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Randomized, Controlled Trial of an Intervention Combining Self-Care and Self-Hypnosis on Fatigue, Sleep, and Emotional Distress in Posttreatment Cancer Patients: 1-Year Follow-Up

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ABSTRACT

Cancer can provoke fatigue, sleep disturbances, and emotional distress. Hypnosis interventions have shown positive short-term effects on these symptoms. However, less is known about their long-term effects. This study assessed the short- and long-term effects of a group intervention combining self-care and self-hypnosis on these symptoms in posttreatment cancer patients. Ninety-five female cancer survivors were randomized to either a hypnosis group intervention or wait-list control. Results showed significant decreases in fatigue, sleep difficulties and emotional distress after intervention for the hypnosis group intervention in comparison to the wait-list control. Most of these positive effects were maintained at 1-year follow-up. Most participants received the hypnosis group intervention approximately 10.65 months after diagnosis, and it is possible that delivering the intervention earlier after diagnosis could have achieved a more robust impact. Further studies are needed to replicate these results in comparison to an active control condition and investigate the best time postdiagnosis for initiating the intervention.

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Cancer; emotional distress; fatigue; hypnosis; self-care

Introduction

Cancer-related fatigue (CRF) is one of the most important consequences of cancer (Wang et al., 2014) and is defined as “a distressing persistent, subjective sense of physical, emotional and/or cognitive tiredness related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (Mock et al., 2007). A meta-analysis showed that 46 to 99% of patients experience CRF (Prue et al., 2006). CRF has social, financial, and functional negative consequences on patients (Jones et al., 2016; Prue et al., 2006) and is associated with other common symptoms: sleep difficulties and emotional distress (Brown & Kroenke, 2009; Kim et al., 2019; Roscoe et al., 2007; Tel et al., 2011). Sleep disturbances are endured by 20 to 50% of cancer patients (Irwin, 2013) and have a severe negative effect on their emotional,

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cognitive, and physical functioning (Die Trill, 2013). Emotional distress can be defined as “an unpleasant experience of an emotional, psychological, social, or spiritual nature that interferes with the ability to cope with cancer treatment” (Dauchy et al., 2013). It is generally conceptualized by the two dimensions of anxiety and depression and negatively influences treatment adherence and results as well as a patient’s general quality of life (Batty et al., 2017; Dauchy et al., 2013). Anxiety is reported by 10 to 44% of cancer patients (Die Trill, 2013), while depression is endured by 5 to 49% of them (Irwin, 2013). CRF, sleep difficulties, and emotional distress are known to persist even for years after treatment completion (Die Trill, 2013; Person et al., 2020; Wang et al., 2014), no matter the type of cancer (e.g., breast, colorectal, prostate, lung; Wang et al., 2014). The evolution of these symptoms during the cancer trajectory is inconsistent among studies: some of them suggest an increase, while others report a decrease or no evolution of the symptoms (Trudel-Fitzgerald et al., 2013). In their prospective study, Trudel-Fitzgerald et al. (2013) investigated the evolution of fatigue, insomnia, depression, and anxiety of 828 cancer patients with different diagnoses over an 18-month period after their surgery. Their results revealed a trend toward a decrease of these symptoms over time. However, this decrease was of very small magnitude for most of the variables (d between 0.001 and -0.19). Only the decrease of anxiety during the first 2 months following the surgery had a medium magnitude ($d = -0.58$; Trudel-Fitzgerald et al., 2013).

Despite their prevalence and their negative impact, these symptoms are underdiagnosed and undertreated in clinical and scientific settings. Yet, some studies showed the positive impact of psychological interventions, such as cognitive-behavioral therapy (CBT), psychoeducation, or relaxation for example, on patients’ CRF, sleep disturbances, and emotional distress (Die Trill, 2013; Garland et al., 2014; Grégoire et al., 2017; Kangas et al., 2008; Mitchell et al., 2014). In oncology settings, there is a growing interest in complementary methods such as hypnosis (Carlson et al., 2017; Saghatchian et al., 2014). Hypnosis is defined as “a state of consciousness involving focused attention and reduced peripheral awareness characterized by an enhanced capacity for response to suggestion” and hypnotherapy (hypnosis intervention) is defined as “the use of hypnosis in the treatment of a medical or psychological disorder or concern (Elkins et al., 2015). It has been theorized to have three major components: absorption, which is the involvement in a perceptual, imaginative, or ideational experience; dissociation, which is the mental separation of different components of experience that would usually be processed as a whole; and suggestibility, which is the responsiveness to social clues, enhancing the propensity to comply with hypnotic instructions and suspending critical judgment (Vanhaudenhuyse et al., 2014).

Some studies showed the positive impact of hypnosis on CRF, sleep, and emotional distress, whether taught alone or combined with cognitive-behavioral or self-care techniques (Cramer et al., 2015; Grégoire et al., 2017, 2020; Montgomery et al., 2014, 2017). However, most of them focused on breast cancer patients and assessed only short-term effects of the interventions (Cramer et al., 2015). Some of them also suffer from some methodological pitfalls such as no randomization or small sample sizes. To address these limitations, the present study reports on a randomized, controlled trial in order to

investigate the short- and long-term effects of a group intervention combining self-care and self-hypnosis in comparison to a wait-list control on posttreatment cancer patients' CRF, sleep difficulties, and emotional distress.

Objectives

The main objective of our study was to assess the efficacy of an 8-week group intervention combining self-care and self-hypnosis to improve CRF and associated symptoms (including sleep difficulties and emotional distress) of posttreatment cancer patients, right after the intervention (short-term effects), in a randomized, controlled trial. These results have already been published, showing positive short-term effects of the intervention on CRF, sleep difficulties, and emotional distress (Grégoire et al., 2020). The present paper is a secondary analysis aiming at assessing the long-term effects (1-year postintervention) of that group intervention on patients' CRF, sleep difficulties, and emotional distress. We hypothesized that the positive effects on the three variables would persist 1 year after the intervention. We also hypothesized that the wait-list control group (WLCG) would not improve between T1 and T2 (as they will not have received the intervention yet) but would improve between T2 and T3 (after they received the intervention), with a maintenance of these effects at T4 (see section 3.1. for details about the measurement times). Finally, if significant differences appeared between the evolution of the two groups, this would allow us to determine which moment is the best to propose the intervention to cancer patients.

Methods

Material and Methods

The protocol of the study has previously been published (Grégoire, Faymonville et al., 2018) and displays detailed information about the design, recruitment, and randomization procedures, sample size calculation, assessments and intervention. Therefore, we will only summarize these aspects here.

Participants

Patients were mainly recruited in the University Hospital of Liège (November 2016 to March 2019). The inclusion criteria were to be at least 18 years old, be fluent in French, present a nonmetastatic invasive cancer, have completed active treatments (surgery, chemotherapy, and/or radiotherapy) since less than a year, and experience baseline difficulties (score at least 4 out of 10 on one of these six items: physical fatigue, moral fatigue, depression, anxiety, fear of recurrence, ruminations).

Design

A longitudinal, randomized wait-list controlled trial design was utilized (see, Figure 1). Participants were randomized into two groups: the first group received the intervention immediately (intervention group), and the second group received it 3 to 4 months later Wait-List Control Group (WLCG). After verification of the inclusion criteria (T0), patients

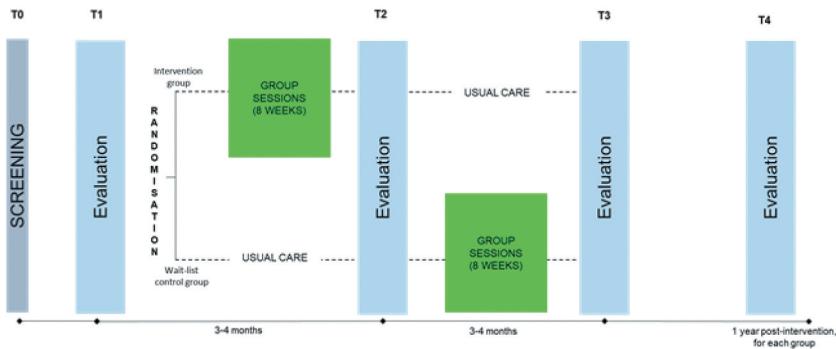


Figure 1. Design of the Study

had to complete assessments at four different times: before the intervention (T1), right after the sessions of the intervention group (T2; at this moment, the WLCG has not yet received the intervention), right after the sessions of the WLCG (T3), and 1 year after the sessions for each group (T4). More information about the exact timing of each measurement time and intervention is displayed in [Figure 1](#).

Measures

Sociodemographic and Medical Data

Gender, age, cultural origin, education level, employment status, marital situation, and number of children were noted, as well as the type of cancer, time since diagnosis, cancer treatments received, history of cancer or other health problems, and consumption of psychotropics.

Fatigue

The Multidimensional Fatigue Inventory (MFI-20; Smets et al., 1995) covers five dimensions: general fatigue (general statements about the person's functional state); physical fatigue; mental fatigue (lack of concentration); reduced motivation, and reduced activity. For people between 40 and 59 years old, a score of 11 (for men) or 12 (for women) or more on the general fatigue subscale suggests significant fatigue (Ouellet et al., 2015). This questionnaire has good internal consistency (average $\alpha = 0.84$) and validity.

Insomnia

The Insomnia Severity Index (ISI; Savard et al., 2005) investigates sleep complaints and their associated distress. Scores of 7 or less suggest no sleep difficulties, between 8 and 14 suggest good probability of sleep difficulties, and 15 and greater suggest clinical insomnia. This questionnaire has good internal consistency ($\alpha = 0.90$) and validity.

Anxiety and Depression

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) measures anxiety and depression. Cutoff scores for each dimension are 7/21 and suggest the presence of anxious or depressive symptoms. This questionnaire has good internal consistency ($\alpha = 0.83$ for the anxiety subscale and 0.82 for the depression subscale) and validity.

Hypnosis Group Intervention

The intervention included eight weekly 2-hour sessions in groups of 8 to 10 participants (1st group in April 2017, last group in September 2019). The number and duration of the group sessions were decided based on our previous and current clinical practice, in which this design is used efficiently. The intervention was developed and led by one of the authors (MEF), who is an anesthetist and international expert on hypnosis (Faymonville et al., 2010). Participants had to complete different self-care tasks and reflections at home between sessions based on, for example, the reinforcement of self-esteem, the enhancement of moment-to-moment awareness, the reengagement in enjoyable activities, the management of ruminations, etc. (see Table 1 for the content of each session). Self-care was also discussed in group during the sessions to help patients benefit from experience sharing. A 15-minute hypnosis exercise was led by the therapist at the end of each session. At-home practice was encouraged with the help of audio recordings of the hypnosis exercises, as it allows participants to learn to induce self-hypnosis to take full advantage of hypnosis without needing to be guided by a therapist. It was expected that the practice of self-hypnosis would influence cognition and emotional regulation and therefore facilitate the completion of the assigned tasks and help to alleviate symptoms (Grégoire et al., 2017; Vanhauzenhuysse et al., 2018). In this way, self-hypnosis is complementary to self-care tasks. Our intervention is based on patient empowerment and self-management approaches. Their aims were to strengthen assertiveness, self-esteem, and self-confidence, and they have been used to improve quality of life, sense of control, social relationships, and fatigue in oncology settings (Kim et al., 2017; Stang & Mittelmark, 2010). Participants were encouraged to observe their thoughts and behaviors, and the tasks proposed during and between sessions helped them to detect and react to difficult situations, in order to make concrete changes aimed at respecting themselves and others (Vanhauzenhuysse et al., 2015, 2018). In many ways, the strategies used in our intervention are similar to those developed in cognitive-behavioral therapy (CBT). CBT can be defined as a “time-sensitive, structured, present-oriented psychotherapy directed toward solving current problems and teaching clients skills to modify dysfunctional thinking and behavior” (Beck Institute for Cognitive Behavior Therapy, 2016). This technique is based on the cognitive model according to which the way that we perceive a situation is more closely linked to our reaction than the situation itself (Beck Institute for Cognitive Behavior Therapy, 2016). However, our intervention did not use several common CBT techniques, such as cognitive restructuring or functional analysis by analyzing a specific situation to understand its origin, but more generally to comprehend the future. Our intervention is also similar, in some points, to mindfulness-based therapies. Indeed, the proposed tasks fostered an adaptive, nonjudgmental, and accepting stance toward experiences and promoted engagement in activities consistent with the patient’s values, needs, and interests. However, practical mindfulness exercises were not proposed, as our intervention focused on hypnosis (e.g., mindful meditation, body scan, respiration exercises, etc.).

Table 1. Topics Addressed in Each Group Session

Session	Topics
Session 1	<ul style="list-style-type: none"> - Explanation: What is hypnosis? - Common beliefs about hypnosis - Answers to participants' questions - Discussion about their choice to participate - Importance of pleasing ourselves everyday - Definition of three realistic goals to be achieved in six months - List of personal needs - Mental imagery exercises
Session 2	<ul style="list-style-type: none"> - Reflection on personal qualities and resources and the importance of knowing them - Distancing from symptoms ("I have" not "I am") - Listening to pleasant music - Discussion of the way to set priorities in life (importance and urgency) - Paying attention to small successes - Hypnosis exercise: Fluffy white cloud
Session 3	<ul style="list-style-type: none"> - Discussion of the way we talk to ourselves and self-esteem, the importance of congratulating ourselves - Doing one thing at a time - Accepting to receive a "no" - Importance of the coherence between our acts and our words - Identification of a safe haven - Hypnosis exercise: Safe haven
Session 4	<ul style="list-style-type: none"> - Reflexion about our control over difficult situations - Discussion of the balance between the energy put in to a task and the gained benefit - Discussion of the ideal parent/spouse/child/colleague ... - Learning to delegate - Assertiveness: Being able to say "no" - Hypnosis exercise: Pain and colors
Session 5	<ul style="list-style-type: none"> - Paying attention to the gifts of life - Discussion of social roles and the way we respond to others' needs - Taking time for ourselves - Importance of physical activity - Psychoeducation about sleep - Hypnosis exercise: Levitation
Session 6	<ul style="list-style-type: none"> - Discussion of personal resources which help to combine work and private life - Discussion of the adequacy between professional activities and personal needs - Finding an object that will be associated with a "Stop!" injunction, to use when we feel stressed and ruminate - Discussion of the importance of being surrounded by positive people - Discussion of ruminations and how to cope with them - Hypnosis exercise: Light journey
Session 7	<ul style="list-style-type: none"> - Assertiveness: How to say "no" or postpone our decision - Assertiveness: How to formulate a demand and chose the right moment - Importance of taking quality time for ourselves instead of always being there for other people - Discussion of the difficulties and constraints encountered in daily life - Hypnosis exercise: Dreamland
Session 8	<ul style="list-style-type: none"> - Discussion of irritating situations and how to cope with them in a more positive way - Importance of enjoying the present moment - Review of the goals determined at the beginning of the sessions: Have they been achieved? The importance of being proud of ourselves, to congratulate ourselves. - Discussion of new objectives - Hypnosis exercise: Stories and metaphors

Data Analyses

All statistical analyses were performed using Statistica 13.3 (TIBCO Software Inc.) and SPSS Statistics 25 (IBM). Baseline (T1) demographic, medical, and psychological data were compared between the intervention group and WLCG to test initial equivalency

with Mann-Whitney tests and Chi-square tests. Group-by-time changes were processed using multivariate analysis of variance with repeated measures (MANOVA), followed by post hoc comparisons (Tukey's HSD test). Effect sizes were calculated using Cohen's *d*, with interpretation as follows: "small" (<0.20–0.50), "medium" (0.50–0.80), and "large" effect sizes (>0.80; Cohen, 1977). All tests were two-tailed, and the results were considered to be significant at $p < .05$.

An intention-to-treat (ITT) analytic strategy was used, involving efforts to maintain participants in the group to which they were randomized. Excluding participants who dropped out of the study from the analyses could lead to biased results, because it compromises the balance created by randomization (Polit & Gillespie, 2010). To deal with missing values due to drop-outs, the most widely used method is *last observation carried forward* (Gravel et al., 2007) in which participants' missing data is replaced by the value they obtained in the previous measurement time.

Results

Description of the Sample

Of the 114 patients initially included, 10 dropped out before T1, leading to a total sample of 104 cancer patients. They were randomized into two groups (intervention group = 52; WLCG = 52). Twelve of them (11.5%) dropped out between T1 and T2 (intervention group = 8; WLCG = 4), 9 (8.7%) between T2 and T3 (intervention group = 1; WLCG = 8), and 11 (10.6%) between T3 and T4 (intervention group = 7; WLCG = 4), for a total of 32 dropouts (30.8% of the initial sample). According to the ITT approach, T2, T3, and/or T4 data of these patients were replaced by their data obtained during the previous completed measurement time. As there were only 9 men in the total sample, we decided to remove them from the analyses, leading to a final sample of 95 women (intervention group = 48; WLCG = 47). Indeed, if we had considered men in our analyses, it would have been difficult to conclude about the impact of the intervention on them, and the sample would not have been homogenous.

Table 2 displays the demographics and medical data for the whole sample and the two groups. Women in our study were on average 53.85 (SD = 11.91) years old and 78.94% of them had breast cancer ($n = 75$), with the second most represented cancer being digestive cancer (5.26%; $n = 5$). This proportion of breast cancers in our sample was not expected and will be discussed later. The two groups did not differ at baseline on all the demographic and medical variables (all $ps > .05$).

Long-Term Impact of the Intervention on Patients' Fatigue, Sleep, and Emotional Distress

Experimental and wait-list control groups did not differ at baseline on the investigated variables (all $ps > .05$). For a better understanding of the evolution of the data, we will briefly present the short-term effects of the intervention already published (see Grégoire et al., 2020 for complete analysis and discussion of short-term effects). Table 3 displays the results from the repeated measures MANOVA (T1 to T4) and

post hoc comparisons for each group. The MANOVA revealed a significant effect of time, $F(24;70) = 4.60$; $p < .001$, but no significant group-by-time effect, $F(24;70) = 1.57$, $p = .074$. This could be understood by the fact that the WLCG received the intervention as well between T2 and T3, which impacted its participants' data. However, post hoc comparisons highlighted different significant changes in our data.

In the intervention group, there were significant improvements in CRF, sleep, and emotional distress between T1 and T2, with medium effect sizes comprised between 0.54 and 0.71. They were already discussed in our previous paper (Grégoire et al., 2020). These effects were maintained at T3 (+ 3–4 months) and T4 (+ 1 year) in this group, except for the Reduced Motivation and Reduced Activity subscales of the MFI-20, which continued to decrease between T2 and T3 but re-increased between T3 and T4. Effect sizes were similar at each measurement time, except for the Mental Fatigue and Depression subscales (d decreased from 0.65 at T2 to 0.51 at T4, and from 0.71 at T2 to 0.52 at T4, respectively). The evolution of data was not statistically significant between T2 and T3, between T2 and T4, nor between T3 and T4.

Table 2. Baseline Participants' Demographics and Medical Data in Each Group

	Total sample (N = 95)	Intervention group (n = 48)	WLCG (n = 47)	<i>p</i>
Demographics				
<i>Age (years)</i>				
Mean (SD)	53.85 (11.91)	51.65 (12.54)	56.11 (10.90)	.068
Range	24–78	24–78	30–78	
<i>Gender, N (%)</i>				
Women	95 (100)	48 (100)	47 (100)	NA
<i>Marital status, N (%)</i>				
Single	6 (6.32)	3 (6.25)	3 (6.38)	
Married/living with partner	63 (66.32)	35 (72.92)	28 (59.57)	.471
Divorced/separated/widowed	15 (15.79)	5 (10.42)	10 (21.28)	
In a relationship but not living together	11 (11.58)	5 (10.42)	6 (12.77)	
<i>Employment status, N (%)</i>				
Employed full-time	7 (7.37)	4 (8.33)	3 (6.38)	
Employed part-time	21 (22.11)	9 (18.75)	12 (25.53)	
Incapacity of work/invalidity	37 (38.95)	22 (45.83)	15 (31.91)	.490
Unemployed/student/ housewife/house-husband	30 (31.58)	13 (27.08)	17 (36.17)	
Retired/other				
Patient medical history				
<i>Cancer diagnosis, N (%)</i>				
Breast cancer	75 (78.94)	38 (79.17)	37 (78.72)	
Others	20 (21.06)	10 (20.83)	10 (21.28)	
Digestive (stomach, peritoneum, pancreas)	5 (5.26)	3 (6.25)	2 (4.26)	
Hematological cancer (lymphoma, leukemia)	4 (4.22)	3 (6.25)	1 (2.13)	.325
Gynecological cancer (cervix, ovaries)	4 (4.22)	3 (6.25)	1 (2.13)	
Skin	2 (2.11)	0 (0.00)	2 (4.26)	
Thyroid	2 (2.11)	0 (0.00)	2 (4.26)	
Ear/nose/throat	1 (1.05)	0 (0.00)	1 (2.13)	
Lung	1 (1.05)	1 (2.08)	0 (0.00)	
Brain	1 (1.05)	0 (0.00)	1 (2.13)	
<i>Time since diagnosis (months)</i>				
Mean (SD)	10.65 (8.69)	9.94 (5.13)	11.38 (11.25)	
Range	1–72	2–24	1–72	.821
<i>Consumption of psychotropic during the study, N (%)</i>				
Yes	50 (52.63)	27 (56.25)	23 (48.94)	.475
No	45 (47.37)	21 (43.75)	24 (51.06)	

Table 3. Short- and Long-Term Impact of the Intervention on Patients' Fatigue, Sleep, and Emotional Distress

Intervention group (N = 48)	T1 (preintervention)		T2 (postintervention)		Effect size (T1-T2)		Evolution (T1-T2)		T3 (+ 3- 4 months)		Effect size (T1-T3)		Evolution (T1-T3)		T4 (+1 year)		Effect size (T1-T4)		Evolution (T1-T4)	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Cohen's d	p	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Cohen's d	p	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Cohen's d	p		
	Multidimensional Fatigue Inventory (MFI-20)																			
	General fatigue																			
	15.63 (2.89)	13.69 (3.51)	0.67	< .001	13.85 (3.95)	0.61	< .001	13.62 (4.09)	0.59	< .001	13.62 (4.09)	0.61	< .001	13.62 (4.09)	0.59	< .001	13.62 (4.09)	0.59	< .001	< .001
	Physical fatigue																			
	14.72 (3.25)	12.73 (3.67)	0.60	< .001	12.58 (4.14)	0.63	< .001	12.35 (4.26)	0.61	< .001	12.35 (4.26)	0.61	< .001	12.35 (4.26)	0.61	< .001	12.35 (4.26)	0.61	< .001	< .001
	Mental fatigue																			
	12.95 (3.64)	11.24 (3.84)	0.65	< .001	11.68 (3.89)	0.46	< .001	11.35 (4.37)	0.51	.032	11.35 (4.37)	0.51	.032	11.35 (4.37)	0.51	.032	11.35 (4.37)	0.51	.032	.002
	Reduced motivation																			
	10.35 (3.38)	8.75 (3.08)	0.54	.001	8.71 (3.48)	0.67	< .001	9.42 (3.68)	0.27	< .001	9.42 (3.68)	0.27	< .001	9.42 (3.68)	0.27	< .001	9.42 (3.68)	0.27	< .001	.265
	Reduced activity																			
	12.13 (3.48)	10.52 (3.26)	0.60	.006	10.44 (3.19)	0.48	.003	11.12 (3.60)	0.45	.003	11.12 (3.60)	0.45	.003	11.12 (3.60)	0.45	.003	11.12 (3.60)	0.45	.003	.289
	Insomnia Severity Index (ISI)																			
	13.71 (6.30)	10.15 (6.44)	0.58	< .001	9.77 (6.63)	0.86	< .001	11.02 (6.55)	0.51	< .001	11.02 (6.55)	0.51	< .001	11.02 (6.55)	0.51	< .001	11.02 (6.55)	0.51	< .001	.002
	Hospital Anxiety and Depression Scale (HADS)																			
	Anxiety																			
	10.52 (4.19)	8.10 (4.38)	0.67	< .001	8.58 (4.57)	0.54	< .001	7.88 (4.53)	0.70	< .001	7.88 (4.53)	0.70	< .001	7.88 (4.53)	0.70	< .001	7.88 (4.53)	0.70	< .001	< .001
	Depression																			
	7.17 (4.23)	4.96 (4.19)	0.71	< .001	5.38 (4.64)	0.50	< .001	5.07 (4.20)	0.52	< .001	5.07 (4.20)	0.52	< .001	5.07 (4.20)	0.52	< .001	5.07 (4.20)	0.52	< .001	< .001

(Continued)

Table 3. (Continued)

	T1 (preintervention)		T2 (postintervention)		Effect size (T1-T2)		Evolution (T1-T2)		T3 (+ 3- 4 months)		Effect size (T1-T3)		Evolution (T1-T3)		T4 (+1 year)		Effect size (T1-T4)		Evolution (T1-T4)	
	Mean	(SD)	Mean	(SD)	Cohen's d	p	Mean	(SD)	Mean	(SD)	Cohen's d	p	Mean	(SD)	Mean	(SD)	Cohen's d	p		
	Mean	(SD)	Mean	(SD)	Cohen's d	p	Mean	(SD)	Mean	(SD)	Cohen's d	p	Mean	(SD)	Mean	(SD)	Cohen's d	p		
Waiting-list control group (WLCG) (N = 47)																				
Multidimensional Fatigue Inventory (MFI-20)																				
General fatigue	15.11	(4.15)	14.36	(3.91)	0.31	.624	13.45	(3.91)	0.60	.002	13.38	(3.96)	0.56	< .001						
Physical fatigue	13.66	(4.19)	12.70	(4.31)	0.33	.472	11.40	(4.31)	0.70	< .001	11.15	(4.47)	0.70	< .001						
Mental fatigue	12.70	(4.03)	12.66	(3.88)	0.02	1.00	12.22	(3.89)	0.16	.934	11.30	(3.95)	0.41	.012						
Reduced motivation	9.19	(2.94)	9.32	(3.48)	0.08	1.00	8.36	(2.46)	0.33	.440	8.87	(2.85)	0.10	.994						
Reduced activity	11.60	(4.04)	11.43	(4.12)	0.06	1.00	10.49	(4.02)	0.37	.191	10.47	(4.05)	0.33	.172						
Insomnia Severity Index (ISI)	12.45	(7.21)	11.89	(6.93)	0.13	.993	9.62	(6.44)	0.73	.001	9.57	(6.75)	0.55	< .001						
Hospital Anxiety and Depression Scale (HADS)																				
Anxiety	9.98	(4.32)	9.17	(3.97)	0.28	.634	7.94	(3.81)	0.56	< .001	7.85	(3.83)	0.65	< .001						
Depression	6.72	(4.10)	6.38	(4.63)	0.14	.994	5.19	(3.74)	0.46	.014	5.05	(3.70)	0.52	.004						

Bold values indicate significant effects.

In the WLCG, there were no significant changes between T1 and T2. Significant effects appeared right after the participants received the group sessions (T3). More specifically, after receiving the intervention, the WLCG showed a decrease of general and physical fatigue ($p = .001$ and $< .001$, respectively), sleep difficulties ($p = .001$), anxiety ($p < .001$), and depression ($p = .014$), with medium effect sizes (d comprised between 0.46 and 0.73). All these effects were still significant 1 year later (T4) (all $ps < .001$, except for HADS-Depression: $p = .004$), with similar effect sizes. In addition, a significant decrease of mental fatigue (MFI-20) appeared at T4 ($p = .012$, with a small effect size of 0.41). There were no significant differences between T3 and T4 data.

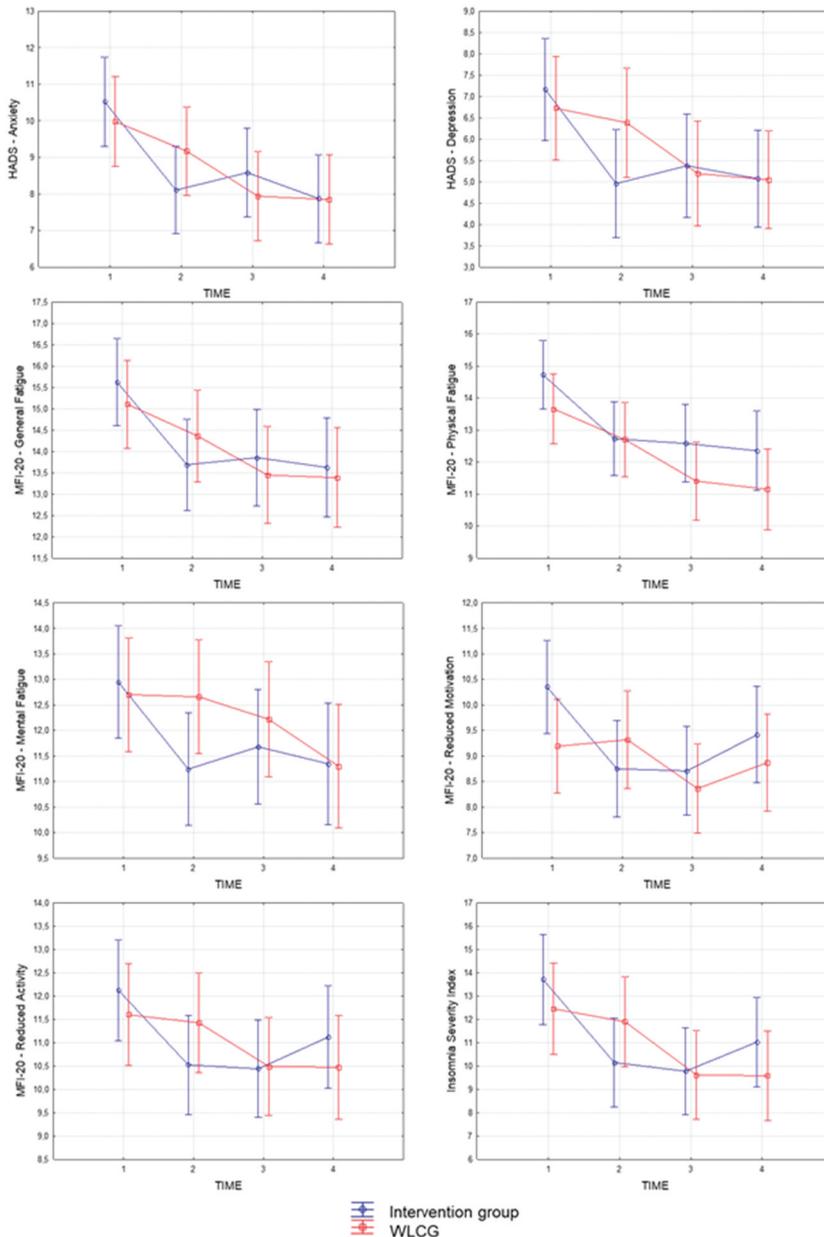


Figure 2. Graphic Evolution of the Data Over Time in Both Groups (Means + SE)

The graphic evolution of the results over time in each group is displayed in [Figure 2](#) (generated with Statistica 13.3). We can see that the highest decrease of several variables happened right after the intervention for both groups (between T1 and T2 for the intervention group, and between T2 and T3 for the WLCG): depression, physical and mental fatigue, reduced motivation, reduced activity, and insomnia. This suggests that these changes are linked to our intervention.

Discussion

The present study found positive long-term effects of our group intervention combining self-care and self-hypnosis on posttreatment cancer patients' CRF (general, physical, and mental fatigue), sleep difficulties, and emotional distress. These long-term effects of the intervention were significant in both groups (intervention group and WLCG), which was expected as they both received the group sessions at some point during the study. Our results are in line with other studies showing the positive impact of different psychological interventions on CRF, sleep, and emotional distress (Die Trill, 2013; Garland et al., 2014; Grégoire et al., 2017; Kangas et al., 2008; Mitchell et al., 2014). They are also confirming studies suggesting the efficacy of hypnosis to improve these symptoms (Cramer et al., 2015; Grégoire et al., 2017, 2020; Montgomery et al., 2014, 2017), especially the results from our previous study that showed the long-term effects (9 months after the intervention) of the combination of self-care and self-hypnosis on fatigue and emotional distress of women with breast cancer (Grégoire et al., 2017), and the study of Montgomery et al. (2014), where a combination of CBT and hypnosis allowed lower levels of fatigue at 6-month follow-up. Effect sizes for fatigue (d range: 0.51–0.70), sleep (d range: 0.51–0.86), and emotional distress (d range: 0.46–0.76) reported in our study are similar to the ones reported in other studies. For example, Mendoza et al. (2016) reported effect sizes of 0.75 for fatigue, 0.76 for sleep difficulties, and 0.87 for depression after an intervention combining CBT and hypnosis during or after treatment for cancer. Montgomery et al. also reported effect sizes between 0.70 and 0.83 for fatigue, and of 0.64 for emotional distress after an intervention combining CBT and hypnosis during radiotherapy (Montgomery et al., 2014, 2017). They also reported a long-lasting effect of their intervention on fatigue (d between 0.69 and 1.69 at 6-month follow-up; Montgomery et al., 2014).

Other effects were expected and were not found in our study. First, the significant short-term effects of the intervention on motivation and activity in the intervention group (T2 and T3) were not maintained 1 year later (T4). This could be explained by the fact that motivation and activity could be hard to maintain in the absence of an intervention or a group, when the participants are not involved in the group sessions anymore and must implement what they learned all by themselves. In the WLCG, there were no significant effects of the intervention on these dimensions at all. As both groups were similar at baseline on all the investigated variables, this could not be explained by any initial difference between them. The only difference between the groups was the timing of the intervention: right after T1 for the intervention group, and 3 to 4 months later for the WLCG (after T2). Knowing that, in our sample, participants received their cancer diagnosis in average only 10.65 months earlier and that they were all in need of a psychological intervention, it is possible that this delay in their participation has impacted our results. Second, the effect of our intervention on mental fatigue only appeared at T4 (1-year follow-up) in the WLCG and not right after the WLCG received the group sessions (T3), contrary to the intervention group in which a significant decrease of mental fatigue was shown right after the

group sessions (T2). Here again, the only difference between both groups was the timing of the intervention, which could have impacted our results. According to our results, proposing the intervention quite quickly after the end of treatments (i.e., about 1 year after diagnosis in our sample) could be a better option to improve several dimensions of fatigue. However, other limitations inherent to our study are likely to have impacted these results as well, such as the ITT approach used or the sample size, which could always be increased to obtain more robust results.

The present study has some noteworthy limitations. First, the disproportion between breast cancers and other cancers and between men and women was not expected, as we tried to target various cancer populations during the recruitment process. However, different studies suggested that men have a tendency to express a higher need for information than for psychological help and to be less interested in and rarely use available psychological interventions (Grégoire, Nicolas et al., 2018; Martin et al., 2015; Mo et al., 2009; Nekolaichuk et al., 2011; Owen et al., 2004; Rosenberg, 2009; Visser, 2013). Women with breast cancer, on the contrary, generally report higher psychological and support needs (Martin et al., 2015; Mo et al., 2009; Nekolaichuk et al., 2011; Sanson-Fisher et al., 2000; Visser, 2013). Our intervention proposed psychological support, sharing of experiences in group, and learning of self-care techniques and self-hypnosis exercises. It did not focus on cancer and medical information. Thus, it is possible that it did not address men's needs but was more pertinent for women. The group setting of our intervention could also have discouraged men to participate, as several studies underlined the interest of individualized approaches to help men at a psychological level, as some of them are reluctant to talk about their difficulties in group settings (Halbert et al., 2010; Helgason et al., 2001). It could explain why women participated more in our study. Thus, as breast cancer is the most frequent cancer in women, it is not surprising that it is the more represented diagnosis in our sample. Second, 30.8% of the sample dropped out the study at some point. More precisely, 11.5% of the sample dropped out between T1 and T2, which is similar or lower than other longitudinal studies in the field (Grégoire et al., 2017; Mendoza et al., 2016; Merckaert et al., 2017). However, some studies showed the association between the study duration and the dropout rate (Hui et al., 2013; Rabinowitz et al., 2009), which could explain why our dropout rate nearly tripled between T2 and T4, which were spaced by more than a year. Reasons for dropout between T1 and T2 were mainly linked to health problems, practical constraints, or not liking the content of the intervention. Reasons for dropout between the end of the group intervention and T4 were mostly linked to a desire not to think about cancer anymore or a lack of time. Another study led by our team showed that the delayed onset of our intervention could increase the dropout rate (Bicego et al., 2021). Thus, participants from the WLCG could have had more time to think or review their expectations before starting the intervention, possibly leading to a decrease of motivation (Brown et al., 1989; Redko et al., 2006). To minimize the impact of dropouts on our results, we decided to adopt an ITT approach. However, the method used to deal with missing data due to dropouts (*last observation carried forward*) still has its own limitations. Finally, the WLCG received the intervention at some point during the study, instead of receiving it after T4, which could have biased our results. It is possible that the short-term effects of the intervention decreased during the months following the sessions and that the significant effects seen at the 1-year follow-up were due to time passing. As stated in the Introduction, the evolution of the burden of symptoms during the cancer trajectory is inconsistent among studies, as some of them reported an increase of symptoms and others a decrease (Trudel-Fitzgerald et al., 2013).

In conclusion, the results of this study underline the potential efficacy of a group intervention combining self-hypnosis and self-care to improve fatigue, sleep, and emotional distress in cancer survivors. This is a first study suggesting long term effects of a hypnosis/self-care-based intervention on fatigue, sleep, and distress after cancer treatment has been completed. The timing of the intervention could possibly be of importance, and our results suggest that proposing the intervention not too long after the treatment completion could be the best option. However, more data are needed to confirm this hypothesis, and our study underlined the interest of studying more the impact of the moment of the intervention on the evolution of patients' fatigue, sleep, and distress. This intervention could be easily implemented in oncology settings by different health professional trained in hypnosis (psychologist, physician, etc.), according to the legislative guidelines for hypnosis use in medical practice (Confédération Francophone d'Hypnose et Thérapies Brèves, 2019; Conseil Supérieur de la Santé, 2020). One could also consider proposing this intervention to patients who are still under treatment, in order to investigate its benefits on this population, and compare them with the outcomes of posttreatment patients.

The results also open different scientific perspectives. First, it could be useful to design another study comparing the intervention group with a control group that would not receive the group sessions at all to ensure that the long-term effects on CRF, sleep, and distress are due to the intervention and not to another factor (e.g., passing time). Second, rethinking the recruitment process could allow the inclusion of more men and more cancers other than breast cancer in the study. To do this, adapting the group intervention content to men's needs and targeting other oncological populations through direct recruitment could be useful. Third, hypnosis could also be combined with other therapeutic modalities such as CBT and be proposed in groups or individual settings. It could be interesting to compare the short- and long-term effects of different hypnosis-based group interventions on cancer patients' fatigue, sleep, and distress in order to propose the best care available. Finally, our intervention could be compared to an active-attention control condition rather than a wait-list control group in which patients only benefit from usual care.

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Availability of Data and Material

The full protocol and dataset of this study is available upon request. Please contact the corresponding author (ch.gregoire@uliege.be).

Disclosure Statement

No potential conflict of interest was reported by the author(s).

Ethics Approval and Consent to Participate

All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the Ethic Committee of the Faculty of Medicine of the University of Liege (N°B707201630321), with each participant providing written consent.

Registration

ClinicalTrials.gov (NCT03144154). Retrospectively registered on the 1st of May, 2017.

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Randomisiert-kontrollierte Untersuchung einer Intervention mittels Selbstfürsorge und Selbsthypnose bei Erschöpfung, Schlafstörungen und emotionalem Stress in der Nachbehandlung von Krebspatienten: eine Katamnese nach einem Jahr.

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Zusammenfassung: Krebs kann Erschöpfung, Schlafstörungen und emotionalen Stress hervorrufen. Hypnoseinterventionen haben positive Kurzzeiteffekte bei diesen Störungen gezeigt. Über Langzeiteffekte ist allerdings weniger bekannt. In dieser Studie wurden Kurz- und Langzeiteffekte hinsichtlich dieser Symptome bei einer Nachbehandlung von Krebspatienten untersucht, welche eine Gruppenintervention bestehend aus Selbstfürsorge und Selbsthypnose erhalten haben. Neunundfünfzig weibliche Krebsüberlebende wurden nach Zufall entweder einer Hypnose-Interventionsgruppe oder einer Warteliste-Kontrollgruppe zugewiesen. Die Ergebnisse zeigten bei der Hypnose-Interventionsgruppe eine signifikante Abnahme von Erschöpfung, Schlafschwierigkeiten und emotionalem Stress im Vergleich zur Kontrollgruppe der Warteliste. Die meisten positiven Wirkungen blieben nach einem Jahr bestehen. Die Mehrzahl der Teilnehmerinnen erhielt die Hypnose Gruppenintervention annähernd 10,65 Monate nach der Diagnose; möglich ist, dass eine Intervention zu einem früheren Zeitpunkt nach Erhalt der Diagnose eine deutlichere Wirkung erzielt hätte. Es bedarf weiterer Studien zur Replizierung dieser Ergebnisse im Vergleich mit einer aktiven Kontrollgruppe sowie zur Erforschung des besten postdiagnostischen Zeitpunkts für den Beginn der Intervention.

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Essai randomisé et contrôlé d'une intervention associant autobienvveillance et autohypnose sur la fatigue, le sommeil et la détresse émotionnelle chez des patients atteints d'un cancer en post-traitement: suivi à 1 an

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Résumé: Le cancer peut provoquer de la fatigue, des troubles du sommeil et une détresse émotionnelle. Les interventions basées sur l'hypnose ont montré des effets positifs à court terme sur ces symptômes. Cependant, leurs effets à long terme sont moins connus. Cette étude a évalué les effets à court et à long terme d'une intervention de groupe combinant autobienvveillance et autohypnose sur ces symptômes chez des patients atteints d'un cancer en post-traitement. Quatre-vingt-quinze survivantes du cancer ont été randomisées en deux groupes: une intervention de groupe basée sur l'hypnose, et un groupe contrôle sous forme de liste d'attente. Les résultats ont montré des diminutions significatives de la fatigue, des troubles du sommeil et de la détresse émotionnelle après l'intervention de groupe basée sur l'hypnose par rapport au groupe contrôle. La plupart de ces effets positifs ont été maintenus après un an de suivi. La plupart des participantes ont reçu l'intervention de groupe basée sur l'hypnose environ 10,65 mois après le diagnostic, et il est possible qu'une intervention effectuée plus tôt après le diagnostic aurait pu avoir un impact plus robuste. D'autres études sont nécessaires pour reproduire ces résultats, notamment par rapport à une condition de contrôle actif, ainsi que pour étudier le meilleur moment après le diagnostic pour proposer l'intervention.

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Ensayo clínico controlado randomizado de una intervención que combina el autocuidado con la autohipnosis para fatiga, sueño y distrés emocional en pacientes oncológicos postratamiento: Seguimiento a un año.

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Resumen: El cáncer puede provocar fatiga, disturbios de sueño y distrés emocional. Las intervenciones hipnóticas han mostrado efectos positivos a corto plazo para estos síntomas. Sin embargo, los efectos a largo plazo no son bien conocidos. Este estudio evaluó los efectos sobre estos síntomas, a corto y largo plazo, de una intervención grupal que combina autocuidado y autohipnosis (intervención hipnótica grupal) en pacientes con cáncer postratamiento. Se asignaron de forma aleatoria a 95 mujeres sobrevivientes de cáncer al grupo de intervención hipnótica grupal o al grupo control de lista de espera. El grupo de intervención hipnótica grupal mostró significativamente menos fatiga, dificultades de sueño y distrés emocional después de la intervención en comparación al grupo control de lista de espera. La mayoría de estos efectos positivos se mantuvieron hasta el seguimiento a un año. La mayoría de las participantes recibieron la intervención hipnótica grupal aproximadamente 10.65 meses después del diagnóstico, y es posible que el realizar la intervención más temprano después del diagnóstico logre un impacto más robusto. Se necesita más investigación para replicar estos resultados en comparación con una condición de control activo y estudiar el mejor momento para iniciar el tratamiento posdiagnóstico.

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