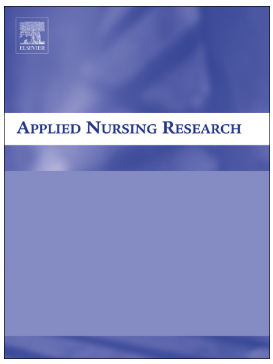

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Evaluating the Effect of a Smartphone App-Based Self-Management Program for People with COPD: A Randomized Controlled Trial

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ABSTRACT

Aim. To examine the effect of a 6-month, smartphone app-based self-management program for people with chronic obstructive pulmonary disease (COPD).

Background. Technological interventions have been used for chronic disease management, but the effect of a self-management program using a smartphone app has not been evaluated in people with COPD.

Methods. For this randomized controlled trial, patients with COPD (N = 44) were recruited in pulmonary medicine outpatient clinics at two, metropolitan, tertiary care, academic hospitals. Eligible participants were randomized into two groups and received group education and exercise sessions in the first month of the 6-month intervention. Participants in the experimental group received a smartphone app-based self-management program, which included education, exercises, self-monitoring of symptoms and exercise, and social support. Participants in the control group received one call a month from the research staff. Self-care behavior was measured as a primary outcome. All measures were administered at baseline and at 6 months.

Results. After randomization, the experimental group numbered 22, the control group numbered 20, and 2 participants dropped out. Significant differences between groups were found in change score for self-care behavior, total activity count per wear time, and percent time spent in moderate-to-vigorous physical activity over 6 months.

Conclusion. A self-management program, using a smartphone app, can effect behavioral change in people with COPD. This program could be a boon to patients with COPD who have limited access to a health care provider, no opportunities for pulmonary rehabilitation, and frequent exacerbations.

Key words*:* Chronic obstructive pulmonary disease, smartphone application, self-management program

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Title; Evaluating the Effect of a Smartphone App-Based Self-Management Program for People with COPD: A Randomized Controlled Trial

1. Introduction

Chronic obstructive pulmonary disease (COPD) is characterized by limited airflow and persistent symptoms such as dyspnea, cough, and sputum production (Global Initiative for Chronic Obstructive Lung Disease [GOLD], 2018). Despite advanced medical treatment, people with COPD become increasingly more dyspneic, which limits activity, and experience frequent exacerbations as their disease progresses, which severely affects them physically, psychologically, and socially (Liang et al., 2014). Considering COPD's progressively declining trajectory, people with the disease should learn how to self-manage it. A self-management program is defined as a "program aimed at teaching skills needed to carry out specific medical regimens specific to the disease and guide health behavior change for patients to control their disease and improve their well-being" (Bourbeau, Nault, & Dang-Tan, 2004, p. 271). Studies have shown that such self-management programs improve health-related outcomes in people with COPD (Cannon et al., 2016; Newham et al., 2017; Wang, Tan, Xiao, & Deng, 2017). One study reported that self-care behavior in Koreans with COPD was poor (Park et al., 2017). Despite the high prevalence of COPD in Korea and the poor self-care behavior of Koreans with the disease, self-management programs to improve self-care behavior have been limited (Hwang, Park, & Yoo, 2017). Pulmonary rehabilitation, which may include a self-management program in addition to structured exercise, has been recommended as a management option for COPD (GOLD, 2018). However, in Korea, pulmonary rehabilitation has not been widely used, it may not be accessible to all patients, and it has limitations such as short duration and attenuation of its beneficial effects over time (Spruit & Singh, 2013). Thus, Koreans with COPD need a new option to learn self-management skills, improve self-care behavior, and achieve better health-related outcomes.

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Such an option should be more convenient, accessible to education, and supportive of their disease self-management.

Many attempts have been made to improve self-management skills and health-related outcomes in people with COPD using information technology such as telephone follow-up, video conferencing, and the internet (Gregersen et al., 2016; Lundell, Holmner, Rehn, Nyberg, & Wadell, 2015; McLean et al., 2012; Polisena et al., 2010). Among the latest technologies is the smartphone, a communication marvel that offers portability, connectedness, continuous uninterrupted data streaming, computational capability, and ease of communication with health care providers (Boulos, Wheeler, Tavares, & Jones, 2011; Wang et al., 2014). Furthermore, people can run specialized applications (apps) on their smartphones (Boulos et al., 2011; Kirwan, Vandelanotte, Fenning, & Duncan, 2013). The high prevalence of smartphones also makes it possible to provide care to patients at their convenience. In 2016, the rate of smartphone use was reported to be as high as 88% in South Korea (Lee, 2018). As an aside, by 2013, 25% of Korean adults aged 55 years and older owned a smartphone (The statistics Portal, 2018). Offering several benefits, smartphone apps now enable health care providers to effectively manage the care of people with many chronic diseases (Lee, Choi, Lee, & Jiang, 2018; Mosa, Yoo, & Sheets, 2012; Wang et al., 2014). Although the smartphone has been used in past studies of COPD patients, it recorded symptoms or physical activity for the most part and was coupled with other physiological medical devices or technologies like the internet (Alwashimi et al., 2016). Recently, studies of COPD have focused on physical activity and pulmonary rehabilitation, taking full advantage of the smartphone app's functionality (Demeyer et al., 2017; Rassouli et al., 2018). However, research into the use of smartphone technology in a self-management program for people with COPD has been limited. This study examined the effect of a comprehensive, smartphone app-based, self-management program (SASMP) on self-care behavior in Koreans with COPD, the

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smartphone app being *the* main intervention.

1.1. Literature review

Past self-management programs, conducted mainly face to face, have been shown to benefit people with COPD (Cannon et al., 2016; Newham et al., 2017; Wang et al., 2017). The interventions have included center-based, individual or group sessions; home care visits; and telephone follow-up. Compared with such programs, self-management programs that use smartphone technology offer several unique benefits. Smartphones enable health care providers to (1) monitor patients anywhere anytime; (2) provide frequent, interactive feedback to patients; (3) provide immediate access to social support from peers and health care providers; (4) provide effective communication between patients and health care providers; and (5) send tailored, motivational text messages (Free et al., 2013; Lee et al., 2018; Mohammadzadeh & Safdari, 2014; Pellegrini et al., 2012). Additionally, the smartphone intervention minimizes the need for patient to travel to health care centers (Finn & Bria, 2009). Thus, a self-management program that uses smartphones may affect health-related outcomes differently than face-to-face self-management programs. This innovative intervention bears investigation with COPD patients to assess its full potential.

Past studies have examined the effect of self-management programs using smartphone apps in people with chronic diseases. For example, four studies examined self-management programs in people with diabetes (Gunawardena et al., 2019; Kim et al., 2015; Kirwan et al., 2013; Zhou, Chen, Yuan, & Sun, 2016). Although the interventions in these studies varied, they mostly included recording glucose, insulin, and diet; educational material; and personalized text messages. These app interventions have shown beneficial effect, such as reduction in HbA1C (Gunawardena et al., 2019; Kirwan et al., 2013; Zhou et al., 2016) and improvements in glucose level, diabetes knowledge, and self-care behavior (Kim et al., 2015; Zhou et al., 2016). In another example, Ong et al.'s (2016) study of people with chronic

kidney disease used an app-based intervention that monitored blood pressure, assessed symptoms, managed medications, tracked laboratory results, and provided feedback on blood pressure and laboratory results. Ong et al. showed that their app-based intervention helped in reducing patients' blood pressure. Finally, to test a mobile health system to support self-management in people with asthma, Licskai, Sands, and Ferrone (2013) developed a smartphone app that provided daily weather forecasts, recorded symptoms and peak flow data, provided automated control assessment, and monitored medication adherence. Licskai and colleagues found improvement in health-related quality of life (HRQOL). Thus, research in fields other than COPD have found apps to be useful interventions.

Relatively few studies have used other technologies to examine the effect of comprehensive self-management programs for people with COPD. Three studies by Nguyen and colleagues evaluated the effect of internet-based, dyspnea self-management programs for people with COPD on dyspnea with activities. The programs included education, exercise, self-monitoring of symptoms and exercise, and support; the researchers did not find favorable results in the primary outcome between groups (Nguyen, Carrieri-Kohlman, Rankin, Slaughter, & Stulbarg, 2005; Nguyen et al., 2008, 2013). In another study, Koff, Jones, Cashman, Voelkel, and Vandivier (2009) examined self-management, which included education and instruction on self-management techniques, enhanced communication, and monitoring for symptoms and physiological data, using a "health buddy system" connected to a telephone line. They found that the participants' HRQOL improved. Kim et al. (2012) also tested the effect of a u-health service program, which included consultation by mobile phone and video phone, on knowledge, attitude, and skill in people with COPD. The main components of the study included education and monitoring of symptoms and physiological data. However, Kim et al. found no difference in knowledge level between groups. In another study, Farmer et al. (2017) tested the effect of self-management support on HRQOL using an

internet-linked tablet computer. The main components of this study included monitoring of symptoms, mood, and physiological data and teaching self-management strategies. Farmer et al. found no improvement in HRQOL. Thus far, researchers have used different technologies to test comprehensive self-management programs for different purposes; their effectiveness, however, has not been definitive. Limited information has been available on the effect of a comprehensive self-management program using a smartphone app for people with COPD. Thus, examining the effect of SASMP in people with COPD will offer health care providers a practical option for COPD management.

The purpose of this study was to examine the effect of a 6-month SASMP on self-care behavior in people with COPD. Secondary outcomes included exercise capacity, exercise, physical activity, symptoms, HRQOL, and health care use. Mediators of treatment effects included self-efficacy, perception of control, and social support.

2. Methods

2.1. Design, Sample, and Settings

A randomized controlled trial design was used. A convenience sample of patients with COPD was recruited from the outpatient clinics of pulmonary medicine departments at two tertiary hospitals in a metropolitan city in Korea. Patients were eligible to participate if they (a) had COPD, (b) were aged 45 years or old, (c) were classified as either GOLD Stage 1, 2, or 3, (d) had a smartphone and could text messages, and (e) were able to communicate. Patients were excluded if they (a) had a psychiatric disorder (b) were hospitalized and discharged within 8 weeks due to a COPD exacerbation, (c) had less than 93% oxygen saturation in a stable state, (d) had their saturation level fall to 85% after a six-minute walk test (6MWT), (e) had severe respiratory symptoms in a stable state, (f) had pulmonary rehabilitation within 12 months, (g) had other diseases that made physical activity and/or exercise difficult, and (h) used assistive devices to walk or had problems with balance.

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In the past, self-care behavior has not been examined as a primary outcome of self-management programs using a smartphone app in people with COPD. Thus, our sample size was estimated based on mean values of self-care behavior in two groups at postintervention in a study of patients with diabetes (Zhou et al., 2016), using G*power 3.1.9.2. That study revealed an effect size of .98. A total sample size of 36 (18 for each group) was required to have this effect with an alpha of .05 and 80% power.

2.2. Measures

2.2.1. Demographic and clinical characteristics.

We interviewed each participant to obtain information on age, gender, education level, economic level, employment, living status, use of oxygen, smoking status, duration of disease, hospital admissions and visits to an emergency department (ED) during the past year due to exacerbations, and previous education on symptom management. Medical records provided information on medications and comorbidities. Forced expiratory volume in 1 second (FEV1) and FEV1/forced vital capacity (FVC) were obtained by spirometry. Following guidelines of the American Thoracic Society (American Thoracic Society, 1995a, 1995b), we performed spirometry on each participant three times. The best of the three results was used for our analysis. GOLD stages were also based on FEV1% predicted value (GOLD, 2018).

2.2.2. Dyspnea.

The University of California, San Diego Shortness of Breath Questionnaire (UCSD-SOBQ) was used to measure the level of dyspnea. Comprising 24 items, this instrument measures dyspnea's effect on 21 daily activities and 3 limitations in daily life (Eakin, Resnikoff, Prewitt, Ries, & Kaplan, 1998). We used only the former in our study. Participants answered the 21 questions on six Likert scales (0-5). Total scores range from 0 (*best*) to 105 (*worst*). The reliability of the UCSD-SOBQ (Cronbach's alpha = .96) and its validity for perceived breathlessness following a 6MWT (r = .45) have been reported in the literature

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(Eakin et al. 1998). In this study, Cronbach's alpha for the UCSD-SOBQ was .93.

2.2.3. Other symptoms.

We used the Profile of Mood States-Short Form (McNair, Lorr, & Droppleman, 1992) to assess the participants' anxiety and depression. The six subscales are included in this instrument: tension-anxiety, depression-dejection, anger-hostility, vigor-activity, fatigue-inertia, and confusion-bewilderment. In our study, only the tension-anxiety and depression-dejection subscales were used. Each subscale comprises five items. Participants were asked to rate each item on a 5-point scale (0-4). Each subscale score ranges from 0 to 20. Higher scores indicate more anxious and depressed states. The instrument's adequate reliability (Cronbach's alpha = .75-.91) and substantiated validity have been reported in the literature (McNair et al., 1992). In this study, Cronbach's alpha for the tension-anxiety and depression-dejection subscales was .78 and .86, respectively.

2.2.4. Exercise capacity.

Following ATS guidelines (ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories, 2002), we performed a 6MWT on each participant to assess exercise capacity. Oxygen saturation, heart rate, respiratory rate, blood pressure, and dyspnea and fatigue, based on the Borg Rating of Perceived Exertion, were assessed before and after the test. The maximum distance covered in 6 min was used for analysis.

2.2.5. Exercise.

Exercise behavior was determined by asking two questions: How many days did you exercise past week? and How much time did you spend for each exercise? Total time spent for exercise in 1 week was calculated based on answers to these two questions.

2.2.6. Physical activity.

We measured physical activity with an accelerometer (wGT-3X-BT, ActiGraph, Shalimar, FL). Participants were instructed to attach the device to an elastic waist belt and

wear it on their right hip for 7 consecutive days during waking hours only. They were also instructed to remove it during water-based activities. This triaxial ActiGraph measures step count, duration and intensity of physical movement (counts per minute [cpm]), and time spent for different physical activities. Data were stored in 1-min epochs. "Nonwear time" is defined as no counts for 60 min with tolerance up to 2 min of activity between 0-100 cpm (Troiano et al., 2008). A "valid day" for analytical purposes is defined as a day when participants wear the device for at least 10 h. In our analysis, we included participants who wore the device at least four valid days. Accelerometer counts from the vertical axis were used for our analysis. We used the cutpoints for physical activity, as recommended by Freedson, Melanson, and Sirard (1998). Sedentary activity was defined as less than 100 cpm, light physical activity was 100-1,951 cpm, and moderate-to-vigorous physical activity (MVPA) was defined as equal to or more than 1,952 cpm. Total activity count per total wear time was analyzed by calculating total activity count divided by total wear time. Percentages of time spent in sedentary activity, light physical activity, and MVPA were analyzed by calculating time spent for each activity divided by total wear time.

2.2.7. Health-related quality of life.

We measured HRQOL with the Medical Outcomes Study 36-Item Short-Form Health Survey. The instrument's 36 items are apportioned into eight measures for physical functioning, role physical, bodily pain, general health perception, vitality, social functioning, role emotional, and mental health. The physical component subscale and mental component subscale were calculated for our analysis. Scores for the two subscales can range from 0 to 100. Higher scores indicate better HRQOL. Adequate reliability for this instrument (Cronbach's alpha = .78-.93) has been reported, and its construct validity has been tested in people with different medical conditions (McHorney, Ware, Lu, & Sherbourne, 1994; McHorney, Ware, & Raczek, 1993). In our study, Cronbach's alphas for this instrument's

eight measures were .86, .69, .87, .75, .60, .69, .88, .62, respectively.

2.2.8. Self-efficacy and perception of control.

We used the Self-Efficacy for Managing Chronic Disease 6-Item Scale (SEMCD) to measure self-efficacy. This instrument records patient confidence in managing their disease and controlling symptoms, physical discomfort, or emotional distress (Lorig et al., 1996). It comprises six questions and uses a 10-point scale (1-10). Higher scores represent better self-efficacy. Adequate reliability of this instrument (Cronbach's alpha = .88-.95) and its validity with activity limitation (r = -.33 - -.53) have been reported in the literature (Ritter & Lorig, 2014). In this study, Cronbach's alpha for the SEMCD was .92.

In addition to using the SEMCD, self-efficacy for dyspnea, exacerbations, and exercise was assessed by asking participants to answer five questions; their answers were recorded on a 10-point scale (1-10). Higher scores indicate more confidence. The five questions asked participants how confident they were that they could keep dyspnea from interfering with desired activity, they could notice early signs of COPD exacerbation, they could maintain exercise, they could increase physical activity, and they could reduce sedentary time to promote better health.

We used the mastery subscale of the Chronic Respiratory Disease Questionnaire to measure perception of control (Wijkstra et al., 1994). This self-administered, standardized instrument comprises four subscales: dyspnea, mastery, emotion, and fatigue (Wijkstra et al., 1994). We used only the mastery subscale for our analysis. That subscale comprises four questions and rates responses on a 7-point rating scale (1-7). Higher scores indicate more control over disease and symptoms. The reliability of this instrument (Cronbach's alpha = .83-.91) and its validity with symptom checklists (r = -.27 ~ -.55) have been reported in the literature (Wijkstra et al., 1994). In this study, Cronbach's alpha for the mastery subscale was .65.

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2.2.9. Social support.

We used the emotional-informational support subscale of the MOS Social Support Survey to assess each participant's level of social support (Sherbourne & Stewart, 1991). This subscale comprises eight questions, which ask how often each of the eight supports is available to participants when needed. Participants were asked to record their answers on a 5-point scale (1-5). Higher scores indicate having a greater support system. The instrument's excellent reliability (Cronbach's alpha =.96) and validity with loneliness (r = -.60) have been reported in the literature (Sherbourne & Stewart, 1991). In this study, Cronbach's alpha for this instrument was .95.

2.2.10. Self-care behavior.

The Alberto Chronic Obstructive Pulmonary Disease Self-Care Behavior Inventory (Alberto, 1990) was used to evaluate the level of self-care behavior. This instrument comprises 36 items and uses a 5-point scale (1-5). Total scores range from 36 to 180. Higher scores indicate having better self-care behavior. Adequate reliability of this instrument (Cronbach's alpha = .87) and its content validity have been reported in the literature (Alberto, 1993). In our study, Cronbach's alpha for this instrument was .83.

2.2.11. Health care use.

Participants were asked to answer the purpose and frequency of ED visits, hospital admissions, and outpatient clinic visits at a tertiary hospital over the past 6 months. Only health care use due to COPD exacerbations was included.

2.2.12. Process metrics.

The participants' engagement in the intervention over 6 months was measured by the frequency of using the smartphone app. Specifically, we analyzed the number of symptom scores and exercise data entered into the smartphone app by participants in the experimental group. The frequency of staff-participant interaction by text messages or calls was also

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counted.

2.2.13. Exit interviews.

We conducted exit interviews with all of our participants. Participants were asked to answer following open-ended question, How was your experience in this program? Satisfaction with the program was also measured by another question; responses were entered on an 11-point rating scale that ranged from 0-100%. Finally, three questions assessed perceived support from the research team; again an 11-point rating scale (0-100%) was used to measure responses. These three questions assessed the support participants received from the research team on managing disease, managing symptoms, and increasing physical activity and reducing sedentary time.

2.3. App Development

The development of a smartphone app for COPD self-management predated our study. To determine the content and design of our app, the principal investigator reviewed relevant literature, educational resources, and the existing smartphone app for COPD management. We consulted a pulmonary physician and a nurse researcher who had experience with smartphone app research before finalizing the content and design of our app. Our app, created by a professional application developer, uses an Android platform (version 2.3 Gingerbread), which is the leading operating system in Korea. The font size of all content can be adjusted for comfortable viewing, which is especially important for older patients. Our consultants, the pulmonary medicine physician and nursing researcher, were asked again for suggestions on how the app-in-development could be further improved. We also asked three patients with COPD to test our prototype and made changes based on their feedback. After several refinements, the final version of our app was ready for field testing.

2.4. Procedures

The human research committees in the two tertiary academic hospitals approved this

study. We translated and then back translated research instruments that were not available in Korean, except for one, Exacerbations of Chronic Pulmonary Disease Tool-Respiratory Symptoms (E-RS). Two individuals translated the original English versions of the instruments into Korean; two different individuals back-translated the Korean versions into English. The original English versions were similar to the back-translated versions of these instruments.

We explained our study's inclusion criteria to physicians and nurses in the outpatient clinics of the pulmonary medicine departments at the two, metropolitan, tertiary care, academic hospitals. After they referred potential participants to our research team, we contacted each person, explained the purpose of study, and obtained signed informed consent if they were willing participants. Subsequently, we used baseline tests to screen all individuals. After screening and baseline testing were done, participants were randomized into two groups. Randomization scheme was generated, using a SAS Software; the randomization was stratified by GOLD stage (i.e., GOLD Stages 1 and 2 vs. GOLD Stage 3). The coinvestigator assigned them to one of two groups using a list of random numbers stratified by GOLD stage. After group assignment, participants received their respective intervention for the 6-month study. See Table 1 for details on the interventions for both groups.

We collected demographic and clinical data, and spirometry testing was performed at baseline. Participants completed all study questionnaires and underwent a 6MWT; they wore an accerelometer at baseline and 6 months. Health care data during the 6-month study was obtained, exit interviews were conducted, and satisfaction and perceived support from the research team were assessed at 6 months. The same research personnel conducted the interventions and testings. To maintain internal validity, all research staff were oriented to the study's protocol. Each participant was instructed on how to follow that standardized protocol.

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2.5. Intervention

After assignment, the experimental group received the SASMP; the control group did not. The SASMP was guided by social cognitive theory (Bandura, 1986) and self-efficacy theory (Bandura, 1997). These theories suggest that self-efficacy has four primary sources: (1) enactive mastery experiences; (2) vicarious experiences; (3) verbal persuasion; and (4) physiological and affective states (Bandura, 1986, 1997). Each source of self-efficacy was incorporated into our study. To address enactive mastery experiences, participants were taught strategies to relieve their symptoms. They were asked to set achievable goals for exercise and physical activity and guided how to successfully reach those goals step by step. To prompt participants to share their experiences, those who successfully achieved exercise and physical activity goals were asked during group texting to relate their experiences. Verbal persuasion followed in due course. Those participants who successfully achieved their exercise and physical activity goals were praised, and their efforts to enter data in apps were encouraged. Finally, participants were taught to pay attention to their physiological and psychological symptoms. Strategies to relieve those symptoms were provided.

Our SASMP incorporated behavioral components of self-monitoring, motivational feedback, and assistance to develop self-management skills and promote self-efficacy. The intervention's main components included education, individually tailored exercise, self-monitoring of symptoms and exercise, and social support. We also incorporated Effing et al.'s (2012) components for self-management programs for people with COPD. At the first education session, participants in the experimental group received instruction on how to use each feature of the smartphone app. The app includes a directory for symptom record, exercise, education materials, and a communication board. Main screens are depicted in Figures 1 and 2.

The four education sessions offered to both groups during the study's first month

included definition, cause, diagnosis, and symptoms of COPD; pharmacological management of COPD; nonpharmacological management (i.e., pulmonary rehabilitation, exercise, physical activity, dyspnea management, smoking cessation, nutrition, comorbidity management, and psychological symptom management); management of COPD exacerbations, and strategies for self-care. An advanced practice nurse led the 30-min sessions. Typical symptoms during exacerbations were discussed, and participants were given an action plan with their specific signs and symptoms. For the experimental group, the educational material presented at the group sessions and video clips demonstrating how to use bronchodilators were available in the smartphone app's directory under *education materials* (Figure 2). Participants in the experimental group were encouraged to review this educational material, which was reinforced by research staff through text messages over the 6 months.

Four group exercise sessions were also offered during the first month of the 6-month intervention period for both groups. Each session, taught by an exercise expert who majored in exercise physiology, lasted about an hour and included stretching, main exercise, and stretching, in that order. The main exercise was circuit training, which focuses on strengthening the upper and lower extremities and abdomen using therabands with different resistance. We evaluated each participant's balance and exercise patterns, gave them a pamphlet that depicted each posture, and advised them how to safely perform each posture at home. Each participant's level of physical activity was also evaluated during the exercise session. The exercise expert helped the participants of both groups set an individualized goal for weekly exercise and physical activity, based on their personal exercise or physical activity status. For the experimental group, a video clip of each posture and motion, which was taught in the group exercise session, was included in the smartphone app's directory under *exercise* (Figure 1). These participants were encouraged to use the exercise video clip as a guide for

exercise at home. They were also asked to use a pedometer to increase their physical activity. We urged participants in the experimental group to increase the frequency and duration of exercise, increase MVPA to at least 150 min a week, and decrease sedentary time. The smartphone app also included a rating of perceived exertion to safeguard participants in the experimental group when performing exercises at home.

Only participants in the experimental group were asked to monitor their symptoms using the E-RS, which comprises 11 respiratory symptoms (Leidy & Murray, 2013). The smartphone app included E-RS in its directory under *symptom record* (Figure 1). Participants were asked to fill out the E-RS at night at least 4 times a week and especially when having an exacerbation. In addition to symptoms, the smartphone app recorded the use of bronchodilators and health care due to worsening symptoms. Total scores for the E-RS were automatically calculated, stored in the symptom record, and depicted in graph form with past results. Participants were encouraged to review the graphic summaries of their symptoms to track their symptoms over time. We also monitored total E-RS scores, bronchodilator use, and health care use every day. Automatic alert messages were sent to the research team if a total E-RS score was above 33, if a total E-RS score increased 1 point above the previous score, and if participants recorded that they visited the pulmonary outpatient clinics or ED for dyspnea. Once alerted that participants had symptoms or needed medical care, we texted them or called. We helped them to recognize worsening symptoms and use the action plan in case of an exacerbation.

Only participants in the experimental group were asked to monitor their exercise and physical activity by smartphone. They were asked to record the type and duration of exercise and step count from their pedometer in the smartphone app's *exercise* directory, whenever they exercised (Figure 1). These data were stored and displayed in their exercise record and presented in graph form with past results in the app. Participants were encouraged to review

their record of past exercise and physical activity to track their progress over time. We contacted the participants every 4 weeks to reset goals for individual exercise and physical activity for the next 4 weeks, based on their progress. New goals were displayed in the app. The achievement rate for exercise and physical activity goals was calculated automatically and also displayed in the app. We monitored the duration of exercise, step counts, and achievement rate for exercise and physical activity goals. We contacted them if they did not perform exercise or physical activity at least four consecutive days. The participants' past performance was discussed and achievement of their goal for exercise or physical activity was encouraged.

The experimental group was encouraged to group-text other participants and communicate with the research team by sending text messages to the smartphone app's *communication board* (Figure 2). The group was encouraged to share their personal experiences with symptom management and exercise such as achievement of exercise and physical activity goals and to contact the research team when worsening symptoms arose. The research team also called those in the control group every month to check on their general health status.

2.6. Data Analysis

All data analyses were performed using SPSS version 23.0. Descriptive statistics were used to present data on demographic and clinical characteristics of total sample and study variables. Demographic and clinical characteristics of samples between both groups and between the dropout group and total sample (n = 42) at baseline were compared using the chi-square test and independent t-test. Variables that were measured before and after the intervention in each group were compared using the paired t-test. Variables that were measured at baseline and 6 months were compared between the two groups using the independent t-test. Health care use over the 6-month period was compared between groups,

using the chi-square test. A p-value less than .05 indicates statistical significance. The intention to treat principle was applied to all statistical analyses.

3. Results

3.1. Comparison of Sample Characteristics Between Groups at Baseline

A flow chart for the final sample (n = 42) is presented in Figure 3. Initially, 44 participants were randomized into one of two groups. Two participants dropped out of study. Finally, 22 participants comprised the experimental group; 20 comprised the control group. Recruitment started in March 2016; all interventions ended in June 2018. No statistical differences were found in all variables between the dropout group (n = 2) and final sample (n = 42; Table 2). The mean age of all participants was 67.88 (Table 2). None used oxygen. Participants were mainly men who had moderate COPD. No statistical differences were found in sample characteristics between the experimental and control groups (Table 2).

3.2. Comparison of Outcomes Between Groups

No statistical differences were found in the outcome variables between groups at baseline and at 6 months, except for self-care behavior (Table 3). At 6 months, the level of self-care behavior in the experimental group was significantly higher than in the control group. Participants in the experimental group showed (a) significant improvement in self-care behavior; (b) longer distance on the 6MWT; (c) an increase in total activity count per wear time, percent time spent in MVPA, and step count; and (d) better self-efficacy for maintaining exercise, increasing physical activity, and decreasing sedentary time, when compared with baseline measures. For the control group, no statistical differences were found in the outcome variables between baseline and 6 months. Significant differences were found in change score for self-care behavior, total activity count per wear time, and percent time spent in MVPA between the two groups over 6 months.

3.3. Process Metrics

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All participants attended the group education and exercise sessions. The weekly frequency of symptom scores and exercise data that the experimental group entered into the smartphone app over 6 months is presented in Table 4. Most entered data 3 or 4 times a week. The alert messages on symptom scores or health care use totaled 75 over 6 months (Table 4). Frequent text messages were sent, and 4 or 5 times call in a month have been made to participants in experimental group over 6 months by research team (Table 4). Two participants sought research staff assistance on logging in to the smartphone app. No adverse events occurred during intervention period.

3.4. Exit interviews

In the exit interviews, participants were asked, "How was your experience in this program?" The experimental group offered the following responses. Thirteen (59.1%) participants reported that they learned more about their disease; the importance of exercise, balanced nutrition, and changes in health behavior; and how to increase physical activity. Their symptom management and level of self-care behavior improved through education. Eleven (50%) participants said that it was good to learn how to do exercise, 7 (31.8%) participants appreciated the support of other participants and research staff, and 4 (18.2%) reported that their exercise time increased by watching the exercise video in the smartphone app. A few participants were grateful to learn how to use bronchodilators properly and avoid triggers for symptoms and being able to ask the research staff questions about COPD. For many, their mood improved, they felt more energy, they learned how to adjust exercise when having dyspnea, and they felt more confident about their health. A few participants mentioned that recording exercise and symptoms in the app was a burden, and sometimes they forgot to do so.

On the other hand, most of the participants in the control group (n = 19, 95%) enjoyed participating in the education and exercise sessions. Some in control group (n = 7, 35%)

reported that this program made them think about COPD and the need to change health behavior, monitor symptoms, and increase exercise time. Others (n = 3, 15%) preferred the group exercise sessions to exercise at home.

Complementing feedback from the exit interviews, all of the participants were asked to answer a question about their satisfaction with this program and three questions about perceived support from the research team (Table 5). Participants in both groups expressed high satisfaction and felt that the research staff provided great support on disease management, symptom management, and the need to increase physical activity and reduce sedentary time.

4. Discussion

This study was designed to examine the efficacy of a SASMP in people with COPD. We found that our intervention had a significant impact on self-care behavior, total activity count per wear time, and percent time spent in MVPA. Its effect on self-care behavior echos Zhou et al.'s (2016) findings in their study of people with diabetes. The reason for such improvement, in part, is that participants in the experimental group were educated about disease management and self-care strategies for COPD, and our research team provided them with ongoing support and consistent reinforcement of that information by using the smartphone app. We also used motivational techniques to actively engage the participants in self-care behavior and provided timely feedback for the evaluation of symptoms and exercise data that was entered on the smartphone, including advice on behavioral changes. Our positive finding on self-care behavior was supported by the fact that physical activity, one of study's secondary outcomes, improved as a result of our intervention. The improvement of physical activity in our study is consistent with Demeyer et al.'s (2017) findings. In our study, participants in the experimental group recorded 37 min a day of MVPA during the 6-month period, a 9.92 min increase from baseline. This achieved the goal for physical activity (at

least 150 min/week), which is recommended for older adults (Paterson & Warburton, 2010). Although physical activity was not our study's main focus, our group education and exercise sessions emphasized its importance and exercise in general for both groups. We suggested individualized goals for exercise and physical activity to each participant in the experimental group, based on our assessment of their exercise and physical activity levels during the group exercise session. We monitored their exercise behavior and level of physical activity, encouraged them to increase physical activity and decrease sedentary time, and provide feedback using convenient technology, which may have influenced their behavior change. It is likely that this improvement in physical activity was partially mediated by enhancing the participants' self-efficacy. However, participants in the experimental group did not reach the "somewhat active" threshold of 7500 steps/day by using our intervention (Tudor-Locke & Bassett, 2004). Thus, continuous efforts are needed to motivate people with COPD to be more active because an active lifestyle has been shown to have a significant relation to better health outcomes in this population (Garcia-Rio et al., 2012). Participants in the experimental group were also able to walk longer distances in the 6MWT after intervention than before, which showed a clinically meaningful effect (Puhan et al., 2008). This finding was expected because level of physical activity has been highly correlated with distance in the 6MWT (Lee et al., 2018; Venkata, DeDios, ZuWallack, & Lahiri, 2012). Overall, our SASMP seemed to be more effective than education and exercise alone in improving self-care behavior and physical activity. This favorable finding indicates that structured education and exercise alone are not sufficient to change health behavior in people with COPD.

To the best of our knowledge, ours is the first study to examine the use of a smartphone app in a comprehensive self-management program for people with COPD. Past studies of COPD used apps to monitor symptoms or physical activity (Alwashmi et al., 2016). According to our findings, apps can be used to deliver comprehensive self-management for

people with COPD. Smartphone technology has superiority over other technologies because it allows for more frequent and interactive feedback, tailored text messages, and immediate access to social support (Pellegrini et al., 2012). Furthermore, smartphones are affordable, apps are inexpensive to use, and installation does not require a specialist. Whether older adults could use a smartphone app was an initial concern, but our participants had no difficulty, except two who experienced technical problems. Nonetheless, compliance by the experimental group was low. Although we had a minimum login requirement (at least 4 times a week), participants did not comply. However, our login frequency did not wane over time, which may explain our favorable findings. Both the experimental and control groups felt that the intervention had positive merit and they were quite satisfied with the results. This may be due in part to the four education and exercise sessions, which established a positive relationship with the research staff and other participants.

Despite our positive findings, this study has some limitations. First, we did not measure outcomes at 1 month, after group education and exercise sessions ended, which may have given us a better understanding of the effect of our self-management program. Second, due to the nature of intervention, the interventionist and participants were not blinded to treatment allotment. The interventionist and outcome assessor were the same person, which could threaten internal validity. Third, we did not have a second control group. Future studies should replicate our research using three groups, including a second control group. Fourth, we only included people who already had a smartphone, which may have skewed the sample toward those of higher socioeconomic status. Finally, we did not include GOLD Stage 4, and the study took place in a metropolitan city, which may limit the study's external validity.

5. Conclusion

Our SASMP effected positive change in self-care behavior and physical activity in people with COPD. These findings further support the feasibility and efficacy of using a

smartphone app for this population. Further studies with larger sample sizes and another control group are needed to show its positive impact on clinically relevant outcomes. The SASMP can be used as an educational or exercise resource at home for patients with COPD and their family. It can be useful to patients who have limited access to a health care provider, do not have opportunities for pulmonary rehabilitation, or have frequent exacerbations. The SASMP can also be easily combined with a formal exercise training intervention or a pulmonary rehabilitation program focused on exercise to improve the self-management skills of patients with COPD.

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Table 1; Components of intervention for experimental and control groups

Components of intervention	Experimental group	Control group
Education	■ Group education sessions (4, once a week) offered in the first month of the 6-month intervention. ■ Educational material installed in smartphone application.	■ Group education sessions (4, once a week) offered in the first month of the 6-month intervention.
Exercise	■ Group exercise sessions (4, once a week) offered in the first month of the 6-month intervention. ■ Exercise expert prescribed individualized exercises for each of participant. ■ Pamphlet of exercises provided. ■ Pedometer provided. ■ Exercise video clips installed in smartphone app.	■ Group exercise sessions (4, once a week) offered in first month of the 6-month intervention. ■ Exercise expert prescribed individualized exercises for each of participants. ■ Pamphlet of exercises provided.
Self-monitoring	■ Participants recorded time and type of exercise and step count from pedometer in smartphone app. ■ Participants recorded symptoms, bronchodilator use, and health care use due to exacerbations in smartphone app.	
Social support	■ Participants were encouraged to communicate with other participants and research team by text messages in smartphone app or call.	■ Research team called participants to check health status once a month over 6 months.

Table 2; Demographic and clinical characteristics of total sample and by groups

	Total sample (n=42)	Experimental group (n=22, 52.4%)	Control group (n=20, 47.6%)	Drop out (n=2)	Comparison between experimental group & control group	Comparison between total sample & drop out group
	Mean ± SD (range); Frequency (Percentage)				t or χ^2, p-value	
Age	67.88 ± 10.49 (45-87)	70.45 ± 9.40	65.06 ± 11.12	68.50 ± 3.54	-1.71, p=.10	-0.08, p=.94
Gender (male)	33 (78.6%)	19 (86.4%)	14 (70.0%)	2 (100.0%)	1.67, p=.27	0.54, p=1.00
Education						
Middle high school & less	18 (42.9%)	9 (40.9%)	9 (45.0%)	2 (100.0%)		
High school & higher	24 (57.1%)	13 (59.1%)	11 (55.0%)	0 (0.0%)	0.07, p=1.00	2.51, p=.20
Income (monthly)						
<$1,000	16 (38.1%)	8 (36.4%)	8 (44.4%)	1 (50.0%)		
≥$1,000	24 (57.1%)	14 (63.6%)	10 (55.6%)	1 (50.0%)	0.27, p=.75	0.08, p=1.00
Living situation						

COPD

Alone	2 (4.8%)	2 (9.1%)	0 (0%)	0 (0.0%)		
Married or Living with someone	40 (95.2%)	20 (90.9%)	20 (100%)	2 (100.0%)	1.91, p=.49	0.10, p=1.00
Working	14 (33.3%)	5 (22.7%)	9 (45.0%)	0 (0.0%)	2.34, p=.19	0.98, p=1.00
Pack years of smoking	17.64 ± 16.39	16.50 ± 14.43	18.90 ± 18.61	12.50 ± 10.61	0.47, p=.64	0.44, p=.67
FEV1 % pred.	65.02 ± 21.57	61.00 ± 18.73	69. 45 ± 24.02	71.50 ± 51.28	1.28, p=.21	-0.39, p=.70
FEV1/FVC ratio	64.14 ± 19.28	62.77 ± 20.79	65.65 ± 17.88	63.50 ± 33.23	0.48, p=.64	0.05, p=.96
GOLD stage						
Stage 1, 2	33 (78.6%)	17 (77.3%)	16 (80%)	1 (50.0%)		
Stage 3	9 (21.4%)	5 (22.7%)	4 (20%)	1 (50.0%)	0.05, p=1.00	0.89, p=.41
Duration of disease (years)	6.93 ± 6.99 (1-32)	7.77 ± 6.63	6.00 ± 7.42	12.00 ± 7.07	-0.82, p=.42	-1.00, p=.32
Comorbidities						
< 2	12 (28.6%)	4 (18.2%)	8 (40.0%)	1 (50.0%)		
≥ 2	30 (71.4%)	18 (81.8%)	12 (60.0%)	1 (50.0%)	2.44, p=.18	0.42, p=.51
Hospitalization during last year due to exacerbation (yes)	6 (14.3%)	2 (9.1%)	4 (20.0%)	0 (0.0%)	1.02, p=.40	0.33, p=1.00

COPD

ED visits during last year due to exacerbation (yes)	4 (9.5%)	2 (9.1%)	2 (10.0%)	0 (0.0%)	0.01, p=1.00	0.21, p=1.00
Education for symptom management	3 (7.1%)	1 (4.5%)	2 (10.0%)	0 (0.0%)	0.47, p=.60	0.15, p=1.00

SD; standard deviation, FEV1; forced expiratory volume in 1 second, FVC; forced vital capacity, GOLD; global initiatives for chronic obstructive lung disease, ED; emergency department

COPD

COPD

Table 3; Comparison of outcome variables between 2 groups

		Experimental group (n=22, 52.4%)	Control group (n=20, 47.6%)	Between group comparison	Between group comparison of change score
		Mean ± SD; Frequency (Percentage)		p-value	p-value
Self-care behavior	Baseline	112.91 ± 13.34	106.05 ± 14.79	.12	
	6 months	122.32 ± 12.23*	106.70 ± 18.47	.01	.05
Exercise capacity (6MWT distance in meter)	Baseline	378.32 ± 96.96	398.10 ± 78.67	.48	
	6 months	433.23 ± 107.23*	437.60 ± 83.62	.89	.63
Exercise (min/week)	Baseline	215.00 ± 225.51	144.37 ± 129.06	.35	
	6 months	267.73 ± 449.96	162.50 ± 212.33	.24	.80
Physical activity					
Total activity count/ wear time	Baseline	215.64 ± 103.16	258.85 ± 105.73	.19	
	6 months	275.09 ± 99.79*	258.59 ± 111.47	.62	.01
Sedentary activity % time	Baseline	.79 ± .10	.77 ± .08	.39	

COPD					
		6 months	.75 ± .08	.77 ± .08	.38	.07
	LPA % time	Baseline	.18 ± .09	.20 ± .06	.49	
		6 months	.21 ± .08	.19 ± .06	.40	.17
	MVPA % time	Baseline	.03 ± .02	.04 ± .02	.35	
		6 months	.05 ± .03*	.04 ± .03	.70	.04
	Daily step count	Baseline	5223.68 ± 2899.61	6756.26 ± 2978.77	.10	
		6 months	6546.77 ± 2354.43*	6890.39 ± 2967.73	.68	.06
Symptom						
	Dyspnea from UCSD-SOB	Baseline	21.18 ± 16.05	19.25 ± 13.83	.68	
		6 months	21.45 ± 17.78	19.70 ± 14.34	.73	.97
	Tension-anxiety from POMS	Baseline	4.86 ± 2.64	5.75 ± 4.29	.42	
		6 months	5.23 ± 3.19	5.80 ± 4.61	.64	.73
	Depression from POMS	Baseline	3.55 ± 2.69	5.20 ± 5.46	.21	
		6 months	3.68 ± 3.29	5.45 ± 6.89	.29	.91
Health related quality of life						
	PCS	Baseline	43.43 ± 9.00	46.36 ± 5.58	.22	
		6 months	43.94 ± 8.97	44.95 ± 5.95	.67	.36

COPD

MCS	Baseline	51.62 ± 8.71	52.13 ± 8.49	.85	
	6 months	50.10 ± 8.33	49.03 ± 11.02	.73	.60
Healthcare use due to exacerbation for 6 months					
ED use		1 (4.5%)	0 (0%)	1.00	
Hospitalization		2 (9.1%)	2 (10.0%)	1.00	
Outpatient clinics		3 (13.6%)	1 (5.0%)	.61	
Self-efficacy					
SEMCD	Baseline	6.71 ± 1.93	6.47 ± 1.64	.66	
	6 months	6.89 ± 1.75	6.69 ± 2.26	.75	.93
Self-efficacy for managing dyspnea	Baseline	6.59 ± 2.21	6.40 ± 2.10	.78	
	6 months	6.73 ± 2.10	6.85 ± 2.06	.85	.53
Self-efficacy for managing exacerbation	Baseline	6.68 ± 1.94	6.20 ± 2.24	.46	
	6 months	6.95 ± 2.01	6.75 ± 1.97	.74	.67
Self-efficacy for maintaining	Baseline	7.45 ± 1.50	6.90 ± 2.05	.32	

COPD					
exercise					
	6 months	7.77 ± 1.31*	6.75 ± 2.29	.08	.46
Self-efficacy for increasing physical activity	Baseline	6.91 ± 2.14	6.90 ± 1.71	.99	
	6 months	7.91 ± 1.66*	6.75 ± 2.15	.06	.06
Self-efficacy for decreasing sedentary time	Baseline	7.18 ± 1.76	6.60 ± 2.09	.18	
	6 months	7.73 ± 1.42*	7.05 ± 1.76	.11	.86
Perception of control	Baseline	4.40 ± .96	4.33 ± 1.22	.83	
	6 months	4.75 ± .91	4.68 ± .97	.80	.99
Social support	Baseline	2.72 ± .85	2.53 ± .92	.49	
	6 months	2.73 ± .88	2.79 ± 1.21	.85	.34

SD; standard deviation, 6MWT; 6 minute walk test, sedentary activity % time; time spent in sedentary activity (minutes/day)/daily wear time for accelerometer, LPA; light physical activity, LPA % time; time spent in LPA (minutes/day)/daily wear time for accelerometer, MVPA; moderate to vigorous physical activity, MVPA % time; time spent in MVPA (minutes/day)/daily wear time for accelerometer, UCSD-SOB; University of California, San Diego Shortness of Breath Questionnaire, POMS; Profile of Mood States-Short Form, PCS; physical component subscale, MCS; mental component subscale, ED; emergency department, SEMCD; self-efficacy for managing chronic diseases 6-item scale.

*; p-value was less than .05 in comparison of variables between baseline and 6 month in each group.

COPD

Table 4; Usage statistics over 6 months in smartphone application in experimental group (n=22)

Usage parameter	Time	Mean ± SD Frequency
Symptom score entered (weekly)	1 month	3.47 ± 1.62
	2 month	3.09 ± 1.27
	3 month	3.10 ± 1.27
	4 month	3.09 ± 1.28
	5 month	3.32 ± 1.15
	6 month	3.46 ± .90
Exercise data entered (weekly)	1 month	3.44 ± 1.54
	2 month	3.22 ± 1.41
	3 month	3.09 ± 1.37
	4 month	3.23 ± 1.45
	5 month	3.36 ± 1.38
	6 month	3.46 ± 1.17
Symptom & healthcare use exception alerts	Over 6 months	75
Reinforcement text messages	Over 6 months	499
Reinforcement phone calls	Over 6 months	134

SD; standard deviation

Table 5; Satisfaction for program and support levels in 2 groups

Items (possible score; 0-100)	Experimental group (n=22)	Control group (n=20)	
	Mean ± SD	Mean ± SD	p-value
Satisfaction for program	94.55 ± 9.63	89.50 ± 10.50	.11
Support for disease management	95.91 ± 9.59	91.00 ± 13.34	.18

Support for symptom management	95.00 ± 9.64	91.00 ± 10.21	.20
Support for increasing physical activity and reducing sedentary time	93.18 ± 12.87	85.50 ± 13.95	.07

SD; standard deviation

Highlights

- Smartphone intervention is feasible for people with COPD.
- Structured education and exercise alone are not sufficient to change health behavior in people with COPD.
- Smartphone app-based self-management program can be used to effectively improve self-care behavior and physical activity in people with COPD.

Figure 1; Main directory & subdirectory of ‘symptom record’ and ‘exercise’ in smartphone app-based self-management program

Figure 2; Main directory & subdirectory of ‘education materials’ & ‘communication board’ in smartphone app-based self-management program

Figure 3; Modified CONSORT diagram showing flow of final sample (n=42)

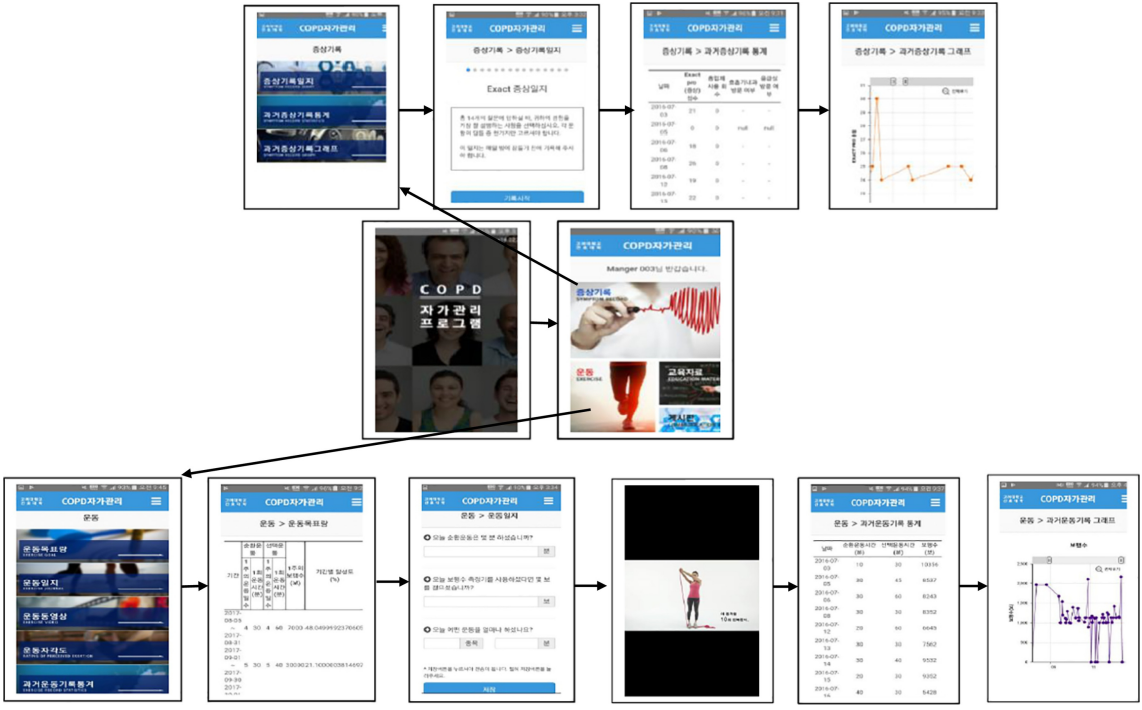
COPD자가관리
증상기록
증상기록일지
과거증상기록통계
과거증상기록그래프
Exact 증상일지
기록시작
증상기록 > 과거증상기록 통계
증상기록 > 과거증상기록 그래프
C O P D
자 가 관 리
프 로 그 램
Manger 003님 반갑습니다.
증상기록
운동
교육자료
운동
운동목표량
운동일지
운동영상
운동자세도
과거운동기록통계
운동 > 운동목표량
운동 > 운동일지
운동 > 과거운동기록 통계
운동 > 과거운동기록 그래프

Figure 1

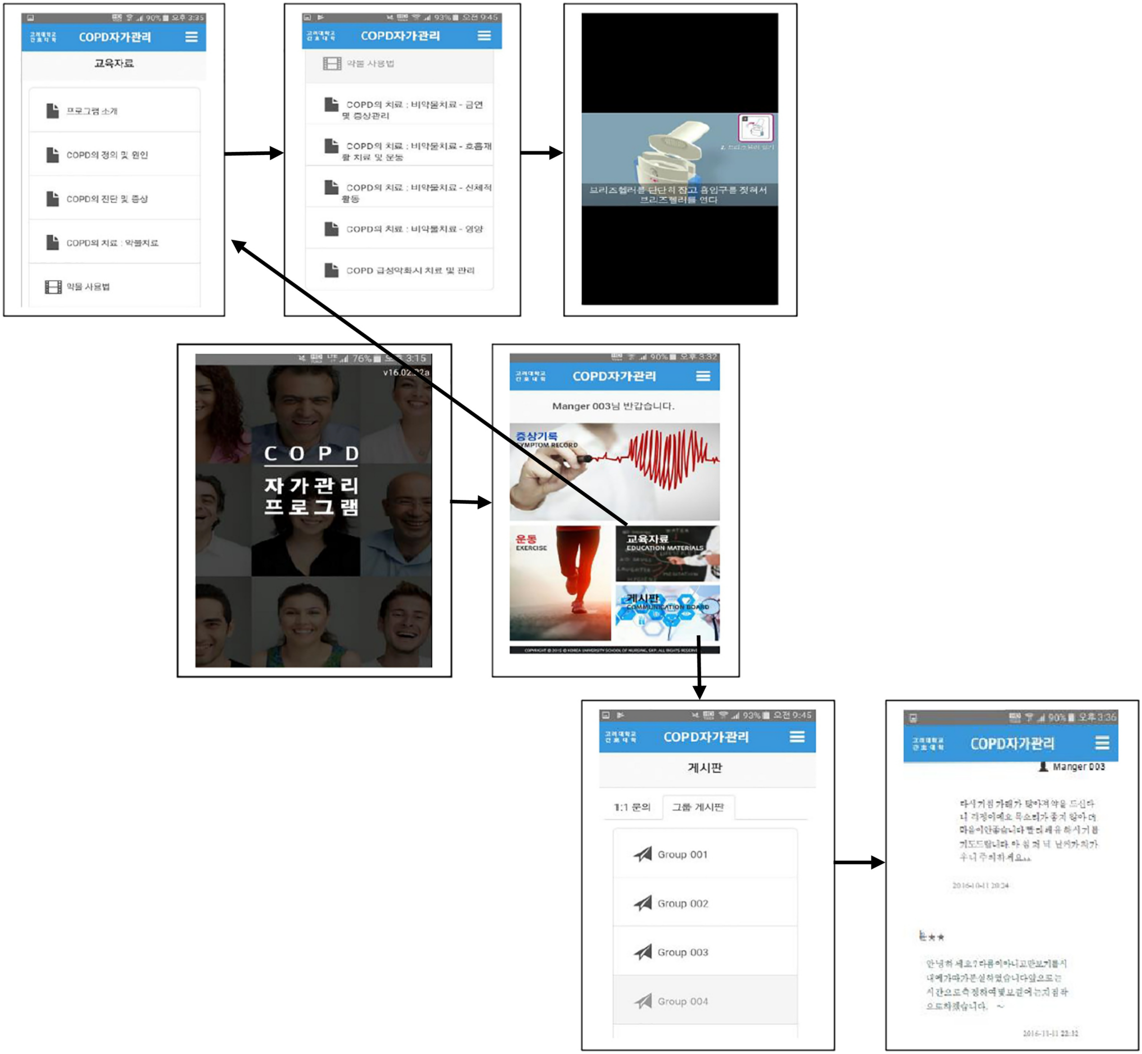
COPD자가관리
교육자료
프로그램 소개
COPD의 정의 및 원인
COPD의 진단 및 증상
COPD의 치료 : 약물치료
약물 사용법
COPD의 치료 : 비약물치료 - 금연 및 증상관리
COPD의 치료 : 비약물치료 - 호흡재활 치료 및 운동
COPD의 치료 : 비약물치료 - 신체적 활동
COPD의 치료 : 비약물치료 - 영양
COPD 급성악화시 치료 및 관리
브리즈헬러를 단단히 잡고 흡입구를 젖혀서 브리즈헬러를 연다
COPD
자가관리
프로그램
Manger 003님 반갑습니다.
증상기록
SYMPTOM RECORD
운동
EXERCISE
교육자료
EDUCATION MATERIALS
게시판
COMMUNICATION BOARD
게시판
1:1 문의
그룹 게시판
Group 001
Group 002
Group 003
Group 004
Manger 003

Figure 2

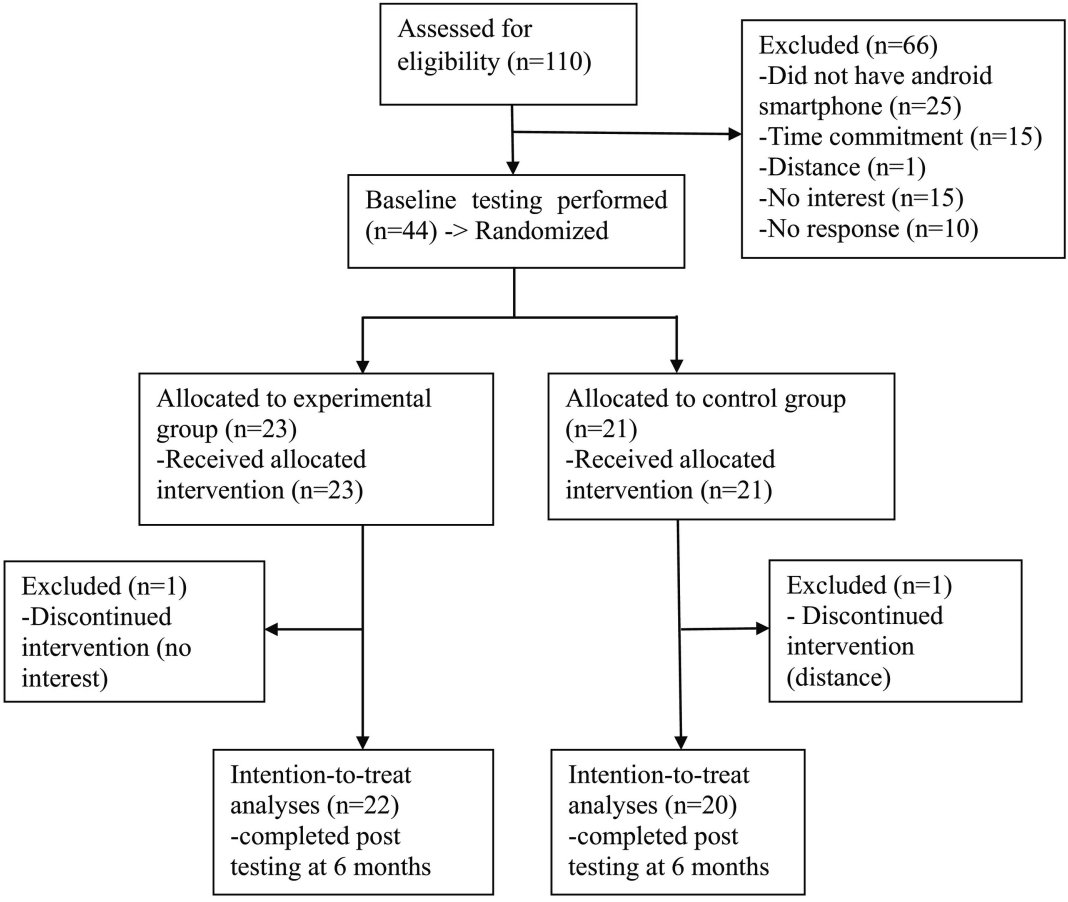
Assessed for eligibility (n=110)
Excluded (n=66)
-Did not have android smartphone (n=25)
-Time commitment (n=15)
-Distance (n=1)
-No interest (n=15)
-No response (n=10)
Baseline testing performed (n=44) -> Randomized
Allocated to experimental group (n=23)
-Received allocated intervention (n=23)
Allocated to control group (n=21)
-Received allocated intervention (n=21)
Excluded (n=1)
-Discontinued intervention (no interest)
Excluded (n=1)
- Discontinued intervention (distance)
Intention-to-treat analyses (n=22)
-completed post testing at 6 months
Intention-to-treat analyses (n=20)
-completed post testing at 6 months

Figure 3