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QualFatigue Study: Which Factors Influence the Use of Specific Interventions for Breast Cancer Survivors with Fatigue? A Cross-Sectional Exploratory Study

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Title page

Title: QualFatigue study: which factors influence the use of specific interventions for breast cancer survivors with fatigue? A cross-sectional exploratory study

Running head: Factors influencing the use of interventions to relieve fatigue

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Declarations

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Abstract

Purpose: International guidelines recommend specific interventions to reduce cancer-related fatigue (CRF). Evidence suggests underutilization of these interventions among breast cancer survivors. The QualFatigue study aimed to explore the potential factors influencing the use of specific interventions, for relief, in patients with CRF through qualitative analyses.

Methods: Patients with stage I–III breast cancer, and CRF ≥ 4 on a 10-point numerical scale were recruited within 6–24 months at the end of their primary treatment. Semi-structured interviews were performed. Emergent themes were identified using a stepped content analysis (QDA Miner software).

Results: Data saturation was achieved with 15 interviews. Four main themes emerged as potential sources of influence in the participants' use of specific interventions: 1) expectations regarding the management of CRF, 2) representations of the benefits provided by the interventions, 3) individual physical and psychological conditions, and 4) social and environmental situations. Six key levers came out transversally to optimize the use of specific interventions to relieve CRF: 1) listening and recognition of the individual difficulties and needs; 2) individual and global health assessments; 3) information and advice on how to manage CRF; 4) discussion groups focused on the management of CRF; 5) group activities; and 6) professional and personalized guidance.

Conclusion: This study calls for multi-level action to address many persistent barriers and exploit levers in the management of CRF.

Key words: breast cancer, survivors, cancer-related fatigue, specific interventions, barriers

Introduction

Breast cancer is the second most prevalent cancer worldwide and accounts for almost 12% of new cases of cancer annually [1]. In most developed countries, up to 85% of patients with breast cancer can expect a long-term disease-free survival [2, 3]. However, a substantial proportion of survivors experience short-term to long-term health effects of cancer and its treatments (e.g., chronic pain, axillary web syndrome, lymphedema, concerns about body image, cognitive impairment...) and, therefore, have impaired quality of life [4, 5, 6].

Cancer-related fatigue (CRF) is one of the most common and disturbing symptoms affecting up to 90% of cancer patients both during and after treatment [7]. Although most patients experience a reduction in their fatigue over time, about 30% endure persistent fatigue for several years after the completion of primary treatment [7, 8]. CRF is defined as “*a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer and/or cancer treatment that is not proportional to recent activity and interferes with usual functioning*” [9]. Compared with the fatigue reported by non-cancer individuals, CRF is more severe and less responsive to rest [9]. It can have a detrimental impact on many levels of the individual’s functioning, capabilities to cope with daily life activities, and fulfilling one’s family, social, and professional roles [7]. CRF demonstrates inter-individual variability, as it is a multifactorial and complex phenomenon [7, 8], and its underlying mechanisms have not been clearly elucidated [10, 11].

Although data that support the use of any pharmacological agent for treating CRF are limited, international clinical practice guidelines recommend specific interventions, such as physical activity (PA), education, and psychosocial (e.g., cognitive-behavioral therapies [CBT]) approaches as the most efficacious strategies to reduce CRF [9, 12, 13]. Particularly, in breast cancer survivors, systematic reviews have reported consistent improvement in CRF after PA interventions, and a significant support from psychological interventions, including CBT; cognitive therapies help patients to better identify unhelpful cognitions and maladaptive behavioral patterns that may be contributing to the CRF [14-16]. Yoga and mindfulness-based interventions have also been proved effective in the short term [17, 18].

However, previous evidence suggests that the implementation of the guidelines and recommendations is still not optimal [11]. Consequently, CRF remains globally undertreated [19]. Several barriers, affecting its management, have been identified at the patient, clinician, and health system levels (e.g., personal factors such as misconceptions, lack of motivation or time, environmental factors such as availability of settings and opportunities) [19, 20].

In Europe, nearly half of the general population do not practice any leisure PA [21]; in France, a third of adults do not meet the public health recommendations for PA, despite the fact that the majority of French people are aware of the beneficial effects of PA on health [22]. In the cancer population, several studies have observed a significant decrease in the level of PA after cancer diagnosis [23, 24] and the estimated rates of patients who are or remain not regularly active during and after treatment completion range up to 30% [25]. Among current or later cancer-related adverse events, CRF is, with pain, one of the main physical obstacles to practicing PA, and can justify, in case of significant physical deconditioning, referral to rehabilitation specialists [9, 26]. Regarding CBT, interventions targeting CRF are very little developed in France, in particular because of a lack of trained professionals and reimbursement related problems [27].

To the best of our knowledge, most of the qualitative studies that have explored CRF focused on patients' perception of fatigue (experience and impact) and their coping strategies [28-30]. Thus far, there is limited understanding on how and why breast cancer survivors use or not use specific interventions to relieve CRF.

Our study aimed to address this gap and to explore possible ways to optimize the uptake of the recommended specific interventions to relieve CRF. The purpose of the study was to investigate the barriers and facilitators that may influence the use of specific interventions to relieve CRF, among French breast cancer survivors, with moderate to severe CRF, after the completion of their primary treatment.

Methods

Design

QualFatigue (*"A qualitative exploration of the use of interventions to relieve fatigue among breast cancer survivors"*) was a monocentric, cross-sectional, and explorative study based on semi-structured interviews. The protocol was approved by the French regulatory and ethics authorities. All participants received oral and written information about the purpose and procedures of the study, and signed a consent form.

Population

Participants were included if they met the following inclusion criteria: 1) stage I-III breast cancer [31], 2) age ≥ 18 years at the time of study entry, 3) within 6–24 months after the end of primary treatment (defined as the endpoint of primary surgery, chemotherapy, or radiotherapy, whichever came last. Anti-human epidermal growth factor receptor therapy and hormonal therapy, if indicated, could be ongoing), and 4) level of CRF ≥ 4 on a 10-point numerical scale (this score was retained because it was considered as an optimal cut-off for identifying clinically moderate CRF [score: 4-6] and severe CRF [score: 7-10]) [12]. The following were the

main exclusion criteria: 1) evidence of relapse, 2) history of other cancers at the time of inclusion, and 3) obvious treatable medical conditions that can explain CRF.

Procedures and measures

From March to July 2019, participants pre-screened, according to the eligibility criteria for the QualFatigue study, from the list of outpatients, with breast cancer, of a French cancer center were approached with the help of their medical oncologists. If interested, patients met one of the investigators who provided them with further information about the study. After signing the consent form, patients were asked to rate their level of fatigue over the past seven days on a 10-point numerical scale from zero (“no fatigue”) to ten (“worst fatigue you can imagine”). Only women with a score $\geq 4/10$ were included. A trained psychologist (with a PhD degree) conducted individual semi-structured interviews by phone. All interviews lasted for approximately 30 to 45 min, and followed a pre-defined interview guide that was developed with diverse inputs from stakeholders, including clinicians, researchers, and breast cancer survivors. The interview guide included open-ended questions to encourage participants to discuss issues and covered the following areas: 1) description of the onset and the stabilization of CRF during treatment; 2) solutions to relieve CRF, including already tried solutions, and those intended; 3) expectations about the management of CRF; and 4) representations of the recommended interventions to manage CRF.

Demographics and medical features of the participants were collected from their medical records, including age, stage at diagnosis, time since the end of primary cancer treatment, treatments received, current hormonal therapy, marital status, family status, level of education, and professional status.

At the end of the interview, participants were given the “Fatigue et Cancer” guide distributed by the French National Institute of Cancer [32].

Analyses

Descriptive statistics were performed to characterize samples according to demographic and medical variables, and the use of specific interventions or other resources, using the Statistical Package for the Social Sciences (SPSS), version 21.0, IBM Software.

All interviews were audio recorded in full, and transcribed verbatim by a medical secretary for analyses, with all personal identifiers removed. After 10 interviews, a preliminary analysis was conducted to check whether information collected was adequate, and to establish the extent at which it would be sufficiently rich; then the interviews were continued until the research team felt that no more information could be obtained. Five more patients were included. Finally, data saturation was achieved with 15 interviews, additional interviews were not

deemed necessary to increase thematic content [33]. A descriptive inductive coding strategy was first applied by a researcher to the transcripts in order to identify and group meaningful phrases according to the primary objectives of the study [34], aided by the QDA Miner software. Following this, thematic matrices were constructed to examine the relationship between response patterns in the codes. The emerging themes were discussed within the research team to achieve valuable inter-coder reliability. Although the thematic analysis was performed by one of the researchers, the results were discussed within the research team. Additionally, the research team presented their interpretation via a seminar, to an independent team involved in clinical research; the interpretation was critically scrutinized.

Results

Sample characteristics

After prescreening, 46 women were considered eligible for inclusion in this qualitative study. Of them, only 15 were included. The flowchart demonstrating the selection process is shown in Fig 1. Demographic and medical characteristics of the participants are summarized in Table 1. Nearly two-thirds of the participants reported severe CRF (≥ 7) (Table 2).

Use of specific interventions to relieve CRF

The majority of participants reported as moderately to highly physically active (Table 2). The most frequent activities were walking, dancing, swimming, and gardening. None of the participants had undertaken any educational or psychosocial interventions. Some participants mentioned using mind-body interventions, such as sophrology and yoga, as alternatives to manage sleep disorders associated with CRF, and several others considered relaxation, meditation, and acupuncture as interesting approaches in the context of CRF, even if they had not tried it.

Barriers and facilitators influencing the use of specific interventions to relieve CRF

Four main themes emerged from the participants' discourse as potential sources of influence in their use of specific interventions. They are presented below without any significance-based prioritization.

Expectations for the management of CRF

Half of the participants considered that they did not require help in CRF management, either because they thought that they had to face difficulties or because they "*knew what to do.*" In addition, almost all patients mentioned rest as the main strategy for coping with CRF, and for some, rest was even considered the only

solution to reduce CRF: *“The only thing I can do when I am like this is lie down and wait for it to pass.”* For most participants, rest meant to lie down, which could last from a few minutes to several hours.

Half of the participants spontaneously mentioned that they raised the problem of CRF with a health care provider. Among those, only two participants had been informed about the benefits of exercise, and in one case, the participant was already physically active. In the other cases, participants described a frequent lack of attention or banalization from health care providers regarding CRF: *“According to my doctor, this is just normal fatigue. It is normal, it takes time,”* *“I have talked to him before, but he does not pay too much attention. When I tell him, I am tired he tells me to take rest.”* In addition, the majority of the participants found impossible to discuss CRF with a health care provider because of the short duration of medical consultations and/or they did not know how to approach the topic: *“Well, talking to the doctor... We see her for about ten minutes you know it’s not easy. There’s really no time to discuss...,”* *“I’ve never been told about my fatigue anyway, and then I do not really talk about it.”* However, several participants expressed the need for listening and recognition of CRF. In addition, global health assessment was expected by some patients, for example, one participant was *“waiting for in-depth medical exams to better understand and treat her fatigue.”* Another said that a physical examination helped to reassure her about the objective existence of CRF: *“When I go to my doctor, I’m happy when she measures my blood pressure and she tells me “you have ten,” because sometimes you wonder if it’s not in your head.”*

Among participants who declared need for more information and support, the preference was clearly given to non-pharmacological interventions, with only a few participants preferring the idea of a medication, defined as a *“stimulant.”* Several participants indicated that they were looking for an energizing effect, which is why some of them had taken dietary supplements (vitamins, probiotics, ginseng, and magnesium) for their *“boost”* effect, or they voluntarily changed their eating habits.

Representations of the benefits provided by the interventions

Almost three-quarters of the participants, including some of them who were not physically active, expressed positive representations about PA. The benefits associated with PA could be general (*“It feels good”*) or specific, including : 1) relief of symptoms, such as CRF, pain, sleep disorders, 2) relief of stress (*“It clears one’s mind,”* *“It allows me to think about something other than the illness”*), 3) maintenance and strengthening of physical capacities (*“It helps me to lose weight,”* *“It keeps me in good physical shape”*), or 4) promotes support (*“Seeing other people”*). None of the participants reported negative representations of PA. All non-physically active participants acknowledged that they *“should move more.”* However, only one had a defined project to start in

order to be physically active, which included starting an individual coaching. In contrast, a large majority of the participants did not have a picture of what educational or psychosocial interventions targeting CRF could be like.

Individual physical and psychological conditions

Several participants mentioned having experienced symptoms known to be associated with CRF, in particular pain - muscular and/or joint and/or neuropathic pain, sleep disorders, and some referred to preexisting chronic diseases, such as obesity or diabetes. Also CRF (*"I am weary quickly"*), pain (*"When I walk sometimes my legs hurt"*), and overweight (*"I'm over 100 kilos, that also makes me tired quickly"*) were cited as obstacles to the use of recommended interventions, particularly PA, as well as psychological factors such as lack of motivation (*"This weekend I didn't have the courage to get up on Sunday to go out"*), or fear (*"Fear of not being able to keep pace with the group and of being misjudged by others"*).

Social and environmental situations

Some participants pointed out the influence of their relatives on their attitudes toward CRF. They talked about the "pressure" from their immediate environment to take a rest: *"They tell me to rest, you must be patient, you must not be too stressed," "I have a friend who always says to me: 'You do too much, you don't care of yourself.'"* On the contrary, one participant reported a lack of understanding by her family and colleagues regarding the intensity of CRF and the need to have regular rest periods: *"And the comments that you heard coming back all the day: 'But go out, go walk, it will do you good' [...] Actually the trick is that people do not understand this fatigue, and me, I do not necessarily want them to see it."* More globally, family responsibilities and workload appeared to be major obstacles to finding the time and energy to devote to specific interventions targeting CRF (*"I don't take the time to do that, I really need to be reminded of that"*). Especially, if these were combined with environmental/logistics aspects, such as long distance to places of practice, bad transportation, and poor weather conditions (*"There are soft gymnastics lessons and it's a long way from home and I have no way to get there," "It's true that in winter, it rains, it's cold, I don't really feel like going out"*).

Social support was considered a major lever for engaging in any of the recommended interventions, particularly PA, however, only one participant mentioned that her family encouraged her to practice PA. In addition, being accompanied by a friend, joining a group of people in a similar life situation or in the same age range, but also personalized coaching were mentioned as motivational factors.

Discussion

Interviews were performed on breast cancer survivors with CRF, to explore the barriers and facilitators that may influence the use of specific interventions, by them, to relieve CRF. Several interesting findings emerged. Regarding the interventions that participants used, PA was cited as a frequent resource to manage CRF, but some participants stated that they did not exercise at all, or mentioned barriers to regular exercise. In addition, participants were mostly unaware of the other recommended treatment options for CRF. This finding was particularly striking regarding the educational and psychosocial interventions, of which they seemed to be totally unaware. The limited use of mind-body interventions was an unexpected result, particularly given the exponential development of this kind of approach and the positive image promoted by the media.

Four main sources of influence in the use of specific interventions were highlighted: 1) expectations regarding the management of CRF, 2) representations of the benefits that interventions could provide, 3) individual physical and psychological conditions, and 4) social and environmental situations.

Needs in terms of information, evaluation, personalization, and support from health care providers were reported by several participants. As previously mentioned in the literature [35], lack of time and attention during medical consultations, but also on the part of participants, the willingness to get by on their own, or the fear of having a drug prescription as the only answer, emerged as factors interfering with patient-provider communication. Unmet needs in this field may have contributed to some participants turning towards products and physical techniques, which have no consistent evidence of efficacy on CRF [36]. The risk is that the complementary and alternative strategies that can have associated adverse events may replace the recommended and proven effective interventions [37].

The influence of representations in the use of specific interventions was most evident in the expected and/or perceived benefits of PA. Although almost all participants considered resting as a core strategy to relieve CRF, PA was unanimously positively represented and associated with numerous benefits, with all participants feeling that *“they had to move.”* On the other hand, participants had no representation of what benefits psychosocial interventions, such as CBT—would provide. In Europe, CBT is particularly seen through the prism of mental disorders and consulting mental health professionals remains difficult for a section of the population due to fears (e.g., stigmatization) and false beliefs (e.g., one must resolve its own problems) [38, 39]. The difference in representations between PA and psychosocial interventions could also be linked to the representations that participants had about CRF. Thus, bodily sensations and physical factors are particularly present in patients'

common descriptions of CRF, unlike the cognitive dimension, which is less represented [35, 40]. This could explain the foremost use of interventions that work on physical aspects.

Consistent with previous studies, the barriers to the use of specific interventions included somatic symptoms such as CRF itself and pain, but also psychological factors, social, environmental, and logistic constraints [24, 26]. Well described for PA, these barriers were also clearly apparent in our study for other interventions such as mind-body approaches. Benefits are largely related to the regularity with which participants practice mind-body techniques [36]. It is possible that having difficulty in focused attention that is prevalent among patients with CRF can be an obstacle for this subset of patients. Moreover, the use of mind-body techniques often implies an initial in-person instruction phase, which allows feedback [41]. For instance, it has been shown that yoga was best undertaken when guided by a qualified instructor [36]. This is why issues of access to professional resources and of distances to be traveled may be a central obstacle for some patients.

Several limitations of this exploratory study should be acknowledged with respect to the generalizability of the results. First, even if thematic saturation was rich, the sample size was small. Second, CRF is a complex symptom, and has a strong association with emotional distress, including depression and anxiety. This is particularly notable in the period after the end primary treatment for breast cancer. Although we have identified the role of some psychological factors, which act as barriers in the treatment of fatigue, we did not explore the contribution of anxiety and depression in the utilization of these interventions. Third, despite a diversified sample (e.g., different age groups, levels of education, and professional status), this monocentric and cross-sectional study design cannot reflect the diversity of the geographical situations and the possible evolution of practices during and after the primary treatment. Worthy of note is the fact that all patients were enrolled in a single French cancer center, which has a psycho-oncology unit, and has been offering a structured set of non-pharmacological interventions complementary to care (e.g. PA, mindfulness-based interventions), for free of charge, since last seven years. We acknowledge that this organization may not be shared by the other centers in France.

As the main clinical implication of this study, six key levers came out in the interviews to overcome identified barriers and optimize the use of specific interventions in patients with CRF: 1) listening and recognition for individual difficulties and needs; 2) individual and global health assessment; 3) information and advice on how to manage CRF; 4) discussion groups focused on the management of CRF; 5) group activities (e.g., walking, soft gymnastics, relaxation); and 6) professional and personalized guidance.

In conclusion, this study suggests that although breast cancer survivors use some of the specific interventions known to relieve CRF, there are still barriers to managing CRF and expectations that are not being met. This study also suggests that multi-level actions can overcome a number of barriers.

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FIG. 1 Flow diagram of the QualFatigue population

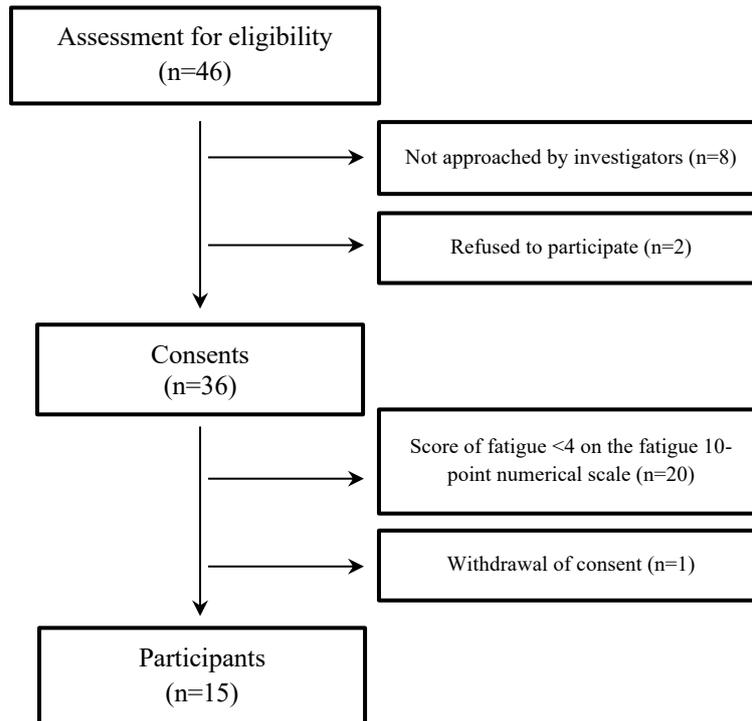


Table 1. Demographic and medical characteristics of QualFatigue sample (n=15)

Characteristics	N (%)
Age (mean/ range, years)	60.3 (45–81)
Cancer stage	
I	4 (26.7)
II	9 (60)
III	2 (13.3)
Time since the end of primary cancer treatment (mean/ range, months)	15.1 (6–24)
Treatments received	
Surgery	12 (100)
Chemotherapy	8 (53.3)
Radiotherapy	14 (93.3)
Current hormonal therapy	12 (80)
Marital status	
Single	5 (33.3)
Living with partner	10 (66.7)
Having children	
Yes	14 (93.3)
No	1 (6.7)
Education level	
< high school degree	6 (40)
≥ high school degree	9 (60)
Professional status	
Working	6 (40)
Retired	7 (46.6)
Disabled	1 (6.7)
Unemployed	1 (6.7)

Table 2. Fatigue characteristics and use of health behavior interventions among the sample

Patients (No.) ^a	Global level of fatigue (NS) ^b	USE OF SPECIFIC INTERVENTIONS			USE OF OTHER RESOURCES	
		Physical activity (+/-) ^c	Psychosocial interventions (+/-) ^c	Mind-body interventions (+/-) ^c	Complementary and alternative medicine (+/-) ^c	Dietary changes (+/-) ^c
1	7	-	-	-	-	+
2	6	+	-	Yoga	Vitamin D, osteopathy	-
3	7	+	-	Sophrology	-	+
4	7	+	-	-	Vitamin C, Ginseng, Acerola	-
5	8	-	-	-	-	-
6	7	+	-	-	Osteopathy	-
7	5	+	-	-	-	-
8	7	+	-	-	Osteopathy	-
9	5	-	-	-	-	-
10	8	-	-	Sophrology	-	-
11	6	+	-	-	Homeopathy, acupuncture, magnesium, probiotics, thermal cure	+
12	7	-	-	-	-	-
13	7	-	-	-	Vitamins	-
14	5	+	-	-	-	-
15	6	+	-	-	-	-
Mean (SD)^d OR No. (%)	6.53 (0.99)	9 (60)	0	3 (20)	6 (40)	3 (20)

^a No., number; ^b NS, numeric scale; ^c + used; - not used; ^d SD, standard deviation