

Effectiveness of a 24-week mobile application-based human coaching program for controlling weight, body mass index, and body composition in breast cancer survivors who are overweight or obese: Single-arm prospective cohort study

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Abstract

Background: Overweight or obesity is a prognostic factor for breast cancer recurrence and breast cancer-related deaths. However, weight control is difficult for breast cancer survivors because of menopause, chemotherapy, anti-hormonal therapy, and psychological issues.

Objective: This study aimed to develop a 24-week mobile application-based human coaching program using Noom and evaluate its efficacy in breast cancer survivors who are overweight or obese.

Methods: In this single-arm prospective cohort study, 130 breast cancer survivors with BMI ?25 were enrolled and received a 24-week program including diet-, exercise-, and psychology-based contents with the trained human coach in Noom during 2019–2021. For a hyperactive group who joined more than 16 weeks, we evaluated weight, BMI, lipid level, bioimpedance, and Quality of Life at baseline, 6-month, and 12-month follow-up.

Results: Among 130 breast cancer survivors, 101 (77.7%) and 93 (71.5%) completed the 6-month and 12-month follow-ups, respectively. In the hyperactive group (68/101, 67%), body weight and body mass index (BMI) significantly reduced (mean difference: -1.97 kg, 95% CI (confidence interval):-2.65—1.26, P<0.001 and -0.86, 95% CI:-1.15—0.56, P<0.001, respectively) at 6 months and maintained at 12 months without the yo-yo effect. Among the lipid panel, triglyceride (TG) levels decreased significantly (-34.13, 95% CI:-58.09- -10.17, P=0.006) and maintained at 12 months. With respect to bioimpedance components, skeletal muscle mass (SMM, kg), body fat mass (BFM, kg), percent body fat (PBF, %), waist-to-hip ratio (WHR), and visceral fat area (VFA, cm2) improved in the first 6 months. However, WHR and VFA increased during the next 6 months. Based on the EORTC QLQ C30 and BR 23, nausea or vomiting, constipation, body image, arm, and breast symptoms significantly improved during the first 6 months.

Conclusions: This study demonstrated that a 24-week mobile application-based human coaching program is beneficial for controlling body weight, BMI, TG, and body composition in terms of bioimpedance for breast cancer survivors who are overweight or obese. Clinical Trial: ClinicalTrials.gov Identifier: NCT 05506189

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Original Paper

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Abstract

Background: Overweight or obesity is a prognostic factor for breast cancer recurrence and breast cancer-related deaths. However, weight control is difficult for breast cancer survivors because of menopause, chemotherapy, anti-hormonal therapy, and psychological issues.

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Conclusions: This study demonstrated that a 24-week mobile application-based human coaching program is beneficial for controlling body weight, BMI, TG, and body composition in terms of bioimpedance for breast cancer survivors who are overweight or obese.

Trial Registration: ClinicalTrials.gov Identifier: <u>NCT</u> 05506189 Keywords: mobile app; body weight; survivor; breast cancer; obesity

Introduction

Obesity is associated with the risk of breast cancer and its recurrence. This relationship involves altered fatty acid metabolism, extracellular matrix remodeling, secretion of adipokines and anabolic and sex hormones, immune dysregulation, and chronic inflammation (1). A previous systematic meta-analysis showed that women with obesity and breast cancer had poorer survival rates than women without obesity (2).

This increase in the number of breast cancer survivors is largely attributable to advancements in early detection and treatment. An estimated 297,790 new cases of invasive breast cancer are expected in women in the U.S., along with 55,720 new cases of noninvasive breast cancer. There are over 3.8 million breast cancer survivors in the United States. The 5-year relative survival rate for patients with breast cancer is 91% (3). Breast cancer survivors face significant challenges in managing their weight because of a confluence of factors, including hormonal changes induced by menopause, side effects of chemotherapy and anti-hormonal treatments, and psychological stressors related to their condition. It is crucial to reduce body mass index (BMI) and maintain an optimal BMI in women with obesity and breast cancer.

Noom is a digital application dedicated to weight management that features functionalities for

monitoring caloric intake and physical activity, facilitating collective encouragement through group involvement, and crucially providing individualized coaching. Unlike programs that prioritize rapid weight reduction, this platform educates users on acquiring new competencies and establishing sustainable healthy practices. Such mobile applications are increasingly used in the healthcare sector. Comparing the dietary data collected on energy and macronutrients, Noom's estimates for mean daily fat intake and percent total energy from carbohydrates are comparable to those of conventional dietary assessment tools. Noom's estimates for daily energy, protein, and carbohydrate intakes are significantly higher. The Noom could be useful for monitoring dietary intake, although more research is needed to determine its accuracy for micronutrients and other dietary components (4). A study of 35,921 Noom Coach app users found that 77.9% experienced weight loss, with dinner input frequency being the most significant factor (OR=10.69), and frequent weight input reducing the yoyo effect (OR=0.59). This study demonstrates the app's clinical utility for weight reduction, especially for users who consistently monitor their weight and diet (5).

This study aimed to develop a 24-week mobile application-based human coaching program using Noom and evaluate its efficacy in breast cancer survivors who are overweight or obese.

Methods and Materials

Trial design and study population

We conducted a single-arm prospective cohort study between 2019 and 2021 at the National Cancer Center, Korea. We provided an informational article tailored to breast cancer survivors within the existing Noom program. Experts in breast cancer, rehabilitation, nutrition, and psychiatry contributed to the writing of this article. A total of 131 breast cancer survivors who were overweight or obese were enrolled and joined a 24-week mobile application-based human coaching program during the first 6 months. They were followed up for 12 months without further application of the Noom program.

The inclusion criteria were breast cancer survivors who had completed their primary treatment and were either scheduled for or currently undergoing follow-up examinations; aged between 18 and 70 years; diagnosed with breast cancer at stages I, II, or III; BMI between 25 kg/m² and less than 40 kg/m²; and capable of using a mobile application, as this was likely a component of the study methodology or follow-up process. All participants were required to sign a research consent form, acknowledge their voluntary participation, and understand the study's aims and procedures.

Individuals were excluded from the study if they met one or more of the following criteria:1) diagnosed with Stage IV breast cancer or carcinoma in situ. 2) Patients who do not use smartphones. 3) Previous treatment for any cancer, including breast cancer. 4) Patients with multiple organ tumors and recurrent or metastatic cancers. 5) Two or more uncontrolled chronic conditions such as stroke, uncontrolled diabetes mellitus (DM), uncontrolled hypertension (HTN), uncontrolled hypercholesterolemia, or uncontrolled psychological disorders. 6) Individuals who have declined to participate in the study. 7) Communication difficulties impeding participation in the study.

We categorized participants into three groups based on the duration of their activities. These groups were defined as hyperactive, active, or inactive. Participants in the hyperactive group engaged in activities for > 16 weeks. Those in the active group participated in activities for 8–16 weeks. Finally, the inactive group included participants with less than 8 weeks of activity.

Procedures

For this study, we developed and implemented a 24-week program including five categorized articles about diet-, exercise-, disease-, lifestyle-, and psychology-related content in the Noom application. The participants were instructed to use the Noom application, a mobile app-based human coaching program. Once familiar with the operation of Noom, the participants were required to log their daily

dietary intake and lifestyle habits into the app for 24 weeks. An assigned Noom coach analyzed the data and provided individualized coaching through in-app messages at least once a week, offering feedback on lifestyle habits and dietary modifications (6).

To assess the effectiveness of the mobile app-based human coaching program in managing nutrition and lifestyle habits, the participants underwent physical measurements, clinical laboratory tests, and quality of life (QOL) surveys at the onset of the study and at the 6-month and 12-month follow-ups. For the QOL assessment, we used the EORTC QLQ-C30 and QLQ-BR23. These tools were scored according to the EORTC scoring manual (7).

Outcomes

The primary outcome was BMI reduction in the hyperactive group with a 24-week mobile app-based human coaching program through personalized nutrition and lifestyle modifications. Secondary outcomes were weight reduction and improvement in body composition, which were assessed using blood tests, bioimpedance, and QOL.

Sample size calculation and statistical analysis

This single-arm study was conducted over 24 weeks. It aimed for a reduction in BMI of at least 0.8 kg/m² in the hyperactive group, with a standard deviation (SD) of 1.45 kg/ m² in the hyperactive group, an alpha of 0.05, and 90% power (8). Considering a dropout rate of 50% after registration to the group of interest and 60% from the group of interest to the hyperactive group, 130 participants were required for this study.

The baseline characteristics were compared among the hyperactive, inactive, and active groups. Comparisons between the two groups were performed using the chi-square test or Fisher's exact test and the two-sample t-test, depending on the type of variable. Changes in body weight, BMI, and body composition from baseline to 6 months in the hyperactive group were compared using paired t-tests. One-way Analysis of Variance (one-way ANOVA) was performed to determine changes over time for patients with physical measurements and QOL completed in 12 months, and changes at each time point were compared using paired t-tests. Categorical variables were summarized as frequencies and percentages, continuous variables as means and SDs, and mean differences as difference values and 95% confidence intervals (CI). Statistical significance was set at P<0.05, and the results were analyzed using R Foundation for Statistical Computing version 4.1.2 (Vienna, Austria).

Ethical approval

This study was approved by the Institutional Review Board of the National Cancer Center of Korea (No.NCC2019-0098) and registered at ClinicalTrials. gov: NCT05506189 (https://clinicaltrials.gov/ct2/show/ NCT05506189). All participants signed an informed consent form prior to enrolment in the study. All experimental protocols were approved by the same Institutional Review Board, and all methods were performed according to the relevant guidelines and regulations.

Results

Between May 2019 and December 2021, 130 participants who met the inclusion criteria were enrolled. A total of 77.5% (101/130) of the participants completed the study at 6 months follow-up using the 24-week program, and 71.5% (93/130) completed all study 12 months follow-up visits (Figure 1).

At baseline, no differences were observed between the groups in terms of BMI, occupational status, clinicopathologic characteristics, and underlying diseases, including HTN, DM, and hyperlipidemia. Among the participants, 67% (68/101) were in the hyperactive group, and 33% (33/101) were in the inactive and active groups. The mean age was 54.9 years for the hyperactive group and 54.2 years for

the inactive & active group (Table 1).

At 6 months, 68 patients in the hyperactive group achieved an average weight loss of 1.96 kg and a mean decrease in BMI of 0.86 kg/m². Additionally, on average, skeletal muscle mass (SMM) increased by 0.75 kg, and body fat percentage decreased by 3.58%. Furthermore, the waist-hip ratio decreased by 0.04, and the visceral fat area decreased by 23 cm² (Table 2).

When comparing the hyperactive group with the active and inactive groups over 6 months, there was a statistically significant decrease in weight, BMI, total cholesterol level, LDL-cholesterol level, body fat mass (BFM, kg), percent body fat (PBF, %), and visceral fat mass (Supplemental Table 1). At 12 months, 61 participants in the hyperactivity group had completed the program. Compared with baseline, there were statistically significant decreases in weight, BMI, fasting blood sugar (FBS) level, TG level, SMM, BFM, PBF, waist-to-hip ratio (WHR), and VFA at 6 months. Furthermore, at 12 months, there were significant decreases in weight, BMI, FBS, TG, BFM, PBF, and VFA. However, when examining the differences in changes between 6 and 12 months for this hyperactive group, the weight change decreased by 0.31 kg and the BMI change increased by 0.2 kg/m² without statistical significance. Furthermore, the differences in WHR and VFA showed statistically significant increases of 0.04 (p=0.0019) and 14.33 cm² (p=0.0115), respectively (Figure 2, Table 3). When comparing QOL using the EORTC QLQ-C30 and EORTC QLQ-BR23 questionnaires among those in the hyperactive group who completed the 12-month program, there was a statistically significant improvement in symptoms related to nausea and vomiting among the symptom scales. During the 6-month program, there were significant improvements in nausea and vomiting, constipation, body image, arm symptoms, and breast symptoms. However, at 12 months, only nausea and vomiting had significantly improved (Table 4).

Discussion

This study showed that a 24-week mobile application-based human coaching program for breast cancer survivors was effective in significantly reducing excessive weight and obesity. The hyperactive group lost 1.96 kg and 0.86 kg/m² at 6 months. Also, the hyperactive group showed improved QOL at 6 months.

Maintaining a healthy weight through diet and exercise can help regulate hormone levels and improve overall health, potentially enhancing survival rates and reducing recurrence. In a previous study, a 16-week monitored program of aerobic and resistance exercises designed to target metabolic syndrome significantly improved QOL, depression symptoms, fatigue levels, and physical fitness in ethnically diverse, inactive, overweight, or obese survivors of breast cancer. These improvements remained evident at the follow-up 3 months later (9).

Our study showed that body weight, FBS, and TG levels decreased over 6 months, which was maintained for up to 12 months; however, no further change was observed between the 6- and 12-month marks. Regarding BMI, an improvement was observed during the initial 6 months of using the Noom application. However, when Noom was discontinued, the following 6–12 months showed a reversal to baseline levels. The limitations in maintaining a diet over an extended period may be influenced by various factors that often make long-term diet adherence challenging.

Being overweight or obese is linked to a higher risk of developing breast cancer, especially in postmenopausal women (10). A study showed significantly poorer outcomes, including overall survival (OS) and disease-free survival (DFS), in patients with severe obesity (BMI \geq 40 kg/m²). This contrast was not observed in patients who are moderately obese (BMI 35.0–39.9 kg/m²), slightly obese (BMI 30.0–34.9 kg/m²), or overweight (BMI 25.0–29.9 kg/m²) when compared with those who are underweight or of normal weight (BMI<25.0 kg/m²) with early breast cancer (11). A total of 301 menopausal women with breast cancer were studied. The findings showed an adjusted odds ratio of 1.37 (95% CI: 0.73, 2.56) for patients with a BMI of 27 kg/m² or more compared to

those with a BMI under 27 kg/m². They suggest that patients with obesity had poorer survival rates (12). A meta-analysis of 43 other studies indicated that women with obesity and breast cancer had lower survival rates than women without obesity. This was consistent for OS (Hazard Ratio=1.33; 95% CI: 1.21, 1.47) and breast cancer-specific survival (Hazard Ratio=1.33; 95% CI: 1.19, 1.50) (2). Breast cancer survivors frequently experience cancer-related symptoms, including cognitive difficulties, pain, insomnia, and urinary incontinence, with 65% experiencing ongoing pain (13-15). Weight management improves the QOL of breast cancer survivors by alleviating side effects, improving mobility, and boosting mental health. A comprehensive randomized controlled trial involving a diverse cohort of breast cancer survivors who are overweight or obese found that, while an intensive, group-based weight loss intervention yielded positive results in reducing weight, it led to only marginal improvements in vitality and transient enhancements in physical functioning and symptomatology (16). Our study yielded similar results. In the hyperactive group, various physical symptoms, including body image, improved during the first 6 months. However, only the alleviation of nausea and vomiting was sustained for more than 12 months.

Mobile interventions for weight management programs are widely used in various diseases, such as diabetes, heart disease, and obesity, especially those where weight management is crucial (5, 6, 8). Among patients with type 2 diabetes, those who completed the program experienced a significant weight reduction of 5.6% (with a standard error (SE) of 0.81; P<.001) after 6 months. They maintained a weight loss of 4.7% (with an SE of 0.88; P<.001) at the 12-month mark. In contrast, the control group showed a negligible weight loss of 0.15% at 6 months (SE=0.64; P=0.85) and a slight weight gain of 0.33% (SE=0.70; P=0.63) at 12 months (17). In the systematic review, seven articles met the inclusion criteria. The most commonly observed measure in these studies was the change in participants' weight, which was noted in 57% of the studies. Additionally, most studies (71%) found statistically significant improvements in at least one area, including weight loss, increased physical activity, dietary habits, reduction in BMI, reduced waist circumference, decreased intake of sugarsweetened beverages, reduced screen time, and measures of satisfaction or acceptability (18). In our study as well, we observed improvements in weight management, physical activity, and QOL in the hyperactive group when the device was applied. The use of these devices is clinically significant for patients with breast cancer. Many of these patients consistently focus on dietary habits and weight management. Therefore, smartphone-based interventions that offer enhanced accessibility could improve patient care and reduce the risk of obesity.

However, this study has a few limitations. The main limitation regards the lack of information to identify the association of this program with OS or DFS in the participants. Further follow-up research is necessary to investigate the mobile health intervention value for OS and DFS. Another limitation of this study is the relatively small number of participants with severe obesity, defined as BMI > 30. Owing to the potential for different patterns of change depending on the degree of obesity, future studies may need to be stratified by similar proportions to address this variable.

Nevertheless, this study demonstrates a shift from the traditional, resource-intensive approaches to nutritional interventions and lifestyle modifications. By utilizing the mobile app-based Noom platform, this study enhanced the accuracy and feasibility of dietary assessment. Furthermore, it implemented personalized nutrition and lifestyle adjustments through human coaching. This study was able to realize improvements in nutrition and lifestyle habits, ultimately contributing to improvement in QOL among breast cancer survivors.

Conclusions

Combating obesity and encouraging healthy lifestyle habits are essential components of preventive and therapeutic strategies for breast cancer. Mobile health intervention strategies could prove beneficial in various programs by providing information and support for the self-monitoring of survivors within supervised settings.

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Conflicts of Interest

J. L. is employed by Noom, Inc., and receives a salary and stock options. The company had no role in this study design, data collection, analysis and article preparation or publication. The other authors have no conflicts of interest.

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Figure legend

Figure 1. Trials diagram of recruitment and completion

Figure 2. Weight, BMI and Body composition change of hyperactive vs non-hyperactive (inactive and active) group at 6 months, 12 months

Figure1.

Figure 1.

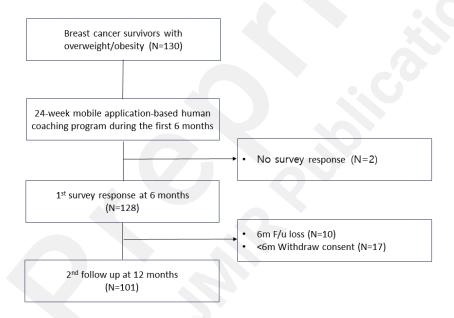


Figure 2.



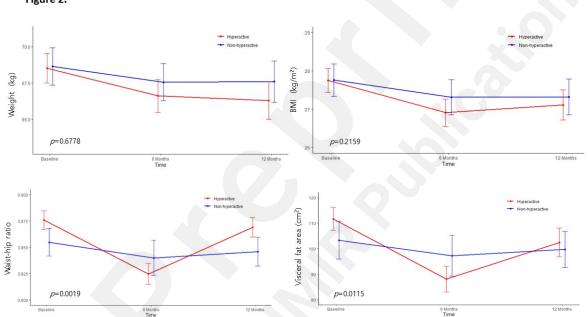


Table 1. Baseline characteristic of study population

Variables	racteristic of study population	Total	Hyperactive	Inactive &Active	P	
		N=101	N=68	N=33	1	
Age	Mean±SD	54.90±7.42	54.24±7.84	56.27±6.38	0.1974*	
Age group	≤40	5 (4.95%)	5 (7.35%)	0 (0%)	0.4654#	
	41-50	26 (25.74%)	18 (26.47%)	8 (24.24%)		
	51-60	43 (42.57%)	27 (39.71%)	16 (48.48%)		
	61-70	27 (26.73%)	18 (26.47%)	9 (27.27%)		
BMI	25-29.9	85 (84.16%)	58 (85.29%)	27 (81.82%)	0.8743†	
	≥30	16 (15.84%)	10 (14.71%)	6 (18.18%)		
Education	Less than a high school diploma	14 (13.86%)	10 (14.71%)	4 (12.12%)	0.1603#	
	High School Diploma	48 (47.52%)	28 (41.18%)	20 (60.61%)		
	College degree or higher	39 (38.61%)	30 (44.12%)	9 (27.27%)		
Education	Less than college degree	62 (61.39%)	38 (55.88%)	24 (72.73%)	0.1577†	
	College degree or higher	39 (38.61%)	30 (44.12%)	9 (27.27%)		
Occupation	Unemployment	56 (55.45%)	37 (54.41%)	19 (57.58%)	0.9310†	
•	Employment	45 (44.55%)	31 (45.59%)	14 (42.42%)		
T stage	1	67 (66.34%)	46 (67.65%)	21 (63.64%)	0.2375#	
8	2	30 (29.7%)	21 (30.88%)	9 (27.27%)		
	3	4 (3.96%)	1 (1.47%)	3 (9.09%)		
N stage	0	68 (67.33%)	51 (75%)	17 (51.52%)	0.0600#	
Š	1	29 (28.71%)	15 (22.06%)	14 (42.42%)		
	2	2 (1.98%)	1 (1.47%)	1 (3.03%)		
	3	2 (1.98%)	1 (1.47%)	1 (3.03%)		
Stage	I	53 (52.48%)	37 (54.41%)	16 (48.48%)	0.4296#	
	II	43 (42.57%)	29 (42.65%)	14 (42.42%)		
	III	5 (4.95%)	2 (2.94%)	3 (9.09%)		
ER	Negative	15 (14.85%)	11 (16.18%)	4 (12.12%)	0.7681#	
	Positive	86 (85.15%)	57 (83.82%)	29 (87.88%)		
PR	Negative	24 (23.76%)	15 (22.06%)	9 (27.27%)	0.7428†	
	Positive	77 (76.24%)	53 (77.94%)	24 (72.73%)		
HER2	Negative	86 (85.15%)	57 (83.82%)	29 (87.88%)	0.7681#	
	Positive	15 (14.85%)	11 (16.18%)	4 (12.12%)		
Surgery	BCS	87 (86.14%)	58 (85.29%)	29 (87.88%)	>0.9999#	
	Mastectomy	14 (13.86%)	10 (14.71%)	4 (12.12%)		
Chemotherapy	Done	49 (48.51%)	31 (45.59%)	18 (54.55%)	0.5270†	
.	Not done	52 (51.49%)	37 (54.41%)	15 (45.45%)		
Radiotherapy	Done	92 (91.09%)	61 (89.71%)	31 (93.94%)	0.7140#	
• •	Not done	9 (8.91%)	7 (10.29%)	2 (6.06%)		
Antihormonal therapy	Done	87 (86.14%)	57 (83.82%)	30 (90.91%)	0.5401#	
* J	Not done	14 (13.86%)	11 (16.18%)	3 (9.09%)		
HTN	Yes	28 (27.72%)	15 (22.06%)	13 (39.39%)	0.1122†	
	No	73 (72.28%)	53 (77.94%)	20 (60.61%)		
DM	Yes	13 (12.87%)	10 (14.71%)	3 (9.09%)	0.5379#	

	No	88 (87.13%)	58 (85.29%)	30 (90.91%)	
Hyperlipidemia	Yes	19 (18.81%)	14 (20.59%)	5 (15.15%)	0.7008†
	No	82 (81.19%)	54 (79.41%)	28 (84.85%)	

BMI: body mass index, T; tumor, N: node, ER: estrogen receptor, PR: progesterone receptor, HER2: human epidermal growth factor receptor 2, HTN: hypertension, DM: diabetes mellitus

*: T-test, †: Chi-squared test, #: Fisher's exact test

Table2. Change of body weight, BMI and body composition of hyperactive group during 6months

Variables	Hyperactive group (N=68)								
Variables	Baseline	6 months	Mean difference	95%CI	P ‡				
Weight (kg)	68.71±7.83	66.75±8.60	-1.96	(-2.65, -1.26)	<.0001				
BMI (kg/m²)	27.77±2.38	26.91±2.69	-0.86	(-1.15, -0.56)	<.0001				
SBP(mmHg)	132.65±13.07	129.66±12.85	-2.99	(-6.45, 0.48)	0.0901				
DBP(mmHg)	78.43±9.99	76.57±8.41	-1.85	(-4.22, 0.51)	0.1223				
FBS (mg/dL)	114.44±29.53	105.97±16.67	-8.47	(-14.79, -2.16)	0.0923				
HbA1C (%)	6.07±0.68	6.01±0.54	-0.06	(-0.15, 0.04)	0.2299				
Total cholesterol (mg/dL)	192.78±42.33	191.9±38.42	-0.88	(-7.85, 6.09)	0.8013				
Triglycerides (mg/dL)	172.68±93.92	138.54±99.29	-34.13	(-58.09, -10.17)	0.0059				
HDL-cholesterol (mg/dL)	56.18±13.90	57.76±13.62	1.59	(-0.79, 3.97)	0.1872				
LDL-cholesterol (mg/dL)	110.49±34.86	109.13±32.45	-1.35	(-7.61, 4.90)	0.6673				
Skeletal muscle mass(kg)	23.85±3.03	24.6±4.00	0.75	(0.12,1.38)	0.0203				
Body fat mass (kg)	25.18±5.23	22.17±6.90	-3.01	(-4.20, -1.81)	<.0001				
Percent body fat (%)	36.47±4.64	32.89±7.97	-3.58	(-5.25, -1.92)	0.0001				
Waist-hip ratio	0.88±0.07	0.84±0.14	-0.04	(-0.07, -0.002)	0.0365				
VFA (cm²)	113.1±34.57	90.09±41.3	-23.00	(-32.86, -13.15)	<.0001				

CI: confidence interval, BMI: body mass index, SBP: systolic blood pressure, DBP: diastolic blood pressure, FBS: Fasting blood sugar, HbA1C: Glycosylated Hemoglobin A1c, HDL: High-Density Lipoprotein, LDL: Low-Density Lipoprotein, VFA: visceral fat area ‡: Paired T-test

Table 3. Change of body weight, BMI and body composition of hyperactive group at 6, 12 month

x, •11	Hyperactive (N=61)		De	6months-Baseline		12months-Baseline		12months-6months		
Variables Baseline 6m	6months	12 months	P¶	Mean difference (95%CI)	Р‡	Mean difference (95%CI)	Р‡	Mean difference(95%CI)	P ‡	
Weight (kg)	68.52±7.88	66.61±8.78	66.3±10.25	0.2206	-1.91(-2.65, -1.17)	<.0001	-2.22(-3.67, -0.77)	0.0034	-0.31(-1.79, 1.17)	0.6778
BMI (kg/m²)	27.75±2.45	26.91±2.8	27.11±3.08	0.3409	-0.84(-1.16, -0.53)	<.0001	-0.64(-1.05, -0.23)	0.0026	0.2(-0.12, 0.53)	0.2159
SBP(mmHg)	132.18±13.43	129.44±13.22	131.98±11.87	0.4248	-2.74(-6.52, 1.04)	0.1526	-0.2(-4.01, 3.61)	0.9181	2.54(-0.74, 5.82)	0.1265
DBP(mmHg)	78.64±9.92	76.69±8.62	76.75±8.63	0.4047	-1.95(-4.54, 0.64)	0.1365	-1.89(-4.63, 0.86)	0.1744	0.07(-2.16, 2.3)	0.9533
FBS (mg/dL)	114.08±30.44	106.11±16.69	105.59±21.21	0.0846	-7.97(-14.82, -1.12)	0.0234	-8.49(-14.98, -2)	0.0112	-0.52(-4.98, 3.93)	0.8147
HbA1C (%)	6.04±0.69	5.99±0.54	6.10±0.70	0.6213	-0.05(-0.15, 0.05)	0.3322	0.06(-0.1, 0.22)	0.4281	0.11(-0.01, 0.24)	0.0725
Total cholesterol (mg/dL)	190.98±41.99	190.51±38.55	186.3±39.55	0.7766	-0.48(-7.89, 6.94)	0.8983	-4.69(-13.69, 4.31)	0.3016	-4.21(-10.26, 1.83)	0.1684
Triglycerides (mg/dL)	174.02±92.65	132.02±69.74	135.72±65.26	0.0044	-42(-63.67, -20.33)	0.0003	-38.3(-58.54, -18.05)	0.0004	3.7(-11.89, 19.3)	0.6364
HDL-cholesterol (mg/dL)	55.77±13.49	57.79±13.03	57.57±14.04	0.6649	2.02(-0.54, 4.58)	0.1203	1.8(-1.01, 4.61)	0.2040	-0.21(-2.51, 2.09)	0.8536
LDL-cholesterol (mg/dL)	109.64±35.16	109.02±32.92	107.8±34.99	0.9560	-0.62(-7.42, 6.17)	0.8551	-1.84(-9.77, 6.1)	0.6452	-1.21(-6.65, 4.22)	0.6569
Skeletal muscle mass(kg)	23.81±3.08	24.73±3.99	24.23±3.21	0.3393	0.92(0.28, 1.56)	0.0059	0.42(-0.09, 0.92)	0.1034	-0.5(-1.23, 0.23)	0.1749
Body fat mass (kg)	25.06±5.28	21.79±6.75	23.04±7.2	0.0204	-3.27(-4.5, -2.04)	<.0001	-2.02(-3.17, -0.87)	0.0009	1.25(-0.19, 2.7)	0.0886
Percent body fat (%)	36.39±4.72	32.36±7.53	33.78±6.85	0.0028	-4.03(-5.7, -2.36)	<.0001	-2.61(-4.08, -1.13)	0.0008	1.42(-0.5, 3.34)	0.1434
Waist-hip ratio	0.88±0.07	0.82±0.08	0.87±0.07	0.0003	-0.05(-0.08, -0.03)	<.0001	-0.01(-0.02, 0.01)	0.4013	0.04(0.02, 0.07)	0.0019
VFA (cm²)	111.68±35.05	88.12±39.47	102.45±43.44	0.0047	-23.56(-33.62, -13.5)	<.0001	-9.23(-16.72, -1.73)	0.0167	14.33(3.33, 25.33)	0.0115

CI: confidence interval, BMI: body mass index, SBP: systolic blood pressure, DBP: diastolic blood pressure, FBS: Fasting blood sugar, HbA1C: Glycosylated Hemoglobin A1c, HDL: High-Density Lipoprotein, LDL: Low-Density Lipoprotein, VFA: visceral fat area P¶: one way ANOVA, P‡: Paired T-test

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Table 4. Comparison of QOL in hyperactive group (N=61) through 12 months

	Hyperactive (N=61)				Hyperactive					
Variables	Baseline 6months		12 months	\square p¶	6months-Baseline		12months-Baseline		12months-6months	
	Mean±SD	Mean±SD	Mean±SD] - "	Mean difference (95%CI)	Р‡	Mean difference (95%CI)	Р‡	Mean difference (95%CI)	Р‡
EORTC QLQ-C30	•			•		•		•	•	
Global health status										
Global Health Status	66.94±19.06	67.49±18.43	70.9±18.92	0.4531	0.55(-4.35, 5.44)	0.8241	3.96(-1.54, 9.47)	0.1552	3.42(-2.21, 9.04)	0.2293
Functional scales										
Physical Functioning	82.62±10.91	84.04±9.98	83.39±13.31	0.7918	1.42(-1.21, 4.05)	0.2840	0.77(-2.43, 3.96)	0.6338	-0.66(-3.85, 2.53)	0.6824
Role Functioning	84.43±19.92	88.8±17.41	89.34±15.82	0.2494	4.37(-0.17, 8.91)	0.0587	4.92(0.16, 9.68)	0.0432	0.55(-4.44, 5.53)	0.8273
Emotional Functioning	82.1±17.54	78.96±21.87	80.87±16.41	0.648	-3.14(-8.39, 2.1)	0.2355	-1.23(-4.82, 2.36)	0.4958	1.91(-3.26, 7.09)	0.4626
Cognitive Functioning	79.51±17.58	80.6±15.57	79.51±18.61	0.9221	1.09(-3.09, 5.28)	0.6035	0(-3.31, 3.31)	1.0000	-1.09(-5.28, 3.09)	0.6035
Social Functioning	89.07±15.48	92.35±15.39	90.44±16.52	0.5168	3.28(-0.83, 7.39)	0.1159	1.37(-3.39, 6.13)	0.5680	-1.91(-7.15, 3.32)	0.4676
Symptom scales	•							•		
Fatigue	30.42±20.17	28.42±17.75	27.69±16.31	0.6907	-2(-6.52, 2.51)	0.3782	-2.73(-6.5, 1.04)	0.1524	-0.73(-4.68, 3.22)	0.7136
Nausea / Vomiting	7.38±13.45	2.73±6.93	3.01±9.38	0.0215	-4.64(-8.23, -1.06)	0.0119	-4.37(-8.02, -0.72)	0.0196	0.27(-1.86, 2.41)	0.7987
Pain	19.67±24.25	19.95±17.7	18.03±22.63	0.8707	0.27(-4.56, 5.11)	0.9104	-1.64(-7.13, 3.86)	0.5529	-1.91(-7.64, 3.82)	0.5071
Dyspnea	16.39±23.27	14.21±19.68	16.39±22.46	0.8162	-2.19(-9.13, 4.76)	0.5315	0(-6.79, 6.79)	1.0000	2.19(-3.41, 7.78)	0.4373
Insomnia	33.88±30.73	39.34±33.61	37.16±32.26	0.6419	5.46(-2.96, 13.88)	0.1992	3.28(-3.64, 10.2)	0.3470	-2.19(-9.96, 5.59)	0.5759
Appetite Loss	7.65±21.42	8.2±17.9	6.01±15.53	0.7932	0.55(-6.16, 7.25)	0.8710	-1.64(-8.15, 4.87)	0.6161	-2.19(-7.56, 3.18)	0.4187
Constipation	23.5±28.77	14.21±20.6	19.67±25.37	0.4901	-9.29(-15.15, -3.43)	0.0024	-3.83(-10.27, 2.62)	0.2398	5.46(-0.81, 11.73)	0.0864
Diarrhea	9.29±16.25	9.84±17.58	6.56±14.68	0.1249	0.55(-4, 5.09)	0.8106	-2.73(-6.64, 1.18)	0.1674	-3.28(-8.13, 1.58)	0.1819
Financial Problems	7.1±17.34	6.01±16.68	7.65±16.55	0.8612	-1.09(-6.25, 4.07)	0.6734	0.55(-3.72, 4.81)	0.7987	1.64(-3.15, 6.42)	0.4958
QLQ-C30 Summary Score	82.27±10.59	83.68±9.14	83.77±9.69	0.6407	1.41(-0.93, 3.75)	0.2339	1.5(-0.63, 3.63)	0.1651	0.09(-2.46, 2.64)	0.9442
EORTC QLQ-BR23	•					,				
Functional scales										
Body Image	67.35±27.19	75±25.69	71.45±25.43	0.2721	7.65(1.64, 13.67)	0.0136	4.1(-2.06, 10.25)	0.1880	-3.55(-8.83, 1.73)	0.1833
Future Perspective	50.82±28.94	58.47±27.66	56.28±28.25	0.3085	7.65(-0.94, 16.24)	0.0800	5.46(-2.81, 13.74)	0.1915	-2.19(-9.31, 4.93)	0.5415
Symptom scales						•		•		
Arm Symptoms	29.69±21.63	22.22±19.88	26.78±20.92	0.1393	-7.47(-12.02, -2.92)	0.0017	-2.91(-8.81, 2.98)	0.3270	4.55(-1.36, 10.46)	0.1285
Breast Symptoms	14.48±15.73	10.79±10.69	12.57±12.42	0.3015	-3.69(-7.33, -0.04)	0.0474	-1.91(-5.34, 1.52)	0.2689	1.78(-0.87, 4.42)	0.1845
Systemic Therapy	23.26±13.53	22.56±12.83	23.11±12.83	0.9526	-0.7(-3.69, 2.28)	0.6396	-0.16(-2.73, 2.42)	0.9040	0.55(-1.99, 3.09)	0.6685

SD: standard deviation, CI: confidence interval

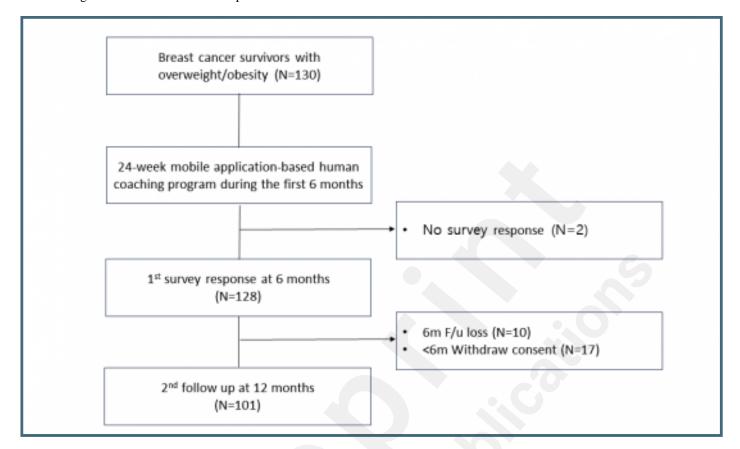
P¶: one way ANOVA, P‡: Paired T-test

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Supplementary Files

Figures

Trials diagram of recruitment and completion.



Weight, BMI and Body composition change of hyperactive vs non-hyperactive (inactive and active) group at 6 months, 12 months.

