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## **Original Article**

# Effectiveness of a Smartphone-Based Self-Management App (BeHealth app) for Women with Breast Cancer: A Randomized Controlled Trial

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#### **Abstract**

**Background:** Self-management and health behaviors are essential for improving the quality of life and preventing subsequent complications in patients with breast cancer. To investigate effects of a smartphone-application-based diet and exercise self-management program (BeHealth app) on self-efficacy, health behaviors, and selected cardiometabolic risk factors (body mass index, waist circumference, blood pressure, and fasting glucose) in women with breast cancer.

Methods: A randomized controlled trial was conducted with 49 participants (24 experimental, 25 control) in Seoul between Jan and Feb 2017, assigned using block randomization via Microsoft Excel. They received counseling and underwent a physical examination and blood testing at both trial's commencement and at a follow-up 12 wk later. The experimental group was given the BeHealth app for setting health goals, keeping a self-diagnosis and health record, and using chat space and health information for 12 wk. Statistical analysis was conducted using SPSS with ANOVA to assess the BeHealth app's effects on self-efficacy, health behaviors, and selected cardiometabolic risk factors over time between and within groups.

**Results:** The experimental group showed significantly increased levels of vegetable intake(P=.017) and significantly reduced levels of fasting blood glucose(P=.037) compared to the control group, suggesting that the Be-Health app may be effective in reducing cardiovascular disease risk factors.

**Conclusion:** The BeHealth app could be further developed to have compatibility with medical data and use in hospitals so that it is more appealing to target breast cancer survivors and increase its effectiveness for decreasing cardiometabolic risk factors in breast cancer survivors.

Keywords: Breast cancer; Diet; Health behavior; Mobile application; Smartphone

#### Introduction

The incidence of female breast cancer in South Korea is 68.6 per 100,000 population, making it the second most common cancer affecting Korean women (1,2). Due to early detection and increased therapeutic efficacy, there is a growing population of breast cancer survivors (2). How-

ever, there still are concerns of recurrence and metastasis of breast cancer in patients completed the initial treatment and survived for more than five years as well as in patients who experience complications in later stages of treatment (3).



Adverse effects associated with cancer treatment threaten the prognosis of women with breast cancer. Breast cancer patients received adjuvant treatment have higher risk for cardiovascular disease due to radiation-related cardiac damage and chemotherapy (4,5). This cardiotoxicity is fatal and carries a poor prognosis (6). Moreover, obesity and unhealthy life habits may lead to chronic diseases and cardiovascular diseases in women with breast cancer (7,8).

Therefore, breast cancer survivors should manage their health in order to prevent later-onset complications of breast cancer and chronic diseases (7,8). Weight reduction is one of representative ways to increase women with breast cancer's chances of survival (4).

Smartphone healthcare management applications (apps) are easily accessible (9). Since patients' smartphones can be used for mobile healthcare services, these services are free from cost involved in purchasing and using new devices. Therefore, using smartphones to provide healthcare services can encourage users to effectively manage their health because the use of smartphones is not limited by space or time with cost-effectiveness (9).

With high incidence rate and prevalence of breast cancer, the development of smartphone apps related to breast cancer is showing a steadily increasing trend. However, evidence-based practice and the involvement of medical professionals in the development of such apps are lacking. Considering such gap in the field, this study implemented a dietary and exercise self-management program for women with breast cancer using a smartphone app "BeHealth." We also examined the app's effects on users' lifestyles, and whether it positively affects selected cardiometabolic risk factors.

#### Methods

#### Study Design

This study was a randomized controlled trial to examine the effectiveness of a smartphone-appbased self-management program for improving self-efficacy, health behaviors, and selected cardiometabolic risk factors in women with breast cancer.

#### **Participants**

Participants were recruited at S Hospital, in Seoul between January and February 2017. Inclusion criteria were: women aged 18 to 69 yr with stage 0–III breast cancer diagnosed more than six months prior, and users of smartphones featuring Android 4.1 or higher.

The number of participants required for this study was calculated using G-power program (version. 3.1.9.2). When repeated measures analysis of variance (ANOVA) was performed with median effect size of 0.25, significant level of 0.05, power of test of 0.90, and the number of measurements of 2, the required number of participants was 46. Overall, 52 participants (26 per group) were finally recruited considering a dropout rate of 15% (10).

Participants were randomly and evenly assigned to experimental or control group using block randomization function of Microsoft Excel. During the trial, two members of the experimental group dropped out (one due to illness, the other did not use the BeHealth app). In the control group, one person dropped out before the posttest due to personal circumstances. Thus, the final number of participants was 24 in the experimental group and 25 in the control group.

# Intervention with BeHealth Smartphone Application (BeHealth App)

BeHealth App is a smartphone application developed based on DIETEX, a web-based self-management program (11). Since DIETEX is a web-based program, users have to use computers at designated locations to access the program. Therefore, BeHealth App, smartphone applications for women with breast cancer were developed to address these issues, promote health, and assist patients in self-management and improving their quality of life.

The BeHealth app was designed and developed by nursing professors, a nursing PhD student in, application developers, and designers between Jan and Dec 2016. Content validity was then validated through previous research and consultation with an endocrinologist, a breast surgeon, and a nursing professor. Afterwards, the final version of the app was tested for a month and confirmed its stability.

Participants in the experimental group of this study were asked to use BeHealth App for 12 wk. The BeHealth app has the following eight features (Fig. 1).

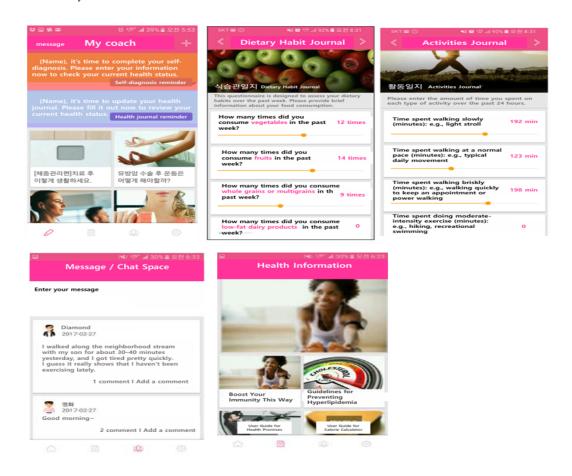


Fig. 1: Screenshot of the BeHealth application

- 1) Self-diagnosis: Users can check their health status by inputting their physical information, dietary habits, physical activity habits, stress level, fatigue, and so on;
- 2) Setting health goals: Users can select areas they wish to improve with regard to dietary habits, physical activity, and lifestyle. They can also set health goals and periodically evaluate their level of achievement of these goals;
- 3) Writing a health journal: Users can record their daily diet and physical activity so that they

- can conduct self-management and selfmonitoring;
- 4) Calorie calculator: When users input foods they have eaten in each meal, this feature analyzes calories and ratios of nutrients in these foods to enable self-monitoring;
- 5) Today's activity: This function can measure each user's level of activity by tracking movements of their smartphones and showing them results. Users can compare today's activities with previous days. Related feedback is also provided;

- 6) Chat space: This function allows users to use social network services to share information and opinions with other users (in this case, other women with breast cancer);
- 7) Health information: This function provides diverse educational content by experts (a nursing professor and a doctor of nursing practice), including diet, exercise, and lifestyle to help women with breast cancer establish goals and plans for the prevention and improvement of hyperglycemia, hypertension, obesity, dyslipidemia, and metabolic syndrome; and
- 8) Messaging: For the experimental group, individual management from experts was provided through expert messages transmitted at least once every week. These messages were based on data concerning each subject's body weight, diet, and physical activity. Further, users could interactively communicate through messaging. The information presented below was tested for content validity by one breast surgeon, one endocrinologist, and three nursing professors. We educated users concerning overweight and obesity and encouraged them to maintain appropriate weight and body fat.

#### **Procedures**

Data collection for this study was approved by the Institutional Review Board of the institutional review board of the Catholic University of Korea (IRB No. MC16FNSI0119).

After participants completed the questionnaire, body measurements were taken and blood samples were collected. Based on health status confirmed through pre- and post-test evaluations, nurses provided initial and final health consultation for 30 min. They explained current health status of the participant and provided information on diet, exercise, and other life habits appropriate for the participant.

The BeHealth app was used for the experimental group subsequently. In a quiet interview room, nurses installed BeHealth app for phones of participants in the experimental group and guided them to sign up for the application. After signing up, participants entered their health status and information about their health-related life habits.

Health diagnosis of participant was quantified and presented according to the logic of the Be-Health app.

#### Measurement

Questionnaire: Self-Efficacy and Health Behaviors

Self-efficacy was measured using a Korean translation of a scale developed by Schwarzer and Renner (12). The scale comprised 10 items (5 nutrition, 5 physical exercise), rated on a 4-point Likert scale, with higher scores indicating greater self-efficacy. Cronbach's alpha was 0.89 for nutrition and 0.91 for physical exercise domains.

Eating habits were surveyed using a modified and supplemented version of a dietary habit and food-intake-frequency questionnaire developed by Oh et al (13). It had 11 items (3 eating habits, 8 food intake type).

Physical activity was measured using a Korean translation of the Godin Leisure-Time Exercise Questionnaire developed by Godin (14). A higher score indicated greater physical activity. Specifically, physical activity was calculated using the following formula: weekly leisure-time activity score =  $(9 \times \text{strenuous}) + (5 \times \text{moderate}) + (3 \times \text{mild})$ .

#### Selected Cardiometabolic Risk Factors

After participants completed the questionnaire, their selected cardiometabolic risk factors were assessed by analyzing anthropometric data, measuring blood pressure, and conducting blood tests. Their heights, weights, and body fat percentage were measured. Body mass index (BMI) was calculated using the following formula: BMI = weight (kg)/height (m)<sup>2</sup>. Waist circumference was measured using a measuring tape. Blood pressure was measured twice with a five-minute interval while the participant was sitting. These two measurements were then averaged. Fasting blood glucose level was measured using 5 ml of venous blood collected after they had fasted for eight hours or longer. After 12 wk, post-test was performed for both groups using the same process as pre-test.

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#### Statistical Analysis

Statistical analysis was performed using SPSS software for Windows (ver. 18.0, Chicago, IL, USA). Chi-square test, Fisher's exact test, and ttest of homogeneity were applied to single categorical variables of the two groups. An independent samples t-test was then used to test differences between means of continuous variables of the two groups. Finally, effects of the Be-Health app on self-efficacy, health behaviors, and selected cardiometabolic risk factors were compared between and within the two groups over time using ANOVA. Pairwise comparisons were conducted using Bonferroni-adjusted post-hoc tests to identify significant differences between time points and groups following significant interaction effects. Statistical significance was set at P < .05.

#### Results

The homogeneity test revealed no significant difference in general characteristics, health status, or breast cancer—related characteristics between the experimental and control groups.

Mean age of the experimental group was 51.6 yr and that of the control group was 52.8 yr. There were 79.2% and 80.0% menopausal women in experimental and control groups, respectively, showing no significant difference between the two groups. The percentage of participants who were receiving chemotherapy during the trial was 12.5% in the experimental group and 8.0% in the control group. In addition, 62.5% and 56.0% of participants in experimental and control groups, respectively, were receiving hormone therapy, showing no significant difference between the two groups (Table 1).

Table 1: Demographics and Baseline Characteristics of the Study Participants

Characteristics	Exp. (N = 24)	Cont. (N = 25)	t/χ²	P
	Mean ± SI	Mean ± SD or N (%)		
Age (yr)	51.6 ± 9.7	52.8 ± 11.2	-0.38	.707
Current employment (yes)	8 (33.3)	13 (52.0)	1.74	.187
Regular physical activity <sup>a</sup> (yes)	15 (62.5)	11 (44.0)	1.68	.195
Taking medication prescribed for the following				
Hypertension	3 (12.5)	5 (20.0)		.702b
Diabetes	1 (4.2)	2 (8.0)		1.00b
Hyperlipidemia	5 (20.8)	3 (12.0)		.463b
Menopausal status (yes)	19 (79.2)	20 (80.0)		1.00b
Menopause age (years)	49.1 ± 5.2	$48.5 \pm 5.7$	0.38	.709
Tumor characteristics				
Stage 0	2 (8.3)	1 (4.0)		.147b
Stage I	5 (20.8)	12 (48.0)		
Stage II	11 (45.8)	10 (40.0)		
Stage III	6 (25.0)	2 (8.0)		
Time since breast cancer diagnosis (months)	$40.5 \pm 29.8$	$54.2 \pm 52.2$	-1.13	.266
Breast cancer recurrence (yes)	4 (16.7)	2 (8.0)		.417b
Current treatment status				
Chemotherapy	3 (12.5)	2 (8.0)		.667b
Radiation therapy	0 (0.0)	0 (0.0)		
Hormone therapy	15 (62.5)	14 (56.0)	0.21	.644
Time elapsed since the last treatment (months)	$22.9 \pm 18.6$	$41.0 \pm 49.0$	-1.60	.118

Exp.: Experimental group, Cont.: Control group, SD: standard deviation.

<sup>&</sup>lt;sup>a</sup>for at least 30 min per session, more than thrice per week. <sup>b</sup> Fisher's exact test.

Post-test score of nutrition self-efficacy tended to be higher than pre-test score in the experimental group and it tended to be lower than pre-test score in the control group. However, there was no significant difference in physical exercise selfefficacy, although the total score of the post-test tended to be higher than the pretest score for both the intervention and control groups (Table 2). Regarding instances of weekly vegetable intake, compared to those during pre-test, the experimental group showed an increase of 0.9 times per week in the post-test while the control group showed an increase of only 0.1 times per week, showing a significant interaction between group and time (P = .017; Table 2).

Table 2: Effectiveness of the BeHealth App in Regard to Promoting Self-Efficacy and Health Behaviors

Variable		Pre-test	Post-test	F(p)		
		Mear	±SD	Time	Group	Time*Group
Self-Efficacy						
Nutrition total score	Exp.	15.8 ± 1.6	$16.5 \pm 2.2$	0.30	2.36	2.08
DI 1 1 1 1 1	Cont.	$15.3 \pm 2.6$	$15.0 \pm 3.2$	(.585)	(.131)	(.156)
Physical exercise total score	Exp. Cont.	$13.5 \pm 1.9$ $12.9 \pm 3.1$	$14.0 \pm 1.9$ $13.4 \pm 3.1$	2.93 (.094)	0.63 (.430)	0.01 (.915)
Eating Habits (number of times pe		12.9 ± 3.1	13.4 ± 3.1	(.094)	(.430)	(.913)
Breakfast	Exp.	$6.0 \pm 1.2$	5.9 ± 1.4	0.61	2.54	1.10
Dicariast	Cont.	$5.0 \pm 2.5$	$5.2 \pm 2.2$	(.440)	(.117)	(.299)
Overeating	Exp.	$1.3 \pm 0.8$	$1.3 \pm 0.9$	0.43	1.54	0.04
Overeating	Cont.	$1.6 \pm 1.8$	$1.8 \pm 1.3$	(.515)	(.221)	(.837)
Eating out	Exp.	$2.0 \pm 1.3$	$2.2 \pm 1.2$	0.32	0.10	2.52
8	Cont.	$2.4 \pm 2.0$	$2.0 \pm 1.3$	(.573)	(.753)	(.119)
Vegetable intake	Exp.	$4.8 \pm 1.9^{a}$	5.7 ± 1.7a, c	8.71	3.63	6.13
<u> </u>	Cont.	$4.2 \pm 1.8^{b}$	$4.3 \pm 1.8$ b, c	(.005)	(.063)	(.017)
Fruit intake	Exp.	$5.7 \pm 1.8$	$5.5 \pm 2.0$	1.21	2.48	0.33
	Cont.	$5.0 \pm 2.1$	$4.6 \pm 1.7$	(.276)	(.122)	(.567)
Dairy production intake	Exp.	$3.7 \pm 2.2$	$3.5 \pm 2.0$	0.22	0.02	1.43
	Cont.	$3.4 \pm 2.5$	$3.9 \pm 2.1$	(.639)	(.891)	(.237)
Vegetable oil intake	Exp.	$4.5 \pm 1.9$	$4.5 \pm 2.0$	0.05	4.62	0.00
	Cont.	$3.4 \pm 2.0$	$3.4 \pm 1.8$	(.832)	(.037)	(.997)
High fat diet	Exp.	$1.3 \pm 1.3$	$1.3 \pm 1.0$	0.14	1.73	0.03
	Cont.	$1.8 \pm 1.5$	$1.6 \pm 1.2$	(.708)	(.195)	(.856)
High calorie snacks intake	Exp.	$1.5 \pm 1.6$	$1.3 \pm 1.2$	2.17	0.16	.416
	Cont.	$1.8 \pm 1.6$	$1.3 \pm 1.3$	(.148)	(.690)	(0.67)
High salt diet	Exp.	$1.0 \pm 1.1$	$0.9 \pm 1.0$	0.02	0.06	0.20
	Cont.	$1.0 \pm 0.9$	$1.0 \pm 1.1$	(.877)	(.811)	(.660)
Sugar intake	Exp.	$1.2 \pm 1.5$	$0.8 \pm 1.0$	0.34	3.42	2.09
DI 1 1 A .1 1	Cont.	1.6 ± 1.5	$1.7 \pm 1.6$	(.564)	(.071)	(.155)
Physical Activity		40.0 1.466	07.0   44.0	40.44	4.40	0.00
Godin leisure-time exercise	Exp.	$18.3 \pm 16.6$	$27.2 \pm 16.0$	13.46	1.63	0.08
score (N=24) C	Cont.	$13.9 \pm 13.3$	$21.5 \pm 17.6$	(.001)	(.208)	(.778)

Exp.: Experimental group (N=24), Cont.: Control group (N=25), SD: standard deviation.

Bonferroni-adjusted post-hoc comparisons: a significant time effect in the Exp. group (P< .001); b not significant in the Cont. group (P=.737)

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Compared to those at pre-test, systolic blood pressure in the experimental group decreased 5.1mmHg from 116.3mmHg to 111.2mmHg after 12 wk of the intervention, whereas systolic blood pressure in the control group decreased 1.1mmHg from 116.2mmHg to 115.1mmHg (P= .037). However, there was no interaction between group and time.

Repeated measures ANOVA of fasting blood glucose showed a significant Time\*Group interaction (P=.037) and a significant main effect of Time (P=.021).

Post-test fasting blood glucose level in the experimental group was decreased by 5.1 mg/dl compared to that at pre-test. However, in the control group, it was decreased by 0.3 mg/dl, showing an interaction between group and time (P=.037). Bonferroni-adjusted post-hoc comparisons revealed Within-group comparisons indicated that fasting blood glucose decreased significantly from baseline to week 12 in the intervention group (P=.003) but not in the control group (P=0.861; Table 3).

Table 3: Effectiveness of the BeHealth App on the Selected Cardiometabolic Risk Factors

Variable		Pre-test	Post-test	F(p)		
		Mean±SD		Time	Group	Time*Group
Weight (kg)	Exp.	59.1 ± 11.2	$58.6 \pm 10.5$	2.84	0.32	0.50
	Cont.	57.4 ± 8.1	$57.2 \pm 8.3$	(.099)	(.574)	(.484)
Body fat Percentage (%)	Exp.	$33.1 \pm 7.2$	$33.1 \pm 7.0$	0.35	0.45	0.78
	Cont.	$32.0 \pm 6.2$	$31.6 \pm 6.4$	(.560)	(.506)	(.380)
Body mass index (kg/m²)	Exp.	$23.5 \pm 3.6$	$23.4 \pm 3.4$	1.91	0.05	0.36
	Cont.	$23.3 \pm 3.4$	$23.2 \pm 3.5$	(.173)	(.830)	(.550)
Waist circumference (cm)	Exp.	85.2 ± 9.4	84.4 ± 8.8	1.07	0.01	0.32
	Cont.	84.6 ± 8.3	84.4 ± 8.1	(.307)	(.908)	(.574)
Systolic blood pressure (mmHg)	Exp.	$116.3 \pm 14.5$	$111.2 \pm 12.7$	4.62	0.24	1.98
	Cont.	$116.2 \pm 14.5$	$115.1 \pm 16.2$	(.037)	(.629)	(.166)
Diastolic blood pressure (mmHg)	Exp.	$75.3 \pm 9.1$	$74.4 \pm 10.6$	0.00	0.63	0.96
	Cont.	$72.2 \pm 9.2$	$73.2 \pm 11.4$	(.950)	(.432)	(.333)
Fasting blood glucose (mg/dl)	Exp.	97.1 ± 13.9 <sup>a</sup>	$92.0 \pm 9.8^{a}$	5.74	0.68	4.62
	Cont.	92.4 ± 9.3 <sup>b</sup>	$92.1 \pm 8.2^{b}$	(.021)	(.415)	(.037)

Exp.: Experimental group (N=24), Cont.: Control group (N=25), SD: standard deviation.

Bonferroni-adjusted post-hoc comparisons: asignificant time effect in the Exp. group (P=.003); b not significant in the Cont. group (P=.861)

#### Discussion

The BeHealth app could increase self-efficacy in women with breast cancer. Moreover, the experimental group's level of vegetable intake was higher than that of the control group. Such increased self-efficacy could change their eating habits. We identified health needs and requirements of our participants by analyzing data of the

experimental group entered into the BeHealth app and personal messages they sent to researchers through the app. Individualized feedback that researchers provided for each app user might have positively affected users' self-efficacy and their eating habits. These findings are similar to those of previous studies reporting that individualized messages are more effective for improving self-efficacy and eating habits than group mes-

sages (15). The self-efficacy improved resulted in self-regulatory behaviors that enabled them to practice healthy dietary habits and physical activities (16,17). For web-health users, even a small increase in self-regulatory behavior can greatly influence their dietary habits and physical activities (17). The BeHealth app applied in this study also seems to improve the participants' selfefficacy by acting as a catalyst that promotes selfregulatory behaviors, and seems to have a positive effect on health behaviors. According to previous studies (16), health behavior self-efficacy functions along with health utilization skills such as health literacy. Hence, to improve self-efficacy, health literacy should be assessed first, and the intervention of more individualized experts must be necessary.

In this study, body weights and waist circumferences of the experimental group were found to be generally reduced to a greater degree than those of the control group, although differences between the two groups were not significant change. These results are similar to those of a previous study showing that implementing a 12week mobile-based health (mHealth) intervention among adults leads to no significant change in waist circumference after the intervention (18). A possible reason for our study's finding is that a 12-week period might be too short to observe significant effects on lifestyle modification. An Internet-based intervention had greater effects when it lasts for more than six months (18). Thus, smartphone interventions may require an intervention period longer than six months to have significant changes. Furthermore, a previous study has shown that applying healthy diet and/or exercise is a successful prognostic management (19). Thus, service programs that can provide personalized diets for each individual need to be developed. This can be achieved by upgrading functions of the BeHealth app to simply record and monitor users' intake.

Our results showed that fasting blood glucose levels in the experimental group were reduced significantly more than those in the control group. This result differs from results of the abovementioned mHealth study which shows no

change of fasting blood glucose level in its participants (18). This is presumable because the Be-Health app involves active participation of participants along with interactive communication with experts who also provide data analysis reports (20). Such feedback for participants has been found to be important for mHealth interventions as it strongly affects improvements in cardiometabolic risk factors (18). In particular, high fasting insulin levels in early breast cancer patients are associated with an increased risk of breast cancer recurrence and death (21). Therefore, the application of the BeHealth app to breast cancer patients is clinically useful and essential for managing fasting blood glucose and fasting insulin levels.

The self-administered program that sets behavioral goals, establishes plans, tracks them, and provides automatic professional feedback has an advantage of promoting health (21). However, when software developers without medical knowledge develop health apps, they face limitations (22). To overcome these limitations, it is necessary to introduce a smartphone application-based intervention program in which experts actively participate in the development, like the BeHealth app used in this study. Thus, through the clinical application of the BeHealth app, breast cancer survivors can prevent the relapse of breast cancer and reduce the cardiometabolic risk factors.

Despite this app's effectiveness, this study has several limitations. First, in the satisfaction survey, convenience of use ranked the lowest. Per most users, its use was interrupted due to Internet connection problems. Correcting such problems is hence necessary to ensure its stable use. Second, further studies on BeHealth with larger sample sizes and longer follow-up duration are warranted. Third, although health behaviors were surveyed using structured questionnaires, the study's aim was limited to obtaining objective data due to the self-administered format of the questionnaire.

#### Conclusion

BeHealth app can improve self-efficacy and health behaviors, while reducing cardiometabolic risk factors in breast cancer survivors. Thus, Be-Health app is recommended for breast cancer survivors to decrease their cardiometabolic risk factors. Additionally, future studies should address BeHealth app's efficacy in preventing weight gain in women newly diagnosed with breast cancer or subjected to different treatment regimens and/or those at an increased risk of breast cancer. Further research should also explore its potential in reducing heart attack risk and other cardiovascular outcomes in this population.

#### Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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#### Conflict of interest

The authors declare that there is no conflict of interests.

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