

Research Article

Efficacy of a Brief Ecologically Boosted Emotion Regulation Group Intervention on Cancer-Related Fatigue in Breast Cancer Survivors: A Randomized Controlled Trial

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Background: Cancer-related fatigue (CRF) is one of the most frequently reported symptoms among breast cancer survivors. Recommendations regarding nonpharmacological treatments for CRF include physical activity, psychosocial, and mind–body interventions. Despite the close association of CRF with psychological symptoms, to our knowledge, no study has assessed the impact of a psychosocial intervention on CRF among patients meeting criteria for clinical levels of psychological symptoms.

Aim: This study presents findings on changes in CRF, sleep disturbances, energy levels, and physical activity from a randomized controlled trial (RCT) evaluating the efficacy of an eight-session emotion and self-regulation group intervention ecologically boosted through daily app-based prompts. The intervention, specifically designed for breast cancer survivors in the early survivorship period who exhibited clinical levels of psychological symptoms, showed its efficacy in targeting some psychological symptoms (i.e., worry, intrusive thoughts, and negative emotions).

Method: At the end of radiation therapy treatment, breast cancer survivors were screened for clinical levels of psychological symptoms and randomly assigned to either an immediate ($n = 61$) or a delayed intervention group ($n = 59$, intervention delayed by 5 months). CRF, sleep disturbances, energy levels, and physical activity were assessed using self-reported questionnaires, visual analog scales, and ecological momentary assessments. Assessments were performed at baseline (T1), 5 months (T2), and 10 months (T3). Mixed models were conducted to evaluate the intervention's efficacy in treating CRF.

Results: Treated patients reported less general fatigue ($p = 0.028$), reduced motivation ($p = 0.005$), and mental fatigue ($p = 0.024$), as well as lower levels of habitual physical fatigue ($p = 0.043$) and momentary fatigue in daily life ($p = 0.009$).

Conclusions: Our study highlights the usefulness of targeting emotion and self-regulation in a brief group intervention to treat CRF among patients with clinical levels of psychological symptoms. Further research is needed to clarify the mechanisms driving the efficacy of the intervention.

Keywords: cancer-related fatigue (CRF); cognitive behavioral therapy (CBT); ecological momentary assessment; ecological momentary intervention; emotion regulation; hypnosis; positive psychology; psycho-oncology; psychological group intervention; psychological symptoms; self-regulation

1. Background

Breast cancer survivors often experience a wide range of co-occurring psychological and physical symptoms, with fatigue being one of the most frequently reported across the cancer trajectory [1, 2]. Cancer-related fatigue (CRF) is a subjective multidimensional symptom that affects physical, cognitive, and emotional functioning [2] and can last for years post-treatment [3, 4]. The origin of CRF is complex and emerges from the disruption of various interconnected physiological, biochemical, and psychological components [5]. For example, numerous symptoms have been identified as contributing factors to CRF, such as sleep disturbances [2, 6–9], physical inactivity [6, 9, 10], anxiety [6, 8, 11], and depression [2, 3, 6–8]. Thus, to effectively reduce CRF, interventions should target these contributing symptoms associated with CRF [12, 13].

Recommendations regarding nonpharmacological treatment of CRF include physical activity, psychosocial, and mind–body interventions [12]. Physical activity interventions are the most tested and aim to increase physical activity to decrease CRF [12]. Regular exercise has been shown to reduce CRF [14–16], anxiety [16], and depression [16] in cancer survivors. Psychosocial interventions mostly integrate cognitive behavioral therapy (CBT) and psycho-education [12]. They have shown efficacy in reducing CRF [17–19], sleep disturbances [19, 20], anxiety, and depression [19, 21]. Finally, mind–body interventions such as mindfulness, yoga, and relaxation exercises have also been found beneficial [12]. Mindfulness-based interventions have shown particularly interesting results in reducing CRF and its contributing factors (i.e., anxiety and sleep disturbances) [17, 19, 21]. Currently, there is no consensus on the most effective type of intervention. A recent meta-analysis showed the superiority of mindfulness-based interventions, but mostly for patients undergoing treatment [17]. Other meta-analyses showed a similar efficacy with small to moderate effect sizes [13, 16, 22] of physical activity and CBT interventions for treating CRF [22]. However, CBT may be more useful for survivors [22].

We conducted a randomized controlled trial (RCT) to assess the benefits of an ecologically boosted eight-session emotion and self-regulation group intervention. This intervention was specifically designed for breast cancer survivors in the early survivorship period who met criteria for clinical levels of psychological symptoms. Patients were screened on numeric rating scales for anxiety, depression, fear of cancer recurrence, and worry [23]. The emotion regulation and self-regulation components were chosen to (1) decrease patients' psychological symptoms [24, 25] and (2) allow patients to develop strategies for self-regulation in their daily lives [26, 27]. The intervention relied on CBT, hypnosis, relaxation practices, and positive psychological techniques. It also included daily prompts as an ecologically boosted modality to promote (1) moment-to-moment self-awareness, (2) attention shifting, (3) physical activity, (4) awareness of one's emotional state and strategic choice of emotion regulation strategies, and (5) patients' autonomy [23].

The primary results of the RCT indicated that the intervention was relevant in targeting psychological symptoms (i.e., worry, intrusive thoughts, and negative emotions) in patients meeting criteria for clinical levels of psychological symptoms during the early survivorship period following breast cancer treatments [23]. To our knowledge, no psychological intervention has specifically targeted patients screened for psychological symptoms while simultaneously offering an emotion regulation intervention addressing CRF.

Emotion regulation difficulties are associated with the presence of various psychological symptoms (anxiety, depression) and also with CRF [28–30]. An intervention targeting emotion regulation could thus lead to reduced CRF among cancer patients. Thus, based on this observation, the previous findings, and the different components and modalities of our intervention (i.e., CBT, relaxation practice, and prompts to promote activity), we expected that it would allow the reduction of CRF and sleep disturbances and increase energy levels and physical activity among participating breast cancer survivors.

2. Methods

2.1. Description of the RCT. A description of the complete methodology of the current RCT has been published [23]. The methods description partly reproduces the wording of this RCT [23].

At the end of radiotherapy, all patients with non-metastatic breast cancer treated at the Institut Jules Bordet (Belgium) were systematically approached to be screened for psychological symptoms (T0).

Inclusion criteria were as follows: having finished radiation therapy treatments, having non-metastatic breast cancer, and presenting psychological symptoms. The assessment was based on the anxiety and depression items of the Edmonton Symptom Assessment System (ESAS) [31] supplemented by two additional items: fear of cancer recurrence and worry. Patients were eligible if they scored ≥ 4 [32] on at least one of the four 11-point numerical rating scales. Exclusion criteria were as follows: age < 18 years, signs of active disease, nonfluency in French, severe cognitive impairment, and/or acute psychiatric disorder. Written informed consents were obtained from all eligible women encountered.

An individual interview was conducted for each patient just before the start of the group to check the appropriateness of the intervention for the patient. No patients were excluded due to an absence of psychological symptoms. The intervention was conducted in groups of patients with a trained clinical psychologist (IM or MC). It consisted of eight 2.5-h group sessions that were conducted over 4 months. It included ER and self-regulation components, both relying on hypnosis, CBT, and positive psychology techniques. The intervention was ecologically boosted using a prompt-based app [23]. Patients received three prompts each day through the LifeData app (LifeData, LLC, 2025) [33] starting from the first group session and continuing until the last session [23]. The complete description of the intervention can be found here [23]. Each patient was

assessed at baseline (first assessment time, T1), 4 months after baseline (second assessment time, T2), and 8 months after baseline (third assessment time, T3). Each assessment time is composed of three parts: the first part is the dynamic emotion regulation task, the second part is the ecological momentary assessment (EMA), and the third part is the attentional task. Patients in the immediate intervention arm received the intervention immediately after T1, whereas patients in the delayed intervention arm received the intervention immediately after T2.

2.2. Assessment Procedure. CRF, sleep disturbances, energy levels, and physical activity were assessed through self-reported questionnaires and EMA in daily life.

Self-reported questionnaires were completed during the dynamic emotion regulation task [23]. EMA of physical activity and sleep disturbances was performed for 9 days using an actigraphic device (Garmin Vivoactive HR). This allowed the recording of sleep duration and number of steps. Fatigue and energy levels were ecologically assessed five times a day from 9:30 a.m. to 7:30 p.m. and/or at the end of the day for at least 7 days using app-based prompts sent in the same randomized schedule unknown to patients (Life-Data, LLC, 2025) [33]. In order to ensure confidentiality, patients were provided with an iPod Touch for the 7 days at both assessment time points to complete the EMA assessment. Self-reported physical activity was assessed during the attentional task after the EMA.

2.3. Outcomes

2.3.1. CRF. CRF was measured with the Multidimensional Fatigue Inventory (MFI-20). This 20-item self-reported questionnaire uses a 5-point scale to assess five components of fatigue: general fatigue (Cronbach's $\alpha=0.82$), physical fatigue (Cronbach's $\alpha=0.78$), reduced activities (Cronbach's $\alpha=0.68$), reduced motivation (Cronbach's $\alpha=0.70$), and mental fatigue (Cronbach's $\alpha=0.80$) [34]. Higher scores reflect greater levels of fatigue.

Habitual physical and emotional fatigue were measured with 100-mm visual analog scales (VAS; with the extreme left defined as “not at all” and the extreme right defined as “extremely”) [35, 36].

Fatigue in daily life was measured during EMA. Patients had to report the intensity of their daily fatigue at the end of the day for seven days on an 11-point numeric scale ranging from 0 to 10. For analysis, a maximum of seven completed prompts per patient were included. The daily fatigue score was determined by calculating the mean of the responses to the seven prompts.

2.3.2. Sleep Disturbances. Insomnia severity was measured with the Insomnia Severity Index (ISI). This 7-item self-reported questionnaire uses a 5-point scale to assess insomnia severity (Cronbach's $\alpha=0.92$). The cutoff scores are 0–7 (no clinically significant insomnia), 7–14 (insomnia needing further investigation), and 15 or more (clinically significant insomnia) [37].

Sleep duration in daily life was measured with an actigraphic device (Garmin Vivoactive HR). Sleep duration in minutes was determined by calculating the mean of the 7 days of assessments.

2.3.3. Energy Levels. Habitual energy was measured with a 100-mm VAS (with the extreme left defined as “not at all” and the extreme right defined as “extremely”) [35, 36].

Energy in daily life was measured during EMA. Patients had to report the intensity of their daily energy levels at the end of the day for seven days on an 11-point numeric scale ranging from 0 to 10. For analysis, a maximum of seven completed prompts per patient were included. The daily energy scores were determined by calculating the mean of the responses to the seven prompts.

2.3.4. Physical Activity. Physical activity was measured with the Global Physical Activity Questionnaire Version 2 (GPAQv2). The GPAQv2 is a questionnaire comprising 16 questions that assesses physical activity in a regular week [38]. This questionnaire provides information on intensity (vigorous or moderate) and duration (hours and minutes on a typical day) of physical activity. It assesses three domains in which physical activity is performed: work, transport, and leisure-time physical activity [38]. Sedentary behavior was also assessed. For this study, we used the duration of weekly moderate and vigorous-intensity activities, and the duration of weekly sedentary behaviors reported in minutes.

The number of steps taken was measured with an actigraphic device (Garmin Vivoactive HR). The outcome of the number of steps was determined by calculating the mean of the 7 days of assessments.

2.4. Data Analyses. Baseline differences between the study arms were assessed using the independent samples *t*-test, Fisher's exact test, or Pearson chi-square test, depending on the variable type. To account for repeated measurements within individuals and to maximize the use of all data despite partial missing data, linear mixed-effect models were used. We hypothesized that participants receiving the intervention would demonstrate significant improvements compared to those who received usual care alone during the time interval T1–T2. The mid-term benefits of the intervention in the immediate intervention arm were investigated during the time interval T2–T3. Sensitivity analyses were conducted treating T1–T2 (for the immediate intervention arm) and T2–T3 (for the delayed intervention arm) outcomes as pre–post comparisons, naming it a pooled model. Only patients who had attended at least one session were included in the model. Effect sizes were calculated using Cohen's *d* and classified as small (<0.20 – 0.50), medium (0.50 – 0.80), or large (>0.80) [39].

All tests were two-sided, with α set at 0.05, and results were considered statistically significant at $p \leq 0.05$. Analyses were performed using R Statistical Software (v4.3.1; R Core Team 2023) [40], including lme4 [41] and emmeans [42] packages.

3. Results

3.1. Patients and Their Sociodemographic and Medical Characteristics. Patient characteristics have been previously described [23]. Data from 120 patients were analyzed. The sociodemographic and medical characteristics of patients who discontinued the study during the T2 and T3 assessments ($n=29$) were similar to those who completed the program, with the exception of cultural background ($p=0.038$). Likewise, patients who declined study participation but agreed to complete a short questionnaire did not differ in sociodemographic or clinical characteristics from those who enrolled.

The majority of patients had Stage I (44%), Stage II (26%) or in situ disease (25%), and hormone therapy (89%). Patients in the immediate intervention arm ($n=61$) and delayed intervention arm ($n=59$) did not differ in sociodemographic characteristics, stage of disease diagnosis, or cancer treatments received. No significant between-group differences were observed at baseline in outcome measures or in session attendance. On average, patients attended 7.3 sessions.

3.2. CRF

3.2.1. Fatigue. The number of patients who completed the MFI-20 questionnaire was as follows: T1—Immediate: 61, Delayed: 59; T2—Immediate: 50, Delayed: 51; T3—Immediate: 49, Delayed: 42.

Efficacy analyses revealed significant treatment effects between arms for T1 to T2 for general fatigue ($\beta=-1.56$, $p=0.028$), reduced motivation ($\beta=-1.51$, $p=0.005$), and mental fatigue ($\beta=-1.33$, $p=0.024$) measures (Table 1; Figure 1).

Between T1 and T2, for the immediate intervention arm, general fatigue ($\beta=-1.61$, $p=0.001$), physical fatigue ($\beta=-1.29$, $p=0.007$), reduced activity ($\beta=-1.54$, $p=0.002$), reduced motivation ($\beta=-1.07$, $p=0.005$), and mental fatigue ($\beta=-1.75$, $p<0.001$) measures decreased significantly with small-to-medium effect size (Table 1; Figure 1). For the delayed intervention arm, no significant changes were observed. Between T2 and T3, for the immediate intervention arm, there were no significant changes, indicating the maintenance of intervention benefits for general fatigue, physical fatigue, reduced activity, reduced motivation, and mental fatigue measures. For the delayed intervention arm, reduced motivation ($\beta=-0.97$, $p=0.016$) and mental fatigue ($\beta=-1.09$, $p=0.014$) measures decreased significantly with small effect sizes (Table 1; Figure 1).

The pooled model confirmed the robustness of these findings, showing that treatment had a significant effect on general fatigue, reduced motivation, and mental fatigue outcomes (Table 2). The combination of the data allowed to reveal changes in physical fatigue and reduced activity measures that became significant after treatment (Table 2).

3.2.2. Habitual Emotional and Physical Fatigue State. The number of patients who completed the habitual emotional and physical fatigue state was as follows: T1—Immediate: 61, Delayed: 59; T2—Immediate: 50, Delayed: 51; T3—Immediate: 49, Delayed: 42.

Efficacy analyses revealed significant treatment effects between arms for T1 to T2 for habitual physical fatigue measure ($\beta=-9.87$, $p=0.043$; Table 1; Figure 1).

Between T1 and T2, for the immediate intervention arm, the habitual emotional fatigue measure decreased significantly with a small effect size ($\beta=-7.78$, $p=0.033$). For the delayed intervention arm, no significant changes were observed in emotional and physical fatigue.

Between T2 and T3, there were no significant changes in the immediate intervention arm, indicating maintenance of intervention benefits for the habitual emotional fatigue measure. For the delayed intervention arm, habitual emotional fatigue decreased significantly, with a small effect size ($\beta=-8.82$, $p=0.024$).

The pooled model confirmed the robustness of these findings, showing a significant effect on habitual physical fatigue (Table 2). The combination of the data allowed to reveal changes in habitual emotional fatigue measures that became significant after treatment (Table 2).

3.2.3. Fatigue in Daily Life. The number of patients who completed the daily fatigue in EMA was as follows: T1—Immediate: 61, Delayed: 58; T2—Immediate: 50, Delayed: 51; T3—Immediate: 49, Delayed: 42. On average, patients completed 32.4 notifications on T1, 30.3 notifications on T2, and 30.3 notifications on T3. Response rates were 93% on T1, 88% on T2, and 87% on T3.

Efficacy analyses revealed significant treatment effects between arms for T1 to T2 for the fatigue in daily life measure ($\beta=-0.66$, $p=0.009$; Table 1; Figure 1).

Between T1 and T2, for the immediate intervention arm, fatigue in daily life decreased significantly with a small effect size ($\beta=-0.38$, $p=0.031$). For the delayed intervention arm, no significant change was observed.

Between T2 and T3, for the immediate intervention arm, there was no significant change, indicating the maintenance of intervention benefits for fatigue in daily life. For the delayed intervention arm, no significant change was observed.

The pooled model confirmed the robustness of these findings, showing that treatment had a significant effect on fatigue in daily life (Table 2).

3.3. Sleep Disturbances

3.3.1. Insomnia Severity. The number of patients who completed the ISI questionnaire was as follows: T1—Immediate: 61, Delayed: 59; T2—Immediate: 50, Delayed: 51; T3—Immediate: 49, Delayed: 42.

Efficacy analyses indicated no significant difference between arms' effects for T1 or T2 for the insomnia severity measure (Table 1).

TABLE 1: Changes in cancer-related fatigue, sleep, energy, and physical activity—efficacy analyses (N= 120).

	Arm	T1		T2		T3		T1-T2 ^a			T2-T3 ^a			Arm by time T1-T2 ^a		
		M	SD	M	SD	M	SD	d	β	p	d	β	p	β	p	
Cancer-related fatigue MFI-20																
General fatigue	II	14.1	3.8	12.6	3.9	13.2	3.6	-0.39	-1.61	0.001	0.21	0.64	0.210	-1.56	0.028	
	DI	14.4	3.6	14.5	3.2	13.6	3.8	-0.06	-0.05	0.920	-0.32	-0.99	0.066			
Physical fatigue	II	12.2	3.8	10.9	3.9	11.6	3.7	-0.36	-1.29	0.007	0.22	0.68	0.159	-1.28	0.055	
	DI	12.5	3.7	12.7	3.4	12.0	3.6	-0.05	-0.01	0.991	-0.22	-0.64	0.207			
Reduced activity	II	11.3	3.7	9.8	3.4	10.2	3.6	-0.51	-1.54	0.002	0.10	0.32	0.515	-1.04	0.126	
	DI	11.4	3.3	11.0	3.7	10.4	3.4	-0.18	-0.50	0.297	-0.22	-0.70	0.179			
Reduced motivation	II	9.8	3.2	8.6	3.0	9.0	2.9	-0.44	-1.07	0.005	0.14	0.40	0.292	-1.51	0.005	
	DI	9.8	3.7	10.4	3.5	9.4	3.5	0.14	0.44	0.242	-0.43	-0.97	0.016			
Mental fatigue	II	12.3	4.0	10.7	3.3	10.9	3.2	-0.55	-1.75	<0.001	0.07	0.18	0.668	-1.33	0.024	
	DI	12.3	3.6	12.1	4.0	11.0	4.1	-0.18	-0.42	0.307	-0.43	-1.09	0.014			
Habitual fatigue (VAS)																
Physical fatigue	II	60.9	25.7	54.2	26.3	55.9	21.1	-0.19	-6.09	0.077	0.08	1.76	0.618	-9.87	0.043	
	DI	65.8	22.5	70.6	18.4	63.3	23.9	0.12	3.78	0.270	-0.36	-7.00	0.059			
Emotional fatigue	II	56.6	29.2	47.8	26.3	46.2	28.0	-0.25	-7.78	0.033	-0.08	-1.68	0.650	-5.68	0.267	
	DI	66.3	25.7	66.5	24.3	58.3	26.6	-0.18	-2.10	0.561	-0.38	-8.82	0.024			
Fatigue in daily life (EMA)																
Daily fatigue	II	4.8	1.6	4.4	1.7	4.5	1.7	-0.33	-0.38	0.031	0.13	0.17	0.353	-0.66	0.009	
	DI	4.8	1.5	5.1	1.6	4.8	1.5	0.18	0.279	0.123	-0.34	-0.29	0.111			
Sleep disturbances ISI																
Insomnia severity	II	11.8	6.8	9.2	6.8	9.9	6.3	-0.30	-2.35	0.006	0.11	0.72	0.400	-1.48	0.211	
	DI	12.3	7.4	11.5	6.1	10.4	5.7	-0.15	-0.86	0.303	-0.25	-0.92	0.308			
Sleep duration in daily life (actigraphic device)*																
Sleep duration ^b	II	508.1	66.9	484.1	69.1	474.4	59.0	-0.31	-23.67	0.036	-0.13	-7.06	0.542	-3.65	0.823	
	DI	504.0	74.8	481.6	76.0	476.8	53.0	-0.27	-20.02	0.094	-0.19	-9.11	0.472			
Energy levels																
Habitual energy (VAS)	II	56.5	25.8	55.1	20.6	52.0	23.5	0.00	-0.90	0.804	-0.14	-3.10	0.405	4.42	0.387	
	DI	48.4	25.8	41.9	22.3	49.6	21.4	-0.12	-5.32	0.141	0.24	6.72	0.085			
Energy in daily life (EMA)																
Daily energy	II	5.8	1.4	5.9	1.5	5.8	1.4	0.12	0.11	0.494	-0.09	-0.09	0.565	0.15	0.512	
	DI	5.5	1.3	5.4	1.2	5.4	1.1	-0.02	-0.04	0.804	0.03	0.03	0.842			

TABLE 1: Continued.

Physical activity GPAQv2 ^{a,b}	Arm	T1		T2		T3		T1-T2 ^a			T2-T3 ^a			Arm by time T1-T2 ^a		
		M	SD	M	SD	M	SD	d	β	p	d	β	p	β	p	p
Sedentary behaviors	II	360.3	187.7	336.3	162.2	321.1	123.0	-0.21	-29.93	0.219	-0.08	-16.85	0.514	-3.28	0.926	
	DI	347.5	149.6	322.5	165.9	358.3	181.0	-0.18	26.65	0.293	0.12	26.74	0.338			
Moderate-intensity activities	II	288.5	242.1	403.3	482.8	355.5	284.3	0.22	116.30	0.026	0.04	-32.70	0.557	137.80	0.068	
	DI	326.1	243.9	302.4	222.4	390.3	301.8	-0.04	-21.50	0.692	0.43	93.00	0.122			
Vigorous-intensity activities	II	10.5	34.7	21.7	48.0	32.3	73.9	0.25	11.12	0.447	0.21	11.36	0.469	3.96	0.851	
	DI	23.5	65.9	29.1	76.5	60.6	166.0	0.19	7.17	0.637	0.16	30.61	0.070			
Number of steps in daily life (actigraphic device)*	II	6793.2	2695.3	7515.9	3443.6	7812.5	3555.0	0.24	600.90	0.144	-0.07	-67.40	0.873	126.4	0.833	
	DI	7626.2	3265.3	8112.9	3004.1	7603.5	3162.2	0.16	474.50	0.278	-0.17	-395.60	0.394			

Note: T1: Immediate Intervention (II) $n = 61$, delayed intervention (DI) $n = 59$; T2: Immediate intervention (II) $n = 50$, delayed Intervention (DI) $n = 51$; T3: immediate intervention (II) $n = 49$, delayed intervention (DI) $n = 42$; Bold values correspond to: p value ≤ 0.050 .

Abbreviations: DI, delayed intervention; EMA, ecological momentary assessment; GPAQv2, Global Physical Activity Questionnaire Version 2; II, immediate intervention; ISI, Insomnia Severity Index; M, mean; MFI-20, Multidimensional Fatigue Inventory-20; SD, standard deviation; VAS, visual analog scales.

*Missing data.

^aLinear mixed-effect models. For outcomes in time analysis, a positive beta indicates higher increase from T1 to T2 or T2 to T3; a negative beta indicates higher decrease from T1 to T2 or T2 to T3. Regarding group by time analysis, a positive beta indicates higher increase from T1 to T2 in the immediate intervention arm or higher decrease from T1 to T2 in the delayed intervention arm; a negative beta indicates higher decrease from T1 to T2 in the immediate intervention arm or higher increase from T1 to T2 in the delayed intervention arm.

^bValues are reported in minutes by night for the sleep duration and by week for the physical activity.

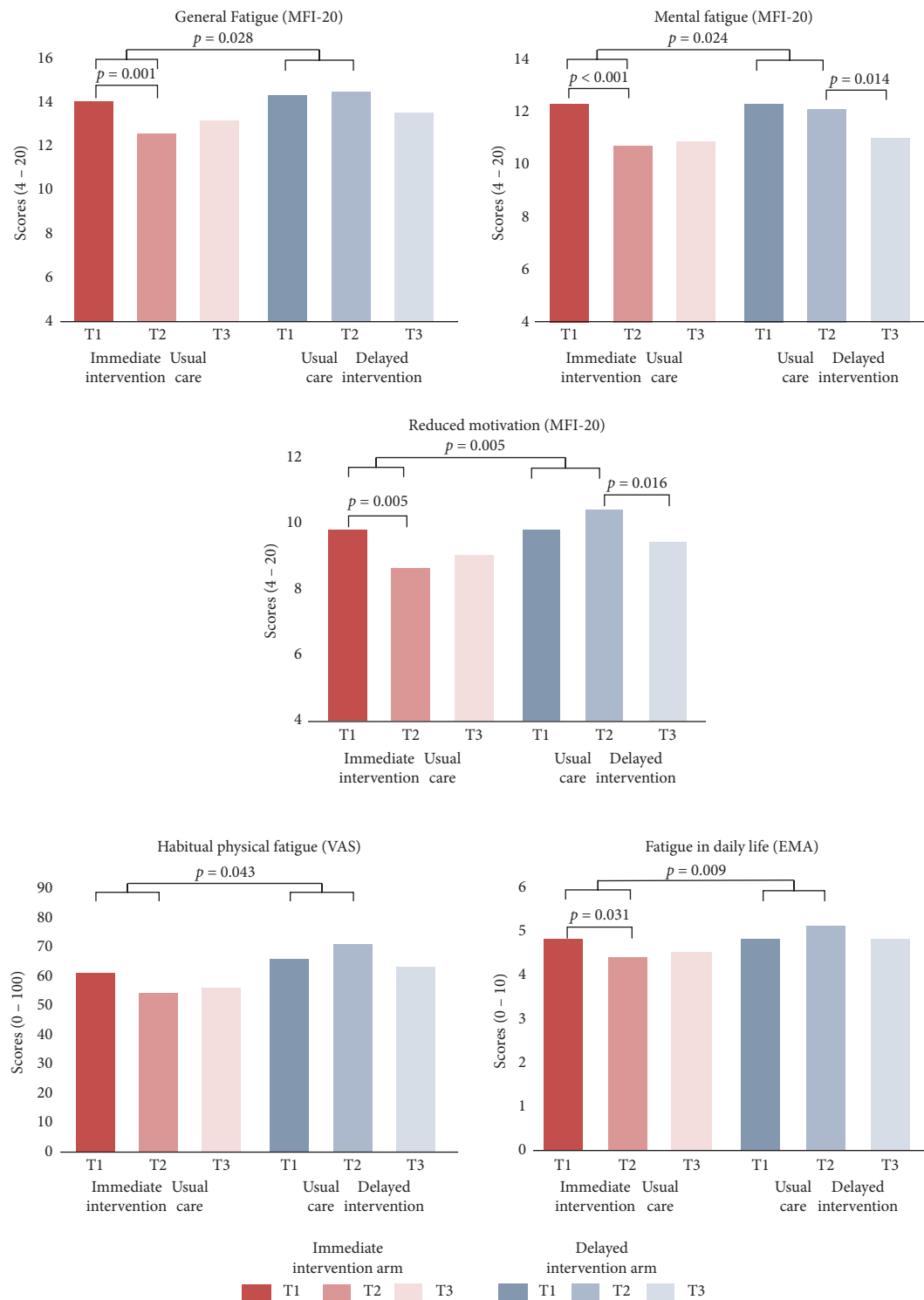


FIGURE 1: Changes in cancer-related fatigue efficacy analyses. T1: immediate intervention $n = 61$, delayed intervention $n = 59$; T2: immediate intervention $n = 50$, delayed intervention $n = 51$; T3: immediate intervention $n = 49$, delayed intervention $n = 42$.

Between T1 and T2, for the immediate intervention arm, the insomnia severity measure decreased significantly, with a small effect size ($\beta = -2.35$, $p = 0.006$). For the delayed intervention arm, no significant change was observed.

Between T2 and T3, there was no significant change in the immediate intervention arm, indicating the maintenance

of intervention benefits for the insomnia severity measure. For the delayed intervention arm, no significant change was observed.

The combination of the data allowed to reveal a change in insomnia severity measure that became significant after treatment, as shown in the pooled model (Table 2).

TABLE 2: Changes in fatigue, sleep, energy, and physical activity before and after the intervention—pooled model.

	Immediate intervention						Delayed intervention						Total					
	Before			After			Before			After			Before			After		
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
Cancer-related fatigue																		
MFI-20																		
General fatigue	14.0	3.9	12.6	3.9	14.4	3.2	13.5	3.8	14.2	3.6	13.0	3.8	14.2	3.6	13.0	3.8	14.2	3.6
Physical fatigue	11.9	3.9	10.9	3.9	12.7	3.5	12.0	3.6	12.2	3.7	11.4	3.8	12.2	3.7	11.4	3.8	12.2	3.7
Reduced activity	11.2	3.8	9.8	3.4	11.1	3.7	10.5	3.4	11.2	3.7	10.1	3.4	11.2	3.7	10.1	3.4	11.2	3.7
Reduced motivation	9.6	3.1	8.6	3.0	10.5	3.3	9.5	3.5	10.0	3.2	9.0	3.2	10.0	3.2	9.0	3.2	10.0	3.2
Mental fatigue	12.2	4.0	10.7	3.3	12.1	3.9	11.2	4.0	12.2	4.0	10.9	3.6	12.2	4.0	10.9	3.6	12.2	4.0
Habitual fatigue (VAS)																		
Physical fatigue	60.2	26.4	54.2	26.3	71.5	18.1	62.6	23.7	65.3	23.6	58.0	25.4	65.3	23.6	58.0	25.4	65.3	23.6
Emotional fatigue	55.5	29.3	47.8	26.3	66.3	25.1	57.6	26.5	60.3	27.9	52.3	26.7	60.3	27.9	52.3	26.7	60.3	27.9
Fatigue in daily life (EMA)																		
Daily fatigue	4.4	1.7	4.7	1.6	5.1	1.7	4.8	1.5	4.9	1.6	4.6	1.6	4.9	1.6	4.6	1.6	4.9	1.6
Sleep disturbance																		
ISI																		
Insomnia severity	11.5	6.7	9.2	6.8	11.7	5.6	10.5	5.7	11.6	6.2	9.8	6.3	11.6	6.2	9.8	6.3	11.6	6.2
Sleep duration in daily life (actigraphic device)*																		
Sleep duration ^b	507.3	68.6	484.1	69.1	483.8	71.5	476.8	53.0	497.9	70.3	480.8	61.9	497.9	70.3	480.8	61.9	497.9	70.3
Energy levels																		
Habitual energy (VAS)																		
Habitual energy	56.7	25.7	55.1	20.6	42.8	23.0	49.5	21.6	50.5	25.4	52.5	21.1	50.5	25.4	52.5	21.1	50.5	25.4
Energy in daily life (EMA)																		
Daily energy	5.8	1.4	5.9	1.5	5.4	1.2	5.4	1.1	5.6	1.3	5.7	1.4	5.6	1.3	5.7	1.4	5.6	1.3
Physical activity																		
GPAQv2* ^b																		
Sedentary behaviors	363.5	191.2	336.3	162.2	319.9	164.7	358.3	181	344.4	180.5	345.7	169.8	344.4	180.5	345.7	169.8	344.4	180.5
Moderate-intensity activities	298.2	247.4	403.3	482.8	290.0	180.9	390.3	301.8	294.6	219.6	397.7	412.8	294.6	219.6	397.7	412.8	294.6	219.6
Vigorous-intensity activities	11.5	36.1	21.7	48.0	31.2	78.8	60.6	166.0	20.1	59.2	38.3	115.3	20.1	59.2	38.3	115.3	20.1	59.2
Number of steps in daily life (actigraphic device)*																		
Number of steps	7035.1	2668.1	7515.9	3443.6	8031.6	3026.2	7603.5	3162.2	7447.4	2847.8	7555.4	3299.6	7447.4	2847.8	7555.4	3299.6	7447.4	2847.8

Note: ≥ 1 session attendance: immediate intervention $n = 55$, delayed intervention $n = 44$; Bold value correspond to: p value ≤ 0.050 .

Abbreviations: EMA, ecological momentary assessment; GPAQv2, Global Physical Activity Questionnaire Version 2; ISI, Insomnia Severity Index; M, mean; MFI-20, Multidimensional Fatigue Inventory-20; SD, standard deviation; VAS, visual analog scales.

*Missing data.

^aLinear mixed-effect models. For outcomes in time analysis, a positive beta indicates higher increase from before to after; a negative beta indicates higher decrease from before to after. Regarding group by time analysis, a positive beta indicates higher increase from before to after in the delayed immediate intervention arm or higher decrease from before to after in the delayed intervention arm; a negative beta indicates higher decrease from before to after in the immediate intervention arm or higher increase from before to after in the delayed intervention arm.

^bValues are reported in minutes by night for the sleep duration, and by week for the physical activity.

3.3.2. Sleep Duration in Daily Life. The number of patients for whom actigraphic sleep duration data were collected was as follows: T1—Immediate: 52 Delayed: 49; T2—Immediate: 39, Delayed: 35; T3—Immediate: 40, Delayed: 33.

Efficacy analyses indicated no significant treatment effects between arms for T1 to T2 for the sleep duration measure (Table 1).

Between T1 and T2, for the immediate intervention arm, the sleep duration measure decreased significantly with a small effect size ($\beta = -23.67$, $p = 0.036$). For the delayed intervention arm, no significant change was observed.

Between T2 and T3, there was no significant change in the immediate intervention arm or in the delayed intervention arm.

The pooled model confirmed the robustness of these findings, showing that treatment had no significant effect on sleep duration (Table 2).

3.4. Energy Levels

3.4.1. Habitual Energy. The number of patients who completed the habitual energy VAS was as follows: T1—Immediate: 61, Delayed: 59; T2—Immediate: 50, Delayed: 51; T3—Immediate: 49, Delayed: 42.

Efficacy analyses indicated no significant treatment effects between arms for T1 to T2 regarding habitual energy measure (Table 1).

No significant changes in habitual energy were observed between T1 and T2 or between T2 and T3 in either the immediate or delayed intervention arms (Table 1).

The pooled model confirmed the robustness of these findings, showing that the treatment had no significant effect on habitual energy outcomes (Table 2).

3.4.2. Energy in Daily Life. The number of patients who completed the energy in daily life in EMA was as follows: T1—Immediate: 61, Delayed: 58; T2—Immediate: 50, Delayed: 51; T3—Immediate: 49, Delayed: 42.

Efficacy analyses indicated no significant treatment effects between arms for T1 to T2 regarding energy in daily life measures (Table 1).

No significant changes in energy in daily life were observed between T1 and T2 or between T2 and T3 in either the immediate or delayed intervention arms (Table 1).

The pooled model confirmed the robustness of these findings, showing that the treatment had no significant effect on energy in daily life outcomes (Table 2).

3.5. Physical Activity

3.5.1. Physical Activity. The number of patients who completed the GPAQv2 was as follows: T1—Immediate: 61, Delayed: 59; T2—Immediate: 50, Delayed: 51; T3—Immediate: 49, Delayed: 42.

Efficacy analyses indicated no significant treatment effects between arms for T1 to T2 regarding physical activity (Table 1).

Between T1 and T2, for the immediate intervention arm, moderate-intensity activity measure increased significantly, with a small effect size ($\beta = 116.3$, $p = 0.026$). For the delayed intervention arm, no significant changes were observed.

Between T2 and T3, there were no significant changes in the immediate intervention arm, indicating the maintenance of intervention benefits for the moderate-intensity activity measure. For the delayed intervention arm, there were no significant changes.

The combination of the data allowed to reveal a change in moderate-intensity activity measure that became significant after treatment, as shown in the pooled model (Table 2).

3.5.2. Number of Steps. The number of patients for whom actigraphic number of step data were collected was as follows: T1—Immediate: 56 Delayed: 53; T2—Immediate: 45, Delayed: 40; T3—Immediate: 45, Delayed: 37.

Efficacy analyses indicated no significant treatment effects between arms for T1 to T2 in terms of the number of steps measured (Table 1).

No significant changes in terms of the number of steps were observed between T1 and T2 or between T2 and T3 in either the immediate or delayed intervention arms (Table 1).

The pooled model confirmed the robustness of these findings, showing that the treatment had no significant effect on the number of steps outcomes (Table 2).

4. Discussion

This study shows the short- and mid-term benefits of an eight-session emotion and self-regulation group intervention ecologically boosted through daily app-based prompts on CRF, sleep disturbances, energy levels, and physical activity. The RCT specifically targeted breast cancer survivors in the early survivorship period exhibiting clinical levels of psychological symptoms.

First, results of the efficacy analysis showed a reduction in CRF in patients receiving the intervention compared to those receiving usual care whose CRF did not change. This effect was maintained at mid-term. The pooled model further supports these findings by confirming the intervention's efficacy in reducing CRF and indicating that the timing of intervention did not influence outcomes. These results align with previous studies reporting small to moderate effect sizes for psychosocial interventions in reducing CRF among cancer patients [17–19, 43]. The effect size is lower in our study compared to a similar interventional study using self-compassion and hypnosis components [43], likely due to differences in recruitment methods. Our study targeted patients with psychological symptoms, whereas the other study screened patients for physical and mental fatigue [43]. Additionally, although patients had moderate (e.g., reduced activity and motivation) to severe (e.g., general, physical, and mental fatigue) levels of CRF [44] prior to the intervention, the levels were lower than those reported in the other study [43]. The observed changes highlight the usefulness of offering an emotion and a self-regulation group intervention

to target multiple psychological symptoms and CRF in breast cancer survivors. Indeed, the previously cited study showed that CRF change was predicted by anxiety, depression, and worry changes, which supports our results and hypotheses [40]. Additionally, a recent study demonstrated that the use of emotion regulation strategies is associated with CRF (i.e., adaptive strategies are associated with lower CRF and maladaptive strategies with higher CRF) and moderates the link between CRF and anxiety [45]. Thus, this positive impact of the intervention could be explained either by its impact on some psychological symptoms (i.e., intrusive thoughts, worry) or by its impact on patients' use of emotion regulation strategies.

Regarding sleep disturbances, no significant differences were observed between intervention and usual care groups in the efficacy analyses. A possible explanation is that patients exhibited subclinical levels of insomnia before the intervention [37]. Similarly, baseline sleep duration averaged 8 h per night, corresponding to the recommended sleep duration for adults [46], suggesting no significant initial sleep deficits. However, the pooled model indicates that the intervention was effective in reducing insomnia symptoms and that intervention timing had no impact on this outcome. These findings suggest that even in patients with subclinical insomnia, the intervention was beneficial and could potentially be even more effective in patients with higher baseline insomnia levels.

For energy levels, no significant intervention effects were observed, as shown both in the efficacy analyses and the pooled model. Participants exhibited moderate energy levels at baseline, and these levels remained stable postintervention.

Finally, regarding physical activity, efficacy analysis showed that the intervention was not more effective than usual care in increasing it. This is consistent with a previous intervention study targeting CRF that reported no changes in physical activity [43]. At baseline, patients practiced approximately 300 min of moderate-intensity physical activity, exceeding current recommendations [47], and the step count is similar to values reported in the literature [48]. The pooled model gives promising results, suggesting that the intervention was effective in increasing moderate-intensity physical activity, with no influence of timing. As with insomnia outcomes, these findings imply that the intervention may have a greater impact on patients with lower baseline physical activity levels.

This study highlights the value of using a multicomponent emotion and self-regulation intervention to help breast cancer patients meeting criteria for clinical levels of psychological symptoms in their survivor journey. Despite its primary focus on emotional symptoms, the intervention proved its efficacy in reducing CRF but also its potential to reduce insomnia and increase moderate-intensity physical activities. This is a significant consideration for clinical psychological practices, as a single intervention addressing multiple symptoms may be more efficient than implementing multiple targeted interventions.

A key strength of the current study was the use of diverse assessment tools and methods. By incorporating both

subjective and objective measures as well as ecological data, this approach enables a deeper exploration of patients' experiences and daily practices. To deepen our findings, future research could explore how changes in emotional symptoms influence improvements in CRF, physical activity, sleep, and, more broadly, quality of life. Additionally, replicating this study in patients with different diagnoses and at various stages of the disease is essential for assessing the generalizability of the effects of the intervention. Finally, we may add components regarding sleep quality and reinforce the importance of physical activity to improve the efficacy of the intervention.

Our study has some limitations. The first is the sleep measurement tool. Regarding self-reported questionnaires, we used the ISI, which assesses insomnia only. The use of the PSQI might have provided a fuller picture and detected other meaningful changes in sleep that were not captured [49]. Regarding the actigraphic measure, we could have measured the number of wake episodes rather than the sleep duration, as it seems to be a more sensitive indicator of sleep disturbances in this population [50]. Both measurement choices may have underestimated the intervention's impact on sleep. Another limitation is the number of missing data in the actigraphic measure of sleep and the GPAQv2, which might have altered the statistical power of our analyses and thus potentially masked true effects. The sample size might also be insufficient to observe changes in some variables, such as insomnia and moderate-intensity activities as shown by the small effect sizes. The limited sample also constrained the complexity of the statistical model. This reduced our ability to fully understand the mechanisms underlying observed changes in CRF.

5. Conclusion

Our study demonstrated the efficacy of a brief, ecologically boosted emotion and self-regulation group intervention in reducing CRF among breast cancer survivors presenting clinical levels of psychological symptoms. The intervention also showed promising effects in reducing insomnia symptoms and increasing moderate-intensity physical activity. Rather than implementing multiple targeted interventions, this multicomponent approach may serve as an effective first-line strategy for patients experiencing a wide range of physical and psychological difficulties. Future research should investigate the long-term benefits of this intervention and further examine the psychological and behavioral factors contributing to improvements in CRF.

Data Availability Statement

The data that support the findings of this study are available upon request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Disclosure

The principal investigator had full access to all data in the study and assumes full responsibility for data integrity and analysis accuracy.

Conflicts of Interest

The authors declare no conflicts of interest.

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