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ORIGINAL ARTICLE

Effects of a 12-week home-based exercise program on quality of life, psychological health, and the level of physical activity in colorectal cancer survivors: a randomized controlled trial

Ji Young Kim[1] · Mi Kyung Lee[1] · Dong Hoon Lee[2] · Dong Woo Kang[3] · Ji Hee Min[1] · Ji Won Lee[4] · Sang Hui Chu[5] · Min Su Cho[6] · Nam Kyu Kim[6] · Justin Y. Jeon[1]

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Abstract

Purpose To examine the effects of a home-based exercise program on quality of life (QOL), psychological health, and the level of physical activity (PA) in colorectal cancer survivors.

Methods Seventy-one colorectal cancer survivors were randomized into either a home-based exercise group ($N = 37$) or control group ($N = 34$). The home-based exercise program included unsupervised walking, stationary bike, or swimming for aerobic exercise, as well as resistance exercise DVDs, a pedometer, and an exercise log. The Functional Assessment of Cancer Therapy-Colorectal, Functional Assessment of Chronic Illness Therapy-Fatigue Scale, patient health questionnaire, and Godin Leisure-Time Exercise Questionnaire were used to assess QOL, fatigue, depression, and PA levels.

Results Among the 71 participants, 30 in the exercise group and 28 in the control group completed the study. The change in the QOL between the intervention and control groups was insignificant. However, QOL was significantly improved in the exercise group (QOL, $p = 0.024$). Sub-domain of QOL, emotional well-being, and trial outcome index-physical/functional/colorectal ($p = 0.015$ and $p = 0.035$, respectively) were improved in the exercise group. The level of PA was significantly increased after 12 weeks in the exercise group (97.0 ± 188.5 vs. 332.6 ± 306.1, $p < 0.001$), and the change significantly differed compared with the control group (mean change 235.6 vs. 16.3, $p < 0.001$).

Conclusions The home-based exercise program may improve the QOL and psychological health in colorectal cancer survivors. We have demonstrated that the home-based exercise program was effective in increasing the level of PA in colorectal cancer survivors.

Keywords Colorectal cancer · Home-based exercise · Quality of life · Psychological health · Physical activity

✉ Justin Y. Jeon
jjeon@yonsei.ac.kr

[1] Department of Sport Industry Studies, Exercise Medicine Center for Diabetes and Cancer Patients (ICONS), Cancer Prevention Center, Yonsei Cancer Center, Yonsei University, 50 Yonsei-Ro, Seodaemun-Gu, Seoul 03722, Republic of Korea

[2] Department of Epidemiology and Nutrition, Harvard T.H. Chan School of Public Health, Boston, MA, USA

[3] Behavioural Medicine Lab, Faculty of Kinesiology, Sport, and Recreation, University of Alberta, Edmonton, Canada

[4] Department of Family Medicine, College of Medicine, Yonsei University, Seoul, Republic of Korea

[5] Department of Clinical Nursing Science, College of Nursing, Biobehavioural Research Center, Yonsei University, Nursing Policy Research Institute, Seoul, Republic of Korea

[6] Department of Surgery, Yonsei University College of Medicine, Seoul, Republic of Korea

Introduction

Recently, the survival rates of colorectal cancer patients have improved through earlier diagnoses and advances in treatment during the past decade [1]. The 5-year survival rates of colorectal cancer patients were 45–65% in developed countries and 8–40% in developing countries [2]. Coleman et al. [3] reported that the mortality rate of colorectal cancer is falling by 2% every 5 years for men and by 5% for women. Since the number of colorectal cancer survivor increases, helping the survivors to prevent recurrence and health maintenance are important issues.

The diagnosis of cancer causes considerable distress to not only cancer patients but also to their families. In particular, cancer and its treatments often produce significant morbidities that weaken the quality of life (QOL) of cancer survivors both

during and after treatments [4]. In addition, psychological distress causes negative outcomes, including depression, sadness, anxiety, fear, worry, anger, or panic in cancer patients [5]. A meta-analysis of 4700 cancer patients reported that 30–40% of patients had mental disorders, such as depression, anxiety, and other adjustment disorders [6]. Zabora et al. [7] also showed that the overall prevalence rate of distress was 35.1% in cancer patients. Furthermore, distress is compounded by practical disruptions to their daily life [8].

Numerous studies have investigated the beneficial effects of exercise on health, such as increased physical fitness, improved body composition, biomarkers, QOL, and decreased disease-related adverse effects [9–11]. Moreover, exercise may enhance the QOL of cancer survivors both during and after treatments [12]. Previous research has shown that participation in a home-based exercise has improved physical functioning, QOL, and mood and has reduced fatigue among colorectal cancer survivors enrolled in physical activity (PA) intervention trials [13, 14]. However, the majority of intervention studies have focused on breast cancer survivors [15–18], and only one randomized trial involving exercise and QOL has focused on colorectal cancer survivors [13]. In addition, the exercise group in this trial did not exhibit any significant changes in QOL as measured using the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) scale. This could potentially be due to possible contamination issues in the control group because individuals may have already been participating in regular exercise or may have been motivated to change their behavior after the diagnosis.

Although the importance of PA and exercise has been recognized, few randomized controlled trials have investigated the effects of exercise on the psychological health of colorectal cancer survivors. Therefore, the aim of this study was to examine the effects of a home-based exercise program on QOL, psychological health, and PA level in colorectal cancer survivors.

Methods

Participants

This study was conducted at the Shinchon Severance Hospital at Yonsei University in Seoul, Korea, between 2011 and 2013. Eligibility criteria included stage II–III colorectal cancer survivors who completed all standard surgery and adjuvant chemotherapy within 4 weeks to 2 years before the study enrollment and were between the ages of 18 and 75 years. Eligible patients were required to (1) understand and provide written informed consent in Korean and (2) to have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Patients were excluded if they had metastasis to other parts of the body and cardiac illness or any condition unsuitable for participation in this study. All participants signed a consent form before participating in the study. The study was approved by the institutional review board at the Yonsei University College of Medicine.

Study design

After the informed consent had been signed, all participants were randomized into either the exercise group or control group at a 1:1 ratio using a computer-generated random number sequence. The allocation sequence was generated by the Research Randomizer website program. The home-based exercise program period was 12 weeks in length, and all assessments were conducted at baseline and 12 weeks.

Home-based exercise program The detailed exercise program has been published previously [19]. In brief, the home-based exercise program aimed to increase the level of PA to 18 metabolic equivalent of task (MET) hours per week during the first 6 weeks, as the beneficial effects have been proven by Meyerhardt et al. [20, 21]. Then, the level of PA was increased to 27 MET-hours per week depending on individual health conditions during the intervention period. The exercise group was provided with two types of exercise DVDs, including both the moderate- and vigorous-intensity version, which comprised 30 min of resistance training using major and core muscles to be performed at home every day. The moderate-intensity version DVD that comprised three sets of seven core and resistance exercises (12–15 reps per set) was provided at baseline assessments. After 6 weeks, the vigorous-intensity version DVD that comprised three sets of five aerobic and resistance combined exercises (12–15 reps per set) was provided to the exercise group. Moreover, they met with exercise trainers once each week at the clinic as a group for the first 3 weeks and again at the sixth week. In addition, the participants were provided weekly phone counsel or small group training sessions to facilitate overcoming barriers, provide positive reinforcement, answer questions, and inquire and assess any problems related to exercise. In addition, they recommended brisk walking, hiking, stationary bike, and swimming for aerobic exercises, and daily text messages were delivered to check whether patients completed their daily exercise.

Control group The participants assigned to the control group were not prescribed a home-based exercise program and were instructed to continue with their usual activities or exercises during the intervention. At the end of the study, they were offered the two types of exercise DVDs and results of clinical tests. In addition, they were provided one education session on colorectal cancer followed by a question and answer period with their surgeon.

Primary endpoint

Quality of life QOL was measured by the FACT-C scale. The FACT-C scale includes subscales for physical, functional, emotional, and social/family well-being, as well as a colorectal cancer subscale. It has been well tested in cancer survivors and found to be reliable, valid, and responsive [22]. Physical function and well-being were assessed using the Trial Outcome Index-physical/functional/colorectal (TOI-PFC). TOI-PEC score was calculated from the FACT-C (PWB + FWB + CCS) [23].

Secondary endpoints

Fatigue was assessed using the Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-FS). The FACIT-FS comprises 13 items designed to assess fatigue regarding its intensity and interference with performing everyday functions. The FACIT-FS has suitable evidence of internal consistency and test-retest reliability [24, 25]. In addition, the Patient Health Questionnaire (PHQ) was administered and was also validated to measure depression in the medical setting [26].

Physical activity assessments Participants underwent assessments of PA at baseline and after completion of exercise program to assess the efficacy of the intervention for PA. The Godin Leisure-Time Exercise Questionnaire is a reliable assessment of PA, which provides data regarding the duration and intensity of the PA performed [27]. The questionnaire comprises three questions that assess the average frequency of mild, moderate, and vigorous exercise during free time in a typical week.

Anthropometric measurements

Weight and body composition were assessed using InBody (Biospace, Korea), and body mass index was defined as weight/height^2 (kg/m^2).

Statistical analysis

All analyses were based on the intention-to-treat analysis, and last observation carry-forward principle was conducted for the missing data. Data were statistically analyzed using the SPSS 21.0 software (SPSS Inc., Chicago, IL, USA). Values were expressed as the mean ± standard deviation (SD) or numbers (or percentage) using a frequency analysis. The baseline characteristics of the study participants were compared using an independent t test for continuous outcomes and a chi-square test for categorical outcomes. Comparisons of changes in QOL, psychological health, and the levels of moderate and vigorous PA between the exercise group and control group were assessed using an analysis of covariance (ANCOVA) after controlling for age, sex, and cancer stage. In addition, a paired t test was used to compare the baseline and 12-week data within the groups. Lastly, ANCOVA was further used to compare the changes in QOL and psychological health between groups (increased in moderate-vigorous PA vs. decreased or no change in moderate-vigorous PA after 12 weeks). A p value of less than 0.05 was considered to be statistically significant.

Results

A total of 725 stage II–III colorectal cancer survivors were assessed for eligibility. Of the colorectal cancer survivors, 71 (71/725 = 16.7%) agreed to participate in the study. A total of 71 participants were randomly assigned at a ratio of one to one for either the exercise (n = 37) or control (n = 34) group. After 12 weeks, the retention rate was 81.1% (30/37) for the exercise group and 82.4% (28/34) for the control group. Figure 1 shows the participant flow and loss to follow-up.

Baseline characteristics

There are no significant differences in baseline characteristics between the groups (Table 1). The mean age was 56.2 ± 9.4 years and the average time since the completion of therapy was 10.7 ± 7.1 months. Of the participants, 64.8% had colon cancer.

Quality of life and psychological health outcomes

Table 2 presents the effects of a home-based exercise program on the QOL and psychological health outcomes. After 12 weeks, no significant difference was observed in the changes of FACT-C, physical well-being, social/family well-being, emotional well-being, functional well-being, colorectal cancer subscale, TOI-PFC, FACIT-FS, and PHQ scores between the groups. However, the FACT-C scores significantly increased by an average of 3.8 (100.5 ± 18.1 vs. 104.3 ± 17.5, p = 0.024) in the exercise group compared to the baseline, while no significant changes were observed in the control group (97.5 ± 19.9 vs. 99.1 ± 19.1, p = 0.407). In addition, the emotional well-being, TOI-PFC, and FACIT-FS scores increased in the exercise group compared with the baseline scores (18.8 ± 4.0 vs. 19.6 ± 3.6, p = 0.015; 64.1 ± 11.2 vs. 66.3 ± 11.8, p = 0.035; 39.7 ± 9.6 vs. 42.6 ± 8.5, p = 0.011).

The level of moderate and vigorous physical activity

Table 3 shows the effects of a home-based exercise program on the level of PA. The level of the moderate and vigorous PA significantly increased in the exercise group compared with

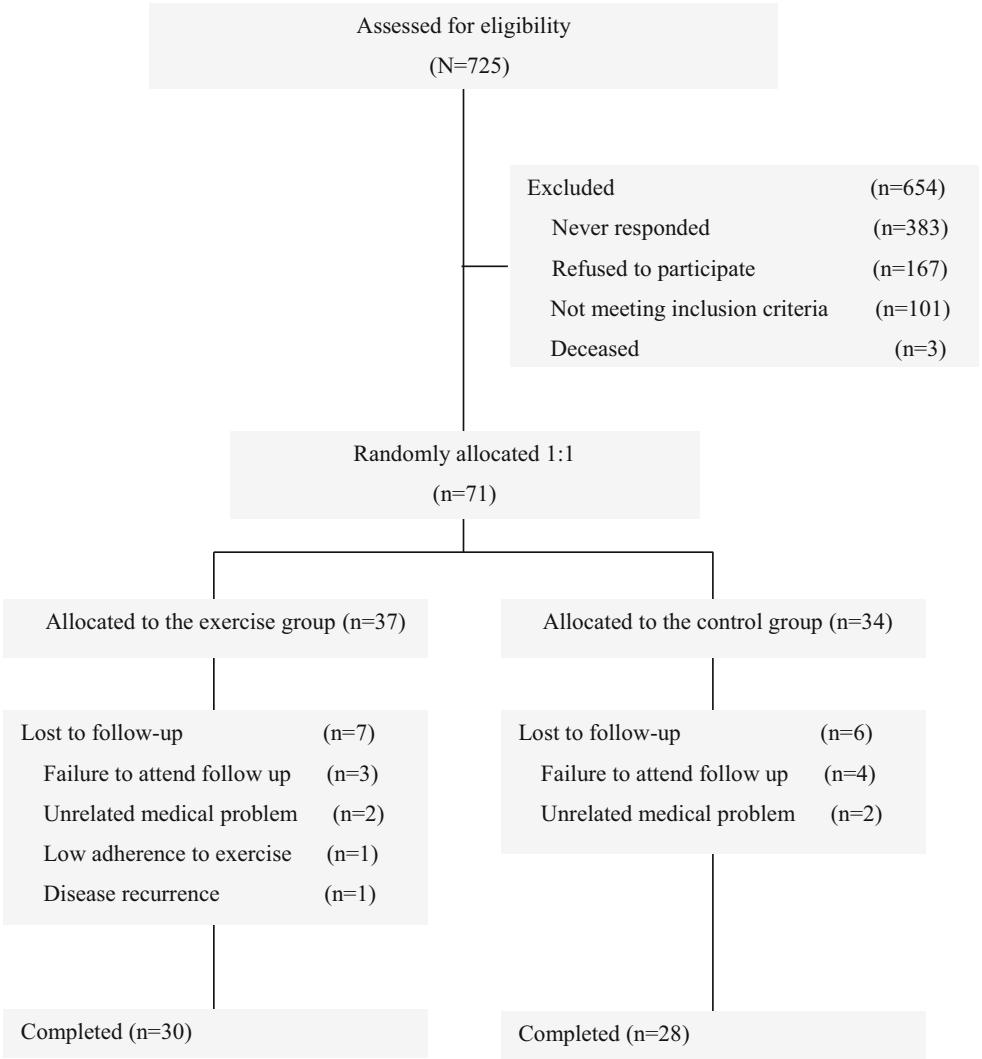

Fig. 1 CONSORT diagram

the control group (mean change 235.6 min vs. 16.3 min, $p = 0.001$). Moreover, the level of PA significantly increased by an average of 235.6 min (97.0 ± 188.5 min vs. 332.6 ± 306.1 min) in the exercise group ($p < 0.001$), while no significant difference was observed in the control group (117.5 ± 218.5 min vs. 133.8 ± 227.8 min, $p = 0.632$).

Association between changes in quality of life, psychological health outcomes, and physical activity levels

Figure 2 presents an ancillary analysis for the QOL and psychological health in colorectal cancer survivors. All participants were divided into two groups: (1) increased in moderate-vigorous PA levels and (2) decreased or no change in moderate-vigorous PA levels. No significant differences were found between the groups except for FACIT-FS. The difference between the groups in changes from baseline to post-intervention was observed for FACIT-FS (mean change 3.74 vs. 0.41, $p = 0.026$).

Discussion

The purpose of the study was to determine the effects of a home-based exercise program on QOL, psychological health, and the level of PA in colorectal cancer survivors. Although no significant changes were observed between the exercise and control groups, QOL and fatigue improved in the exercise group compared to the baseline.

In particular, the differences of at least five points on the FACT-C and three points on the FACIT-FS are considered to be clinically important differences [23, 28]. Our study showed that an average of 3.8 points on the FACT-C and 2.9 points on the FACIT-FS increased in the exercise group. Although these findings were not statistically significant, we have observed somewhat clinically important differences in the exercise group. According to previous studies, regular and sustained moderate-vigorous PA was associated with health-related QOL and reduced fatigue symptoms in colorectal cancer survivors [29–31]. Grimmett et al. [32] also found that an

Table 1 Baseline characteristics ($n = 71$)

Variable	Control group ($n = 34$)		Exercise group ($n = 37$)		
	No.	%	No.	%	*p*
Age (years)					0.621
Mean		56.8		55.7	
SD		10.2		8.7	
Male	17	50.0	18	48.6	0.909
Weight (kg)					0.688
Mean		62.5		63.5	
SD		12.6		9.1	
BMI (kg/m^2)					0.606
Mean		23.3		23.7	
SD		3.6		2.9	
Cancer type					0.132
Colon	19	55.9	27	73.0	
Rectal	15	44.1	10	27.0	
Cancer stage					0.070
II	12	35.3	21	56.8	
III	22	64.7	16	43.2	
Time since completed therapy (months)					0.928
Mean		10.6		10.8	
SD		8.4		5.8	
Marital status					0.591
Married	27	79.4	28	75.7	
Widowed	2	5.9	4	10.8	
Divorced	3	8.8	1	2.7	
Never married	2	5.9	4	10.8	
Completed college	11	32.4	19	51.4	0.105
Income > $3000/month	13	38.2	20	54.1	0.182
Smoking					0.442
Never smoke	14	41.2	20	54.1	
Used to smoke	18	52.9	14	37.8	
Currently smoke	2	5.9	3	8.1	
Alcohol intake	4	11.8	2	5.4	0.336

SD standard deviation, *BMI* body mass index

Data are presented as either the number (%) or as the mean ± standard deviation

increase in PA was associated with lower fatigue, lower rates of insomnia, and decreased overall pain. In addition, Lewis, Xun, and He [33] determined that vigorous exercise was an important predictor of a higher QOL in stage II colon cancer patients. Moreover, patients who increased recreational PA exhibited an improved QOL compared with those who decreased recreational PA over 24 months following the diagnosis of colon cancer. In our study, we also found that moderate and vigorous activity might improve the QOL and psychological health in colorectal cancer survivors. Moreover, participants with increased PA levels may have an improved QOL and psychological health compared with participants who exhibited a decrease or a lack of change in PA levels.

We found that non-intensive intervention could increase the level of PA in colorectal cancer survivors. The level of moderate and vigorous PA significantly increased in the exercise group compared with the control group. In general, PA levels tend to be decreased following the colorectal cancer diagnosis and did not return to prediagnosis levels [14]. Moreover, over two thirds of patients with cancer are insufficiently physically active [34, 35]. We observed that there was a moderate and vigorous PA time increase of approximately 235 min in the exercise group compared to the baseline. Our findings indicate that it is possible that a home-based exercise program may increase the level of PA among colorectal cancer patients. Of note, we incorporated supervised components (e.g., counseling,

Table 2 Quality of life and psychological health outcomes at baseline and at 12 weeks ($n = 71$)

Variable	Control group ($n = 34$)							Exercise group ($n = 37$)							p value[2]
	Baseline		12 weeks		ΔChange		p value[1]	Baseline		12 weeks		ΔChange		p value[1]	
	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD		
Quality of life															
FACT-C (0–132)	97.5	19.9	99.1	19.1	1.6	11.3	0.407	100.5	18.1	104.3	17.5	2.9	9.2	*0.024*	0.283
Physical well-being (0–28)	24.3	4.2	24.8	4.5	0.5	3.0	0.344	24.4	4.8	25.3	4.8	0.8	2.9	0.083	0.506
Social/family well-being (0–24)	16.3	6.8	16.5	6.1	0.2	3.9	0.776	17.6	6.2	18.3	5.1	0.2	5.1	0.450	0.631
Emotional well-being (0–24)	17.7	4.4	18.3	4.4	0.6	4.6	0.461	18.8	4.0	19.6	3.6	0.9	2.1	*0.015*	0.451
Functional well-being (0–28)	19.1	6.5	19.3	6.1	0.1	3.6	0.849	19.8	5.3	20.3	4.9	0.5	3.1	0.315	0.414
Colorectal cancer subscale (0–28)	20.0	4.8	20.2	4.1	0.2	4.3	0.753	19.9	3.9	20.7	4.4	2.7	6.7	0.127	0.710
TOI-PFC (0–84)	63.4	13.1	64.3	12.4	0.9	7.1	0.488	64.1	11.2	66.3	11.8	2.2	6.1	*0.035*	0.254
Psychological health															
FACIT-FS (0–52)	41.0	8.1	42.3	7.5	1.2	5.4	.191	39.7	9.6	42.6	8.5	2.7	6.7	*0.011*	0.212
Depression (0–30)	4.2	4.3	3.2	4.8	− 1.0	4.0	.154	4.0	4.5	3.0	4.5	− 1.1	3.0	0.053	0.968

[1] p values between baseline and 12 weeks in the each group

[2] p values between groups

Adjusted for age, sex, and stage

exercise/education session) into the home-based setting to provide instruction and feedback in a regular basis which contributed to participants' adherence and safety of the exercise program. Previously, in our pilot study, we found that a casually intervened home-based protocol, which provides an exercise log, a pedometer, and counseling with physicians, was as effective as an intensely intervened home-based protocol which provided additional exercise DVDs, four exercise education sessions, and weekly phone calls [9]. In the pilot study, participants in the casually intervened home-based program group increased their level of PA from 10.00 ± 8.49 MET hours per week to 46.07 ± 45.95 MET hours per week, while the intensely intervened home-based program group increased the level of PA from 12.08 ± 11.04 MET hours per week to 35.42 ± 27.42 MET hours per week. Similarly, Park et al. [36] found that the oncologist's exercise recommendation accompanied by a simple exercise motivation package consisting of a pedometer, an exercise diary, exercise DVDs, and a 15-min exercise education session increased the level of exercise by 80 min per week. In addition, Jones and Courneya [37] determined that colorectal cancer survivors are motivated to change behaviors after their diagnosis. Therefore, colorectal cancer survivors were highly motivated to exercise, and a small amount of encouragement may be sufficient to increase the level of PA. Furthermore, relatively small increases in the level of PA may prevent cancer recurrence and improve overall survival. Meyerhardt et al. [20, 21] showed that stage II–III colon cancer patients who participated in 18 MET hours

Table 3 The level of physical activity at baseline and at 12 weeks ($n = 71$)

Variable	Control group ($n = 34$)							Exercise group ($n = 37$)							p value[2]
	Baseline		12 weeks		ΔChange		p value[1]	Baseline		12 weeks		ΔChange		p value[1]	
	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD		
Physical activity level (min)															
Vigorous physical activity	0	0	0	0	0	0	0	0	0	8.1	32.1	8.1	32.1	0.134	0.282
Moderate physical activity	117.5	218.5	133.8	227.8	16.3	197.1	.632	97.0	188.5	324.5	298.6	227.5	276.2	*< 0.001*	*0.001*
Total physical activity	117.5	218.5	133.8	227.8	16.3	197.1	0.632	97.0	188.5	332.6	306.1	235.6	280.8	*< 0.001*	*0.001*

[1] p values between baseline and 12 weeks in the each group

[2] p values between groups

Adjusted for age, sex, and stage

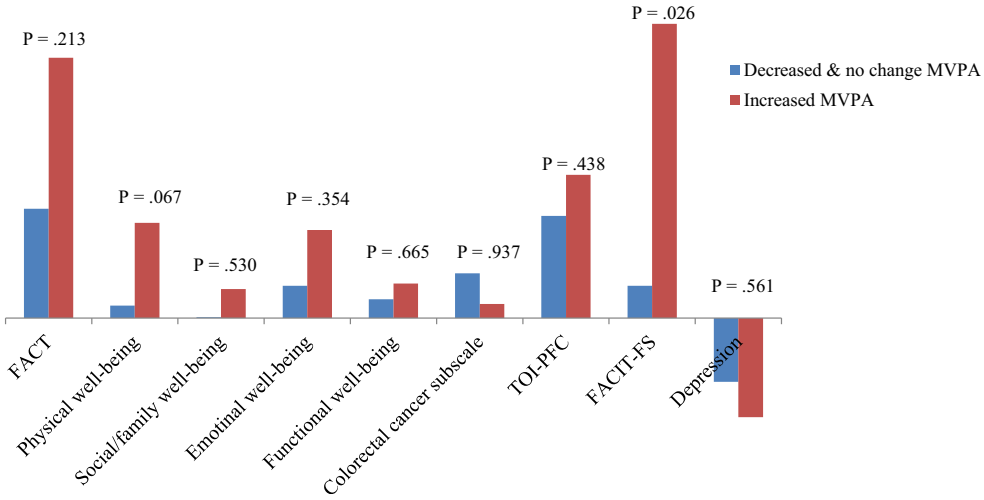

Fig. 2 Changes of QOL and psychological health after 12-week home-based exercise program. MVPA moderate and vigorous physical activity. Adjusted for age, sex, and stage

per week of PA have approximately a 50% reduction in their colon cancer-specific and all-cause mortality. Therefore, colorectal cancer survivors should be encouraged to increase or maintain their PA levels not only to improve QOL and psychological health but also to reduce the risk of mortality.

There are several limitations to the study. First, the sample size was somewhat small, and the study was conducted at a single center. In addition, the level of PA was measured by a self-report questionnaire, which can be associated with over-reporting. Finally, a total of 18.3% of enrolled participants were lost to follow-up.

In conclusion, we determined that a 12-week home-based exercise program may improve the QOL and psychological health of colorectal cancer survivors. Moreover, a home-based exercise program can be used to increase the level of PA among colorectal cancer survivors. Further research is required to elucidate how the effects of exercise can be maintained over a longer period after completion of an exercise program as well as to determine type of exercise, length of program or exercise session, and intensity of exercise required for colorectal cancer survivors.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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