

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, MPH⁵; Madeline Polak, BS⁵; Paola N. Cruz Rivera, BA⁵; David R. Gagnon, MD, MPH, PhD^{6,7}; Amber Samuelson, BSN³; Sheila Moore, BS³; Reema Kadri, MLIS⁸; Caroline R. Richardson, MD⁸; Marilyn L. Moy, MD, MSc^{5,9}

¹Center for Healthcare Organization and Implementation Research (CHOIR), Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA, USA

²Pulmonary Division, Boston University School of Medicine, Boston, MA, USA

³Birmingham VA Medical Center, Birmingham, AL, USA

⁴Pulmonary, Allergy, & Critical Care Medicine, Department of Medicine, University of Alabama at Birmingham, AL, USA

⁵Pulmonary and Critical Care Medicine Section, VA Boston Healthcare System, Boston, MA, USA

⁶Department of Biostatistics, Boston University School of Public Health, Boston, MA, USA

⁷Massachusetts Veterans Epidemiology Research and Information Center, Veterans Affairs Boston Healthcare System, Boston MA

⁸Department of Family Medicine, University of Michigan, Ann Arbor, MI, USA

⁹Harvard 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 dyspnea 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 Rating 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.