ERJ open research
THE BEST IN OPEN ACCESS BASIC, TRANSLATIONAL & CLINICAL RESPIRATORY RESEARCH

Early View

Original article

A randomised trial of a web-based physical activity self-management intervention in COPD

Stephanie A. Robinson, J. Allen Cooper, Rebekah L. Goldstein, Madeline Polak, Paola N. Cruz Rivera, David R. Gagnon, Amber Samuelson, Sheila Moore, Reema Kadri, Caroline R. Richardson, Marilyn L. Moy

Please cite this article as: Robinson SA, Cooper JA, Goldstein RL, *et al*. A randomised trial of a web-based physical activity self-management intervention in COPD. *ERJ Open Res* 2021; in press (https://doi.org/10.1183/23120541.00158-2021).

A Randomized Trial of a Web-based Physical Activity Self-Management Intervention in COPD

Stephanie A. Robinson, PhD[1,2]; J. Allen Cooper Jr., MD[3,4]; Rebekah L. Goldstein, MPH[5]; Madeline Polak, BS[5]; Paola N. Cruz Rivera, BA[5]; David R. Gagnon, MD, MPH, PhD[6,7]; Amber Samuelson, BSN[3]; Sheila Moore, BS[3]; Reema Kadri, MLIS[8]; Caroline R. Richardson, MD[8]; Marilyn L. Moy, MD, MSc[5,9]

[1]Center for Healthcare Organization and Implementation Research (CHOIR), Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA, USA,[2]Pulmonary Division, Boston University School of Medicine, Boston, MA, USA,[3]Birmingham VA Medical Center, Birmingham, AL, USA,[4]Pulmonary, Allergy, & Critical Care Medicine, Department of Medicine, University of Alabama at Birmingham, AL, USA,[5]Pulmonary and Critical Care Medicine Section, VA Boston Healthcare System, Boston, MA, USA,[6]Department of Biostatistics, Boston University School of Public Health, Boston, MA, USA, [7]Massachusetts Veterans Epidemiology Research and Information Center, Veterans Affairs Boston Healthcare System, Boston MA,[8]Department of Family Medicine, University of Michigan, Ann Arbor, MI, USA,[9]Harvard Medical School, Boston, MA, USA

Corresponding Author: Marilyn L. Moy, 857-203-6622, marilyn.moy@va.gov

Support Statement: This work was supported by Merit Award Number I01 RX001150 from the United States Department of Veterans Affairs Rehabilitation Research & Development Service. Dr. Robinson is supported by the National Heart, Lung, and Blood Institute (K12HL138049). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Take home message: A web-based self-management intervention improved physical activity, but not exercise capacity. There is a need to develop and study accessible self-management interventions for COPD.

Abstract

Improving exercise capacity is a primary objective in chronic obstructive pulmonary disease (COPD). Declines in exercise capacity result in reduced physical activity (PA) and health-related quality of life (HRQL). Self-management interventions can teach patients skills and behaviours to manage their disease. Technology-mediated interventions have the potential to provide easily accessible support for disease self-management. We evaluated the effectiveness of a web-based self-management intervention, focused on PA promotion, on exercise capacity in COPD. This 6-month randomized controlled trial (NCT02099799) enrolled 153 persons with COPD at two U.S. sites (VABoston, n=108; VABirmingham, n=45). Participants were allocated (1:1) to the web-based self-management intervention (PA promotion through personalized, progressive step-count goals, feedback, online COPD-related education, and social support via an online community), or usual care. The primary outcome was exercise capacity (6-minute walk test distance [6MWD]). Secondary outcomes included PA (daily steps per day), HRQL (St. George's Respiratory Questionnaire Total Score), dyspnoea, COPD-related knowledge, and social support. Change in step-count goals reflected intervention engagement. Participants were 69±7 years old, mean FEV_1% predicted 61±21%. Change in 6MWD did not differ between groups. Intervention participants improved daily step counts by an average of 1,312 more than usual care (p<0.001). Groups did not differ on other secondary outcomes. VABirmingham participants were significantly more engaged with the intervention, although site did not modify the effect of the intervention on 6MWD or secondary outcomes. The intervention did not improve exercise capacity, but improved PA at 6 months. Additional intervention modifications are needed to optimize its COPD self-management capabilities.

Key Words: Internet-Based Intervention, Exercise Capacity, Daily Step Counts, Health-Related Quality of Life, Dyspnoea, COPD Self-Management

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a leading cause of death in the US(1) and a major contributor to morbidity, mortality, and resource utilization worldwide(2, 3). Patients with COPD are limited in their exercise capacity, which can result in deleterious downstream effects including reduced physical activity (PA) and health-related quality of life (HRQL)(4). With no cure, proactive self-management of COPD is critical to maintaining or improving health outcomes(5). Ultimate goals of COPD self-management include optimizing and preserving exercise capacity, reducing symptoms and functional impairments in daily life, and increasing emotional and social well-being, and HRQL. Self-management interventions for COPD are often multicomponent, structured, and personalized programs with goals of motivating, engaging and supporting patients to adopt positive health behaviours (e.g., physical activity [PA]) and develop skills to better manage their disease(6, 7). Technology-based platforms may offer a promising approach to promote disease self-management and bring interventions directly to patients(8, 9). Such solutions are particularly relevant during the COVID-19 pandemic when many in-person programs are closed. Rigorous examination of how effective technology-based self-management interventions are in promoting key COPD outcomes, such as exercise capacity, is needed(10).

We designed a web-based self-management intervention focused on PA promotion for persons with COPD(11-13). This multi-component intervention, based on the Theory of Self-Regulation(14), promotes PA through individualized, progressive goal setting and iterative step-count feedback, delivers online COPD-related education and motivational messages, and provides social support via an online community forum. Our intervention focuses on promoting

walking since persons with COPD who walk more have better HRQL(11), and decreased risks of acute exacerbations(15) and mortality(16, 17).

We have previously demonstrated at a single site that use of our web-based PA self-management intervention for 3(13) and 4 months(11) resulted in significant, clinically meaningful improvements in daily step counts(11, 13) and HRQL(11). In the current randomized controlled trial (RCT), we extend our previous work in two ways: 1) the duration of the intervention was increased to 6 months to assess if it could improve exercise capacity in addition to PA, and 2) we enrolled COPD participants at two geographically distinct study sites to assess response to the intervention in a heterogenous cohort. Our primary hypothesis was that participants assigned to the intervention would demonstrate significant improvements in exercise capacity compared to controls at 6 months. Our secondary hypothesis was that participants in the intervention group would demonstrate significant improvements in other COPD self-management outcomes (HRQL, dyspnoea, PA, disease education, social support, and occurrence of acute exacerbations) compared to controls. Some of the results of this study have been previously reported in the form of an abstract(18).

MATERIAL and METHODS *(See Online Supplement for description of the intervention)*

Study Participants

Participants were recruited from May 2015-February 2019 at two US sites. At VABoston (BOS), mailings were sent to COPD patients in outpatient pulmonary clinics. VABirmingham (BIR) patients were approached by their provider (J.A.C.) who referred interested participants to the research coordinator. The study was approved by the Institutional Review Boards (BOS

#2791 and BIR #01534) and registered on ClinicalTrials.gov (NCT02099799). Participants provided written informed consent.

Baseline Assessment and Randomization

At baseline, demographics, medical history, postbronchodilator FEV_1% predicted, and outcomes were assessed(19). Rural-urban commuting area codes (RUCA) classified participants' rurality(20). Participants wore a Fitbit Zip pedometer (San Francisco, CA, USA) for 10 days with a sticker covering the display to prevent feedback. Participants who met inclusion criteria (Table 1) and had ≥7 valid wear-days at baseline (>200 steps/day) (21) were randomized 1:1 to either the internet-mediated, pedometer-based PA intervention or usual care (control) for 6 months (Figure 1). The study statistician (D.G.) generated the random allocation sequence.

Randomization Groups

Participants in both the intervention and control groups received verbal encouragement to increase daily PA and an education booklet that contained COPD self-management information about aerobic endurance and strengthening exercises, an action plan for COPD acute exacerbations, how to resume exercise after an acute exacerbation, oxygen use during exercise, and smoking cessation(6). The usual care control group did not have contact with the blinded study staff until the in-person outcome assessments 3 and 6 months following the baseline visit. Participants randomized to the intervention were mailed detailed instructions about the study website. The intervention group was instructed to wear the pedometer daily and received access to the content on the website. The intervention supports the cycle of self-regulation with four unique components to promote PA and COPD self-management: 1) objective walking assessment and feedback, 2) individualized step-count goals, 3) educational tips and motivational messages, and 4) an online community (Figure 2)(12, 13). Participants were asked to upload

their step-count data at least weekly. Participants received weekly automated, personalized step-count goals that progressively increased if previous goals were achieved(13). Follow-up, in-person assessments occurred at 3 and 6 months for both groups. At each follow-up visit, study staff reminded participants not to disclose randomization assignment and that they should be working to increase their walking and exercise. The outcome assessor and statistician were blinded to randomization assignment.

Outcome Measures

All outcomes were assessed during in-person visits at baseline, 3, and 6 months; daily step counts were assessed over a 14-day period after 3- and 6-months visits. The primary outcome was change in exercise capacity from baseline to 6 months. This was assessed with participants' 6-minute walk test distance (6MWD), performed according to ATS guidelines (except no practice walk was performed in either randomization group) (22). Secondary outcomes included PA, HRQL, dyspnoea, COPD knowledge, social support, and acute exacerbations. At 3 and 6 months, PA (steps/day) was averaged over ≥4 valid pedometer wear-days within a 14-day period. The St. George's Respiratory Questionnaire Total Score (SGRQ-TS)(23) measured HRQL and the modified Medical Research Council (mMRC) assessed dyspnoea(24). We evaluated COPD knowledge and social support with the Bristol COPD Knowledge Questionnaire (BCKQ)(25) and Medical Outcomes Study Social Support (MOS-SS) scale (MOS-SS)(26). Self-reported acute exacerbations of COPD, with or without hospitalization were assessed at the 3- and 6-month study visits. Participants were coded as either having experienced at least one exacerbation in the 6 months or none. Other serious (defined as non-COPD acute exacerbation-related hospitalizations and/or deaths) or musculoskeletal (new or worsening leg, foot and/or back pain or discomfort) adverse events were also self-reported and

tracked at 3 and 6 months to assess safety. Participants were coded as having experienced a serious adverse event or not, and as having experienced a musculoskeletal event or not.

Within the intervention group, engagement was assessed with change in weekly step-count goals at 6 months from baseline. Participants who met their goals received a higher goal the following week. Thus, a positive change in step-count goals indicated engagement. An intervention feedback questionnaire administered at 6 months also assessed engagement. Participants were asked if: 1) they would recommend the intervention to others with COPD, 2) the intervention helped them adhere to their walking for exercise, 3) they will continue to walk for exercise after the research study ends, 4) they looked at graphs of the step counts, 5) the motivational messages and educational tips were easy to understand, and 6) they learned helpful information using the online community forum. Participants could respond true, false, or indicate that they did not use the component.

Sample Size

Using the minimum clinically important difference in 6MWD of 54 meters(27) and a SD of 100 meters(27), we estimated that 110 participants (55/group) at 6 months would provide adequate power (β=80%) at an α=0.05.

Statistical Analysis

Independent samples *t*-tests and Chi-square tests assessed between-group and between-site differences in baseline characteristics and adverse events. Chi-square tests assessed between-site differences in intervention feedback responses. In intention-to-treat analyses, generalized linear mixed effects models (PROC MIXED, SAS v9.4, Cary, NC) for repeated measures employing a first-order auto-regressive covariance matrix were constructed. Change in outcomes was predicted by randomization group (intervention vs. usual care), study visit (3 and 6 months),

and the interaction between randomization group and study visit. Models adjusted for FEV_1% predicted, age, site, and rurality. *P* value <0.05 was considered statistically significant. Season of enrolment was initially included as a covariate but had no significant impact on the results and was therefore removed for a more parsimonious model.

RESULTS

Of the 204 eligible participants, 153 participants were randomized to either the intervention (n=75) or control (n=78) group (Figure 1). Those who were randomized (n=153) reported significantly higher SGRQ-TS (worse HRQL) compared to those who were not randomized (n=51) (SGRQ-TS 38 ± 18 versus 27 ± 23, respectively, p=0.005). There were no other significant differences between those who were and were not randomized. A significantly larger proportion of participants who were lost to follow-up were rural (p=0.048), less educated (p=0.016), and enrolled at BIR (p=0.008) compared to those who completed the 6-month study.

There were no significant between-randomization group differences in baseline characteristics or occurrence of severe or musculoskeletal adverse events during the study (p*'s*>0.05; Table 2).

Primary Outcome

There was no significant difference between randomization groups in 6-month change in 6MWD (mean difference of -12 meters; p=0.189). Both groups demonstrated statistically and clinically significant within-group changes in 6MWD at 6 months compared to baseline (Table 3). The intervention group increased by 25 meters (p=0.010) and the control group increased by 37 meters (p<0.001).

Secondary Outcomes

The intervention group significantly increased PA by an average daily step count of 1,312 steps/day (95% CI [600, 2,024], $p<0.001$) more than the control group at 6 months (Table 3). The intervention group increased by 673 steps/day, compared to the control group who decreased by 639 steps/day from baseline to 6 months. Change in SGRQ-TS, mMRC dyspnoea score, BCKQ score, MOS-SS score, or number of acute exacerbations (total and COPD-related hospitalizations) at 6 months did not significantly differ between randomization groups at 6 months (Table 3).

Site

Participants at the two study sites differed on several baseline measurements. Compared to BOS, BIR participants were significantly younger, had a higher proportion of non-white participants and those who currently used oxygen, made less than $30,000 annually, and were rural (*p's*<0.05; Table 2). BIR participants also had lower FEV_1% predicted, lower 6MWD, lower daily step counts, and higher SGRQ-TS (worse HRQL) (*p's*<0.05; Table 2). Of the 114 (out of 153) participants who completed the 6-month visit, more BOS participants reported experiencing a musculoskeletal adverse event compared to BIR (59% vs. 22%; $p=0.001$).

Because site was a significant predictor of 6-month change in 6MWD ($p=0.006$) and HRQL ($p= 0.005$) in our *a priori* models, we conducted exploratory analyses to examine if site modified the effect of intervention on outcomes. Two exploratory models predicting outcomes at 6 months were examined, which included site, randomization group, the interaction between site and randomization group, and covariates (age, FEV_1% predicted, and rurality). There were no

significant interactions between site and randomization group on any of the outcomes at 6 months.

Intervention Engagement

In those assigned to the intervention, BIR participants' daily step-count goals increased by an average of 437 more steps/day across the 6-month (24-week) study period compared to BOS(Figure 3), although the difference between-groups was not significant (p=0.239). Both sites showed significant increases in step-count goals across the 6-month study period, compared to baseline. For example, BOS participants increased their daily step-count goal by an average of 505 steps/day (p=0.014), while BIR participants had an increase of 807 steps/day (p=0.021).

Of the 60 intervention participants (out of 75) who completed the 6-month visit, 44 (73%) responded to the intervention feedback questionnaire. The majority (n=42, 95%) indicated they would recommend the intervention to others with COPD, 33 (75%) thought the intervention helped them stick to their walking, and 42 (95%) reported they would continue to exercise after the research study ended. Regarding engagement with intervention components, 38 (86%) looked at the step-count graphs. Twenty-four (55%) found the motivational and educational tips easy to understand, while 20 (45%) reported that they did not use this component. Eleven (25%) participants indicated they learned helpful information from the online forum, while 33 (75%) reported they did not use this forum.

DISCUSSION

This dual-site RCT ~~rigorously~~ assessed the impact of a web-based self-management intervention on exercise capacity, PA, HRQL, dyspnoea, disease education, social support, and acute exacerbations. The intervention showed no significant change in the primary outcome,

exercise capacity, despite having participants enrolled in the study for a duration of 6 months which is longer than our prior work(11, 13). Extending our previous work at a single site(11, 13), this dual-site study demonstrated significant and clinically meaningful increases in daily PA (1,312 steps/day) in the intervention compared to the control group, independent of lung function and site. This change exceeds findings from both our prior studies (779(11)-804(13) steps/day) and the minimum clinically important difference (MCID) for daily step counts in COPD (30,31). The were no significant changes in HRQL, dyspnoea, COPD knowledge, social support, or acute exacerbations compared to controls. We hypothesized that use of the web-based intervention across 6 months would significantly improve exercise capacity, demonstrated by increased 6MWD. While we found strong evidence that our intervention improved physical activity, this improvement did not translate to improved exercise capacity. Previous research has shown weak correlations between exercise capacity and physical activity(28). Exercise capacity, as measured by the episodic 6MWD, represents what the patient can do. Physical activity, integrated over time and in the home environment, represents what the patient does do, accounting for many factors (e.g., psychosocial, environmental) other than the underlying COPD that may impact physical activity(29).

Our results suggest that if technology-based self-management interventions are to improve exercise capacity, they will need to focus on both PA duration and intensity(30). Our self-management intervention did not include an aerobic exercise training component as the goal was to promote walking which most patients with COPD can do. The importance of exercise training can be seen in the PHYSACTO trial(31), which examined the effects of a self-management intervention coupled with placebo or tiotropium/olodaterol and with or without high intensity, in-person exercise training. The combination of a self-management intervention

with pharmacological treatment and exercise training resulted in the greatest improvements in exercise capacity compared to self-management with placebo, or self-management with pharmacological treatment (and no exercise training) (31). Similarly, a community-based exercise program (including walking, cycling, and strength exercises) coupled with a self-management program (COPE-active) resulted in significant between-group differences in both exercise capacity and PA after 12 months(32).An important difference between the current study and the PHYSACTO and COPE-active trials is that our self-management intervention, fully automated and remotely delivered, could be accessed by those who cannot attend in-person programs.

Technology-mediated interventions vary in the level of automation and how self-guided they are (i.e., some may include more contact or guidance from research or clinical staff). Our technology-mediated intervention increased PA but not exercise capacity; this is in line with other technology-mediated trials which also used a more self-guided internet-mediated PA intervention(33). In a contrasting example, Vorrink et al.(34) had participants who recently completed PR use a smartphone app-mediated PA intervention for 12 months, with a physiotherapist-facing component which allowed for personalized text messaging. In that study, participants decreased PA but were able to maintain their post-rehabilitation exercise capacity levels (36). Demeyer et al.(35) found increases in both PA and 6MWD in an intervention that included interviews with the investigator to discuss motivation, barriers, favourite activities, and strategies to become more active. In addition, automatically updated goals could be changed by the research staff, and participants received text messages with activity proposals from the investigator, taking local weather into account. In our study, we had contact with the participant only when we called them weekly to give them their step-count goals and during the 3- and 6-

month study visits. Taken together, it appears that technology-mediated interventions can be more widely accessible, but conventional in-person programs, or a combination of both, may be more motivating and engaging given the accountability of in-person contact with healthcare professionals. Since one size does not fit all, it is important to develop and evaluate as many interventions as possible to give patients choices to support their exercise capacity, PA, and COPD self-management. It is important to identify the type of program that would allow for the greatest adherence and engagement for the unique circumstances of an individual patient.

Participants provided positive feedback about the intervention, indicating they would recommend it to others with COPD, that it helped them 'stick' to their walking, and that they would continue to walk after the study. Variable levels of engagement with the website as reported in the feedback questionnaire provide context for why we did not see significant changes in other secondary outcomes besides PA. Educational tips on COPD medications, symptom management, oxygen use, smoking cessation, and acute exacerbations, as well as motivational messages were provided on the website. The majority of participants looked at their step-count graphs, though almost half of participants indicated they did not look at the motivational and educational tips, and most participants did not look at the online forum. While technology-mediated interventions coupled with guidance from healthcare professionals may yield significant improvements, they likely require more staff labour, training, and higher costs. Modification of our intervention with additional guidance or encouragement by research staff or clinical team members to increase use of its components may improve COPD self-management and associated outcomes.

While BIR participants (intervention and control groups) improved more than BOS participants in 6MWD and HRQL, there was no statistical evidence that site modified the effect of the intervention on the specified outcomes. However, there was some evidence to suggest that for those assigned to the intervention, sites differed in their level of engagement with the PA promotion component. The differences observed in engagement by site may be explained by the notable differences in their sample characteristics and recruitment strategies. BIR participants appeared more limited by their disease (i.e., lower average 6MWD, FEV_1% predicted, and daily step counts at baseline), compared to BOS, and thus may have more potential for improvement. Additionally, BIR participants were recruited pragmatically by their usual provider, whereas BOS participants were recruited with a less personal approach through mailings by research staff. Thus, BIR patients may have been more motivated to increase their walking because of their personal connection with the provider recruiting for the research study. Recruitment at BIR may have been influenced by selection bias since participants who were more likely to be successful or engaged in the intervention may have been enrolled.

Using two sites, we demonstrate that our web-based self-management intervention can significantly improve PA at an urban site like BOS as well as a more rural site like BIR that enrolled participants with lower annual income and were more likely from rural areas. Along with greater risk for poor health status, acute exacerbations, hospitalizations, and mortality, rural patients with COPD have limited access to in-person care and centre-based PR programs(36). Thus, our intervention may be a "better than nothing" alternative to promote PA in a diverse group of patients with COPD. This trial compared our intervention to usual care. Future research

would benefit from a comparative-effectiveness or inferiority trial to conventional PR which is standard of care in promoting COPD self-management.

Limitations and Future Directions

Strengths include the randomized and blinded study design, dual-site approach, 6-month time frame, and examination of HRQL, COPD knowledge, social support, and acute exacerbations using validated questionnaires(37, 38). Current guidelines for the 6MWT, published in 2014, recommend a practice walk 24 hours before the actual test(39). When we started this study in 2015, we chose not to include a practice walk to reduce participant burden and not require travel to the medical centre on 6 separate occasions (twice at baseline, 3 months, and 6 months). Because we did not ask participants to perform a practice walk, there was a possibility that the within-group increase in 6MWD from baseline to 6 months in both groups could be attributable to a learning effect. However, it is known that this learning effect dissipates after 3 months(39). We evaluated change in 6MWD after 6 months; therefore, any learning effect is likely to be even less. Additionally, although 6MWD consistently increased at the second walk test performed 2-5 days apart, Spencer et al. demonstrated that changes in 6MWD at 3 months compared to baseline after pulmonary rehabilitation did not differ significantly from each other regardless of whether one chose the first, second, or better 6MWD at each time point(40). Thus, our results examining change scores at 6 months are unlikely to be different had practice walks been performed. While the study expanded our past work with a more socioeconomically diverse sample, our cohort was self-selected and majority white male, limiting generalizability in some respects. The 6-month study period extends our prior work, and it is promising that significant improvements in daily step counts were maintained. Future work should extend the follow-up period beyond 6 months, focus on exercise intensity to optimize

effects on exercise capacity, and maximize engagement with other components of the intervention.

Conclusion

A web-based PA self-management intervention did not improve exercise capacity, but improved PA in COPD over 6 months. Modifications are needed to optimize engagement with other components of the intervention to see changes in other health outcomes in COPD. It is important to develop and rigorously test novel, engaging, and accessible self-management interventions that can reach a variety of patients with COPD.

ACKNOWLEDGEMENTS

We thank the Veterans for their participation in this research study, and the Data Safety and Monitoring Board (Huong Nguyen, PhD, Linda Nici, MD, and Elizabeth Klings, MD).

REFERENCES

1. Kochanek KD, Murphy SL, Xu J, Arias E. Deaths: Final Data for 2017: U.S. Department of Health and Human Services; 2019.
2. Celli BR, Decramer M, Wedzicha JA, Wilson KC, Agusti A, Criner GJ, MacNee W, Make BJ, Rennard SI, Stockley RA, Vogelmeier C, Anzueto A, Au DH, Barnes PJ, Burgel PR, Calverley PM, Casanova C, Clini EM, Cooper CB, Coxson HO, Dusser DJ, Fabbri LM, Fahy B, Ferguson GT, Fisher A, Fletcher MJ, Hayot M, Hurst JR, Jones PW, Mahler DA, Maltais F, Mannino DM, Martinez FJ, Miravitlles M, Meek PM, Papi A, Rabe KF, Roche N, Sciurba FC, Sethi S, Siafakas N, Sin DD, Soriano JB, Stoller JK, Tashkin DP, Troosters T, Verleden GM, Verschakelen J, Vestbo J, Walsh JW, Washko GR, Wise RA, Wouters EF, ZuWallack RL, Ats Ers Task Force for COPD Research. An Official American Thoracic Society/European Respiratory Society Statement: Research questions in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 2015; 191: e4-e27.
3. Waschki B, Kirsten AM, Holz O, Mueller KC, Schaper M, Sack AL, Meyer T, Rabe KF, Magnussen H, Watz H. Disease Progression and Changes in Physical Activity in Patients with Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med* 2015; 192: 295-306.
4. Watz H, Pitta F, Rochester CL, Garcia-Aymerich J, ZuWallack R, Troosters T, Vaes AW, Puhan MA, Jehn M, Polkey MI, Vogiatzis I, Clini EM, Toth M, Gimeno-Santos E, Waschki B, Esteban C, Hayot M, Casaburi R, Porszasz J, McAuley E, Singh SJ, Langer D, Wouters EF, Magnussen H, Spruit MA. An Official European Respiratory Society Statement on Physical Activity in COPD. *Eur Respir J* 2014; 44: 1521-1537.

5. Murphy LA, Harrington P, Taylor SJ, Teljeur C, Smith SM, Pinnock H, Ryan M. Clinical-Effectiveness of Self-management Interventions in Chronic Obstructive Pulmonary Disease: An Overview of Reviews. *Chronic Respiratory Disease* 2017; 14: 276-288.

6. Effing TW, Vercoulen JH, Bourbeau J, Trappenburg J, Lenferink A, Cafarella P, Coultas D, Meek P, Van Der Valk P, Bischoff EWMA, Bucknall C, Dewan NA, Early F, Fan V, Frith P, Janssen DJA, Mitchell K, Morgan M, Nici L, Patel I, Walters H, Rice KL, Singh S, Zuwallack R, Benzo R, Goldstein R, Partridge MR, Van Der Palen J. Definition of a COPD Self-management Intervention: International Expert Group Consensus. *European Respiratory Journal* 2016; 48: 46-54.

7. Vogelmeier CF, Criner GJ, Martinez FJ, Anzueto A, Barnes PJ, Bourbeau J, Celli BR, Chen R, Decramer M, Fabbri LM, Frith P, Halpin DM, Lopez Varela MV, Nishimura M, Roche N, Rodriguez-Roisin R, Sin DD, Singh D, Stockley R, Vestbo J, Wedzicha JA, Agusti A. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease 2017 Report. GOLD Executive Summary. *Am J Respir Crit Care Med* 2017; 195: 557-582.

8. Robinson S, Troosters T, Moy M. Technology to Enhance Engagement in Physical Activity. In: Moy M, Blackstock F, Nici L, editors. The Art and Science of Enhancing Patient Engagement in Pulmonary Healthcare: Springer; 2020.

9. Ding H, Fatehi F, Maiorana A, Bashi N, Hu W, Edwards I. Digital Health for COPD Care: The Current State of Play. *J Thorac Dis* 2019; 11: S2210-S2220.

10. Spruit MA, Singh SJ, Garvey C, ZuWallack R, Nici L, Rochester C, Hill K, Holland AE, Lareau SC, Man WD, Pitta F, Sewell L, Raskin J, Bourbeau J, Crouch R, Franssen FM, Casaburi R, Vercoulen JH, Vogiatzis I, Gosselink R, Clini EM, Effing TW, Maltais F, van der Palen J, Troosters T, Janssen DJ, Collins E, Garcia-Aymerich J, Brooks D, Fahy BF, Puhan MA, Hoogendoorn M, Garrod R, Schols AM, Carlin B, Benzo R, Meek P, Morgan M, Rutten-van Molken MP, Ries AL, Make B, Goldstein RS, Dowson CA, Brozek JL, Donner CF, Wouters EF, ATS ERS Task Force on Pulmonary Rehabilitation. An Official American Thoracic Society/European Respiratory Society Statement: Key Concepts and Advances in Pulmonary Rehabilitation. *Am J Respir Crit Care Med* 2013; 188: e13-64.

11. Moy ML, Collins RJ, Martinez CH, Kadri R, Roman P, Holleman RG, Kim HM, Nguyen HQ, Cohen MD, Goodrich DE, Giardino ND, Richardson CR. An Internet-Mediated Pedometer-Based Program Improves Health-Related Quality-of-Life Domains and Daily Step Counts in COPD: A Randomized Controlled Trial. *Chest* 2015; 148: 128-137.

12. Moy ML, Martinez CH, Kadri R, Roman P, Holleman RG, Kim HM, Nguyen HQ, Cohen MD, Goodrich DE, Giardino ND, Richardson CR. Long-Term Effects of an Internet-Mediated Pedometer-Based Walking Program for Chronic Obstructive Pulmonary Disease: Randomized Controlled Trial. *J Med Internet Res* 2016; 18: e215.

13. Wan ES, Kantorowski A, Homsy D, Teylan M, Kadri R, Richardson CR, Gagnon DR, Garshick E, Moy ML. Promoting Physical Activity in COPD: Insights from a Randomized Trial of a Web-Based Intervention and Pedometer Use. *Respir Med* 2017; 130: 102-110.

14. Cameron LD, Leventhal H. The Self-Regulation of Health and Illness Behaviour. Psychology Press; 2003.

15. Wan ES, Kantorowski A, Polak M, Kadri R, Richardson CR, Gagnon DR, Garshick E, Moy ML. Long-Term Effects of Web-Based Pedometer-Mediated Intervention on COPD Exacerbations. *Respir Med* 2020; 162: 105878.

16. Moy ML, Gould MK, Liu IA, Lee JS, Nguyen HQ. Physical Activity Assessed in Routine Care Predicts Mortality after a COPD Hospitalisation. *ERJ Open Res* 2016; 2: 00062-02015.

17. Vaes AW, Garcia-Aymerich J, Marott JL, Benet M, Groenen MT, Schnohr P, Franssen FM, Vestbo J, Wouters EF, Lange P, Spruit MA. Changes in Physical Activity and All-Cause Mortality in COPD. *Eur Respir J* 2014; 44: 1199-1209.

18. Robinson S, Goldstein R, Cruz Rivera P, Kadri R, Cooper J, Richardson C, Moy M. Results from a Multi-Site Web-Based Physical Activity Intervention in COPD: Between Group and Site Differences. American Thoracic Society; 2020.

19. Hankinson JL, Odencrantz JR, Fedan KB. Spirometric Reference Values from a Sample of the General US Population. *Am J Respir Crit Care Med* 1999; 159: 179-187.

20. Hart LG, Larson EH, Lishner DM. Rural Definitions for Health Policy and Research. *Am J Public Health* 2005; 95: 1149-1155.

21. Hart TL, Swartz AM, Cashin SE, Strath SJ. How Many Days of Monitoring Predict Physical Activity and Sedentary Behaviour in Older Adults? *International Journal of Behavioral Nutrition and Physical Activity* 2011; 8: 62.

22. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med* 2002; 166: 111-117.

23. Jones PW, Quirk FH, Baveystock CM, Littlejohns P. A Self-Complete Measure of Health Status for Chronic Airflow Limitation. The St. George's Respiratory Questionnaire. *Am Rev Respir Dis* 1992; 145: 1321-1327.

24. Mahler DA, Wells CK. Evaluation of Clinical Methods for Rrating Dyspnea. *Chest* 1988; 93: 580-586.

25. White R, Walker P, Roberts S, Kalisky S, White P. Bristol COPD Knowledge Questionnaire (BCKQ): Testing what we Teach Patients about COPD. *Chron Respir Dis* 2006; 3: 123-131.

26. Sherbourne CD, Stewart AL. The MOS Social Support Survey. *Soc Sci Med* 1991; 32: 705-714.

27. Redelmeier DA, Bayoumi AM, Goldstein RS, Guyatt GH. Interpreting Small Differences in Functional Status: The Six Minute Walk Test in Chronic Lung Disease Patients. *Am J Respir Crit Care Med* 1997; 155: 1278-1282.

28. Moy ML, Danilack VA, Weston NA, Garshick E. Daily Step Counts in a US Cohort with COPD. *Respir Med* 2012; 106: 962-969.

29. Koolen EH, van Hees HW, van Lummel RC, Dekhuijzen R, Djamin RS, Spruit MA, van't Hul AJ. "Can do" versus "do do": a novel concept to better understand physical functioning in patients with chronic obstructive pulmonary disease. *Journal of clinical medicine* 2019; 8: 340.

30. Morris NR, Walsh J, Adams L, Alision J. Exercise Training in COPD: What is it about Intensity? *Respirology* 2016; 21: 1185-1192.

31. Troosters T, Maltais F, Leidy N, Lavoie KL, Sedeno M, Janssens W, Garcia-Aymerich J, Erzen D, De Sousa D, Korducki L, Hamilton A, Bourbeau J. Effect of Bronchodilation, Exercise Training, and Behavior Modification on Symptoms and Physical Activity in Chronic Obstructive Pulmonary Disease. *Am J Respir Crit Care Med* 2018; 198: 1021-1032.

32. Effing T, Zielhuis G, Kerstjens H, Van Der Valk P, Van Der Palen J. Community Based Physiotherapeutic Exercise in COPD Self-management: A Randomised Controlled Trial. *Respiratory Medicine* 2011; 105: 418-426.

33. Arbillaga-Etxarri A, Gimeno-Santos E, Barberan-Garcia A, Balcells E, Benet M, Borrell E, Celorrio N, Delgado A, Jane C, Marin A, Martin-Cantera C, Monteagudo M, Montella N, Munoz L, Ortega P, Rodriguez DA, Rodriguez-Roisin R, Simonet P, Toran-Monserrat P, Torrent-Pallicer J, Vall-Casas P, Vilaro J, Garcia-Aymerich J. Long-term Efficacy and Effectiveness of a Behavioural and Community-based Exercise Intervention (Urban Training) to increase physical activity in patients with COPD: a randomised controlled trial. *Eur Respir J* 2018; 52: 1800063.

34. Vorrink SN, Kort HS, Troosters T, Zanen P, Lammers JJ. Efficacy of an mHealth Intervention to Stimulate Physical Activity in COPD Patients after Pulmonary Rehabilitation. *Eur Respir J* 2016; 48: 1019-1029.

35. Demeyer H, Louvaris Z, Frei A, Rabinovich RA, de Jong C, Gimeno-Santos E, Loeckx M, Buttery SC, Rubio N, Van der Molen T. Physical Activity is Increased by a 12-week Semiautomated Telecoaching Programme in Patients with COPD: A Multicentre Randomised Controlled Trial. *Thorax* 2017; 72: 415-423.

36. Jackson BE, Coultas DB, Suzuki S, Singh KP, Bae S. Rural-Urban Disparities in Quality of Life Among Patients with COPD. *J Rural Health* 2013; 29 Suppl 1: s62-69.

37. Blackstock FC, Lareau SC, Nici L, ZuWallack R, Bourbeau J, Buckley M, Durning SJ, Effing TW, Egbert E, Goldstein RS, Kelly W, Lee A, Meek PM, Singh S, American Thoracic Society, Thoracic Society of Australia and New Zealand, Canadian Thoracic Society, British Thoracic Society. Chronic Obstructive Pulmonary Disease Education in Pulmonary Rehabilitation. An Official American Thoracic Society/Thoracic Society of Australia and New Zealand/Canadian Thoracic Society/British Thoracic Society Workshop Report. *Ann Am Thorac Soc* 2018; 15: 769-784.

38. Reijnders T, Schuler M, Jelusic D, Troosters T, Janssens W, Schultz K, von Leupoldt A. The Impact of Loneliness on Outcomes of Pulmonary Rehabilitation in Patients with COPD. *COPD* 2018; 15: 446-453.

39. Holland AE, Spruit MA, Troosters T, Puhan MA, Pepin V, Saey D, McCormack MC, Carlin BW, Sciurba FC, Pitta F. An official European Respiratory Society/American Thoracic Society Technical Standard: Field Walking Tests in Chronic Respiratory Disease. *European Respiratory Journal* 2014; 44: 1428-1446.

40. Spencer LM, Alison JA, McKeough ZJ. Six-minute Walk Test as an Outcome Measure: Are Two Six-minute Walk Tests Necessary Immediately after Pulmonary Rehabilitation and at Three-month Follow-up? *American journal of physical medicine & rehabilitation* 2008; 87: 224-228.

Table 1. Inclusion and Exclusion Criteria

Inclusion	Exclusion
1. 40 years of age	1. COPD exacerbation in the previous 1 month
2. Diagnosis of COPD (defined by FEV_1/FVC <0.70, or CT evidence of emphysema, or prior documentation of FEV_1/FVC <0.70 and clinical evidence of COPD [≥10 pack-year cigarette smoking history, dyspnoea, or on bronchodilators])	2. Inability to ambulate with or without assistance
3. Medical clearance from a healthcare provider to participate in an exercise program	3. Clinical signs of unstable cardiovascular disease or congestive heart failure
4. Access to a computer with an internet connection, a USB port or Bluetooth capability, and Windows XP/Vista/7/8/10 or higher, or Mac OSX 10.5 or higher operating system, or willing to come to VA Medical Center to use study computers	4. Hypoxemia during 6MWT, i.e. oxygen saturation <85%, with or without using supplemental oxygen
5. Pedometer with >90% accuracy compared to manual counts on a short clinic walk	5. Inability to complete questionnaires
6. Competent to provide informed consent	6. Inability to collect at least 7 out of 10 days of baseline step counts
7. Willingness to make return visits and be available by telephone for duration of study	7. Participation in a pulmonary rehabilitation program at time of screening or within the previous 3 months
	8. Participation in another exercise-related research study at time of screening
	9. Plans to participate in an exercise-related research study in the next 12 months
	10. Plans to enrol in a supervised exercise program, such as pulmonary rehabilitation, in the next 6 months
	11. Average daily baseline step counts ≥ 10,000 steps per day

Table 2. Characteristics by randomization group and site

	All (N=153)			Boston (n=108)		Birmingham (n=45)		
Baseline Characteristic	Intervention	Control	Between-group *p*	Intervention	Control	Intervention	Control	Between-site *p*
n	75	78		54	54	21	24	
Age	69.2 (7.2)	70.4 (7.3)	0.307	70.4 (7.4)	70.8 (7.5)	65.8 (5.7)	69.4 (7.0)	0.024
Male, n (%)	70 (93)	72 (92)	0.806	52 (96)	51 (94)	18 (86)	21 (87.5)	0.058
White, n (%)	69 (92)	69 (89)	0.462	51 (94)	50 (93)	18 (86)	19 (79.2)	0.032
BOS, n (%)	54 (72)	54 (69)	0.707	--	--	--	--	--
Annual Income <$30,000, n (%)	32 (43)	34 (44)	0.908	18 (33)	20 (37)	14 (67)	14 (58.3)	0.002
Greater than High School Education, n (%)	53 (71)	63 (81)	0.145	38 (70)	46 (85)	15 (71)	17 (71)	0.380
Rural, n(%)	4 (5)	11 (14)	0.068	0 (0.00)	4 (7)	4 (19)	7 (29)	<0.001
FEV_1% predicted	60.6 (23.1)	61.5 (19.8)	0.794	68.1 (20.4)	64.7 (18.6)	41.51 (18.3)	54.5 (20.9)	<0.001
Current Oxygen Use, n (%)	19 (25)	22 (28)	0.689	8 (15)	8 (15)	11 (52)	14 (58)	<0.001
6MWT	360.8 (92.0)	357.2 (103.5)	0.822	381.7 (90.9)	382.6 (106.3)	307.0 (72.4)	300.1 (70.1)	<0.001
Daily Step-Count	3176.6 (2211.6)	3210.2 (2247.9)	0.926	3385.0 (2197.2)	3516.0 (2511.7)	2640.8 (2210.1)	2522.1 (1290.5)	0.013
SGRQ-TS	40.0 (15.3)	38.0 (17.8)	0.474	36.3 (14.4)	32.2 (14.7)	49.4 (13.6)	53.4 (16.3)	<0.001
mMRC Dyspnoea	2.0 (1.2)	2.1 (1.2)	0.596	2.1 (1.3)	2.1 (1.3)	1.8 (0.8)	2.2 (1.1)	0.578
BCKQ	46.9 (15.0)	46.1 (16.2)	0.751	46.3 (12.7)	47.3 (15.5)	48.6 (20.2)	42.8 (18.0)	0.773
MOS-SS	76.8 (23.8)	69.4 (27.7)	0.081	74.5 (25.5)	70.6 (29.6)	83.0 (17.5)	65.9 (22.1)	0.702
Adverse Events (n=114)*								
Serious non-COPD Adverse Event, n (%)	7 (12)	9 (17)	0.443	6 (13)	9 (22)	1 (7)	0 (0)	0.077
Musculoskeletal Adverse Event, n (%)	32 (53)	23 (43)	0.252	27 (59)	23 (56)	5 (36)	0 (0)	0.001

Note. All values represent the mean (SD) unless otherwise noted. BOS = Boston site. 6MWT = 6-minute walk test. SGRQ-TS = St. George's Respiratory Questionnaire – Total Score. mMRC = modified Medical Research Council. BCKQ = Bristol COPD Knowledge Questionnaire. MOS-SS = Medical Outcomes Study Social Support Survey. *Number of participants who provided information about adverse events.

Table 3. Between-group differences in change in primary and secondary outcomes from baseline to 3 and 6 months, n=153

	Intervention		Usual Care Control		Mean Difference	*p*-value*
	Mean	SE	Mean	SE		
Primary Outcome						
Δ6MWD						
3 months	23.86	9.58	27.58	9.51	-3.72	0.686
6 months	25.14	9.61	37.41	9.63	-12.27	0.189
Secondary Outcomes						
ΔDaily Step Count						
3 months	645.95	391.97	-385.78	411.45	1031.73	0.005
6 months	672.90	392.48	-639.38	415.31	1312.28	<0.001
ΔSGRQ-TS						
3 months	-14.63	3.59	-13.86	3.22	-0.78	0.833
6 months	-13.05	3.59	-15.13	3.22	-28.18	0.572
ΔmMRC Dyspnoea						
3 months	-0.17	0.21	0.07	0.21	-0.25	0.225
6 months	-0.06	0.21	0.00	0.21	-0.05	0.799
ΔBCKQ						
3 months	1.44	1.81	0.76	1.66	0.69	0.692
6 months	0.92	1.81	1.97	1.66	-1.05	0.544
ΔMOS-SS						
3 months	-4.93	4.24	-1.01	4.30	-3.92	0.279
6 months	0.55	4.25	4.38	4.36	-3.83	0.293
Acute Exacerbations	n	%	n	%	Difference	*p*-value[+]
Total						
3 months	2	3	3	6	-1	0.563
6 months	7	12	5	9	2	0.676
With Hospitalization						
3 months	1	2	1	2	0	0.940
6 months	1	2	3	6	-2	0.260

Δ=Change. 6MWD = 6-minute walk test distance (meters). SGRQ-TS=St. George's Respiratory Questionnaire Total Score. mMRC = modified Medical Research Council. BCKQ = Bristol COPD Knowledge Questionnaire. MOS-SS = Medical Outcomes Study Social Support survey. Acute exacerbations are displayed as number and percentage of participants from study sample (n, %).*Based on linear mixed-effect model adjusting for group, 3- and 6-month indicators, group×time interaction indicators, site, age, FEV1% predicted, and rurality. [+]Obtained from Chi-square test.

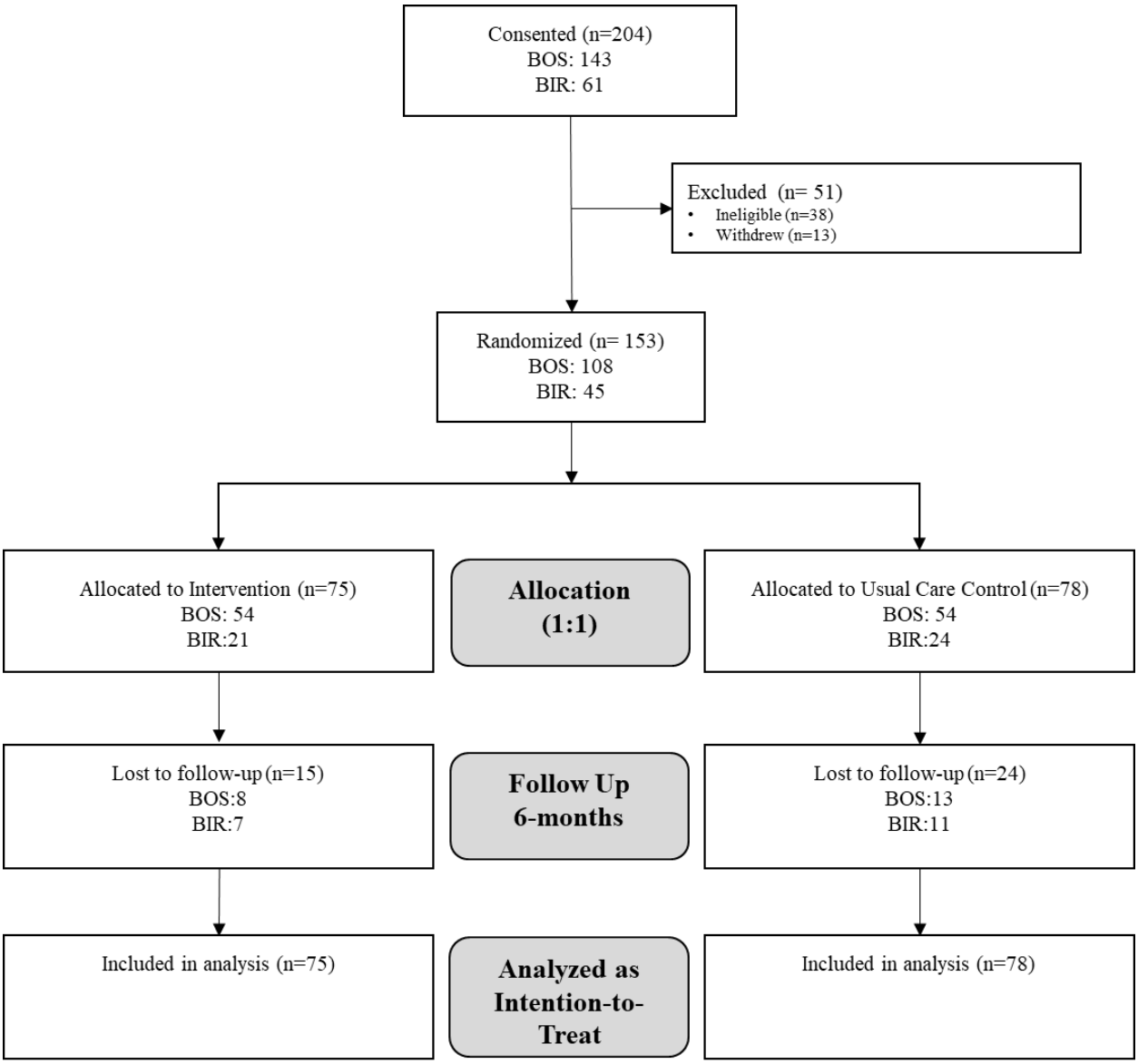

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) diagram. BOS = VABoston; BIR = VABirmingham.

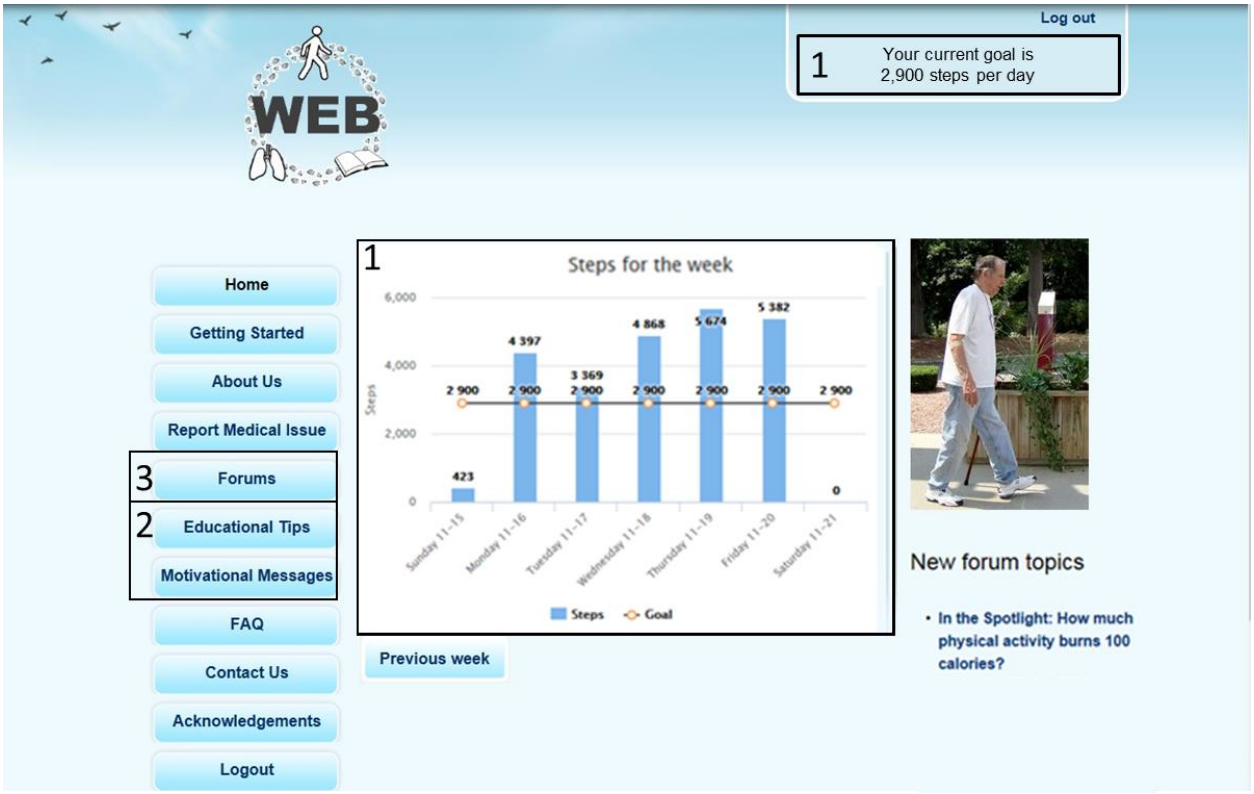

Figure 2. Screenshot of intervention webpage. The intervention supports PA and self-management with four unique components: 1) objective walking assessment and feedback, 2) individualized step-count goals, 3) educational tips and motivational messages, and 4) an online community.

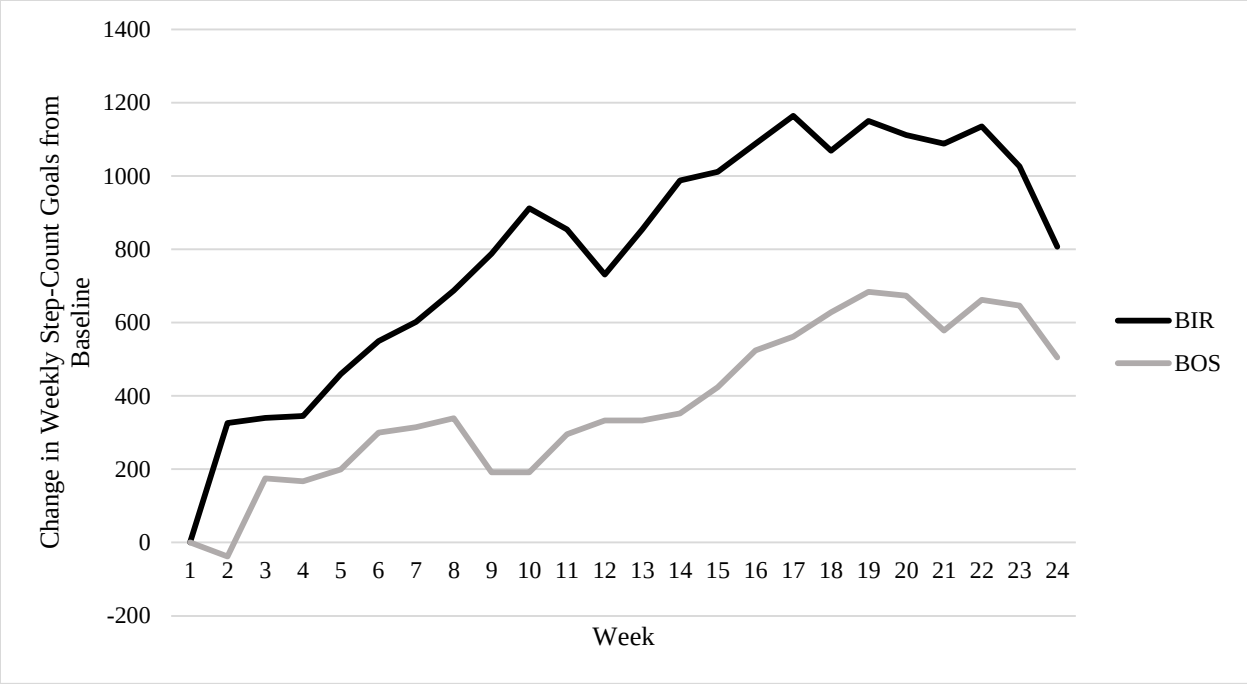

Figure 3. Within the intervention group, change in step-count goal from baseline across the 24-week (6-month) study period by site. BOS = VABoston; BIR = VABirmingham. A higher change in step-count goal reflects higher engagement in the intervention. Values plotted on the y-axis represent the least squares means from a general linear mixed-effects model for repeated measures, employing a first-order auto-regressive covariance matrix, adjusted for age, FEV_1% predicted, and rurality. Both sites demonstrated increased within-group change in weekly step-count goals from baseline to 24 weeks (BOS p=0.014; BIR p=0.021), with BIR goals consistently higher than BOS goals.

A Randomized Trial of a Web-based Physical Activity Self-Management Intervention in COPD

Stephanie A. Robinson, PhD[1,2]; J. Allen Cooper Jr., MD[3,4]; Rebekah Goldstein, MPH[5]; Madeline Polak, BS[5]; Paola N. Cruz Rivera, BA[5]; David R. Gagnon, MD, MPH, PhD[6,7]; Amber Samuelson, BSN[3]; Sheila Moore, BS[3]; Reema Kadri, MLIS[8]; Caroline R. Richardson, MD[8]; Marilyn L. Moy, MD, MSc[5,9]

[1]Center for Healthcare Organization and Implementation Research (CHOIR), Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA, USA
[2]Pulmonary Division, Boston University School of Medicine, Boston, MA, USA
[3]Birmingham VA Medical Center, Birmingham, AL, USA
[4]Pulmonary, Allergy, & Critical Care Medicine, Department of Medicine, University of Alabama at Birmingham, AL, USA
[5]Pulmonary and Critical Care Medicine Section, VA Boston Healthcare System, Boston, MA, USA
[6]Department of Biostatistics, Boston University School of Public Health, Boston, MA, USA
[7]Massachusetts Veterans Epidemiology Research and Information Center, Veterans Affairs Boston Healthcare System, Boston MA
[8]Department of Family Medicine, University of Michigan, Ann Arbor, MI, USA
[9]Harvard Medical School, Boston, MA, USA

ONLINE SUPPLEMENT

Randomization

Participants were recruited from two academic hospital settings (VA Boston Healthcare System, Boston, MA, USA and Birmingham VA Medical Center, Birmingham, AL, USA). Assessments at baseline, 3 and 6 months were conducted in-person at each site. Participants completed baseline assessments and collection of daily step counts using the Fitbit Zip pedometer (San Francisco, CA, USA) prior to randomization. By connecting the pedometer to a computer with a dongle, participants upload step-count data to the dedicated research website which was accessed via a URL. After collecting 10 days of step counts, participants with at least 7 days of valid step-count data (>200 steps/day) and who met inclusion criteria were randomized.

Eligible participants were randomized to 1) a web-based self-management intervention focused on physical activity (PA) promotion (intervention group), or 2) usual care (control group). The study statistician (D.G.) generated the random allocation sequence. This RCT used blocked randomization (1:1), with the randomization scheme concealed and unpredictable. Unblinded study staff called the participants to inform him/her of the randomization assignment. Separate study staff who conducted follow-up in-person assessments and the statistician were blinded to group assignments. In addition to the local Institutional Review Boards, the study was overseen by an independent Data and Safety Monitoring Board that convened by telephone every 6 months. There were no interim concerns and the study ended when recruitment goals were achieved.

Randomization Groups

Usual Care Control Group

Using a standardized script at the randomization phone call, unblinded study staff delivered verbal instructions to increase one's walking slowly and steadily each week. Verbal instructions were reinforced with a 42-page written booklet that contained disease self-management information about aerobic endurance and strengthening exercises, an action plan for identifying symptoms of COPD acute exacerbations, and how to resume exercise after a COPD acute exacerbation. The booklet also provided information about oxygen use during exercise and available resources for smoking cessation. The next contacts with blinded study staff for outcome assessments occurred at in-person visits 3 and 6 months following the baseline visit. To collect daily step-count data, participants were sent home from the clinic visit at months 3 and 6 with the Fitbit pedometer to wear for 14 days and return by postage-paid mailer. At each follow-up visit, study staff reminded participants not to disclose randomization assignment and that they should be working to increase their walking and exercise. Participants were given the pedometer to keep at the end of the study.

Intervention Group

Participants randomized to the internet-mediated, pedometer-based self-management intervention were mailed detailed instructions about the study website. These instructions were based on feedback from participants in a prior study using a similar intervention to ensure understanding of website features and to maximize their use(1). Additionally, participants received written instructions identical to that the control group received which provided disease self-management education. Participants who were randomized to the intervention group were contacted by unblinded study staff via telephone to receive website access instructions. The next contact with study staff occurred at in-person visits 3 and 6 months after the baseline visit. Since the intervention group was already using the pedometer, daily step counts were averaged over

the 14 days that followed the participant's in-person clinic visit at months 3 and 6. At each follow-up visit, study staff reminded participants not to disclose randomization assignment and that they should be working to increase their walking and exercise. Participants were given the Fitbit to keep at the end of the study, but no longer had access to the content of the research website.

Description of the Intervention

The intervention is based on Self-Regulation Theory which emphasizes an iterative, rational process of behavior change(2). The web-based self-management intervention supports the cycle of self-regulation with four unique components to promote walking as part of disease self-management: 1) objective walking assessment and feedback, 2) individualized step-count goals, 3) educational tips and motivational messages, and 4) an online community.

The Fitbit Zip pedometer objectively assessed walking. It accurately measures step counts in the majority of persons with COPD, is easy to use, and interfaces with the study server to allow participants to upload step-count data to the research website. Participants were instructed not to use the commercially available Fitbit website.

To promote PA, an automated algorithm, developed by the investigators, computed gradually incrementing, individualized step-count goals(1, 3). The personalized step-count goals were calculated as the minimum value of three possible numbers: 1) the previous goal + 400 steps per day, 2) the average of the most recently uploaded seven days of step counts + 400 steps per day, or 3) 10,000 steps per day. Since goals were based on step-count data uploaded weekly, they reflected the participant's current level of walking. Goals did not necessarily increase over

time. For example, if a participant was sick, and thus recorded low step counts for one week, the subsequent week's goal was lower than the goal for the week the participant was sick.

Participants were asked to wear the pedometer every day, except while sleeping or showering/bathing, and to upload their step-count data to the study website as often as they wish, but at least weekly. Participants' daily step-count goals in the first week were calculated from their baseline step counts. Each week thereafter, the study computer ran the goal-calculation algorithm which progressively increased step-count goals if the previous week's goal had been achieved. The week's daily step-count goal was prominently displayed on each subject's personal study webpage in the text and the graphs. In addition, unblinded study staff called participants to inform them of their weekly step-count goals. Study staff called participants to remind them to upload step-count data if they had not uploaded step counts in more than 7 days.

The education and motivational content were developed through a multidisciplinary collaboration between a pulmonary physician who directs the VA Boston Pulmonary Rehabilitation program (MLM) and behavioral psychologist. The content was based on topics – such as medication knowledge, management of symptoms of dyspnea, anxiety, and depression, and identification of acute exacerbations – commonly addressed in the education portion of conventional Pulmonary Rehabilitation programs and as part of COPD self-management programs(4, 5). Participants viewed this content on their personalized study page of the research website. Educational tips discussed disease self-management, the benefits of physical activity, and behavior change. Some messages were tailored to smokers or oxygen users for targeted information. Persons who are sedentary or who have chronic disease face general and disease-specific barriers to starting and maintaining a walking program. Specific strategies and

behavioral techniques for overcoming these barriers were addressed as part of the motivational messaging component.

An online community within the website facilitated social support. Participants and research staff posted questions, shared personal experiences to motivate walking, and provided encouragement within this forum.

Outcomes

Participants performed the 6-minute walk test (primary outcome), spirometry, and secondary outcome assessments. Secondary outcomes related to COPD self-management included: physical activity measured as steps per day, HRQL measured with the St. George's Respiratory Questionnaire Total Score (SGRQ-TS), dyspnea (modified Medical Research Council Scale), COPD knowledge measured with the Bristol COPD Knowledge Questionnaire (BCKQ), social support measured with the Medical Outcomes Study Social Support (MOS-SS) scale, and number of participants who experienced at least once COPD acute exacerbations. The Fitbit Zip pedometer objectively measured steps per day for 10 days at baseline and 14 days after each follow-up visit. Scores on the SGRQ-TS range from 0-100 with lower scores indicating better HRQL(6). Scores on the mMRC dyspneoa scale range from zero to four, with four indicating the highest level of dyspnea(3, 7). The BCKQ is a 65-item instrument to assess the level of COPD knowledge across 13 topics: 1) epidemiology, 2) etiology, 3) symptoms, 4) breathlessness, 5) phlegm, 6) infections, 7) exercise, 8) smoking, 9) vaccination, 10) inhaled bronchodilators, 11) antibiotics, 12) oral steroids, and 13) inhaled steroids. The total score represents the sum of the scores of all 13 topics and range from 0 to 65, with a higher score indicating greater COPD knowledge(8). The MOS-SS is a 19-item survey that consists of four

subscales. An overall social support index was calculated with the average of the subscales and the last item, then transformed to a 0-100 scale. A higher score indicates more support(9). The occurrence of COPD acute exacerbation of COPD or pneumonia were self-reported and tracked at 3 and 6 months. Acute exacerbations were coded to indicate whether they resulted in hospitalization.

References

1. Wan ES, Kantorowski A, Homsy D, Teylan M, Kadri R, Richardson CR, Gagnon DR, Garshick E, Moy ML. Promoting Physical Activity in COPD: Insights from a Randomized Trial of a Web-Based Intervention and Pedometer Use. *Respir Med* 2017; 130: 102-110.
2. The Self-Regulation of Health and Illness Behaviour. New York, NY, US: Routledge; 2003.
3. Moy ML, Collins RJ, Martinez CH, Kadri R, Roman P, Holleman RG, Kim HM, Nguyen HQ, Cohen MD, Goodrich DE, Giardino ND, Richardson CR. An Internet-Mediated Pedometer-Based Program Improves Health-Related Quality-of-Life Domains and Daily Step Counts in COPD: A Randomized Controlled Trial. *Chest* 2015; 148: 128-137.
4. Effing TW, Vercoulen JH, Bourbeau J, Trappenburg J, Lenferink A, Cafarella P, Coultas D, Meek P, Van Der Valk P, Bischoff EWMA, Bucknall C, Dewan NA, Early F, Fan V, Frith P, Janssen DJA, Mitchell K, Morgan M, Nici L, Patel I, Walters H, Rice KL, Singh S, Zuwallack R, Benzo R, Goldstein R, Partridge MR, Van Der Palen J. Definition of a COPD Self-Management Intervention: International Expert Group Consensus. *European Respiratory Journal* 2016; 48: 46-54.
5. Zwerink M, Brusse- Keizer M, van der Valk PD, Zielhuis GA, Monninkhof EM, van der Palen J, Frith PA, Effing TJCDoSR. Self Management for Patients with Chronic Obstructive Pulmonary Disease. 2014.
6. Jones PW, Quirk FH, Baveystock CM, Littlejohns P. A Self-Complete Measure of Health Status for Chronic Airflow Limitation. The St. George's Respiratory Questionnaire. *Am Rev Respir Dis* 1992; 145: 1321-1327.

7. Mahler DA, Wells CK. Evaluation of Clinical Methods for Rrating Dyspnea. *Chest* 1988; 93: 580-586.

8. White R, Walker P, Roberts S, Kalisky S, White P. Bristol COPD Knowledge Questionnaire (BCKQ): Testing What We Teach Patients about COPD. *Chron Respir Dis* 2006; 3: 123-131.

9. Sherbourne CD, Stewart AL. The MOS Social Support Survey. *Soc Sci Med* 1991; 32: 705-714.