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Cardiorespiratory fitness in breast cancer survivors: a randomised controlled trial of home-based smartphone supported high intensity interval training

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► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/bmjspcare-2021-003141>).

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Received 21 April 2021

Accepted 4 June 2021



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To cite: Ochi E, Tsuji K, Narisawa T, *et al.* *BMJ Supportive & Palliative Care* Epub ahead of print: [please include Day Month Year]. doi:10.1136/bmjspcare-2021-003141

ABSTRACT

Background A strategy for maintaining and/or improving cardiorespiratory fitness (CRF) in the growing population of cancer survivors is of major clinical importance, especially in the COVID-19 era. The effect of unsupervised high-intensity interval training (HIIT) on increasing CRF in breast cancer survivors is unknown.

Purpose The purpose of this study was to determine whether the newly developed habit-B programme, which involves home-based smartphone-supported HIIT using body weight exercises, improves CRF in early-stage breast cancer survivors.

Methods This single-centre, 12-week, parallel-group, single-blind, randomised controlled trial involved 50 women with stage I-IIa breast cancer, aged 20–59 years, who had completed initial treatment except for hormone therapy. Participants were randomised to either the exercise or control group. The primary outcome was the 12-week change in peak oxygen uptake ($\dot{V}O_{2peak}$). Other outcomes included muscle strength, 6 min walk test, resting heart rate, physical activity, fatigue, safety and quality of life.

Results The change in $\dot{V}O_{2peak}$ and leg strength increased significantly in the exercise group compared with the control group ($p < 0.01$). Changes in other outcomes were not significantly different between the groups.

Conclusion A home-based HIIT intervention can lead to improve CRF and muscle strength in early-stage breast cancer survivors.

INTRODUCTION

Exercise may play a role in maintaining and improving common cancer-related

Key messages

What was already known?

- Cardiorespiratory fitness is inversely associated with cardiovascular and all-cause mortality in breast cancer survivors.
- Exercise may prevent cancer and improve a variety of cancer health-related outcomes (eg, fatigue, quality of life, functioning, depression and anxiety).

What are the new findings?

- We confirmed that originally developed 12-week home-based smartphone-supported exercise programme (habit-B programme) improved peak oxygen uptake and muscle strength compared with treatment as usual in sedentary breast cancer survivors in Japan.

What is their significance?

- This clinical trial was the world's first home-based high-intensity interval training programme using Information and Communication Technology (ICT) to increase cardiorespiratory fitness and muscle strength in sedentary breast cancer survivors.
- The habit-B programme was designed based on the theory of Bandura for sedentary breast cancer survivors to develop exercise habits.
- Collaborative work with professionals in the field of clinical oncology, exercise science, mental health, rehabilitation, public health, nursing and cancer survivors constitutes a new model for cancer survivorship care.

health outcomes, including physical fitness, quality of life (QOL) and fatigue.¹ Exercise guidelines for cancer survivors

issued by multiple international organisations recommend maintaining high levels of physical activity.^{1–3} Previous studies of physical activity and exercise intervention among breast cancer survivors have mainly focused on weight loss,⁴ impairment of endothelial function and lower bone density in postmenopausal women. The exercise and nutrition to enhance recovery and good health for you (ENERGY) trial, an early and representative study conducted in the USA, demonstrated the effectiveness of a home exercise programme and nutritional advice to promote weight loss among breast cancer survivors.⁴ However, because the proportion of overweight adults in Japan is lower than that in the USA, it is not appropriate to adopt the US-developed programme in Japan. It would appear suitable though to develop intervention around cardiorespiratory fitness (CRF), which is the globally important health indicator.^{5,6} In addition, given that the COVID-19 pandemic has made getting sufficient exercise difficult,⁷ there is an urgent need for a home-based exercise programme that can improve CRF.^{5,6}

With the aim of increasing CRF, recent studies have focused on the use of high-intensity interval training (HIIT). HIIT consists of repeated sets of short bursts of high-intensity exercise followed by a rest interval. Most of previous studies were conducted in supervised experimental settings, which appeared to be more beneficial than usual care in cancer survivors at all stages of treatment and aftercare.^{8,9} However, to our knowledge, no study has investigated the effects of an unsupervised home-based HIIT programme in breast cancer survivors.⁹

Therefore, the aim of this study was to clarify the effects and feasibility of the newly developed home-based high-intensity interval training and behavioral modification using information and communication technology on cardiorespiratory fitness and exercise habits among sedentary breast cancer survivors (habit-B) program.¹⁰ We hypothesised that the habit-B programme would improve peak oxygen uptake ($\dot{V}O_{2\text{peak}}$) compared with a control group.

METHODS

The study protocol has been described elsewhere.¹⁰ Briefly, this was a 12-week, parallel-group, single-blind, randomised controlled trial, in which participants were randomly assigned to intervention either with the habit-B programme or control with a smartwatch (Fitbit Versa; Fitbit, San Francisco, California, USA). The protocol was registered with UMIN-CTR (ID: 000036400). Outcomes were assessed at baseline and postintervention (12 weeks). Recruitment was carried out between 27 May 2019 and 14 August 2020 at the National Cancer Center Hospital. Participants were registered using an electronic data capture (EDC) system. After baseline assessments, participants were randomly assigned to one of the two arms by the minimisation method, a form of dynamic computer-generated

randomisation, using two prognostic factors: $\dot{V}O_{2\text{peak}}$ and age. The allocation sequence was concealed from the clinical and research staff. The contents of the smartphone app that the participants used during the trial were assigned automatically to either the habit-B programme or control and data security was protected using blockchain technology.¹¹ Objective physical measurements were performed by trained and blinded assessors unaware of the assignment information.

habit-B programme interventions

The habit-B programme involves home-based exercise for 12 weeks (three times per week) with counselling/exercise guidance and support provided via personalised email and a newly developed smartphone app (mobile push notifications).¹⁰ The details of these exercises were divided into three stages according to $\dot{V}O_{2\text{peak}}$ at week 0 and the contents of training were designed to increase physical strength incrementally in accordance with the individual's level of strength. Maximum rated perceived exertion during exercise was monitored to evaluate whether the intensity of the exercise performed was appropriate (18 ± 2). The control group was given with a smartwatch at the start of the intervention. At the end of the study period, all participants were offered the habit-B programme.

Assessment measures

The primary outcome measure was CRF ($\dot{V}O_{2\text{peak}}$). $\dot{V}O_{2\text{peak}}$ was measured using the incremental multi-stage load method with a bicycle ergometer (Ergomic 828E, Monark, Stockholm, Sweden) at 60 revolutions per min (rpm). The test began at 29.4 watt and increased by 14.7 watt per min until exhaustion. When the participant's pedal rotation speed dropped below 55 rpm three times, the test was deemed concluded. Secondary outcomes included a 6 min walk test, one-repetition maximum (1RM) for leg press, grip strength, chair stand test, resting heart rate and blood pressure, and body composition analysis (MC-780A-N; Tanita, Tokyo, Japan). Also, the following electronic patient-reported outcomes (PROs) were obtained: Global Physical Activity Questionnaire score, Cancer Fatigue Scale¹² and health-related QOL.¹³ Exercise adherence was monitored by input into the app and by heart rate on the smartwatch. The safety of the intervention was assessed through emails, phone calls and input into the app from participants.

Data collection, management, monitoring and auditing

PRO data were collected using the electronic PRO system on the smartphone app and the EDC was used to manage and monitor the data.

STATISTICAL ANALYSES

The sample size was calculated by using changes in $\dot{V}O_{2\text{peak}}$ with the exercise intervention as described.¹⁰

Differences between the habit-B group and the control group were compared by an independent two-sample t-test to evaluate the degree of change in all outcomes from baseline to week 12. One-sided tests were used for $\dot{V}O_{2peak}$ (mL/kg/min) and two-sided tests were used for others. Analyses were performed using IBM SPSS Statistics V.26. Data were collected from 30 November 2020 to 27 May 2019. Data analysis, which followed the intention-to-treat approach, was performed from 28 December 2020 to 6 January 2021.

RESULTS

Fifty breast cancer survivors were randomised to either the habit-B group (n=25) or the control group (n=25) (online supplemental figure 1). One participant in the habit-B group dropped out and five other participants could not complete outcome assessment because of issues related to the COVID-19 pandemic (n=4) and poor physical condition (n=1). Baseline characteristics

did not differ between the two groups (online supplemental table 1).

Primary outcome

Participants in the habit-B programme group showed significantly larger improvement in $\dot{V}O_{2peak}$ compared with those in the control group (0.9 (95% CI 0.1 to 1.7) vs -0.8 (95% CI -1.5 to -0.1), $p<0.01$) (table 1). The difference in the amount of change between the two groups was 1.7 (95% CI 0.7 to 2.7), and the effect size (ES) was 1.06.

Physical function and examination

Participants in the habit-B programme group also showed a significant improvement in 1RM for leg press ($p<0.01$; table 1). No significant intervention effect was found for the other physical functions (table 1). Resting heart rate was maintained by the habit-B programme ($p=0.041$; online supplemental table 2).

Table 1 Changes in cardiorespiratory fitness and muscle strength from baseline to week 12

	habit-B (n=21)	Control (n=23)	Between-group difference		
	Mean (SD)	Mean (SD)	Mean (95% CI)	ES	P value
Primary endpoint					
$\dot{V}O_{2peak}$ (mL/kg/min)					
Baseline	25.0 (3.0)	24.9 (4.6)			
Week 12	25.9 (2.8)	24.1 (4.0)			
Within-group difference	0.9 (1.7)	-0.8 (1.6)	1.7 (0.7 to 2.7)	1.06	<0.01
Secondary endpoint					
Cardiorespiratory fitness					
6MWT (m)*					
Baseline	586 (43)	603 (59)			
Week 12	615 (42)	631 (68)			
Within-group difference	30 (30)	29 (40)	1 (-21 to 23)	0.26	0.93
$\dot{V}O_{2peak}$ (L/min)					
Baseline	1.33 (0.18)	1.32 (0.29)			
Week 12	1.39 (0.23)	1.29 (0.26)			
Within-group difference	0.06 (0.11)	-0.03 (0.09)	0.10 (0.03 to 0.16)	0.95	<0.01
Muscle strength					
Grip strength (kgw)					
Baseline	22.4 (3.8)	23.3 (4.2)			
Week 12	23.2 (4.2)	23.7 (3.4)			
Within-group difference	0.8 (2.0)	0.4 (2.1)	0.4 (-0.9 to 1.6)	0.26	0.53
Leg press 1RM (kg)*					
Baseline	93.6 (24.3)	98.7 (40.6)			
Week 12	106.6 (26.7)	98.2 (30.9)			
Within-group difference	13.0 (15.9)	-0.5 (18.1)	13.5 (2.9 to 24.1)	0.79	0.01
Chair stand test (s)*					
Baseline	14.4 (3.2)	13.7 (2.5)			
Week 12	13.5 (2.9)	13.3 (2.5)			
Within-group difference	-0.9 (2.7)	-0.4 (1.8)	-0.5 (-1.9 to 0.9)	-0.21	0.50

*The number of 6MWT, Leg press 1RM and Chair stand test were 20 for habit-B and 23 for control. ES, Effect Size; 6MWT, 6 min walk test; 1RM, one-repetition maximum; $\dot{V}O_{2peak}$, peak oxygen uptake.

PRO measures

Compared with the control group, the habit-B programme group showed some beneficial effects in terms of fatigue (ES=0.50, $p=0.09$) but not for physical activities or QOL (online supplemental table 3).

Adherence and adverse event

The adherence rate was 86% (range 19%–100%). No serious (grade ≥ 3) adverse events occurred.

DISCUSSION

This is first study to reveal that a home-based 12-week HIIT regimen involving body weight exercises improves $\dot{V}O_{2peak}$ as the primary endpoint and maintains resting heart rate as the secondary endpoint in sedentary breast cancer survivors. Given that previous observational studies have demonstrated an association between increased CRF and reduced cancer-related mortality,¹⁴ it is reasonable to expect that improving $\dot{V}O_{2peak}$ may improve health-related outcomes in cancer survivors. The present findings related to CRF are consistent with those of a previous meta-analysis study focusing on supervised HIIT in cancer survivors (10 trials; 2.1 mL/kg/min).¹⁵ Although the present programme led to slightly less improvement (1.7 mL/kg/min) compared with these earlier supervised and lab-based studies, we believe that our home-based programme is promising for cancer survivors as a feasible intervention.

In addition, we confirmed that the habit-B programme improved leg strength (15.6%), which was similar to that reported in a previous study involving supervised HIIT (13.3%).⁶ This result might be an important outcome related to avoiding sarcopaenia in the future. Although the habit-B programme did not affect body composition or physical activity, it led to a meaningful reduction in fatigue, which could be a potential target symptom for exercise intervention.

There are two limitations of our study. Given that our results may not be generalisable to all breast cancer survivors, we need to conduct further large-scale multi-centre studies. In addition, due to movement control order implemented to contain the spread of COVID-19, we had to stop our face-to-face assessments and consequently postponed the outcome measurements except for PRO. A subanalysis demonstrated similar results ($\dot{V}O_{2peak}$, 1.5, 95% CI 0.5 to 2.5; 1RM, 15.7, 95% CI 3.6 to 27.7) even when we excluded the participants who could not visit our lab on their scheduled date, suggesting that our programme may not have been substantially affected by the COVID-19 pandemic.

In summary, our findings support the incorporation of home-based and unsupervised exercise programmes into breast cancer survivorship care plans, especially in the COVID-19 era. The strengths of our programme are its efficiency, feasibility and safety in terms of improving CRF by using a home-based setup

of e-health technology and unsupervised body weight exercises.

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Acknowledgements The authors wish to thank Professors Uchitomi (National Cancer Centre Japan), Imoto (Kyorin University) and Iwata (Aichi Cancer Centre) and Dr Shimazu (National Cancer Centre Japan) for their generous support and helpful advice. We are grateful for the contributions of Fitbit for research support. The authors also wish to thank the following current or former staff compensated for their efforts in data management and outcome measurement of this project: Ms Akutsu, Dr. Ishino, Ms Mitsuyama, Mr Hirayama and Ms Shimoji. We thank Dr Kinoshita for intellectual input in protocol development. This study was supported by the National Cancer Centre Research and Development Fund (30-A-17).

Contributors EO, AK and YM conceived and designed the study. AS, KJ and ST recruited the subjects. KT and AK conducted the data analysis. EO, KT and YM drafted the main text, figure and tables. All authors reviewed the manuscript and contributed to acquisition, analysis and interpretation of data. All authors have approved the completed version of the manuscript. EO and YM are cocorresponding authors for this manuscript.

Funding This study is supported by a National Cancer Centre Research and Development Fund (30-A-17).

Competing interests EO has received research support from Nippon Suisan Kaisha. AK has received speaking fees from Chugai Pharmaceutical. TU is a president and shareholder of SUSMED. YM has received speaker fees from Suntory, Pfizer, Mochida, Eli Lilly, Morinaga Milk and Cimic.

Patient consent for publication Not required.

Ethics approval The protocol was approved by the Institutional Review Board of the National Cancer Center Japan on 28 February 2019 (No: 2018–274).

Provenance and peer review Not commissioned; externally peer reviewed.

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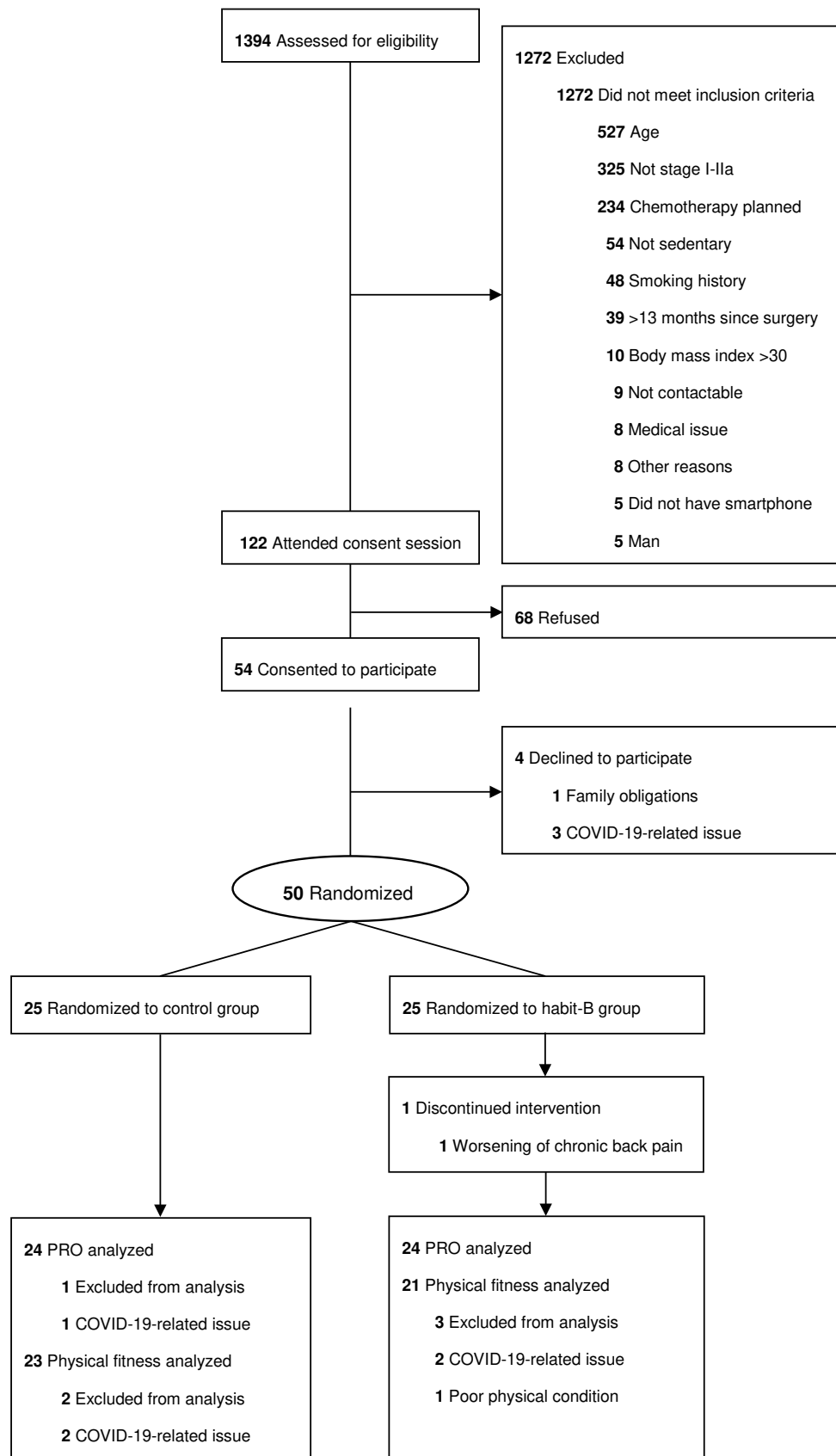
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Supplementary Table 1. Demographic and medical characteristics		
Characteristics	habit-B (<i>n</i> = 25)	Control (<i>n</i> = 25)
Age, mean (<i>SD</i>), y	48 (6)	49 (5)
Body mass index, mean (<i>SD</i>), kg/m ²	21.0 (2.2)	20.9 (2.0)
Diastolic blood pressure, mean (<i>SD</i>), mmHg	78 (8)	81 (10)
Systolic blood pressure, mean (<i>SD</i>), mmHg	119 (13)	129 (11)
Alcohol consumption, <i>n</i> (%)		
≤weekly	8 (32)	5 (20)
1–6 drinks per week	15 (60)	19 (76)
Daily	2 (8)	1 (4)
Highest Education, <i>n</i> (%)		
Junior high school	0 (0)	1 (4)
High school	3 (12)	0 (0)
College or more	22 (88)	24 (96)
Employment status, <i>n</i> (%)		
Full- or part-time worker	21 (84)	21 (84)
On leave	1 (4)	0 (0)
Housewife	3 (12)	4 (16)
Time the patient can use for herself, <i>n</i> (%)		
<14 hours/week	10 (40)	5 (20)
14–25 hours/week	8 (32)	11 (44)
>25 hours/week	7 (28)	9 (36)
Past history of medical illness, <i>n</i> (%)	6 (24)	6 (24)
Breast cancer stage		
I	18 (72)	18 (72)
IIA	7 (28)	7 (28)
Tumor		
Estrogen receptor positive	24 (96)	25 (100)
Progesterone receptor positive	24 (96)	24 (96)
HER2 positive	1 (4)	0 (0)
Receiving hormone therapy, <i>n</i> (%)	24 (96)	23 (92)
Tamoxifen, <i>n</i> (%)	18 (72)	18 (72)
Anastrozole, <i>n</i> (%)	1 (4)	4 (16)
Other, <i>n</i> (%)	5 (20)	1 (4)
Receiving radiotherapy, <i>n</i> (%)	11 (44)	12 (48)
Time since surgery, mean (<i>SD</i>) months	5 (4)	6 (4)

SD, standard deviation; HER2, human epidermal growth factor receptor 2

Supplementary Table 2.

Changes in heart rate, blood pressure, and body composition from baseline to week 12

	habit-B (<i>n</i> = 21)		Control (<i>n</i> = 23)		Between-group difference	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (95% CI)	ES	<i>p</i>
Resting heart rate (bpm)						
Baseline	81 (8)	75 (9)				
Week 12	80 (9)	82 (11)				
Within-group difference	0 (9)	6 (11)		-7 (-13 to 0)	-0.64	0.04
Systolic blood pressure, (mmHg)						
Baseline	120 (14)	129 (11)				
Week 12	118 (11)	124 (13)				
Within-group difference	-2 (10)	-6 (11)		4 (-2 to 10)	0.38	0.22
Diastolic blood pressure, (mmHg)						
Baseline	79 (7)	82 (10)				
Week 12	78 (9)	80 (13)				
Within-group difference	-1 (9)	-2 (8)		1 (-4 to 6)	0.12	0.70
Body mass (kg)						
Baseline	53.4 (6.6)	53.1 (6.0)				
Week 12	53.8 (7.2)	53.5 (6.2)				
Within-group difference	0.4 (1.8)	0.4 (1.2)		0.0 (-0.9 to 0.9)	-0.01	0.98
Body mass index, (kg/m²)						
Baseline	21.1 (2.3)	21.0 (2.0)				
Week 12	21.3 (2.4)	21.2 (2.0)				
Within-group difference	0.2 (0.7)	0.2 (0.5)		0.0 (-0.4 to 0.3)	-0.01	0.98
Fat mass (kg)						
Baseline	16.1 (4.2)	15.8 (3.9)				
Week 12	16.5 (5.0)	16.1 (3.8)				
Within-group difference	0.4 (1.7)	0.4 (0.9)		0.6 (-0.8 to 0.9)	0.04	0.89
Body fat (%)						
Baseline	29.8 (4.6)	29.3 (4.6)				
Week 12	30.2 (5.1)	29.8 (4.2)				
Within-group difference	0.5 (2.1)	0.5 (1.3)		-0.01 (-1.1 to 1.1)	0.00	0.99
Lean mass (kg)						
Baseline	35.2 (2.9)	35.3 (2.6)				
Week 12	35.2 (2.9)	35.3 (3.0)				
Within-group difference	0.0 (0.6)	0.0 (0.7)		-0.1 (-0.5 to 0.4)	-0.09	0.77

SD, standard deviation; CI, confidence interval

Supplementary. Table 3. Changes in subjective measures from baseline to week 12

	habit-B (<i>n</i> = 24)		Control (<i>n</i> = 24)		Between-group difference	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (95% CI)	ES	<i>p</i>
Physical activity (GPAQ)						
Total score (min/week)						
Baseline	89 (112)	142 (179)				
Week 12	309 (564)	257 (354)				
Within-group difference						
Baseline to week 12	220 (520)	115 (239)	105 (-130 to 340)	0.26	0.37	
MVPA (min/week)						
Baseline	8 (17)	7 (25)				
Week 12	39 (90)	49 (108)				
Within-group difference						
Baseline to week 12	31 (93)	47 (101)	-11 (-69 to 47)	-0.11	0.71	
Sedentary time (min/day)						
Baseline	454 (184)	453 (194)				
Week 12	386 (212)	408 (270)				
Within-group difference						
Baseline to week 12	-64 (177)	-45 (237)	-19 (-141 to 103)	-0.09	0.75	
Fatigue (CFS)						
Baseline	20.17 (9.54)	18.71 (7.53)				
Week 12	17.50 (9.84)	19.96 (10.29)				
Within-group difference						
Baseline to week 12	-2.67 (7.76)	1.25 (7.81)	3.92 (-8.44 to 0.61)	-0.50	0.09	
QOL (EQ-5D total score)						
Baseline	0.95 (0.62)	0.94 (0.83)				
Week 12	0.92 (0.07)	0.88 (0.09)				
Within-group difference						
Baseline to week 12	-0.03 (0.07)	-0.06 (0.10)	0.03 (-0.02 to 0.08)	0.34	0.25	

SD, standard deviation; CI, confidence interval; GPAQ, Global Physical Activity Questionnaire score; MVPA, moderate to vigorous physical activity; CFS, Cancer Fatigue Scale; QOL, quality of life; EQ-5D, EuroQOL 5 dimensions (a standardized instrument for measuring generic health status)