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Institute of Nursing Research
College of Nursing, Korea University

발 간 사

서 문 경 애
간호학연구소장

안녕하십니까?

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Development and Effects of College-Based Lifestyle Modification Program for Menstrual Health of Young Adult Women with Irregular Menses: A Randomized Controlled Trial

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Introduction

Irregular menstruation is a characterized abnormal uterine bleeding (AUB) together with unpredictable menstrual volume, and the regularity of menstruation has been taken as an indicator of women's health [1]. A regular menstrual cycle demonstrates a normal sex hormone profile and functioning of reproductive organs, whereas irregularity may suggest a dysfunctional sex hormone profile or disorder of reproductive organs [2].

AUB appearing in the early stage of adulthood comprising the period from puberty to ages before 30 (young adult women) is involved with diverse factors; among them, ovulatory dysfunction is dominant, and the bleeding patterns can range from amenorrhea to irregular heavy menstrual bleeding [1]. Ovulatory dysfunction in young adult women is mostly a result of immaturity or temporary/chronic disturbances of the hypothalamic - pituitary - ovarian axis (HPO axis) [1]. The temporary or chronic disorder in the HPO axis is associated with androgen excess syndrome (ex. polycystic ovary syndrome; PCOS), hypothalamic dysfunction (due to eating disorders, weight loss and dieting, obesity, excessive physical exercise, poor nutrition, alcohol and drug abuse, or stress), thyroid diseases, and so on [1,3].

According to a study investigating causes about secondary amenorrhea in one hospital from 1998 to 2008, PCOS, body weight, and stress occupied the dominance of 3/4 of entire causes [4]. PCOS increases the risk of obesity, dyslipidemia, type 2 diabetes mellitus, and cardiovascular diseases in addition to the reproductive problems such as infertility resulting from

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ovulatory dysfunction, endometrial hyperplasia, and endometrial cancer [5,6]. The three main criteria for PCOS diagnostics are clinical/biochemical hyperandrogenism, menstrual dysfunction suggesting oligo-ovulation or anovulation, and polycystic ovary [3]. However, in 2012, the criteria of insulin resistance and metabolic syndrome were newly added to the standards, thereby enabling the presentation of four phenotypes of PCOS. The phenotypes demonstrate that PCOS is heterogeneous based on genetic background or ethnicity and can be influenced by the individual's lifestyle [6].

The eating disorders that are frequently observable from women in puberty/early adulthood also cause menstrual disorders such as amenorrhea or irregular menstruation [7]. Women with low body weight who suffer anorexia nervosa manifest behaviors of restrictive eating and women with normal body weight suffering bulimia nervosa demonstrate compensatory behaviors of binge eating with purging [7]. As result, factors such as rapid loss of body weight, low body weight, overweight, eating behaviors, and subsequent problems related with deficiency of nutrient intake or lifestyle can be associated with menstrual disorder.

Furthermore, previous studies that have investigated the causes of irregular menstruation showed results suggesting the relationship between irregular menstruation and individual lifestyles such as body mass index (BMI), ratio of body fat, perceived stress, drinking, and smoking. For instance, in the study that analyzed the factors associated with irregular menstruation of women of the age over 19 years in the data of the Korea National Health and Nutrition Examination Survey (KNHANES) conducted from 2007 to 2014, smoking, obesity, and stress were reported as relevant factors to irregular menstruation [8]. In addition, in the study that analyzed the factors relevant to irregular menstruation from 3194 Korean women between 19 - 40 years in the fifth KNHANES (2010 - 2012), perceived stress and BMI were reported as factors significantly relevant to irregular menstruation [2].

In the study conducted with 2613 Danish women from 18 to 40 years, low level of physical activities and excessive drinking appeared related to the increase of irregular menstruation [9]. The women who exhibited behaviors of lifetime binge eating showed higher frequency of amenorrhea or oligomenorrhea than women with no binge eating behaviors [10]. Additionally, in the longitudinal study that traced menstruation conducted for one year for 54 women who restored their body weight of BMIs over 18.5 at the time of discharge from hospitals after treatment of anorexia nervosa, 35.2% were reported with resumption of menstruation; the ratio of body fat was reported as a major predictive factor of the resumption of menstruation [11]. In addition, women with insufficient sleep were at increased risk of menstrual disturbances and insulin resistance [12].

In short, previous studies have primarily suggested an approach to control individual lifestyles such as BMI, ratio of body fat, smoking/drinking, physical activities/exercises, stress, dietary uptake, and sleep to improve menstrual health for women in their puberty/early adulthood suffering from amenorrhea or oligomenorrhea.

In the meantime, intervention studies based on modified lifestyle including exercises and dietary control for women suffering irregular menstruation such as amenorrhea or oligomenorrhea were mostly conducted for obese or overweight women diagnosed

with PCOS [13]. Little attention has been given to non-overweight women with PCOS [14] or for women only having problems of irregular and infrequent menstruation such as amenorrhea or secondary oligo-menorrhea in healthy population. In particular, it is unknown whether modified lifestyle behaviors can lead to improved biochemical androgenic and metabolic indicators in these women with irregular and infrequent menstruation.

To fill the gaps, this study first intended for the development of the 'College-based Lifestyle Modification Program (College-based LMP)' for the menstrual health of young adult women, who are experiencing irregular menstruation such as amenorrhea or oligomenorrhea. Second, the developed College-based LMP was applied to young adult women experiencing irregular menstruation to verify the effects of improving menstrual health. Accordingly, the hypotheses of this study to evaluate the effects of the developed College-based LMP, were as follows:

1. There will be differences in variables of primary outcome (menstrual cycle index－MCI), sex hormone-binding globulin (SHBG), and androgenic profile) between the experimental group who were provided with College-based LMP and the control group.

2. There will be differences in the variables of outcome (premenstrual symptoms－PMS), menstrual volume, glycemic parameters, sleep duration, perceived stress and body composition parameters, and nutrients intake) between the experimental group and control group.

Methods

2.1. Study Design

The study intended to develop a College-based LMP for healthy menstruation of young adult women with irregular menstruation including secondary amenorrhea and oligomenorrhea, and for the verification of its effects by randomized controlled trial (RCT).

2.2. Setting and Samples

This study's subjects were selected among 121 female students in the undergraduate and graduate school of K-University from a study conducted in 2017 [15]. The selection criteria were female students who reported irregular menstruation and menstruating less than 10 times in a year. Exclusion criteria were female students taking oral contraceptive pills (estrogen, progestin) or other drugs associated with menstrual disorder, or those under pertinent care.

The sample size was estimated with previous study [16]. The study was done for females with PCOS and compared its effects between the group taking metformin and the group applying a lifestyle modification program. In the previous study, the MCI changes (baseline MCI: 0.330 ± 0.194; at six months MCI: 0.706 ± 0.097) were reported from the group applying the lifestyle modification program. On this result basis, the effect size 1.0 was applied to this study. Thereby, the number of participants was calculated as 34 subjects based on an effect size 1.0, significance level (α) of 0.05, and power (1-β) of 0.80 by G*power 3.1.9.2. (Heinrich Heine University, Dusseldorf, Germany).

However, the number of participants was determined as 46 subjects, comprising 23 as per the experimental and control group, by considering the possible drop out due to the long period (six months). The randomized assignment was done by simple randomization using the random table containing

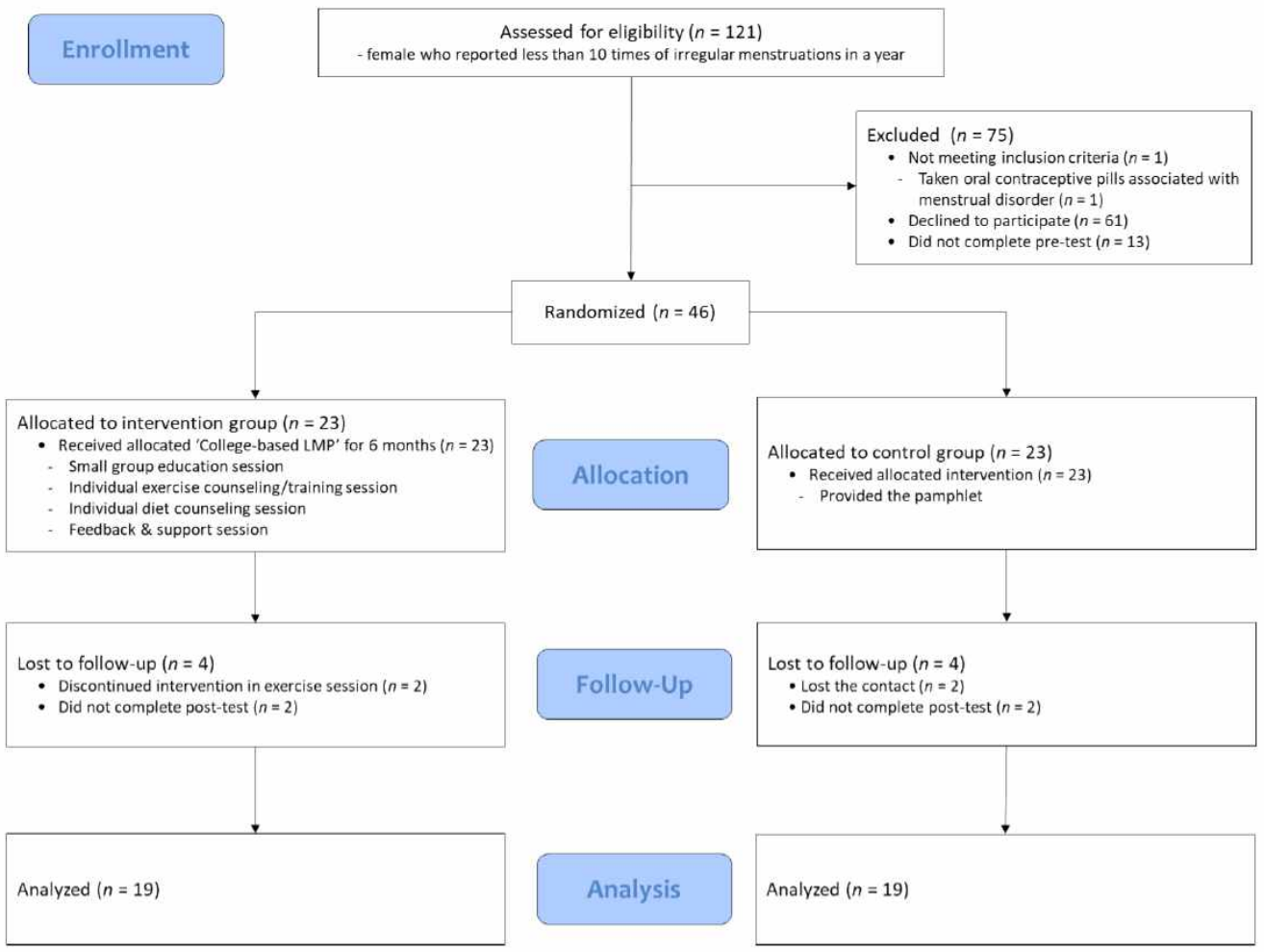

Figure 1. Participant flow diagram

Note. College-based LMP = College-based Lifestyle Modification Program.

individual IDs, which were allocated on completion of pre-test conducted before the application of intervention. Intervention allocation was not concealed for participants because of the nature of the program. The final analysis included 38 participants, comprising 19 women in each group. Four participants in each group quit their participation in exercises during intervention and were absent from the post-test (Figure 1).

2.3 Ethical Consideration

This study was approved by the Institutional Review Board (IRB) of the university where the researcher served (IRB No. 1040548-KU-IRB-18-83-A-1). The participants, who agreed to participate in the study, were provided with an informed document about the purposes of the study, utilization of collected data, risk/benefit on participation, confidentiality of personal information, procedures for storing and destroying questionnaire/samples after experiment, and the right to withdraw from the at study anytime. Their consent on participating in the study was voluntarily signed by participants. In addition, the explanations on securing the anonymity of participants, and the usage of data restricted to purposes of research were provided with all the

procedures complying with regulations of KUIRB. The participants in the control group, who were restricted to participation in the College-based LMP, were provided with a pamphlet ('Healthy menstruation and lifestyle') after pre-test. After post-test, they were provided with a nutrient intake evaluation and the results of the blood examination.

2.4. Measuremnets and Instruments

2.4.1. Primary outcome variables

MCI: In this study, MCI was defined as a ratio, the number of menstruations during the experiment (six months) divided by six. A ratio close to one implies the menstruation occurs frequently.

SHBG & Androgenic Profile: The total testosterone (T) and SHBG were measured through blood examination. Thereafter, the free androgen index (FAI) was calculated by a formula consisting of T and SHBG [FAI = T (nmol/L) * 100/SHBG (nmol/L)]. Normal ranges of SHBG and T were distributed in the ranges of 32.40 - 128.0 nmol/L and 0.084 - 0.481 ng/mL, respectively; and the criteria for biochemical hyperandrogenism were either T ≥ 0.520 ng/mL or FAI ≥ 5.36 as presented in the previous study [15].

2.4.2..Outcome Variables

Menstrual volume: In this study, the modified pictorial blood assessment chart (PBAC) was employed to measure the menstrual volume. PBAC was designed to appraise the loss of menstrual blood in a previous study [15,17]. It visualizes the blood clots on a pad or tampon to record the amount of blood. The scale factors for the pad comprised of 'little' denoted by 1 point, 'ordinary' by 5 points, and very large' by 20 points, whereas the scale factors for the tampon comprised of 'little' denoted by 1 point, 'ordinary' by 5 points, and 'very large' by 10 points. The size of blood clots was analogized with the size of count where the 'little' was counted as 1 point while the 'large' counted as 5 points. The higher the total score implies a bigger volume of menstruation, a total score exceeding 100 points was defined as menorrhagia.

PMS: For the measurement of PMS, Daily Record of Severity of Problems (DRSP) was used [18,19]. DRSP was developed to discriminate PMS/ premenstrual dysphoric disorder (PMDD) of Diagnostic Statistical Manual-IV (DSM-IV). In this study, the Criteria A of DSRP consisting of 21 questions providing 11 domains for the assessment of PMS, which was used in the previous study [15], was used as it was in the retrospective measurement on the first day of menstruation. The scores of items were distributed in the range from 'no symptoms' of 1 point to 'very severe' of 6 points; a total score of over 50 points on 21 questions in Criteria A were interpreted as experiencing PMS. In this study, Cronbach's alpha representing internal consistency of 21 items in Criteria A was 0.93.

Glycemic parameters: The homeostatic model assessment-insulin resistance (HOMA-IR) was calculated using the formula [HOMA-IR = Insulin (μ U/mL) * FBS (mg/dL)/450]. Fasting blood sugar (FBS) and level of insulin were measured through blood examination. In this study, the normal ranges of FBS and insulin were 70 - 110 mg/dL and 2.6 - 24.9 μU/mL, respectively.

Body composition parameters: Body fat, muscle mass, ratio of body fat, and body weight were measured by the body composition analyzer (InBody 230, InBody, Seoul, Korea). At pre-test, the heights of the participants were also measured using the

measuring instrument of height (DS-102, Dong Sahn Jenix Co. Ltd., Seoul, Korea). According to the criteria presented by Korean Society for the Study of Obesity, we categorized BMI (kg/m2) less than 18.5 as underweight; 18.5 - 22.9 as normal; 23 - 24.9 as overweight; 25 - 29.9 as obese class I; and above 30.0 as obese class II.

Nutrients intake: A questionnaire designed to record the frequency of food intake was used for the calculation of nutrient intake. It was configured by referring to the 5th- and 7th Korea National Health and Nutrition Examination Survey (KNHANES); this was employed in a previous study [15] and applied in this study as is. It consists of 11 groups of foods (grains, beans, meats/eggs, fishes, vegetables, seaweeds, fruits, milk (products), beverage, alcoholic liquors and others), and the frequency of intake of foods was distinguished into nine categories: daily '3 ′ /'2 ′ /'1 ′ times, weekly '4~6 ′ /'2~3 ′ /'1 ′ times, monthly '2~3 ′ /'1 ′ times, and 'almost no intake'. In the category of 'fruits', the 'fruits of season' was distinguished additionally, and was provided with weight as it was included in the 7th KNHANES. The standard amount of each uptake of foods was specified, where the amount of 'little', 'ordinary', and 'plentiful' of foods were selected by participants whose weights thereof were granted as 0.5, 1, and 2, according to the database of CAN-Pro 5.0 (for Professionals).

Sleep duration/perceived stress: Sleep duration means the average sleeping hours per day, whereas perceived stress was defined as a degree of stress felt subjectively, which was measured based on the response to one question. The answers distributed in the range of 'none' of 1 point to 'very severe' of 6 points; the higher score point was interpreted as higher level of stress felt subjectively.

General characteristics: The questionnaire on the general characteristics of participants consisted of items on age, marital status, socioeconomic status, enrollment, and grade of university/graduate school, and the age of menarche.

2.5. Experiment Application and Data Collection

2.5.1. Pre-Experiment and Post-Experiment Data Collection

The pre-experiment data collection consisting of questionnaires, measurement of body composition, and blood examination were carried out from 11 June to 30 June 2018. The post-experiment data collection was performed from 26 December to 31 December 2018. The measurement of body composition and blood examination were conducted from 9 o'clock to noon, in the Health Center of K-University.

The data collection for the pre- and post-experiment was led by three researchers who were licensed nurses. The time needed for sessions of questionnaires, measurement of body composition, and blood examination was 20 to 30 min. Researchers who collected data did not become aware of which group the participants belonged to. The bloods collected from participants were refrigerated after centrifugation. For the analysis of blood, the bloods were transferred to and analyzed by the C-Medical Foundation directly in the afternoon of the day of blood collection.

2.5.2. College-Based LMP for Menstrual Health

College-based LMP for menstrual health was developed by the research team based on the results of studies in the literature associated with internal- and external environmental factors (e.g., physical activity, fit body mass, diet, nutrients etc.) relevant to

aspects of menstruation cycle. The College-based LMP, preliminarily developed for healthy menstruation, was modified and supplemented upon completion of validation of the program through the advice of two specialists in the disciplines of physical education and nutrition. The finally elaborated College-based LMP comprised of four sessions (small group education, individual physical exercise counseling/ training, individual diet counseling, and feedback and support). The contents in each session are as follows:

First, the small group education session provided a small group of participants with education on the knowledge of menstruation to help them understand healthy menstruation. We developed a pamphlet entitled 'Healthy menstruation and lifestyle' for this session. Contents of the pamphlet included: 'Understanding of female reproductive organs', 'Ovulation and physiology of menstruation', 'What is heathy menstruation?', 'Issues on healthy menstruation', 'Health issues related with abnormal menses (particularly for irregular menses, oligomenorrhea or secondary amenorrhea)', 'Relationship between menstruation and lifestyle', and 'Lifestyle for menstrual health'.

Second, the session of 'Individual physical exercise counseling/training' intended for accomplishment of 'Fit body mass' was based on analyses of individual body composition parameters that were identified at pre-test. The physical exercise comprised of aerobic exercise using a treadmill and bicycle for 30 - 45 min, 3 - 4 times in a week, and anaerobic exercise to reinforce muscle power, which were selected by the preference of individuals. The fitness center, located around the university, was provided as a place for exercise; the individuals participated in exercises at their own preferred times.

Third, in the 'Individual diet counseling session', the participants were provided with counselling on the intake of optimal calorie and balanced nutrition. This was based on the result of analyses on the body composition parameters and nutrient intake of participants identified through pre-test in a previous study [15]. We developed the 'Diet counselling record' by individual. The title of the developed 'Diet counselling record' was 'What is the desirable nutrition for myself?' and was comprised of the following items: 'How is my body composition and BMI?', 'The intake and evaluation on nutrients for myself (29 nutrients: calorie, macronutrients, fat-soluble/water-soluble vitamins, macro/micro minerals)', and 'Recommended dietary intake (RDI)'.

Fourth, the feedback and support session provided the participants with rewards (complimentary mobile text and coupons) of positive feedback in cases of accomplishment of individual objectives by the degree of participation in individual exercises every month.

2.5.3. Experimental Application

The experimental group was provided with the applications of the following components in College-based LMP to improve the health of menstruation. In the small group education session, the participants were supposed to participate in a session at the available times of 10 A.M., 2 P.M., and 4 P.M. among the four days of 25, 26, 28, and 29 June, 2019 using the 'Healthy menstruation and lifestyle' pamphlet. The number of participants in the small group was 2 - 5 people and the session went for 40 - 50 min. A lecture room in K-University was provided for the session. The session of individual physical exercise counseling/training was carried out in the adjacent fitness center 3 - 4 times a week, with

a session going for 30 - 45 min for six months, thus supporting the sustainable participation in physical exercises of the participants through contract. The individual participant objectives about physical exercise were shared with specialists at the fitness center to be available for participants on request. The specialists advised and supervised the participants during exercise on an individual basis. The participants who participated in exercises 3 - 4 times every week were compensated with a monthly reward.

The session of individual diet counseling was performed individually based on the 'Diet counselling record' upon completion of the education of the small group. The session required 10 - 20 min of time and was conducted by the research director.

The participants in the control group were provided with the pamphlet, 'Healthy menstruation and lifestyle', which was used in the small group education session through online services after completion of the pre-test.

2.6. Data Analysis

The collected data were analyzed by the pc-SAS Program (Version 9.2, SAS Institute, Cary, NC, USA), while the analysis of nutrient intake was undertaken by the CAN-Pro 5.0 (for Professionals; The Korean Nutrition Society, Seoul, Korea). Analysis followed per protocol analysis.

The assumption of the normal distribution of variables were tested by the Shapiro - Wilks test, and for the cases that failed to fulfill the assumption, the nonparametric test was carried out. To identify the pre- and post-test intergroup- and intragroup differences in MCI, SHBG, androgenic profile, glycemic parameters, sleep duration, perceived stress, body composition parameters, and general characteristics, the Wilcoxon rank sum test was used. The t-test and ANCOVA were carried out for the analysis of pre- and post-test intragroup- and intergroup differences in PMS between the experimental- and control group. To attain the descriptions and distributive characteristics of MCI, SHBG, androgenic profile, PMS, menstrual volume, sleep duration, perceived stress, glycemic parameters, body composition parameters, nutrient intake, and general characteristics of participants in the experimental and control group, descriptive statistics such as frequency, percentage, mean, and standard deviation of variables were used. For the analysis on the difference between the experimental and control group, the t-test, Wilcoxon rank sum test, and Fisher-exact test were conducted.

Results

3.1. Similarity between Experimental and Control Group

No statistically significant differences were found at baseline scores between the experimental- and control group in variables as follows: (a) general characteristics (age, socioeconomic level, marital status, occupation, age of menarche); (b) variables of primary outcome－MCI, SHBG, androgenic profile (T, FAI); and (c) variables of outcome－PMS, menstrual volume, glycemic parameters (FBS, Insulin, HOMA-IR), sleep duration, perceived stress, body composition parameter (body fat mass, muscle mass, ratio of body fat, BMI), nutrients intake; (Table 1 - 5).

3.2. Primary Outcome Analysis

The results of the primary outcome analysis are as summarized in Table 2.

The score of MCI increased 0.49 to 0.65 in the

experimental group, and 0.54 to 0.74 in control group, respectively, after intervention (after six months). MCI score of the control group appeared lower than the experimental group in post-test, however, it showed no statistical significance (Z = −1.07, p = 0.285).

The level of SHBG increased 63.05 nmol/L to 80.67 nmol/L in the experimental group, and 77.04 nmol/L to 82.45 nmol/L in the control group. The level of increase regarding SHBG appeared larger in the experimental group than in the control group. However, the post measurement of SHBG exhibited no significant differences between the two groups (Z = 0.00, p < 0.999).

Among the androgenic profiles, the level of T in the experimental group varied from 0.38 ng/mL to 0.40 ng/mL, whereas that of the control group changed from 0.44 ng/mL to 0.43 ng/mL; the post measurement of T of the experimental group appeared lower than that of the control group, however, no significant differences were found (Z = 0.07, p = 0.942). Regarding FAI, the score of FAI in the experimental group exhibited a slight increase from

Table 1. General characteristics in the experimental and control groups at baseline (n = 38).

Variables	Experimental Group (n = 19)		Control group (n = 19)		X^2 or Z (p)
	Mean ± SD [Range]	n (%)	Mean ± SD [Range]	n (%)	
Age (year)	22.37 ± 2.50		21.74 ± 2.51		0.84 (0.401) [b]
Socioeconomic status					
High		3 (15.8)		3 (15.8)	
Middle		15 (79.0)		15 (79.0)	0.00 (<0.999) [a]
Low		1 (5.3)		1 (5.3)	
Educational status					
Undergraduate student		16 (84.2)		16 (84.2)	0.00 (<0.999) [a]
Graduate student		3 (15.8)		3 (15.8)	
Menarche age (yr)	12.45 ± 1.44 [11.0 – 17.0]		12.97 ± 1.99 [11.0 – 17.0]		−0.49 (0.622) [b]

[a] Fisher exact test; [b] Wilcoxon rank sum test.

Table 2. Comparison of primary outcome variables in the experimental and control groups (n = 38).

Variables		Experimental Group (n = 19)	Control Group (n = 19)	Z (p)
		Mean ± SD	Mean ± SD	
MCI				
	Pre-test	0.49 ± 0.23	0.54 ± 0.23	−0.64 (0.519) [a]
	Post-test	0.65 ± 0.25	0.74 ± 0.26	−1.07 (0.285) [a]
SHBG				
	Pre-test	63.05 ± 25.27	77.04 ± 58.86	−0.26 (0.793)
	Post-test	80.67 ± 60.22	82.45 ± 58.24	0.00 (<0.999)
Androgenic profile				
T (ng/mL)	Pre-test	0.38 ± 0.19	0.44 ± 0.29	−0.69 (0.493)
	Post-test	0.40 ± 0.20	0.43 ± 0.23	0.07 (0.942)
FAI	Pre-test	2.54 ± 1.92	3.29 ± 3.05	−0.32 (0.748)
	Post-test	2.70 ± 2.37	3.13 ± 3.18	−0.06 (0.953)

[a] Wilcoxon rank sum test; FAI = Free androgen index; MCI = Menstrual cycle index; SHBG = Sex hormone binding globulin; T = Testosterone.

Table 3. Comparison of premenstrual symptoms in the experimental and control groups (n = 38).

Categories (No of items)		Experimental Group (n = 19)	Control Group (n = 19)	t (p)	F (p) [a]
		Mean ± SD	Mean ± SD		
Felt depressed/hopeless/worthless (3)	Pre-test	6.11 ± 3.03	7.26 ± 4.01	−1.00 (0.322)	4.95 (0.033)
	Post-test	4.63 ± 1.57	7.28 ± 4.14	−2.54 (0.019)	
Anxious, tense, or on edge (1)	Pre-test	3.26 ± 1.59	3.42 ± 1.71	−0.29 (0.770)	5.82 (0.021)
	Post-test	1.95 ± 1.18	3.06 ± 1.59	−2.42 (0.021)	
Mood swings/Sensitive to rejection (2)	Pre-test	5.05 ± 2.82	6.05 ± 3.39	−0.99 (0.329)	1.30 (0.262)
	Post-test	3.74 ± 2.10	5.11 ± 2.95	−1.64 (0.110)	
Felt Angry, irritable/Conflicts or problems with people (2)	Pre-test	4.58 ± 1.92	5.53 ± 2.84	−1.21 (0.236)	0.03 (0.861)
	Post-test	4.37 ± 2.14	5.00 ± 2.87	−0.76 (0.227)	
Less interest in usual activity (1)	Pre-test	3.05 ± 1.58	2.63 ± 1.61	0.81 (0.421)	1.49 (0.231)
	Post-test	2.68 ± 1.57	3.00 ± 1.57	−0.61 (0.544)	
Difficulty concentrating (1)	Pre-test	3.11 ± 1.68	2.53 ± 1.39	1.16 (0.255)	0.44 (0.512)
	Post-test	2.74 ± 1.52	2.72 ± 1.49	0.03 (0.977)	
Lethargic, tired, fatigued or lack of energy (1)	Pre-test	3.58 ± 1.71	3.68 ± 1.49	−0.20 (0.841)	1.05 (0.312)
	Post-test	3.16 ± 1.39	3.61 ± 1.46	−0.97 (0.339)	
Increased appetite/Cravings for specific foods (2)	Pre-test	5.42 ± 2.85	5.53 ± 2.87	−0.11 (0.910)	0.80 (0.376)
	Post-test	5.16 ± 2.59	4.39 ± 2.87	0.86 (0.398)	
Slept more/Trouble sleeping (2)	Pre-test	4.84 ± 2.61	5.42 ± 3.24	−0.61 (0.548)	0.63 (0.433)
	Post-test	4.42 ± 2.55	5.17 ± 2.23	−0.95 (0.351)	
Overwhelmed, cannot cope/Out of control (2)	Pre-test	3.11 ± 2.05	3.47 ± 2.46	−0.50 (0.619)	1.66 (0.207)
	Post-test	2.58 ± 1.17	3.50 ± 2.62	−1.37 (0.184)	
Physical symptoms (4)	Pre-test	11.16 ± 4.25	11.68 ± 4.24	−0.38 (0.705)	1.94 (0.172)
	Post-test	8.89 ± 4.08	10.83 ± 4.34	−1.40 (0.170)	
Total (21)	Pre-test	53.11 ± 19.03	57.21 ± 20.99	−0.63 (0.532)	1.81 (0.188)
	Post-test	44.32 ± 16.83	53.67 ± 21.24	−1.49 (0.146)	

[a] Analysis of covariance (ANCOVA).

2.54 to 2.70, while the score in the control group dropped slightly from 3.29 to 3.13; the post score of FAI in the experimental group appeared slightly lower than that of the control group, however, it showed no significant differences (Z = −0.06, p = 0.953).

3.3. Outcome Analysis

Regarding PMS, the participants in the experimental group showed a decrease from 53.11 to 44.32, whereas the participants in the control group exhibited a decrease from 57.21 to 53.67; the level of decrease appeared greater in the experimental group, however, no significant differences between the two groups were found from the analysis of covariance taken pre-scores as covariate (F = 1.81, p = 0.188). Among the 11 domains of PMS, the depression scores in the experimental group showed a decrease in score from 6.11 to 4.63, whereas the score in the control group showed slight increase from 7.26 to 7.28; the difference between scores of the two groups appeared statistically significant in the analysis of covariance taken pre-scores as covariate (F = 4.95, p = 0.033). In

the domain of anxiety, both the experimental- and control group commonly showed decreases from 3.26 to 1.95 (experimental group) and 3.42 to 3.06 (control group); the level of decrease in the experimental group appeared greater than that in the control group, and the results in the analysis of covariance taken pre-scores as covariate showed statistical significance in the difference between scores (F = 5.82, p = 0.021). The rest domains showed no statistically significant differences between the two groups (Table 3).

Regarding the menstrual volume, the participants in the experimental group showed a decrease from 109.11 to 106.37 while the participants in the control group showed an increase from 108.53 to 117.42; however, no statistically significant differences in menstrual volumes before and after the experiment between two groups were found (z = 0.88, p = 0.381) (Table 4).

Regarding the glycemic parameters, the post-test FBS (z = −0.66, p = 0.511), insulin (z = 0.26, p = 0.793), and HOMA-IR (z = 0.15, p = 0.884) all showed no statistically significant differences between the two groups. The analysis on the differences between pre- and post-test scores showed no statistically significant

Table 4. Comparison of body composition parameters, glycemic parameters, perceived stress, sleeping duration, and menstrual volume in the experimental and control groups (n = 38).

Variables		Experimental Group (n = 19)	Control Group (n = 19)	X^2 or Z (p)
		Mean ± SD	Mean ± SD	
Body composition parameters				
Body fat mass (kg)	Pre-test	17.44 ± 5.24	16.24 ± 5.52	1.18 (0.237)
	Post-test	18.32 ± 4.88	17.25 ± 5.92	1.22 (0.224)
Muscle mass (kg)	Pre-test	20.89 ± 1.83	20.32 ± 2.22	0.89 (0.373)
	Post-test	20.80 ± 1.82	20.38 ± 2.12	0.49 (0.627)
BMI (kg/m²)	Pre-test	21.25 ± 2.87	20.67 ± 2.41	0.95 (0.342)
	Post-test	21.56 ± 2.81	21.11 ± 2.72	0.93 (0.354)
Ratio of body fat (%)	Pre-test	30.49 ± 5.73	29.61 ± 6.94	0.73 (0.465)
	Post-test	31.75 ± 5.60	30.75 ± 7.21	0.79 (0.430)
Glycemic parameters				
FBS (mg/dL)	Pre-test	89.95 ± 7.28	89.74 ± 8.19	0.29 (0.770)
	Post-test	90.05 ± 8.51	92.68 ± 6.36	−0.66 (0.511)
Insulin (μU/mL)	Pre-test	7.50 ± 6.35	6.83 ± 4.84	0.23 (0.815)
	Post-test	7.91 ± 5.47	7.78 ± 5.40	0.26 (0.793)
HOMA-IR	Pre-test	1.72 ± 1.64	1.56 ± 1.21	0.20 (0.838)
	Post-test	1.77 ± 1.26	1.83 ± 1.34	0.15 (0.884)
Perceived stress				
	Pre-test	3.58 ± 1.07	3.89 ± 0.73	−0.87 (0.386)
	Post-test	3.32 ± 1.00	4.00 ± 1.41	−1.77 (0.078)
Sleep duration (hours)				
	Pre-test	6.21 ± 1.07	6.37 ± 1.34	−0.07 (0.941)
	Post-test	6.63 ± 1.05	5.74 ± 1.38	2.23 (0.026)
Menstrual volume				
	Pre-test	109.11 ± 81.83	108.53 ± 111.21	0.42 (0.672) [a]
	Post-test	106.37 ± 68.67	117.42 ± 171.33	0.88 (0.381) [a]

[a] Wilcoxon rank sum test; BMI = Body mass index; FBS = Fasting blood sugar; HOMA-IR = Homeostasis model assessment—insulin resistance.

Table 5. Comparison of nutrients in the experimental and control groups (n = 38).

Nutrients		Experimental Group (n = 19)	Control group (n = 19)	Z (p)
		Mean ± SD	Mean ± SD	
Calorie (kcal)	Pre-test	1553.77 ± 636.68	1591.37 ± 614.67	0.90 (0.365)
	Post-test	1378.45 ± 576.73	1456.64 ± 780.77	1.26 (0.209)
Carbohydrate (gm)	Pre-test	231.42 ± 100.95	242.49 ± 105.08	0.58 (0.559)
	Post-test	214.81 ± 104.75	211.17 ± 114.76	1.11 (0.267)
Fat (gm)	Pre-test	41.36 ± 24.07	40.19 ± 17.30	0.64 (0.521)
	Post-test	34.11 ± 13.46	41.83 ± 26.98	0.38 (0.704)
Protein (gm)	Pre-test	61.93 ± 29.23	61.78 ± 28.63	1.08 (0.280)
	Post-test	50.40 ± 20.30	58.50 ± 38.11	1.11 (0.267)
Fiber (gm)	Pre-test	20.34 ± 14.74	19.23 ± 14.56	1.11 (0.267)
	Post-test	13.60 ± 6.18	17.69 ± 11.64	0.47 (0.640)
Vitamin D (μg)	Pre-test	4.05 ± 2.99	4.40 ± 3.45	1.28 (0.199)
	Post-test	2.79 ± 1.73	2.84 ± 1.54	0.99 (0.321)
Folic acid (μg)	Pre-test	483.46 ± 301.23	463.17 ± 313.81	1.37 (0.170)
	Post-test	322.75 ± 102.26	417.24 ± 280.71	0.53 (0.599)
Calcium (mg)	Pre-test	582.71 ± 405.53	562.09 ± 430.70	2.01 (0.044)
	Post-test	345.41 ± 190.38	373.56 ± 279.24	1.51 (0.129)
Phosphorus (mg)	Pre-test	1044.16 ± 569.62	1017.85 ± 567.26	1.25 (0.217)
	Post-test	784.37 ± 321.77	861.81 ± 537.71	1.26 (0.209)
Sodium (mg)	Pre-test	1614.34 ± 868.01	1577.39 ± 688.19	0.15 (0.884)
	Post-test	1408.73 ± 617.77	1501.22 ± 921.96	0.64 (0.521)
Magnesium (mg)	Pre-test	95.95 ± 66.18	98.50 ± 76.57	1.28 (0.199)
	Post-test	64.25 ± 36.85	91.10 ± 60.95	0.09 (0.930)
Iron (mg)	Pre-test	13.71 ± 8.31	13.20 ± 7.90	1.28 (0.199)
	Post-test	10.02± 4.08	11.64 ± 6.87	1.14 (0.255)
Selenium (μg)	Pre-test	65.79 ± 51.14	61.90 ± 41.92	1.05 (0.293)
	Post-test	44.47 ± 21.54	52.07 ± 29.97	0.70 (0.484)
Omega-3	Pre-test	0.56 ± 0.46	0.76 ± 0.87	−0.38 (0.704)
	Post-test	0.75 ± 0.79	0.85 ± 0.93	−0.50 (0.620)
Omega-6	Pre-test	3.33 ± 2.86	3.90 ± 3.00	−0.35 (0.726)
	Post-test	4.49 ± 5.18	3.97 ± 4.58	0.29 (0.770)
Chromium picolinate (μg)	Pre-test	3.91 ± 2.93	5.10 ± 3.26	0.56 (0.579)
	Post-test	4.40 ± 3.24	3.40 ± 2.67	1.71 (0.088)

differences in each group except the FBS of the control group (Table 4).

The experimental group's sleep duration increased from 6.21 h to 6.63 h, while it decreased from 6.37 h to 5.74 in the control group; the difference in sleep duration between the two groups was statistically significant (z = 2.23, p = 0.026). Perceived stress of participants in the experimental group decreased from 3.58 to 3.32 and increased from 3.89 to 4.00 in the control group. However, the difference between the groups was statistically insignificant (z = −1.77, p = 0.078) (Table 4).

Regarding body composition parameters, the body fat mass (z = 1.22, p = 0.224), muscle mass (z = 0.49, p = 0.627), BMI (z = 0.93, p = 0.354), and ratio of body fat (z = 0.79, p = 0.430) of the participants

showed no statistically significant differences between the two groups after intervention (Table 4).

In the analysis of pre- and post-test scores of nutrient intake, all 16 nutrients showed no statistically significant differences between the two groups after intervention, and between pre- and post-test scores in each group (Table 5).

Discussion

In the study, the hypotheses, which stated that there will be differences in variables of primary outcome such as MCI, SHBG, T, and FAI between participants of the experimental group provided with College-based LMP and the control group upon completion of the trial after six months, were rejected with insignificant differences. That is, the positive effect of College-based LMP, which was defined as MCI, SHBG, T, and FAI to represent the improvement in menstrual health, were not identified.

These findings differ from those reported in previous studies. For example, in a study that carried out dietary control and physical exercises for four months for female of severe obesity suffering from PCOS, the results showed improvement in the level of total testosterone and SHBG [20]. In addition, there was the meta-analysis that reported the effect of lifestyle intervention including exercises and dietary control in overweight/obese females suffering from PCOS and significant positive effects regarding FSH, SHBG, total T, androstenedione, FAI, and Ferriman-Gallwey Score were shown. The subjects of the seven studies included in the analysis were also overweight/obese PCOS women with an average BMI of 26.8 to 40.4 [21]. In contrast, few studies have ever been carried out with women of normal body weight but suffering PCOS. In prior studies, the positive results of decreasing menstruation period from 46.1 days to 27.3 days from females in the experimental group were reported by the structured exercise that lasted for 8-weeks and applied to females of normal body weight suffering PCOS [14].

However, the participants in the present study were young adult women who reported experiences of irregular menstruation and oligomenorrhea less than 10 times a year with BMIs in the normal range; a mean value of 21.25 for the experimental group and 21.56 for the control group, distributed within the range 16.4 - 28.1. In this study, the number of subjects suspected to be suffering from PCOS was five in the experimental group and six in the control group; this was estimated based on the criteria (T > 0.520 ng/mL or FAI > 5.36) employed in previous study [15]; among them, two in the experimental group and three in the control group had overweight/obesity (BMI ≥ 23). Thus, there are limitations in comparing the results of the present study with the results of lifestyle modification for women with PCOS in the previous studies cited above.

Nonetheless, the results of analysis on the changes in MCI and SHBG, before and after six months of the trial between the experimental- and control group, showed a common increase of MCI from 0.49 to 0.65 and from 0.54 to 0.74, respectively. Regarding SHBG, the two groups appeared with a common increase of SHBG from 63.05 nmol/L to 80.67 nmol/L in the experimental group and from 77.04 nmol/L to 82.45 nmol/L in the control group. The College-based LMP in this study consisted of small group education participation, exercise, nutrition counseling, and feedback and support. Of these, the educational materials used for small group education

were provided to the experimental group at the time of participation in education, and to the control group by email. This may have a positive effect of improving menstrual health even though the control group did not directly participate in small group education, and this may cause an effect on the change in the positive direction of MCI or SHBG. However, in this study, individual nutrition counseling, which is a component of the program, was provided to the experimental group based on the individual dietary intake analysis data, but was not directly intervened by actual nutrition and dietary management. Moreover, since the subjects of this study were undergraduate or graduate students in early adulthood, it may be limited to apply them in conjunction with nutrition and dietary management in their lives. Therefore, further research is required to include specific methods and strategies to ensure that each component of the college-based LMP can be applied to real life.

This study used following variables of outcome to identify effects of College-based LMP, PMS, sleep duration, perceived stress, menstrual volume, glycemic parameter (FBS, Insulin, HOMA-IR), body composition parameters, and nutrient intake. Accordingly, we made the hypothesis that stated that there were differences in these variables between the experimental group who were provided with the College-based LMP and the control group after intervention (after six months). However, the differences appeared insignificant except for the partial domain of premenstrual symptoms (depression, anxiety) and sleep duration. Thus, these hypotheses, except for parts of premenstrual symptoms (depression, anxiety) and sleep duration, were rejected.

Regarding PMS, the score of the experimental group decreased from 53.11 to 44.32 while the score of the control group decreased from 57.21 to 53.67, showing a bigger decrease in the score of the experimental group, but indicating statistically insignificant variation. In the analysis of each domain of PMS, the experimental group showed significant decrease in two domains, the depression and anxiety, among 11 domains than those of the control group. This seems ascribable to the results of the composition of College-based LMP that consisted of exercises and dietary control intended for the improvement of menstrual health.

Sleep duration increased in the experimental group after intervention, whereas it appeared to decrease in the control group with the difference indicating statistical significance. One recent study reported that women who reported less than 6 h of sleep had significantly higher odds (OR = 2.1) of an abnormal menstrual cycle length (short or long), a significantly higher mean BMI, fasting insulin levels, and HOMA-IR than women with six or more hours of sleep [12]. In this regard, the increase in MCI in the experimental group and the control group after the experiment shown in this study may potentially suggest the relationship between sleep duration and MCI. Actually, in the experimental group, the association between MCI and sleep duration was significant ($r = 0.470$, $p = 0.042$). The perceived stress decreased in the experimental group, while it increased in the control group, but it was statistically insignificant ($t = -1.77$, $p = 0.078$).

Regarding menstrual volume, the experimental group manifested a decrease from 109.11 to 106.37, while it appeared to increase from 108.53 to 117.42 in the control group with the difference showing no statistical significance. The frequency of menorrhagia of young adult women participated in this study

appeared higher than 21.8% of Turkish female university students who participated in the study employing the PBAC, which was used in the present study [22]. Contrary to the cited study that studied ordinary population as subjects, in this study, the subjects consisted of women who reported irregular menstruation in the aspect of oligomenorrhea experiencing less than 10 times a year among an ordinary population of females in the early stage of adulthood; thus, the subjects participated in the present study may represent potential possibilities of unpredictable menorrhagia together with irregular menstruation.

Variables of glycemic parameters (FBS, insulin, HOMA-IR) and parameters of body composition (body fat mass, ratio of body fat, BMI, muscle mass) all showed differences of no statistical significance between two group participants in the present study. In the meta-analysis and systematic review regarding the effects of lifestyle intervention on the body composition of overweight/obesity women with PCOS, the exercises alone or exercises with dietary intervention, that is, the lifestyle intervention including exercises, had positive effects on parameters of body composition than sedentary control, placebo, diet only or usual care including metformin [23]. In addition, lifestyle intervention was reported from a systematic review on non-drug intervention that exhibited the effect of improvement in androgenic syndrome such as hirsutism in glycemic outcomes and in decrease of BMI [24].

In contrary to studies cited above, the participants in this study consisted of women of low/normal weight (experimental group: 73.7%, control group: 84.2%). Therefore, the variables of body composition or glycemic parameters representing changes between pre- and post-test should be considered that the sensitivity of variables may not be sufficient enough to detect distinguishable changes.

Nonetheless, results suggesting a relationship between oligomenorrhea and metabolic syndrome of females with normal body weight, have been reported from a study conducted recently. The study was conducted on 1174 females from the ages of 19 years to 39 years experiencing irregular menstruation, where the females suffering from severe oligomenorrhea (severe OM; menstrual cycle length >60 days) and mild oligomenorrhea (mild OM; menstrual cycle length 40 - 60 days) were compared to each other. The subjects of severe OM appeared with the odds ratio of metabolic syndrome risk twice higher than subjects of mild OM [25].

Regarding the analysis of nutrient intake of the 16 nutrients (calorie, carbohydrate, fat, protein, fiber, vitamin D, folic acid, calcium, phosphorus, sodium, magnesium, iron, selenium, omega-3, omega-6, chromium picolinate), no statistically significant difference was observed between the two groups after intervention. According to studies that reported the relationship between irregular menstruation and nutrient intake, the low level of 25-hydroxyvitamin D was found to be related to irregular menstruation; this suggests that vitamin D is involved with anti-Mullerian hormone, insulin, and androgens that may influence regularity of the menstrual cycle [26]. The administration of omega-3 supplementation to overweight/obesity women with irregular menstruation, suffering PCOS, resulted in a significant decrease of T. After trial, 47.2% of women that returned to a regular menstrual cycle in the group administered with omega-3 was higher than 22.9% in the group administered with the placebo [27]. The administration

of folic acid to female subjects of BMI over 25 and suffering PCOS, resulted in the effect of significant decrease in plasma homocysteine, HOMA-IR score, and total cholesterol/HDL-cholesterol ratio [28]. Thus, for women with PCOS, a carefully prepared low-calorie diet to keep healthy weight or for weight loss for improvement of insulin resistance and metabolic- and reproductive functions, and restriction on the intake of simple sugar or refined carbohydrate, foods of low glycemic index, saturated trans-fatty acid, and taking care of deficiency in vitamin D, chromium, and Omega-3, were suggested [29]. Most studies cited above were conducted with females suffering PCOS, raising limitations in comparison with the subjects that participated in the present study. The insignificant differences of nutrient intake in the present study can be attributed to the intervention on personal nutrition counseling based on the analysis of nutrients and on personal BMIs in our program, rather than direct intervention on individual daily dietary intake; thus, this result may reflect limitations in the application of the intervention to the actual daily lives of young adult women who might have encountered difficulties in applying the intervention to day after day.

In summary, the College-based LMP showed positive effects of improvement in variables of partial domain of PMS (depression and anxiety) and sleep duration, but did not render the MCI, SHBG, T, and FAI. This study was significant in that it confirmed the effect of healthy lifestyles on menstrual health in young adult women with irregular menstruation such as oligomenorrhea and secondary amenorrhea.

There are several limitations in this study. First, factors of organic diseases (ex. Cushing's syndrome etc.) among diverse causes of irregular menstruation such as oligomenorrhea or amenorrhea were not distinguished. Second, there is a limitation in generalizing to other women due to the results on the small number of women. Finally, the intervention time for six months might not be enough for women with healthy BMI and no previous diagnosis of PCOS. Thus, further studies are suggested to secure a larger population of subjects based on different BMIs together with supplementation to the limitations.

Conclusions

In the present study, the College-based LMP was developed to improve the menstrual health of young adult women who experienced irregular menstruation less than ten times a year, and its effects were examined through RCT. The College-based LMP consisted of the education in small groups, individual counseling on exercises and training, and individual counselling on diet and feedback and support. Consequently, the College-based LMP showed positive effects of the alleviation of depression and anxiety, which are partial domains of PMS for women experiencing irregular menstruation, and improvement of sleep duration. However, the positive effects of the College-based LMP were not found for MCI, SHBG, T, FAI, overall PMS, menstrual volume, body composition parameters, and nutrient intake. Further studies are suggested to repeat this study with supplementation to the limitations of this study.

Author Contributions

Conceptualization Y.J.P.; Methodology, Y.J.P. and I.C.; Software, S.J.; Validation, Y.J.P. and H.S.; Formal analysis, S.J. and I.C.; Investigation, S.J., I.C., and

H.J.P.; Resources, Y.J.P.; Data curation, S.J., I.C. and H.J.P.; Writing－original draft preparation, Y.J.P.; Writing－review and editing, Y.J.P., H.S., and I.C.; Visualization, I.C.; Supervision, Y.J.P. and H.S.; Project administration, Y.J.P.; Funding acquisition, Y.J.P. All authors have read and agreed to the published version of the manuscript

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Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of Korea University (protocol code KU-IRB-18-83-A-1 and date of approval 05.07.2018).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy.

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Conflicts of Interest

The authors declare no conflicts of interest.

Trial registration

Clinical Research Information Service (CRiS) number (KCT0005538)

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Development and Effects of College-Based Lifestyle Modification Program for Menstrual Health of Young Adult Women with Irregular Menses: A Randomized Controlled Trial

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Purpose: This study was conducted to develop the 'College-based Lifestyle Modification Program' (College-based LMP) for young adult women with irregular menstruation and examine its effects after intervention. ***Methods:*** The College-based LMP consisted of small group education, individual physical exercise counseling/training, individual diet counseling, and feedback and support. Participants were comprised of 38 females who reported less than 10 irregular menstruations in a year and were randomly assigned to the experimental and control groups. The primary outcome variables consisted of menstrual cycle index (MCI), sex hormone binding globulin (SHBG), and androgenic profile (testosterone－T, free androgen index－FAI), while the outcome variables included premenstrual symptoms (PMS), menstrual volume, body composition parameters, glycemic parameters (fasting blood sugar－FBS, insulin, HOMA-IR), sleep duration, perceived stress, and nutrient intake. ***Results:*** There were no significant differences in primary outcome variables (MCI, SHBG, T, and FAI). In the variables, there were no significant differences except for the partial domain of PMS (symptoms of depression and anxiety) and sleep duration. ***Conclusions:*** The study was significant in that it demonstrated the importance of lifestyle, which could provide ordinary young adult women with healthy menstruation. The College-based LMP needs to be elaborated with further studies.

Keywords: irregular menstruation; women; healthy lifestyle; young adult; randomized controlled trial

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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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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

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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. 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 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-elated outcomes differently than face-to-face self-anagement 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-anagement 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.

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.

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

2.21. 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).

2.22. 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 (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.

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 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.

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

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.

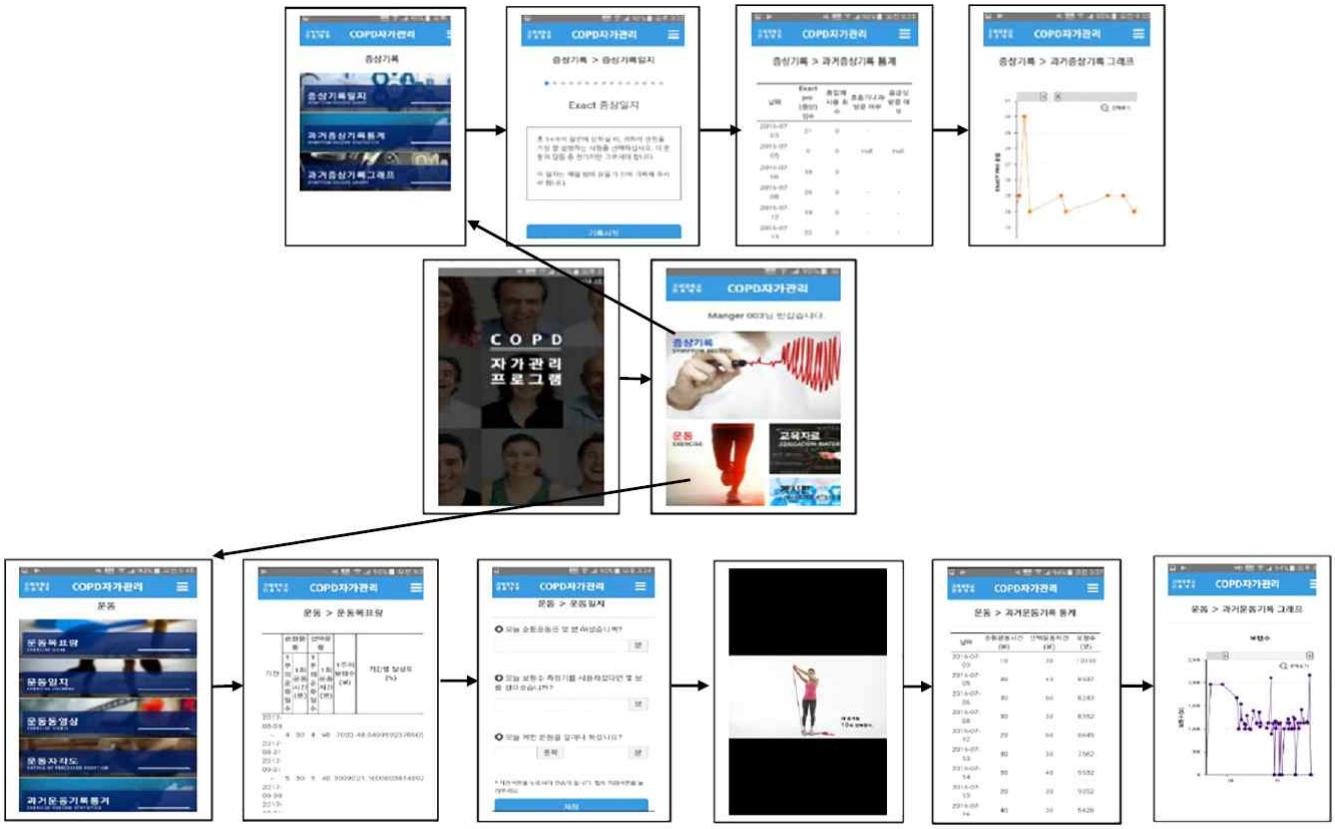

Fig. 1. Main directory & subdirectory of 'symptom record' and 'exercise' in smartphone app-based self-management program.

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

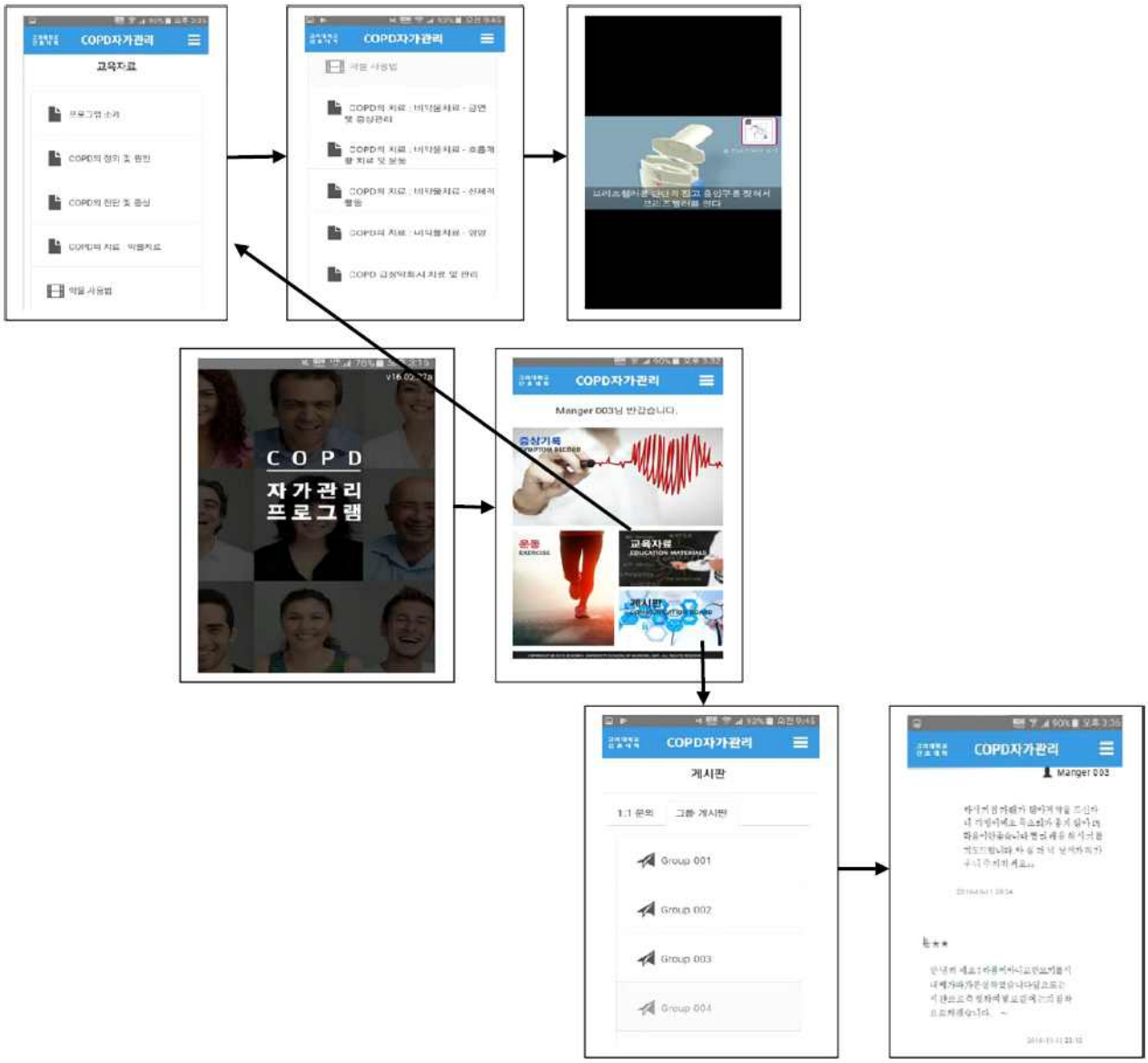

Fig. 2. Main directory & subdirectory of 'education materials' & 'communication board' in smartphone app-based self-management program.

(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.

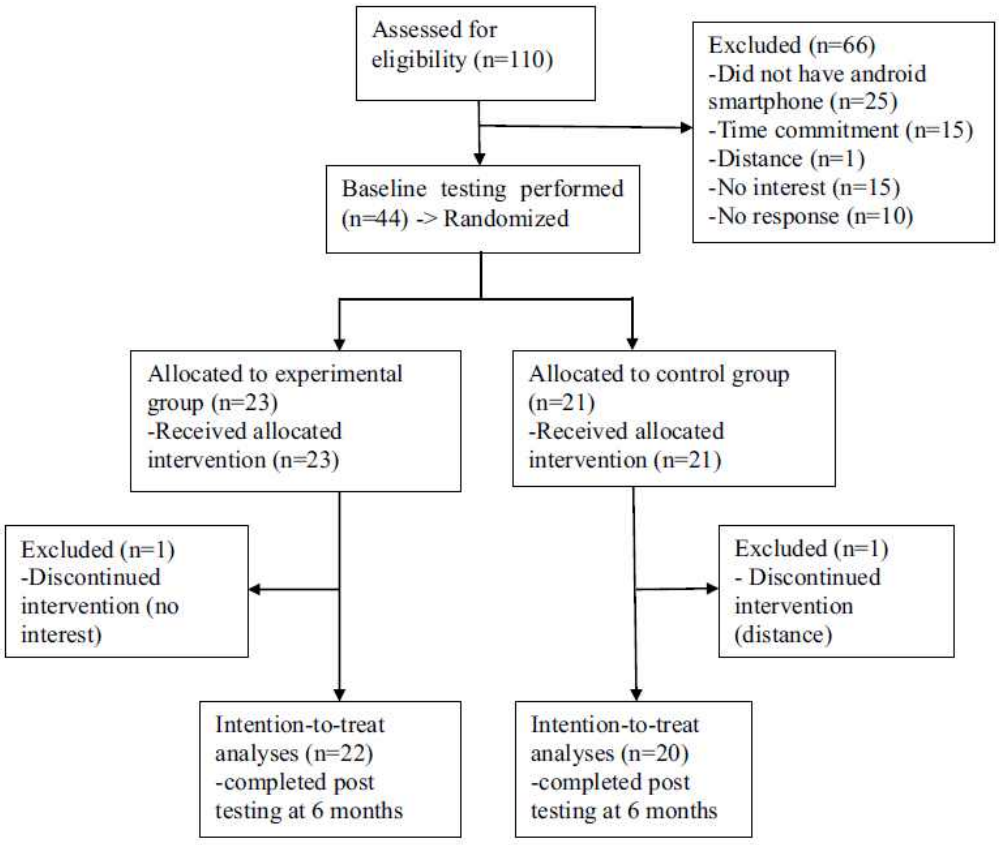

Fig. 3. Modified CONSORT diagram showing flow of final sample (n = 42).

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.

Results

3.1. Comparison of Sample Characteristics Between Groups at Baseline

No statistically significant differences were found at baseline scores between the experimental- and control group in variables

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

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)						
< $1000	16 (38.1%)	8 (36.4%)	8 (44.4%)	1 (50.0%)		
≥$1000	24 (57.1%)	14 (63.6%)	10 (55.6%)	1 (50.0%)	0.27, p = .75	0.08, p = 1.00
Living situation						
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
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 s, FVC; forced vital capacity, GOLD; global initiatives for chronic obstructive lung disease, ED; emergency department.

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).

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	0.12	
	6 months	122.32 ± 12.23*	106.70 ± 18.47	0.01	0.05
Exercise capacity (6MWT distance in meter)	Baseline	378.32 ± 96.96	398.10 ± 78.67	0.48	
	6 months	433.23 ± 107.23*	437.60 ± 83.62	0.89	0.63
Exercise (min/week)	Baseline	215.00 ± 225.51	144.37 ± 129.06	0.35	
	6 months	267.73 ± 449.96	162.50 ± 212.33	0.24	0.80
Physical activity					
Total activity count/wear time	Baseline	215.64 ± 103.16	258.85 ± 105.73	0.19	
	6 months	275.09 ± 99.79*	258.59 ± 111.47	0.62	0.01
Sedentary activity % time	Baseline	0.79 ± 0.10	0.77 ± 0.08	0.39	
	6 months	0.75 ± 0.08	0.77 ± 0.08	0.38	0.07
LPA % time	Baseline	0.18 ± 0.09	0.20 ± 0.06	0.49	
	6 months	0.21 ± 0.08	0.19 ± 0.06	0.40	0.17
MVPA % time	Baseline	0.03 ± 0.02	0.04 ± 0.02	0.35	
	6 months	0.05 ± 0.03*	0.04 ± 0.03	0.70	0.04
Daily step count	Baseline	5223.68 ± 2899.61	6756.26 ± 2978.77	0.10	
	6 months	6546.77 ± 2354.43*	6890.39 ± 2967.73	0.68	0.06
Symptom					
Dyspnea from UCSD-SOB	Baseline	21.18 ± 16.05	19.25 ± 13.83	0.68	
	6 months	21.45 ± 17.78	19.70 ± 14.34	0.73	0.97
Tension-anxiety from POMS	Baseline	4.86 ± 2.64	5.75 ± 4.29	0.42	
	6 months	5.23 ± 3.19	5.80 ± 4.61	0.64	0.73
Depression from POMS	Baseline	3.55 ± 2.69	5.20 ± 5.46	0.21	
	6 months	3.68 ± 3.29	5.45 ± 6.89	0.29	0.91
Health related quality of life					
PCS	Baseline	43.43 ± 9.00	46.36 ± 5.58	0.22	
	6 months	43.94 ± 8.97	44.95 ± 5.95	0.67	0.36
MCS	Baseline	51.62 ± 8.71	52.13 ± 8.49	0.85	
	6 months	50.10 ± 8.33	49.03 ± 11.02	0.73	0.60
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%)	0.61	
Self-efficacy					
SEMCD	Baseline	6.71 ± 1.93	6.47 ± 1.64	0.66	
	6 months	6.89 ± 1.75	6.69 ± 2.26	0.75	0.93
Self-efficacy for managing dyspnea	Baseline	6.59 ± 2.21	6.40 ± 2.10	0.78	
	6 months	6.73 ± 2.10	6.85 ± 2.06	0.85	0.53
Self-efficacy for managing exacerbation	Baseline	6.68 ± 1.94	6.20 ± 2.24	0.46	
	6 months	6.95 ± 2.01	6.75 ± 1.97	0.74	0.67
Self-efficacy for maintaining exercise	Baseline	7.45 ± 1.50	6.90 ± 2.05	0.32	
	6 months	7.77 ± 1.31*	6.75 ± 2.29	0.08	0.46
Self-efficacy for increasing physical activity	Baseline	6.91 ± 2.14	6.90 ± 1.71	0.99	
	6 months	7.91 ± 1.66*	6.75 ± 2.15	0.06	0.06
Self-efficacy for decreasing sedentary time	Baseline	7.18 ± 1.76	6.60 ± 2.09	0.18	
	6 months	7.73 ± 1.42*	7.05 ± 1.76	0.11	0.86
Perception of control	Baseline	4.40 ± 0.96	4.33 ± 1.22	0.83	
	6 months	4.75 ± 0.91	4.68 ± 0.97	0.80	0.99
Social support	Baseline	2.72 ± 0.85	2.53 ± 0.92	0.49	
	6 months	2.73 ± 0.88	2.79 ± 1.21	0.85	0.34

SD; standard deviation, 6MWT; 6 min 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 < 0.05 in comparison of variables between baseline and 6 month in each group.

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 ± 0.90
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)	p-Value
	Mean ± SD	Mean ± SD	
Satisfaction for program	94.55 ± 9.63	89.50 ± 10.50	0.11
Support for disease management	95.91 ± 9.59	91.00 ± 13.34	0.18
Support for symptom management	95.00 ± 9.64	91.00 ± 10.21	0.20
Support for increasing physical activity and reducing sedentary time	93.18 ± 12.87	85.50 ± 13.95	0.07

SD; standard deviation.

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

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.

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.

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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Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board of Korea University (protocol code KU-IRB-18-83-A-1 and date of approval 05.07.2018).

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Data Availability Statement

The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy.

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The authors wish to express their appreciation to the participants of this study.

Conflicts of Interest

The authors declare no conflicts of interest.

Trial registration

Clinical Research Information Service (CRiS) number (KCT0005538)

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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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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.

Keywords: Chronic obstructive pulmonary disease, smartphone application, self-management program

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