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# Efficacy of health coaching and a web-based program on physical activity, weight, and distress management among cancer survivors: A multi-centered randomised controlled trial

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## Abstract

**Objectives:** To investigate the efficacy of health coaching and a web-based program on survivor physical activity (PA), weight, and distress management among stomach, colon, lung and breast cancer patients.

**Methods:** This randomised, controlled, 1-year trial conducted in five hospitals recruited cancer survivors within 2 months of completing primary cancer treatment who had not met  $\geq 1$  of these behavioural goals: (i) conducting moderate PA for at least 150 minutes/week or strenuous exercise for over 75 minutes per week or, in the case of lung cancer patients, low or moderate intensity exercise for over 12.5 MET per week, (ii) maintaining normal weight, and (iii) attaining a score  $>72$  in the Post Traumatic Growth Inventory (PTGI). Participants were randomly assigned to one of three groups: the control group, a web-only group, or a health coaching + web group. The primary endpoint was based on a composite of PA, weight, and PTGI score at 12 months.

**Results:** Patients in the health coaching + web group (difference = 6.6%,  $P = .010$ ) and the web-only group (difference = 5.9%,  $P = .031$ ) had greater overall improvements across the three-outcome composite than the control group. The health coaching + web group had greater overall improvement in PTGI (difference = 12.6%;  $P < .001$ ) than the control group, but not in PA and weight.

**Conclusion:** The web-based program, with or without health coaching, may improve health behaviours including PA, weight, and distress management among cancer survivors within 2 months of completing primary cancer treatment. The web-based program with health coaching was mainly effective for reducing psychological distress.

#### KEYWORDS

body weight, coaching, distress management, oncology, physical activity

## 1 | INTRODUCTION

In the transition from treatment to survivorship, many cancer patients face persistent health problems.<sup>1</sup> Many settle into physical inactivity, weight gain, and psychological distress, all of which lower their health-related quality of life (HRQOL).<sup>2-4</sup> These problems suggest that cancer should be managed as a chronic illness.<sup>5</sup> Although there have been a few interventions conducted for improvements in health behaviour, changes such as PA, weight control, and distress management,<sup>5-9</sup> the cancer-care continuum needs a paradigm shift to empower patients to strengthen self-management (SM) for survivorship.<sup>10</sup> Some randomised controlled trials (RCTs) with behavioural interventions for chronically ill patients based on the Chronic Care Model (CCM) showed health improvements,<sup>11</sup> but the CCM has not yet been effectively applied to cancer patients as an SM strategy. New strategies to see patients through their cancer crisis and enhance their HRQOL are needed, but few studies have investigated the long-term effects of interventions designed to improve multiple cancer survivor behaviours simultaneously.<sup>11,12</sup> We developed Smart Management Strategies for Health (SMASH) to help patients proactively manage their health.<sup>13,14</sup> We conducted a RCT to evaluate the efficacy of health coaching plus Healthing U on physical activity (PA), weight, and post-traumatic positive growth against a usual care control in a large sample of patients. Health coaching empowers patients to take care of themselves and Healthing U is a SMASH-based online health management program.

## 2 | METHODS

This was a prospective RCT with three arms. Three hundred and ninety-four cancer patients within 2 months of treatment termination were randomly assigned to usual care (control group), a web-based program (Healthing U) (intervention group I), or health coaching by trained nurses plus Healthing U (intervention group II). Health coaching lasted for the first 6 months with a 6-month follow-up. The study protocol was approved by the Seoul National University

Hospital (SNUH) Institutional Review Board (1501-117-645). Written informed consent was obtained from participants, and the study was performed in accordance with the Declaration of Helsinki. This trial is registered with ClinicalTrials.gov, number NCT02650661.

### 2.1 | Participants

We recruited cancer patients who met the following criteria: (i) 20 years or more of age, (ii) within 2 months of completion of primary cancer treatment, (iii) failed, according to a questionnaire, to meet one or more of the following behavioural goals of the study: (i) conducting moderate PA for at least 150 minutes/week or strenuous exercise for over 75 minutes per week or, in the case of lung cancer patients, low or moderate intensity exercise for over 12.5 MET per week, (ii) maintaining a normal body mass index (BMI,  $\text{kg}/\text{m}^2$ ) (18.5-22.9;  $\geq 18.5$  for lung cancer patients),<sup>4</sup> (iii) achieving a total score of  $>72$  points in the (Post Traumatic Growth Inventory [PTGI]), and (iv) consenting to participate in the study. In the transition from treatment to survivorship, many cancer survivors require intervention for health behaviors immediately after active treatment. Therefore, we enrolled patients who had stomach, colon, lung, and breast cancer (the most common cancers in Korea) and who were within 2 months of treatment termination.

Patients were excluded from the study if they (i) were currently receiving cancer treatment, (ii) had a progressive malignant disease or a recurrent, metastasized, or additional primary cancer, (iii) had a condition that might compromise adherence to an unsupervised exercise program, such as uncontrolled congestive heart failure or angina, a recent myocardial infarction, breathing difficulties requiring oxygen use or hospitalization, used a walker or wheelchair, or were planning hip or knee replacement surgery, (iv) had a condition that could interfere with a diet high in vegetables and fruit, such as kidney failure or chronic warfarin use, (v) had a serious psychological disorder, such as bipolar disease, schizophrenia, or an eating disorder, (vi) had an infection (body temperature  $\geq 37.2^\circ\text{C}$  or WBC  $\geq 11\,000\text{ mm}^3$ ), (vii) had a visual or motor dysfunction, or (viii) were pregnant. Patients eligible to

participate in the study were recruited by the physician in charge and asked to provide written informed consent.

## 2.2 | Enrollment

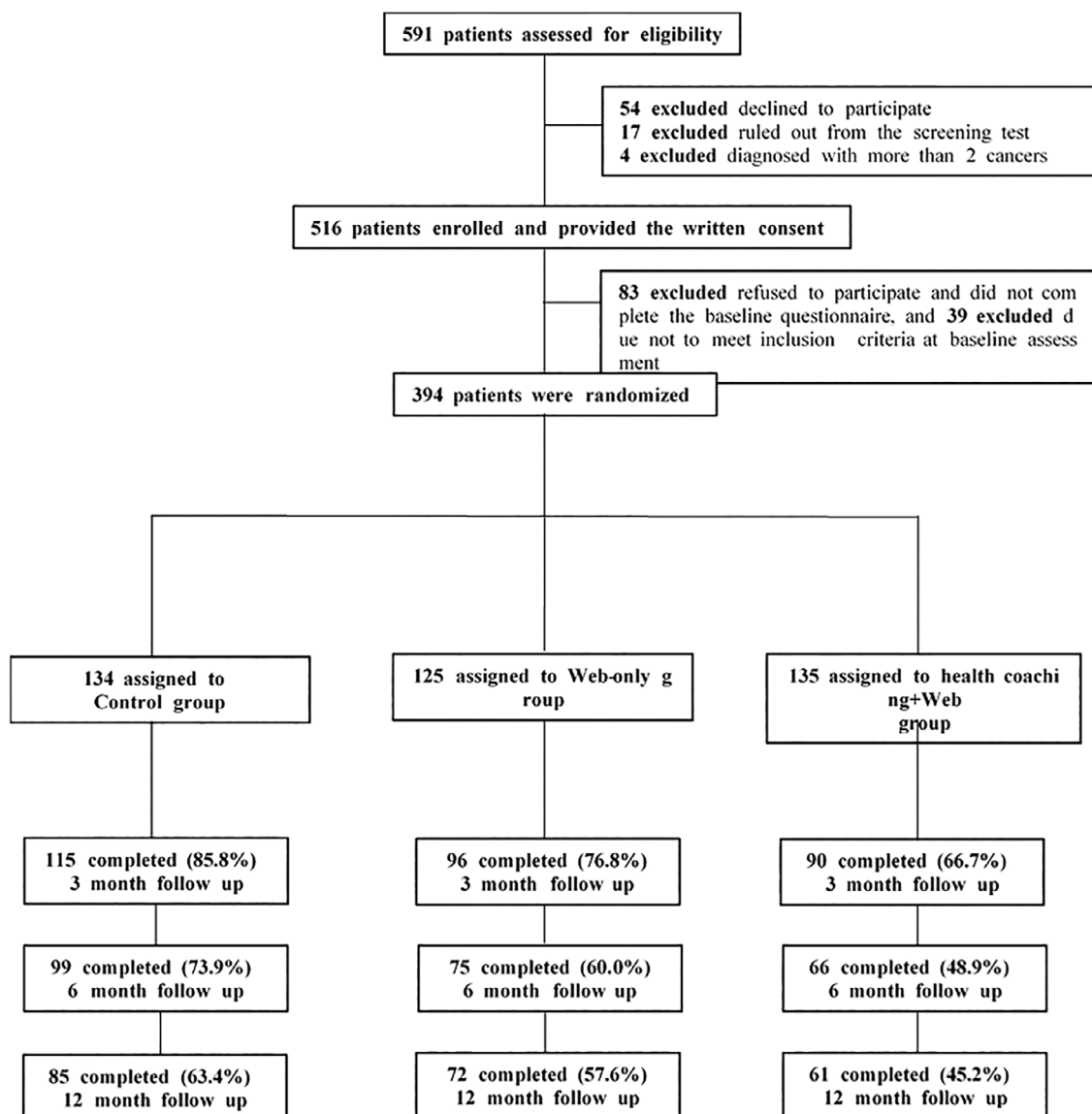
A physician and a clinical research coordinator (CRC) in each study hospital screened patients for eligibility criteria by reviewing medical records and blood test results. The CRC explained the details of the study to the participants who met the eligibility criteria (Figure 1).

From November 2015 to April 2016, using cancer registries of five South Korean hospitals, we identified patients with breast, stomach, colon (but not rectum), or lung cancer who were within 2 months of having completed primary cancer treatment. The Institutional Review Boards of the five hospitals approved the study protocol, and the patients' physicians provided permission to contact the patients.

We randomly assigned patients to the control and two intervention groups using a computerised random number generator (SAS 9.1.3; Proc plan). To minimise the effects of potential confounding variables, we stratified the patients by cancer type (breast, stomach, colon, or lung), sex, and the enrollment hospital. A research assistant generated the random allocation sequence and assigned participants to interventions. Blinding of participants was not possible because of the nature of the interventions. The CRCs who measured study outcomes were blinded to group allocation.

## 2.3 | Control condition

A health education booklet on 10 health topics (eg, PA, diet, and distress management) was passively disseminated to the control group. This booklet was different from that given to the experimental groups and



**FIGURE 1** Flow of participants through study

was disseminated in a different manner. In addition, the control group was encouraged to continue usual care. Booklets were sent at the baseline and at the second and fourth month. Usual care was defined as returning to their pre-study and being provided by routine care.

## 2.4 | Intervention: a Web-based program or health coaching by trained nurses plus web-based program

The 6-month SMASH intervention included (i) SMASH-based online health management program (Healthing U), (ii) SMASH-based health education booklet and a health strategy workbook for cancer patients, (iii) SMASH-based telephone coaching, and (iv) a workshop for empowerment of patients' SM ability. Intervention group I participated in the SMASH-based online health management program and was provided with the SMASH-based health education booklet and a health strategy workbook for cancer patients. Intervention group II also participated in the SMASH-based online health management program and was also provided with the SMASH-based health education booklet and a health strategy workbook for cancer patients. In addition, intervention group II participated in 20 health coaching sessions and 3 workshops. The intervention program covered all behaviours of physical activity (PA), diet, and post-traumatic positive growth for intervention group. (see Appendix S1).

## 2.5 | Outcome assessments

We evaluated the primary outcomes (PA, weight, and positive growth) at baseline and at months 3, 6, and 12. PA, weight, and positive growth are independent prognostic value for long-term survival in cancer survivors.<sup>2-4</sup> We measured PA with the modified version of the Godin Leisure-Time Exercise Questionnaire, which is widely used, reliable, and valid.<sup>15</sup> The goal was to achieve moderate-intensive PA for over 150 minutes per week or strenuous exercise for over 75 minutes per week, (low- or moderate-intensity exercise for over 2.5 hours per week for lung cancer patients).<sup>16</sup>

We measured positive growth using the PTGI, which includes 21 questions with five domains. Each question uses a 6-point (0-5) Likert scale. Positive growth is defined as a positive psychological change experienced as a result of a traumatic event in order to rise to a higher level of functioning.<sup>17</sup> The results are summed to measure PTGI change. Higher scores indicate greater post-traumatic positive growth.<sup>17</sup> The study goal was to achieve a PTGI score of over 72 points. We also set achieving a normal BMI of 18.5 to 22.9 kg/m<sup>2</sup> ( $\geq 18.5$  kg/m<sup>2</sup> for lung cancer patients) as a goal.

Participants were asked to measure their behaviours (10 Rules for Highly Effective Health Behavior) with five scales: (i) pre-contemplation, (ii) contemplation, (iii) preparation, (iv) action, and (v) maintenance, all based on the transtheoretical model.<sup>7</sup> We assessed the SM strategies of health with the SMASH Assessment Tool (SAT), which is a three-set, 16-factor, 91-item tool (ie, the core strategies with 28 items, preparation strategies with 30 items, and

implementation strategies with 33 items) that assesses the patients' ability to overcome their health-related crisis.<sup>13</sup>

We evaluated anxiety and depression with the Hospital Anxiety and Depression Scale (HADS), which consists of 14 items (7 for anxiety and 7 for depression),<sup>18</sup> the Brief Fatigue Inventory (BFI) scale, which consists of nine items that rate fatigue severity and interference on a 0-to-10 scale,<sup>19</sup> and the social support (2 items) and spiritual (6 items) scales of the McGill Quality of Life (McGill QOL) scale.<sup>20</sup>

Participants completed the same questionnaires, which take about 30 minutes to complete, at baseline and at months 3, 6, and 12.

## 2.6 | Sample size

To ensure stability and a sufficient number of subjects, we used primary index as a categorical variable when calculating sample size. The primary endpoints were three categorical indicators (regular exercise, weight, and positive growth), to which a power of 90%, type 1 error, control group's natural improvement rate of 5%, and the intervention group's improvement rate of 25% were attributed. Thus, a 20% difference between the groups is applied, while a 1:1:1 ratio is used to calculate the sample size of the control and intervention group, resulting in 429 people. In addition to the previous calculation, a 10% dropout rate was taken into consideration. Thus, the sample size was estimated at 477 people.

## 2.7 | Statistical methods

Intervention effects were explored using an intention-to-treat approach that compared data with that of the original randomised groups. We described the characteristics of the experimental and control groups using numbers and percentages for categorical variables and means and SDs for continuous variables. We evaluated the homogeneity of the baseline characteristics of the three groups using analysis of variance (ANOVA) (for evaluation of continuous variables) and the chi-squared test (for evaluation of categorical variables).

We estimated between-group differences in the changes of categorical outcomes for primary and secondary outcomes from baseline to the latest available outcome by analysis of covariance with generalised estimation equation modelling using the SAS GENMOD procedure (SAS Institute Inc., Cary, NC). The categorical outcomes were measured as the percentage of the achieved target goal for BMI, PA, and post-traumatic growth at 3, 6, and 12 months. As the intervention program was developed to cover all behaviours of physical activity, weight management, and post-traumatic positive growth; the primary endpoint was based on a composite of PA, weight, and PTGI score at 12 months. Two-outcome composite was coded as 1 if the participants achieved two or all of three goals, otherwise as 0. Three-outcome composite was coded as 1 if the participants achieved all of three goals, otherwise as 0. The individual comparisons identified which components were responsible for the change. All statistical tests were two sided and performed using Stata/SE for Windows (version 14-0), SAS 9-4 (SAS Institute Inc., Cary, NC), and R software (version 3-5-1).

**TABLE 1** Baseline characteristics of participants (n = 394)

	Control group (N = 134)	Web-based support without health coaching group (N = 125)	Web-based support with health coaching group (N = 135)	P-value <sup>a</sup>
Age, Mean $\pm$ SD, years	54.39 $\pm$ 11.02	54.37 $\pm$ 11.04	52.69 $\pm$ 10.52	.342
Sex, No. (%)				
Male	53 (39.6)	49 (39.2)	51 (37.8)	.951
Female	81 (60.4)	76 (60.8)	84 (62.2)	
Education, No. (%) (n = 131)				
$\geq$ College graduate	62 (47.3)	43 (36.8)	62 (48.4)	.131
$\leq$ High-school graduate	69 (52.7)	74 (63.2)	66 (51.6)	
Marital status, No. (%) (n = 132)				
Married or with partner	105 (79.5)	89 (76.1)	103 (82.4)	.816
Widowed, divorced or separated	17 (12.9)	15 (12.8)	13 (10.4)	
Single	10 (7.6)	13 (11.1)	9 (7.2)	
Residence, No. (%) (n = 129)				
Metropolitan	62 (48.1)	56 (48.7)	75 (59.0)	.332
Urban/suburban	51 (39.5)	47 (40.9)	43 (33.9)	
Rural	16 (12.4)	12 (10.4)	9 (7.1)	
Religion, No. (%) (n = 132)				
No	51 (38.6)	38 (32.8)	58 (45.3)	.132
Yes	81 (61.4)	78 (67.2)	70 (54.7)	
Household income, No. (%) (n = 126)				
< 2000 USD	29 (23.0)	31 (27.7)	33 (26.6)	.551
2000 to 4000 USD	53 (42.1)	42 (37.5)	40 (32.3)	
$\geq$ 4000 USD	44 (34.9)	39 (34.8)	51 (41.1)	
Cancer type, No. (%)				
Breast cancer	49 (36.5)	43 (34.4)	48 (35.5)	.997
Lung cancer	34 (25.4)	33 (26.4)	36 (26.7)	
Colorectal cancer	30 (22.4)	28 (22.4)	27 (20.0)	
Stomach cancer	21 (15.7)	21 (16.8)	24 (17.8)	
Cancer stage, No. (%)				
Stage I	83 (61.9)	77 (61.6)	83 (61.5)	.745
Stage II	29 (21.6)	27 (21.6)	28 (20.7)	
Stage III	21 (15.7)	16 (12.8)	21 (15.6)	
Others	1 (0.8)	5 (4.0)	3 (2.2)	
Body-mass index, Mean $\pm$ SD	23.3 $\pm$ 3.0	23.1 $\pm$ 3.0	23.3 $\pm$ 3.1	.838
Physical activity (MET), Mean $\pm$ SD	14.6 $\pm$ 27.4	18.9 $\pm$ 34.5	18.3 $\pm$ 28.4	.459
Posttraumatic growth inventory, Mean $\pm$ SD	58.1 $\pm$ 20.9	61.7 $\pm$ 18.6	59.1 $\pm$ 18.4	.060

<sup>a</sup>P-value was calculated by Chi-square for categorical value and analysis of variance (ANOVA) for continuous value.

### 3 | RESULTS

#### 3.1 | The study population

A total of 394 patients were enrolled from November 23, 2015, to April 15, 2016, and were randomly assigned to the control group (134 patients), the web-only group (125 patients), or the health coaching + web group (135 patients) (Figure 1). The statistical power

of this study was maintained at 0.92. Table 1 shows the baseline characteristics of the three study groups. There were no significant differences in baseline characteristics among the patients who failed to meet one, two, or three behaviour goals, and a comparison of the data among the three study groups did not reveal any significant differences (Appendix S1). Of all the members of the SMACH + web group, 72.6% (98 of 135) completed 1 or more coaching sessions, and 54.1% completed 16 or more coaching sessions in 3 months. Sixty or more

of the SMASH + web group completed 20 coaching sessions in 6 months.

### 3.2 | Primary outcomes

At 12 months, the patients in the health coaching + web group did not show improvement in the physical activity and BMI except for PTGI than those in the control group (Table 2). Patients in the web-only without health coaching group also did not show significant improvement in PA, BMI, and PTGI.

At 12 months, the patients in the health coaching + web group showed significantly greater improvement in the three-outcome composite than those in the control group ( $P = .010$ ) (Table 2). Patients in the web-only without health coaching group also showed a significant

improvement ( $P = .031$ ). The differences between the intervention I, intervention II, and control groups in three outcome composites were 6.63% in the health coaching + web group and 5.92% in the web-only group. Differences between intervention and control groups on individual primary outcome scores for weight, PA, and PTGI were significant for PTGI score only between the health coaching + web and control groups, (difference = 12.62%;  $P < .001$ ).

### 3.3 | Secondary outcomes

At 12 months after the intervention, the reduction in anxiety score was greater for the health coaching+ web group than the control group (difference = 1.89 points;  $P = .045$ ), but depression score changes did not differ significantly in the three groups (Table 3). The

**TABLE 2** Efficacy of smart management strategy for health (SMASH) program for primary outcome

Time point <sup>a</sup>	Control Group (N = 134)		Web-based support without health coaching (N = 125)			Web-based support with health coaching (N = 135)		
	Success, No. (%)	Change <sup>b</sup>	Success, No. (%)	Change <sup>b</sup>	P-value <sup>c</sup>	Success, No. (%)	Change <sup>b</sup>	P-value <sup>c</sup>
Physical activity								
Baseline	27 (20.2)		31 (24.8)			33 (24.4)		
3 months	49 (36.6)		48 (38.4)			48 (35.6)		
6 months	36 (26.9)		32 (25.6)			28 (20.7)		
12 months	46 (34.3)	14.2	54 (43.2)	18.4	.077	47 (34.8)	10.4	.346
Body mass index (BMI)								
Baseline	54 (40.3)		51 (40.8)			57 (42.2)		
3 months	54 (40.3)		40 (32.0)			34 (25.2)		
6 months	43 (32.1)		29 (23.2)			21 (15.6)		
12 months	51 (38.1)	-2.2	41 (32.8)	-8.0	.888	36 (26.7)	15.6	.300
Post-traumatic growth inventory (PTGI)								
Baseline	48 (35.8)		47 (37.6)			41 (30.4)		
3 months	38 (28.4)		45 (36.0)			46 (34.1)		
6 months	34 (25.4)		28 (22.4)			37 (27.4)		
12 months	43 (32.1)	-3.7	42 (33.6)	-4.0	.442	53 (39.3)	8.9	<.001
Two-outcome composite <sup>d</sup>								
Baseline	30 (22.4)		42 (33.6)			34 (25.2)		
3 months	45 (33.6)		40 (32.0)			47 (34.8)		
6 months	38 (28.4)		35 (28.0)			34 (25.2)		
12 months	42 (31.3)	8.9	43 (34.4)	0.8	.972	43 (31.9)	6.7	.289
Three-outcome composite <sup>e</sup>								
Baseline	0 (0.0)		0 (0.0)			0 (0.0)		
3 months	13 (9.7)		13 (10.4)			15 (11.1)		
6 months	6 (4.5)		7 (5.6)			12 (8.9)		
12 months	6 (4.5)	4.5	13 (10.4)	10.4	.031	15 (11.1)	11.1	.010

<sup>a</sup>If the 12-month data was missing, latest visit values were used.

<sup>b</sup>The change is the baseline proportion to the 12-month proportion.

<sup>c</sup>The comparison of success rate change between groups was calculated by a generalised estimation equation (GEE) compared to the control group.

<sup>d</sup>Two-outcome composite was coded as 1 if the participants achieved two or all of three goals (physical activity, BMI, and PTGI), otherwise as 0.

<sup>e</sup>Three-outcome composite was coded as 1 if the participants achieved all of three goals (physical activity, BMI, and PTGI), otherwise as 0.

**TABLE 3** Differences in clinical and quality-of-life measures

Time point <sup>a</sup>	Control group (N = 134)		Web-based support without health coaching (N = 125)			Web-based support with health coaching (N = 135)		
	Mean (SD)	Change <sup>b</sup>	Mean (SD)	Change <sup>b</sup>	P-value <sup>c</sup>	Mean (SD)	Change <sup>b</sup>	P-value <sup>c</sup>
Hospital anxiety and depression scale (HADS)								
Anxiety score								
Baseline	6.2 (4.0)		5.4 (3.7)			5.90 (4.1)		
3 months	5.2 (3.3)		4.9 (3.4)			4.74 (3.3)		
6 months	5.4 (3.6)		4.3 (4.1)			3.39 (3.0)		
12 months	5.9 (3.6)	−0.4	5.4 (4.3)	0.0	.645	4.39 (3.3)	−1.5	.045
Depression score								
Baseline	6.8 (3.1)		6.3 (2.9)			6.4 (3.0)		
3 months	6.6 (3.1)		5.8 (3.0)			5.7 (2.6)		
6 months	6.0 (3.1)		4.8 (3.0)			4.2 (3.0)		
12 months	6.7 (2.8)	−0.1	6.0 (2.9)	−0.2	.822	5.8 (2.8)	−0.6	.290
Smart management strategy for health assessment tool (SAT) ( $\geq 66.6$ ), No. (%)								
Core strategy								
Baseline	57 (42.5)		59 (47.2)			60 (44.4)		
3 months	54 (40.3)		53 (42.4)			48 (35.6)		
6 months	50 (37.3)		40 (32.0)			29 (21.5)		
12 months	53 (39.6)	−3.0	54 (43.2)	−4.0	.368	51 (37.8)	−6.7	.246
Preparation strategy								
Baseline	36 (26.9)		36 (28.8)			36 (26.7)		
3 months	30 (22.4)		34 (27.2)			27 (20.0)		
6 months	32 (23.9)		25 (20.0)			18 (13.3)		
12 months	40 (29.9)	3.0	37 (29.6)	−0.8	.787	34 (25.2)	−1.5	.711
Implementation strategy								
Baseline	27 (20.2)		22 (17.6)			22 (16.3)		
3 months	26 (19.4)		22 (17.6)			28 (20.7)		
6 months	24 (17.9)		23 (18.4)			15 (11.1)		
12 months	27 (20.2)	0.0	30 (24.0)	6.4	.127	32 (23.7)	7.4	.030
Brief fatigue inventory								
Baseline	3.81 (2.7)		3.96 (2.4)			3.9 (2.7)		
3 months	3.97 (2.3)		3.44 (2.3)			3.0 (2.0)		
6 months	3.76 (2.1)		3.07 (2.4)			3.27 (2.0)		
12 months	3.65 (2.2)	−0.2	3.23 (2.1)	−0.7	.112	3.01 (2.1)	−0.9	.072
McGill quality of life								
Existential well being								
Baseline	6.8 (2.0)		7.5 (1.4)			7.0 (1.8)		
3 months	7.1 (1.8)		7.6 (1.4)			7.4 (1.6)		
6 months	7.3 (1.6)		7.6 (1.7)			7.4 (1.6)		
12 months	7.3 (1.8)	0.5	7.4 (2.0)	−0.1	.085	7.2 (1.9)	0.2	.329
Social support								
Baseline	7.5 (2.0)		7.7 (1.7)			7.6 (1.9)		
3 months	7.2 (2.0)		7.6 (2.0)			7.6 (1.8)		
6 months	7.1 (2.0)		7.6 (1.9)			7.4 (1.6)		
12 months	7.3 (1.9)	−0.2	7.5 (1.2)	−0.1	.811	7.4 (2.2)	−0.2	.991

(Continues)



**TABLE 3** (Continued)

Time point <sup>a</sup>	Control group (N = 134)		Web-based support without health coaching (N = 125)			Web-based support with health coaching (N = 135)		
	Mean (SD)	Change <sup>b</sup>	Mean (SD)	Change <sup>b</sup>	P-value <sup>c</sup>	Mean (SD)	Change <sup>b</sup>	P-value <sup>c</sup>
Self-reported health status (very good or best)								
Baseline	0.9 (1.4)		1.1 (1.5)			0.9 (1.4)		
3 months	1.1 (1.7)		1.3 (1.5)			1.4 (1.6)		
6 months	1.3 (1.6)		1.6 (1.8)			1.5 (1.7)		
12 months	1.2 (1.7)	0.3	1.5 (1.8)	0.4	.749	1.7 (1.8)	0.9	.046
Health behaviour maintenance (more than half of health behaviour), No. (%)								
Baseline	31 (23.1)		33 (26.4)			40 (28.9)		
3 months	34 (25.4)		38 (30.4)			53 (39.3)		
6 months	52 (38.8)		40 (32.0)			49 (36.3)		
12 months	58 (43.3)	20.2	57 (45.6)	19.2	.533	72 (53.3)	24.4	.006

<sup>a</sup>If the 12-month data was missing, latest visit values were used.

<sup>b</sup>The change is the baseline mean (or proportion) to the 12-month mean (or proportion).

<sup>c</sup>The comparison of success rate change between groups was calculated by a generalised estimation equation (GEE) compared to control group.

health coaching + web group had the highest proportion with improvement in the SAT implementation strategy (difference = 7.40%;  $P = .030$ ). After 12 months, however, the three groups did not differ significantly in fatigue and quality of life. For health status, the number that felt very good or best increased significantly in the health coaching + web group ( $P = .046$ ). The proportion of those who maintained more than half of the 10 health habits increased significantly only in the health coaching + web group (difference = 4.29%;  $P = .006$ ).

## 4 | DISCUSSION

In this RCT of cancer survivors who were within 2 months of completing their cancer treatment, the intervention involving health coaching combined with a web program built on the SMASH program compared with usual care showed a significantly greater overall 12-month improvement of a three-outcome composite of health behaviours and PTGI. Compared with patients in the control group, patients in the web program only group showed a significantly greater overall 12-month improvement of the three-outcome composite. It appears that the composite results were driven entirely by a reduction in post-traumatic growth, and the use of a composite outcome with three components might have caused us to overestimate the effects of the intervention.

The extent of improvements in primary outcomes in our trial compared favourably with findings from earlier behavioural interventions for cancer survivors based on the transtheoretical model, cognitive behavioral therapy, and health coaching.<sup>8,9,12</sup> In the LEACH program, cancer survivors coached by trained long-term survivors did not show improvement in PA or dietary habits.<sup>13</sup> The interventions that improved HROQL at 12 months targeted HRQOL for primary outcomes.<sup>21</sup> Nor did telemonitoring for heart failure improve

outcomes among recently hospitalised patients.<sup>22</sup> Additionally, an earlier web-based RCT showed that management by a pharmacist combined with a web program improved blood pressure at 12 months—but the web program alone did not.<sup>23</sup> Furthermore, a web-based SM program (Cancer Aftercare Guide) showed limited improvement at 6 months.<sup>24</sup> Some RCTs with an IT program, including one we tested earlier, showed improvement of some HRQOL items, such as fatigue, in the short term.<sup>25–27</sup> Some programs did not improve HRQOL in the long-term<sup>28</sup> while others did so only to a limited extent.<sup>29</sup>

“Healthing U”, the web program applied in this study, was developed to effect multiple behaviour changes as primary outcomes. The findings were explained by the possibility that the SMASH-based online health management program consisting of self-assessment, self-planning, self-learning, and self-monitoring with automatic feedback could lead to optimal SM.<sup>25</sup> This program could allow participants to obtain information from the webpages at their own pace and allow participants access to all the components of optimal SM (immediate and easy access to the intervention, tailored short messaging service to mobile telephones, personalised action plan, Internet-based monitoring of progress).<sup>25</sup>

With earlier trials, our study suggested that intervention based on the SM strategy might be effective in addressing psychological distress but not effective for changing behaviours such as PA and weight management in the long term. Intervention programs effective, more than programs based on the SM strategy for changing multiple behaviours, including PA and weight management, should be developed.

### 4.1 | Study limitation

This study has several limitations. First, 29.5% of the study patients (44 of 149) eligible for tele-coaching combined with the web program did not participate in the intervention. Second, only 59.8% (64 of 107) of the patients who participated in tele-coaching completed all



20 sessions at 6 months, which might have been insufficient. The insufficient participation in the intervention and the low attribution of web+ coaching group suggest that this web+ coaching intervention based on the SM strategy should be improved to increase acceptability and compliance with further studies. Third, there were large SDs for baseline rates of PA, BMI, and PTGI, and this study's participants were already high performers. These aspects of the study might have caused bias in the conclusion of intervention benefit. Further studies are warranted with populations whose members are low performers. Furthermore, main limitation is the low attrition to interventions. At 3-, 6-, and 9-month adherence rates decrease from 85.8% to 63.4% in the control group, from 76.8% to 57.6% in the web-only group and from 66.7% to 45.2% in the health coaching + web group. The difference of attrition rates among groups could lead to biased comparisons. The use of intention-to-treat analysis was predetermined in the study protocol. Generally, intention-to-treat analysis is a more conservative approach than per-protocol analysis. Also, a relatively low attrition rate at 12 months would limit the implication of the per-protocol analysis. Finally, the primary PA and BMI endpoints differed for lung cancer survivors, and the targets might not have been achievable for them. In addition, our previous study showed that a BMI  $\geq 23$  decreased the mortality hazard.<sup>4</sup> Further studies are needed to confirm the BMI goal for lung cancer survivors.

## 4.2 | Clinical implication

We believe tele-coaching combined with a web program, as well as a web program alone, might be successful for cancer survivors within 2 months of completing primary cancer treatment who might be highly motivated to change multiple behaviours in order to improve their health. Because the composite results of multiple behaviours were driven entirely by a reduction in post-traumatic growth and there were no similar effects for other components of the composite, caution may be needed when interpreting the results.

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## CONFLICT OF INTEREST

The author(s) declare that they have no conflicts of interest.

## DATA AVAILABILITY STATEMENT

Research data are not shared.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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