1(-141.1 to 461.3) | 0.3 |
|  |  |  |  |  | **Odds Ratio** **(95% CI)3** | **p-****value** |  |  | **Odds Ratio (95% CI)3** | **p-****value** |
| **MRC Dyspnoea Scale** |  |  | 0.8(0.6 to 1.2) | 0.4 |  |  | 1.1(0.7, 1.5) | 0.8 |
|  Level 1 | 89 (31%) | 76 (26%) | 77 (32%) | 84 (32%) |  |  | 69 (31%) | 74 (28%) |  |  |
|  Level 2 | 200 (69%) | 212 (74%) | 137 (58%) | 158 (60%) |  |  | 137 (61%) | 163 (61%) |  |  |
|  Level 3 | - | - | 14 (6%) | 18 (7%) |  |  | 16 (7%) | 27 (10%) |  |  |
|  Level 4 | - | - | 8 (3%) | 5 (2%) |  |  | 4 (2%) | 5 (2%) |  |  |
|  Level 5 | - | - | 1 (<1%) | 0 (-) |  |  | 0 (-) | 0 (-) |  |  |
| **Smoking cessation** |  |  |  |  |  |  |  |  |
|  Quit Smoking† | 75 (26%) | 55 (19%) | 14 (22%) | 9 (18%) | - | 0.6 | 7 (13%) | 13 (25%) | - | 0.1 |

Data are presented as mean (SD) or n (%) as appropriate.

 † Baseline data is reported as current smokers at baseline. Only patients who reported they were current smokers at baseline were included in the analyses on quitting smoking at 6 and 12 months.

1Telephone PSM compared to usual care (negative values favour Telephone PSM).

2Telephone PSM compared to usual care (positive values favour Telephone PSM).

3Telephone PSM compared to usual care (Odds Ratio >1 favours Telephone PSM).

**Secondary outcomes**

At six months, there were no significant differences in the SGRQ-C total and sub-scores (table 2). At six and 12 months, there were also no differences in the EQ-5D-5L, HADS, Stanford self-efficacy scale or level of breathlessness (MRC) (table 2). At six months, total self-reported physical activity, walking, moderate and vigorous intensity activity were all significantly higher in the intervention arm (table 2). Whilst differences still favoured the intervention arm at 12 months, they did not remain statistically significant. There was no difference in moderate or vigorous activity measured using accelerometry at 12 months. There was also no difference in smoking cessation rates at 6 and 12 months (table 2).

**Health care utilisation**

At six months, intervention participants reported significantly lower GP and pharmacist consultations, but higher all-cause emergency department visits. There were no differences at 12 months (table 3). At six and 12 months, 106 (43%) and 89 (37%) of the intervention group respectively had been prescribed at least one course of antibiotics compared to 105 (37%) and 96 (35%) of the usual care group.

**Table 3: Health care utilisation**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Baseline** | **6 months** | **Incidence Rate Ratio¹****(95% CI)** | **p-value²** | **12 months** | **Incidence Rate Ratio¹****(95% CI)** | **p-value²** |
|  | **Telephone PSM**  | **Usual Care** | **Telephone PSM** | **Usual Care** |  |  | **Telephone PSM** | **Usual Care** |  |  |
| Hospital Admissions |  |  |  |  |  |  |  |  |  |  |
|  All Cause | N=2770.11 (0.4) | N=2810.12 (0.4) | N=2480.07 (0.3) | N=2830.08 (0.3) | 0.86 (0.45 to 1.62) | 0.6 | N=2390.06 (0.3) | N=2770.06 (0.3) | 0.90\* (0.39 to 2.09) | 0.8 |
|  Respiratory | N=2810.02 (0.2) | N=2830.02 (0.1) | N=2480.02 (0.1) | N=2830.03 (0.2) | 0.55\* (0.15 to 2.07) | 0.4 | N=2390.01 (0.1) | N=2770.01 (0.1) | 0.56\* (0.08 to 4.11) | 0.6 |
| Emergency department |  |  |  |  |  |  |  |  |  |  |
|  All Cause | N=2860.22 (0.5) | N=2800.23 (0.6) | N=2480.33 (1.8) | N=2830.16 (0.5) | 1.87\* (1.06 to 3.27) | 0.03 | N=2380.26 (0.8) | N=2760.23 (0.7) | 1.06\* (0.62 to 1.83) | 0.8 |
|  Respiratory | N=2860.04 (0.2) | N=2820.02 (0.1) | N=2480.04 (0.2) | N=2830.03 (0.2) | 1.48\* (0.50 to 4.43) | 0.5 | N=2390.04 (0.2) | N=2770.01 (0.1) | 2.85\* (0.67 to 12.20) | 0.2 |
| Primary care consultations |  |  |  |  |  |  |  |  |  |  |
|  GP -all Cause | N=2881.18 (1.7) | N=2851.23 (1.5) | N=2431.41 (1.5) | N=2821.76 (2.2) | 0.80\* (0.66 to 0.96) | 0.02 | N=2361.45 (1.8) | N=2721.67 (1.8) | 0.85\* (0.70 to 1.03) | 0.1 |
| Practice Nurse -all Cause | N=2880.60 (1.8) | N=2850.65 (1.4) | N=2430.71 (1.5) | N=2820.72 (1.4) | 0.98\* (0.73 to 1.31) | 0.9 | N=2340.56 (1.0) | N=2720.67 (1.0) | 0.81\* (0.62 to 1.07) | 0.1 |
| Pharmacist -all Cause | N=2880.10 (0.9) | N=2850.13 (0.6) | N=2430.05 (0.4) | N=2820.17 (0.8) | 0.27\* (0.10 to 0.75) | 0.01 | N=2330.10 (0.6) | N=2680.11 (0.5) | 0.75\* (0.29 to 1.91) | 0.5 |
|  Respiratory | N=1860.63 (0.9) | N=1900.84 (1.1) | N=1640.90 (1.1) | N=1970.96 (1.3) | 0.99\* (0.72 to 1.35) | 0.9 | N=1320.77 (1.0) | N=1670.83 (1.2) | 0.84\* (0.60 to 1.19) | 0.3 |

Data are presented as mean (SD).

¹ Telephone PSM compared to Usual Care (Incidence Rate Ratio <1 favours Telephone PSM).

² Statistical Significance determined from a chi-squared test.

\*Estimate from a negative binomial model rather than a Poisson regression model

**Activities targeted by the telephone health coaching intervention**

Physical activity and smoking cessation rates have been described above. There was no difference between the groups in smoking quit attempts in the previous 6 months or attendance at smoking cessation services at either follow-up point. At six months, participants in the intervention group reported improved medication adherence, with significantly higher proportions having an inhaler check in the past six months (68% vs. 55%), an agreed care plan with a health care provider (44% vs. 30%), written advice about what to do if symptoms worsened (23% vs. 17%) and having an antibiotic rescue pack (37% vs. 29%). However, they did not report improved confidence in the use of rescue packs. At 12 months, many of these improvements were sustained (table 4).

**Table 4: Self-reported self-management behaviours**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **6 months** | **p-value** | **12-months** | **p-value** |
|  | **Telephone PSM** | **Usual care** | **Telephone PSM** | **Usual care** |  | **Telephone PSM** | **Usual care** |  |
| Smoking quit attempt in past 6 months | - | - | 29 (54%) | 21 (49%) | 0.7 | 30 (58%) | 21 (53%) | 0.5 |
| Attendance at smoking cessation service1 | - | - | 3 (10%) | 1 (5%) | 0.6 | 3 (10%) | 4 (19%) | 0.4 |
| Median medication adherence score2 (0-24) (IQR, n) | 1 (0-2, 273) | 1 (0-2, 265) | 1 (0-2, 219) | 1 (0-2, 255) | 0.01 | 1 (0-1, 218) | 1 (0-2, 255) | 0.1 |
| Inhaler check in past 6 months | - | - | 168 (68%) | 157 (55%) | 0.01 | 156 (65%) | 153 (55%) | 0.02 |
| Agreed a care plan with health care provider3 |  |  |  |  |  |  |  |  |
|  in past 6 months | 80 (28%) | 82 (29%) | 108 (44%) | 85 (30%) | 0.002 | 79 (33%) | 75 (27%) | 0.02 |
|  >6 months ago | 25 (9%) | 26 (9%) | 53 (21%) | 70 (25%) |  | 72 (30%) | 70 (25%) |  |
|  never | 165 (57%) | 156 (54%) | 63 (25%) | 104 (37%) |  | 68 (28%) | 111 (40%) |  |
| Written advice on what to do if symptoms get worse | 49 (17%) | 49 (17%) | 57 (23%) | 47 (17%) | 0.05 | 54 (23%) | 52 (19%) | 0.1 |
| Has antibiotic rescue pack | 77 (27%) | 75 (26%) | 93 (37%) | 81 (29%) | 0.02 | 97 (40%) | 83 (30%) | 0.02 |
|  confident in its use | 71 (92%) | 68 (91%) | 85 (91%) | 76 (94%) | 0.5 | 95 (98%) | 76 (92%) | 0.1 |
| Has steroid rescue pack | 56 (19%) | 51 (18%) | 63 (25%) | 60 (21%) | 0.2 | 70 (29%) | 58 (21%) | 0.03 |
|  confident in its use | 52 (93%) | 47 (92%) | 53 (84%) | 55 (92%) | 0.4 | 65 (93%) | 54 (93%) | 1.0 |

1Denominator is participants who made a quit attempt in previous 6 months

2Medical Adherence Score: Ranges from 0-24, where low scores are good and high scores are bad.

3Baseline Assessment Only: (Yes < 12 months, Yes ≥12 months, No).

Percentages do not add up to 100% due to missing data

**Sensitivity and subgroup analyses**

There were no differences in the findings for (i) the per-protocol analysis (ii) when regression imputation was used to impute missing data; or (iii) when the analysis excluded questionnaires returned either early or late (see web appendix 3). Subgroup analyses also found no evidence that the effect size differed by age, gender, ethnicity, comorbidities, baseline MRC level, smoking status, HADS, physical activity, FEV1 predicted (≥80/<80), degree of limitation of activities in the SGRQ-C, active engagers, or self-efficacy. There was some evidence of an interaction with baseline SGRQ-C (p=0.04); with a greater benefit for intervention in participants with a baseline score of ≥25 (i.e. those with poorer quality of life) (mean difference -3.0, 95% CI -6.4 to 0.3) compared to those with a baseline score <25 (2.3, 95% CI -1.6 to 6.2).

**Adverse events**

There were 44 serious adverse events reported by participants; 24 in the intervention and 20 in the usual care arm. No serious and related events occurred. The five deaths were all in the intervention group and were due to cor pulmonale, stroke, ruptured aortic aneurysm, and malignancy (2), none were considered to be related to the intervention.

**Discussion**

**Principal findings**

This trial is the first to evaluate the effectiveness of a nurse-led telephone health coaching intervention to support self-management for patients living with mild symptoms of COPD. Whilst we showed an improvement in self-reported self-management activities in the telephone coaching group compared to usual care, we did not observe a significant difference in our primary outcome of health related quality of life measured by the SGRQ-C, nor in the impact, symptom or activity domains, although the confidence intervals did include the minimal clinically important difference of 4 points for the activity and symptom domains. Self-reported physical activity was higher at 6 months in the intervention group, but this was not sustained at 12 months. In addition, activities targeted by the intervention, including patients asking a health care professional to check their inhaler technique, asking their general practitioner to agree a care plan and having a rescue pack were significantly higher in the intervention group at 6 and 12 months follow-up, compared to usual care, suggesting that a proportion of intervention participants adopted active self-management.

**Comparison with other studies**

Our approach was novel in comparison to other trials of self-management and telephone coaching interventions by targeting people with mildly symptomatic disease. Most previous trials of COPD self-management have excluded participants with GOLD stage I (mild airflow obstruction),[9, 40] whereas a third of our participants, were in this category, as we particularly wanted to evaluate an intervention for more mildly affected patients, who are a clinically important, but largely neglected group despite having a reduced health related quality of life.[41]

Systematic reviews of self-management interventions have reported significant improvements in COPD related quality of life, measured by the SGRQ[9, 40, 42] with a mean difference of -2.40 at 12 months follow-up.[42] All reviews reported effects larger than the -1.3 points difference at 12 months found in our trial. Health related quality of life has been favoured as the main outcome for trials of COPD self-management as functional status is important to patients and is sensitive to change, whilst lung function has a natural variation making it difficult to interpret change over short follow-up periods. Compared to other studies of self-management in COPD, even those in milder populations,[39] the SGRQ total score in our study was very low at baseline (representing a good HRQoL). This potentially led to a floor effect, where change may be unlikely to be achievable, or improvement may only be observed over a much longer time scale. However for the activity sub-score of the SGRQ, the mean difference at 12 months (-3.2) found in our trial compares well with those of the systematic reviews, which report statistically significant mean differences of -2.21[40] and -2.75.[9] These findings are consistent with the significant differences found at six months (at the end of the PSM-COPD intervention) in self-reported physical activity (IPAQ). However, this result of reduced limitations to physical activities was not reflected in the self-reported quantity or intensity of physical activity (IPAQ) or our objective measures of physical activity where there were no differences between groups at 12 months.

An Australian RCT of a 12 month intensive telephone health mentoring intervention for primary care patients with moderate to severe COPD also did not report a difference in the SGRQ at 12 months; but did achieve greater improvements in self-management capacity and in COPD knowledge than usual care.[43] Similar to our trial, a 12 week RCT of an intensive automated telecoaching programme reported significant improvements in physical activity and the functional domain of the Clinical COPD Questionnaire, but not health related quality of life (COPD Assessment Test) at the end of the 12 week intervention period.[44] Conversely, an RCT of telephone-mentoring for home-based walking demonstrated no benefit in exercise capacity in patients with COPD prior to commencing a pulmonary rehabilitation programme, and also had a high withdrawal rate.[45] In keeping with our findings, a rapid review of 30 RCTs of the effects of telephone health coaching to support self-management of long-term conditions reported improvements in health behaviours, but did not find conclusive evidence of improvements in quality of life.[5]

Observed short-term improvements in self-reported physical activity may have required a longer duration of support or intermittent maintenance activities to sustain changes. Primary care consultations were also lower in the intervention group at 6 months, which again may reflect the increased telephone contact in this period. A consistent message of the intervention was for intervention participants to use their routine appointments with primary care for their inhaler technique to be checked or to discuss a care or action plan and it appears that participants heeded this message and did not book additional consultations for self-management advice or support.

**Strengths and limitations of this study**

There were many strengths of this study. Firstly, focusing on a mildly symptomatic patient group who are largely excluded from other trials provided novelty and potential for clinical benefit. We used a multi-centre study design incorporating a large sample of GP practices representative of the general UK population; a pragmatic design to accommodate a broad patient group with no selection by motivation to change health behaviours; spirometry was undertaken using trained staff and quality assured and we achieved a good follow-up rate. The intervention was underpinned by social cognitive theory and included techniques such as goal setting that have been shown to be effective in modifying behaviour[46] and was at an intensity that might potentially be delivered in a publically funded health service. We achieved good fidelity of delivery of the intervention, with 75% of intervention participants receiving all four calls and only 4 participants receiving none. There did not appear to be any contamination or change in behaviour in the usual care group with their self-reported self-management behaviours remaining static throughout the trial. In keeping with the pragmatic nature of this intervention, we did not check whether those who checked inhaler technique had adequate training, but this is a core component of primary care management of COPD.[24]

Our study has some limitations. The intervention was in a group of people with only mild symptoms of breathlessness, who may not have considered themselves ill, thus a high degree of motivation may have been needed to take part. Highly motivated patients would be more likely to self-manage their condition and change lifestyle behaviours. Our sample reported high levels of regular physical activity exceeding the lower recommended amount of moderate or vigorous activity per week at baseline; so, despite our efforts to recruit all eligible patients from primary care there is likely to have been self-selection of people to the study, which may have affected capacity to improve, which is a feature of most behaviour change trials. The intervention did not meet the needs of some participants who withdrew from the intervention and in some cases also withdrew from the trial, resulting in an imbalance in follow-up rates between study arms. The participants who withdrew gave reasons including feeling that the intervention did not meet their needs as they were already physically active and some that were too unwell following an exacerbation. This may point to the need for more individual tailoring than actually occurred. In addition, delivery by telephone may give less opportunity for the building of rapport between the participant and nurse.Issues of rapport, acceptability and tailoring of the intervention will be addressed in more detail in a separate publication of the qualitative evaluation. We did not observe large differences in the characteristics of those who withdrew from the trial, nor any differences in the interpretation of the primary outcome with a sensitivity analysis to assess the impact of missing data. The power calculation was based on detecting a 4 point difference in the SGRQ-C at 1 year (mean score 39, SD 15). Although participants in PSM-COPD had less severe disease at baseline (28.7) than expected, the SD was 14.5 meaning we still have 80% power to detect the 4 point difference. However, due to the lower SGRQ score at baseline, this 4 point difference now corresponds to a 14% proportional reduction compared to the 10% proportional reduction in the original sample size.

We trained our nurses for two days with further role plays and group calls to discuss challenges once the intervention had started. Our evaluation of the logs of their telephone calls and audio-recorded calls identifies a variation in communication style from patient centred to a more directive approach. Further, due to the nature of recruitment across different sites, the distribution of calls completed by nurses was uneven. It was apparent that some participants were reluctant to set physical activity goals. It is possible that longer nurse training would have led to greater communication skills and more behavioural change, but this was a pragmatic study that aimed to evaluate an intervention that could be rolled out in practice. It is possible that a longer intervention duration, with calls beyond three months, would have led to greater effects and that in our group with predominantly mild disease, follow-up beyond 12 months might be needed to detect changes.

**Implications for clinicians and policy**

Adding telephone health coaching to support self-management did not improve health related quality of life in our patient population with only mildly symptomatic disease and who were already quite physically active at baseline. It did, however, lead to an increase in self-reported physical activity at 6 months, which is likely to result in health benefits,[15, 16] and self-management activities which are likely to reduce the frequency and severity of exacerbations. Whilst there is still uncertainty about best practice for managing people with mildly symptomatic disease, inhaled therapies are widely used in this group and improved engagement with education about correct delivery technique will help to realise improved outcomes for these patients.[18, 19] Currently, whilst self-management support is recommended, it is not likely to be well implemented.[47] Much evidence for COPD self-management support comes from patients recruited from secondary care and there needs to be a synthesis of the findings of support for self-management in patients recruited from a primary care setting. It may be that among people with mildly symptomatic disease, self-management support should be provided for those with poorest health related quality of life, which is the greatest predictor of future quality of life,[48] or in those with the most frequent exacerbations.[14] It may also be that a different health related quality of life outcome measure is needed for people with mild/early COPD that addresses limitations specific to the stage of their disease.

There is a lack of evidence of effective interventions for patients with mild COPD and this trial, while improving some self-management behaviours, did not show evidence of clinical benefit. There remains a need to identify successful interventions for COPD patients with milder symptoms and this also has clear implications for screening or case-finding activities, which would identify patients with mild disease, and cannot be recommended whilst there is a lack of effective treatment options for this patient group. There are wider implications in the use of telephone health coaching; a rapid review reported that it appears to be most effective in vulnerable populations, who have difficulty accessing health services,[4] which is not reflective of our study population. Supporting self-management in people with early disease, or risk factors, remains a challenge. Apart from diabetes prevention programmes, health services generally focus self-management support and rehabilitation services on people with more advanced disease, but there is the potential for considerable health and health service gains if we could facilitate self-management in people with early disease and slow their decline. Establishing whether this is possible will require long-term follow-up studies.

**Conclusions and policy implications**

A novel telephone health coaching intervention to promote behaviour change in patients with mild symptoms of dyspnoea in primary care led to changes in self-management activities, but did not significantly improve health related quality of life. There remains a clear need to identify risk mitigating interventions that can effectively prevent or delay disease progression in this patient group.

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**Competing interests**

All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf). RJ reports grants from NIHR and PA reports grants from NIHR School for Primary Care Research during the conduct of the study. CHen has received expenses and fees for his media work. He has received expenses from the WHO and holds grant funding from the NIHR, the NIHR School of Primary Care Research, The Wellcome Trust and the WHO. He has received financial remuneration from an asbestos case. He has also received income from the publication of a series of toolkit books published by Blackwells. On occasion, he receives expenses for teaching EBM and is also paid for his GP work in NHS out of hours. CEBM jointly runs the EvidenceLive Conference with the BMJ and the Overdiagnosis Conference with some international partners which are based on a non-profit making model.

**Authors’ contributions**

KJ led the design of the trial, with contributions and advice from PC, AD, RJ, CHen, SS, PA, SJ, LD and DF. KJ, RJ, PA, AD and DF contributed to decisions on outcome measures. DF advised on involving GP practices, RJ and PA advised on lung function testing. AD and KJ designed the intervention. SJ designed the economic evaluation. KJ, PC, CHen and Rhian Hughes (Keele University) were the local PIs. CHew and NI developed the statistical analysis plan and undertook the analyses. KJ drafted the paper with MS, with critical input from all other authors. KJ and MS contributed equally to this paper. All authors have read and approved the final draft. KJ is guarantor.

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**Ethical approval**

The study received ethical and research governance approval from the NHS Research Ethics Service, West Midlands, Solihull (Reference 13/WM/0206). All participants gave informed consent.

**Data sharing**

Requests for access to data from the PSM COPD study or the interventional materials should be addressed to the corresponding author at c.b.jolly@bham.ac.uk. All the individual participant data collected during the trial (including the data dictionary) will be available, after de-identification, immediately after publication with no end date. The study protocol has been published. All proposals requesting data access will need to specify how it is planned to use the data, and all proposals will need approval of the trial co-investigator team before data release.

**Transparency**

The guarantor (KJ) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Figure Legend

**Figure 1:** **PSM COPD Consolidated Standards of Reporting Trials (CONSORT) trial profile**

**Summary box**

What is already known on this topic

Recent policy for the prevention and management of long term conditions focusses on efforts to prevent onset or slow progression of disease early in the disease trajectory. This prevention paradigm has only recently been adopted in COPD.

Systematic reviews have shown that self-management support for people with COPD is effective in improving health related quality of life and in reducing hospital admissions, but the evidence comes largely from people with moderate or severe disease and predominantly recruited from secondary care.

What this study adds

Our study, in people with mildly symptomatic COPD recruited from primary care, showed that telephone health coaching comprising components that were theoretically associated with slowing decline of lung function, did improve self-management activities that were targeted by the intervention, but did not improve health related quality of life over the 12 month follow-up period.

**Web appendix 1: Outline of the intervention components**

|  |
| --- |
| **Week 1**Telephone:Medication management: Inhaler technique: timing of last check, set goal to get technique checked. Medication adherence (if relevant) –memory prompts, restructuring environment, support from partner.Smoking: Discussion of smoking behaviours, quit attempts and barriers to quit. Encouragement to set goal to contact smoking cessation service and to seek social support to support a quit attempt.Physical activity: current levels and breathlessness, goal to increase activity (duration and or intensity) and record in diary.Action planning: discussion of management of exacerbations, did they have written action plan, confidence with use of rescue pack. Prompt to discuss at routine appointment with GP if lacking understanding or confidence.Postal: Physical activity booklet including information on benefits for COPD and overcoming barriersPhysical activity diaryPedometer with instructionsSmoking information booklet (smokers only) with contact details of smoking cessation serviceInhaler technique instruction leaflet |
|  |
| **Week 3**Telephone:Discussion of progress with goals set in previous session and any barriers to achieving goals.Review of physical activity levels and setting of new goals.Discussion of smoking, medication management and action planning as required.Postal:Information on opportunities for physical activity in the localityInformation leaflet: What are SMART goals?SMART goals sheet |
|  |
| **Week 7**Telephone:Discussion of progress with goals set in previous session and any barriers to achieving goals.Review of physical activity levels and setting of new goals.Discussion of smoking, medication management and action planning as required.Postal:SMART goals sheet |
|  |
| **Week 11**Telephone:Discussion of progress with goals set in previous session and any barriers to achieving goals.Review of physical activity levels and setting of new goals.Discussion of smoking, medication management and action planning as required.Postal:SMART goals sheet |
|  |
| **Week 16**Postal SMART goals sheet |
|  |
| **Week 24**Postal:Information on opportunities for physical activity in the localityLeaflet on tips for sustaining physical activity |

**Web appendix 2: Accelerometry methods and adherence**

At the baseline assessment a GENEactiv accelerometer was fitted on the participant’s non-dominant wrist, which they were asked to return by post in a pre-paid envelope after 7 days of continuous wear. At 12 month follow-up accelerometers were posted to participants with a follow-up telephone call to explain how to start the recording. They were asked to wear them continuously for 7 days and return them by post. Non-responders were telephoned and given the option of completing the questionnaire over the telephone.

*Analysis*

Data were collected in 60 second epochs. In order to be considered a valid day, participants needed to wear the accelerometer for at least 10 waking hours. A minimum of 5 days of valid data was necessary for inclusion in the final analysis. The criterion for non-wear was 120 minutes of zero counts. The default cut-points for adult physical activity were used to determine the amount of time spent in moderate to vigorous physical activity. These cut-points in g.min were 483 for the threshold from sedentary to light activity, 678 for moderately intense activity and 2264 for vigorous activity.

*Adherence*

At baseline 535 participants returned an accelerometer with data on, of which 522 (90.5%) had valid data for inclusion in the analyses. At 12 months follow-up, 416 accelerometers were returned with data, of which 411 had valid data for analysis; this was 71.2% of the initial sample.

**Web appendix 3: Results of sensitivity analyses for the PSM-COPD study**

|  |  |  |
| --- | --- | --- |
|  | **Baseline** | **12 months** |
|  | **Telephone PSM**mean (sd) | **Usual Care**mean (sd) | **Telephone PSM**mean (sd) | **Usual Care**mean (sd) | **Mean difference¹ (95% CI)** | **p-value** |
| **Per-protocol analysis** |
|  SGRQ-C total | 26.5 (13.5) | 29.5 (14.5) | 27.6 (14.6) | 30.8 (17.0) | -1.4 (-3.6, 0.8) | **0.2** |
|  SGRQ-C symptom | 48.1 (21.1) | 47.8 (20.7) | 49.2 (21.2) | 50.0 (22.7) | -1.9 (-4.9, 1.2) | **0.2** |
|  SGRQ-C activity | 34.1 (19.8) | 38.7 (21.3) | 33.9 (20.1) | 39.3 (24.4) | -2.4 (-5.6, 0.8) | **0.1** |
|  SGRQ-C impact | 14.4 (12.3) | 17.5 (13.9) | 15.8 (13.8) | 19.3 (15.6) | -1.6 (-3.8, 0.5) | **0.1** |
| **Analysis to assess impact of assessment window** |
|  SGRQ-C total | 27.1 (13.9) | 29.1 (14.2) | 28.1 (15.5) | 30.7 (16.8) | -1.1 (-3.3, 1.1) | **0.3** |
|  SGRQ-C symptom | 48.6 (21.2) | 47.7 (20.7) | 49.3 (21.4) | 50.0 (22.6) | -1.6 (-4.7, 1.4) | **0.3** |
|  SGRQ-C activity | 35.0 (19.9) | 38.5 (21.1) | 34.4 (20.7) | 39.1 (24.2) | -2.5 (-5.6, 0.7) | **0.1** |
|  SGRQ-C impact | 14.8 (12.8) | 17.0 (13.4) | 16.4 (14.8) | 19.2 (15.3) | -1.1 (-3.3, 1.0) | **0.3** |
| **Imputation** **to assess impact of missing data** |
|  SGRQ-C total | 27.9 (14.5) | 29.5 (14.5) | 28.5 (15.9) | 31.1 (17.3) | -1.4 (-3.4, 0.6) | **0.2** |
|  SGRQ-C symptom | 48.3 (21.8) | 47.7 (20.5) | 48.6 (21.1) | 50.2 (22.4) | -2.0 (-4.7, 0.7) | **0.1** |
|  SGRQ-C activity | 36.3 (21.0) | 38.5 (21.2) | 34.7 (21.4) | 39.2 (23.8) | -3.0 (-5.9, -0.2) | **0.04** |
|  SGRQ-C impact | 15.5 (13.4) | 17.6 (13.8) | 17.5 (15.3) | 19.9 (15.5) | -0.9 (-2.9, 1.1) | **0.4** |

1Telephone PSM compared to usual care (negative values favour Telephone PSM).