

Research Article

Experience and Perceptions With a Phone-Based Weight Loss Intervention Among Overweight and Obese Survivors of Breast Cancer Enduring Cancer-Related Fatigue in France: A Qualitative Study Within a Randomized Clinical Trial

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Introduction: The MEDEA randomized clinical trial evaluated the impact of a telephone-based weight loss intervention focused on calorie restriction and lifestyle behavior change among overweight and obese breast cancer (BC) patients on cancer-related fatigue in France. The intervention was linguistically and culturally adapted from the North American BWEL-A011401. Since patient acceptability and engagement with weight loss interventions are influenced by cross-country cultural differences in dietary, social, and behavioral habits, we conducted a qualitative study to explore these factors and inform future implementation. **Methods:** Among 220 patients with Stage I–III BC who participated in MEDEA, 110 were randomized to receive the weight loss intervention delivered by dietitians through 24 semistructured calls over 12 months. Twenty patients receiving the intervention accepted participation in four focus groups to explore barriers and facilitators for uptake and engagement, as well as acceptability, satisfaction, and improvement suggestions. A thematic content analysis was performed using Nvivo12 software.

Results: Four focus groups were conducted. Overall, patients generally expressed positive perceptions of the intervention, highlighting several key themes: (1) satisfaction with the intervention, reporting objective benefits, including measurable weight loss and reduced symptom burden; (2) recognition of intervention as a catalyst for sustainable behavioral change; and (3) appreciation for the convenience of a telephone-based format. However, participants also identified several barriers to uptake and engagement, along with suggestions for improvement: (1) The need for tools to sustain engagement such as postintervention follow-up calls, psychological support, and resources for self-monitoring; (2) for the importance of further cultural adaptation; and (3) a call for a more patient-centered research ecosystem, encompassing the selection of relevant patient-reported outcomes, improved communication, and enhanced community-building efforts).

Conclusions: The MEDEA intervention was found to be acceptable and positively experienced, suggesting that a North American weight loss program seems adaptable to a different language and cultural context. This qualitative analysis also informed refinements to optimize weight loss interventions in a European context.

Trial Registration: ClinicalTrials.gov identifier: NCT04303924

Keywords: acceptability; breast cancer; cancer-related fatigue; diet; exercise; obesity; overweight; qualitative research; survivorship; telephone-based intervention

1. Introduction

Breast cancer is the most frequent cancer diagnosed among women worldwide, with over 2.3 million women diagnosed in 2020 [1] and more than 61,000 new cases diagnosed in metropolitan France alone in 2023 [2]. Nevertheless, thanks to improvements in breast cancer detection, treatment, and care over the past 2 decades, breast cancer mortality rate is progressively declining, and the 5-year survival rate for patients is up to 90% in Western society [3, 4].

The growing number of breast cancer survivors has led to the need for better management of long-term cancer-related side effects [5, 6]. Cancer-related fatigue, defined as a “persistent, subjective sense of tiredness related to cancer and cancer treatment that interferes with usual functioning” [7], is one of the most frequent and distressing cancer-related side effects [5, 6]. Among these, cancer-related fatigue is a complex and highly prevalent condition. Literature suggests cancer-related fatigue is linked with a wide array of factors, which can contribute to fatigue directly or indirectly, acting as predisposing, precipitating, or perpetuating factors. These include, but are not limited to, inactivity and unfavorable energy balance, pretreatment fatigue, concomitant medical conditions, comorbidities, and psychosocial factors including anxiety and depression, as well as treatment-related characteristics [8–10]. Literature also suggests that elevated body mass index (BMI) represents a risk factor for cancer-related fatigue [11–13]. Indeed, higher prevalence of fatigue was observed in obese breast cancer survivors compared to their leaner counterparts [14–16]. Furthermore, obesity was identified as a significant predictor of post-treatment fatigue in a cohort of 304 breast cancer survivors. Specifically, 45% of obese women reported experiencing fatigue approximately 4 years after treatment completion, compared to 26% of non-obese women [14]. Evidence from the CANTO cohort further supports this observation, as an analysis involving over 5000 breast cancer patients demonstrated that elevated BMI was associated with an increased risk of fatigue [10].

In addition to representing a risk factor for cancer-related fatigue and quality of life deterioration, obesity has been linked to several adverse outcomes among cancer

survivors, including an increased overall and breast cancer specific mortality rate after breast-cancer diagnosis [17–19].

The safety and effectiveness of weight-loss interventions among overweight or obese breast cancer patients has been demonstrated in a number of clinical trials [20, 21]. Notably, Lake et al. [20] performed a systematic review of reviews in 2022 evaluating the effectiveness of lifestyle interventions, observing in 7 out of 12 reviews a significant reduction of two or more anthropometric outcomes (weight, BMI, and body composition), as well as quality of life (8/11), mental health (4/7), and physical functioning (2/3). Three major multicenter clinical trials have demonstrated the feasibility and efficacy of remotely delivered, telephone-based lifestyle interventions for weight loss in breast cancer survivors. The ENERGY trial ($n = 692$) compared a group-based behavioral intervention—featuring weekly sessions for 4 months, followed by monthly meetings and supplemented by 2 years of telephone counseling and personalized newsletters—with a less intensive program offering standard weight management resources and two dietary counseling sessions. The LISA trial ($n = 338$) evaluated a 2-year, telephone-based weight loss intervention against an educational control group. Similarly, the SUCCESS C trial ($n = 1785$) randomized women with intermediate- to high-risk early breast cancer to either a 2-year telephone-based lifestyle program with mailed materials or a control group that received only mailed general recommendations. Across all three trials, participants in the intervention arms achieved sustained weight loss, with reductions ranging from 5% to 6% in the first year and 3.6% in the second year [22–24]. Benefits were also reported in blood pressure and biological parameters (glucose and lipids) as well as physical activity levels [24–26]. Additionally, the POWER-Remote trial found that a $\geq 5\%$ weight loss after 6 months improved symptoms related to endocrine therapy, including fatigue and anxiety [27].

The ongoing Breast Cancer Weight Loss (BWEL) study, which randomized 3181 survivors, recently reported that women in the intervention arm lost an average of 4.8% of their baseline body weight at 12 months, compared to a 0.8% weight gain in the control group ($p < 0.0001$), with full results expected soon [28].

The motivating to exercise and diet, and educating to healthy behaviors after breast cancer. MEDEA trial is a French multicenter randomized trial, which enrolled 220 patients with Stage I–III breast cancer within 12 months of primary treatment and BMI ≥ 25 kg/m². MEDEA evaluated the impact on cancer-related fatigue of a telephone-based health education weight-loss program based on motivational coaching, exercise, and diet delivered by dietitians through 24 semistructured calls over 12 months (intervention arm) versus a standard health educational program (control arm) [29]. The study intervention was adapted from the BWEL trial (A011401) [28].

While several studies have proven the effectiveness of weight loss interventions in achieving weight loss in clinical trial settings, its practical implementation remains challenging [30, 31]. Qualitative studies investigating the feasibility and acceptability of such programs are fewer and, a minority of large, randomized trials have included qualitative interviews. At present, existing data generally show a high level of overall satisfaction with the planned interventions. Nevertheless, several key barriers to implementations were highlighted, such as difficulty at self-monitoring; the need for enhanced group interactions, longer coaching periods, and infrastructures to support behavioral change, and engagement challenges in adapting to a new lifestyle including becoming more physically active [32–34]. Further, all of these qualitative studies were conducted in a North American population.

Cultural adaptation plays a relevant role in the effectiveness of behavioral interventions, such as weight loss programs, as strategies who might be effective in a region or population might not be directly translated to another due to varying cultural, behavioral, and environmental factors. Indeed, research comparing weight loss maintenance in North American and European populations reports some gaps in behavioral and psychological characteristics [35–39], despite differences in inclusion criteria, procedures, and measures limiting the possible cross-cultural insights. Qualitative research can be useful in examining the underlying psychosocial, behavioral, and environmental factors across diverse cultures and calls to inform the implementation of behavioral interventions in clinical practice. Thus, a deeper understanding is important in developing culturally tailored weight loss programs that account for distinct regional and cultural differences, ultimately improving the sustainability of weight loss across global populations.

Behavioral interventions focusing on improving nutritional aspects are a complex and charged topic, with far-reaching ramification and cultural differences both on a local and cross-country basis; indeed, patients' relationship to food can vary widely based on social, economic, behavioral, and environmental factors. This can in turn affect acceptability, feasibility, and engagement with weight loss interventions across different countries, populations, and cultures. To better understand these factors, we performed a qualitative study to explore barriers and facilitators for uptake and engagement within the MEDEA trial, as well as acceptability, satisfaction, and suggestions of improvement

to inform future implementation. A qualitative approach was selected to explore the complex and nuanced factors influencing patients' experiences with the intervention. In contrast to quantitative methods that emphasize numerical outcomes or predetermined items and domains, qualitative research allows patients to articulate their perspectives in their own words, uncovering deeper cultural, personal, and contextual factors that shape engagement and acceptability. Such insights are essential for informing and refining future implementation efforts. One of the strengths of the study is the adaptation of an American intervention within a European group of patients in a randomized controlled trial. By doing so, we were able to test the cross-cultural effectiveness of these programs. This evaluation not only highlights the feasibility of implementing such interventions across different healthcare systems but also offers insights into how cultural, social, and environmental factors may influence their success in diverse populations.

2. Methods

2.1. Summary of the MEDEA Trial and Intervention. Details of the MEDEA trial design were previously published [29]; the study intervention was linguistically and culturally adapted from the BWEL trial (A011401).

2.1.1. Health Education Program (Arms 1 and 2). All patients in both the intervention and health education control arm received a standardized Health Education Program focusing on healthy living. At study entry, participants received a welcome letter, paper brochures, and links to websites focused on healthy living and cancer-related themes. In addition, all study participants received a quarterly newsletter including an update about study enrollment, a summary of a new study published regarding breast cancer, suggestions for activities (e.g., Nordic walking and Dragon Boat) and seasonal recipes.

2.1.2. Intervention (Arm 2). The intervention in MEDEA was delivered by phone by trained dietitians who coached patients, providing behavioral support to facilitate lifestyle change. Participants were paired with an individual coach, with whom they worked through all phases of the 1-year weight loss program. The behavioral change program was based on Social Cognitive Theory, which hypothesizes that the interactions between environmental, personal, and behavioral elements determine behavioral change [40].

The intervention utilized a toolbox approach, allowing for tailoring the intervention to the individual participant. Examples of possible toolbox solutions included alternative dietary approaches (low glycemic, Mediterranean, etc.), instructions for strength-training exercises, physical activity to deal with neuropathy or lymphedema, applications, videos, and books to help develop a healthy diet, and information about both meal prep and batch cooking. Toolbox solutions also provided the ability to tailor the intervention to meet the needs of specific ethnic, socioeconomic, or other populations. Finally, at the end of the intervention, patients

were sent a thank you email along with a certificate of completion of the intervention.

A series of semistructured and standardized telephone calls formed the core of the intervention, supplemented by a detailed participant workbook. Data on compliance, changes in diet, physical activity, and weight reported by participants were captured and recorded electronically during the calls. The intervention was implemented through 24 telephone calls, delivered over 1 year. Calls were scheduled as follows: Intensive phase (months 1–3)—weekly calls for 12 weeks; consolidation phase (months 4–6)—calls every 2 weeks, Maintenance phase (months 7–12)—calls once per month. Further information regarding the detailed intervention arm was previously published [29].

2.2. Selection of Participants for the MEDEA Qualitative Analysis. Eligible participants for the qualitative analysis were selected among those enrolled in the intervention arm of MEDEA [41]. Among the 110 participants in the intervention arm, 75 consecutive patients who had completed the intervention and were disease-free at the time of the qualitative study were invited to participate. Overall, 52 agreed to participate in focus groups. The inclusion of 20 participants in the focus groups was guided by the principle of thematic saturation [41], defined as the point at which no new themes or insights emerge from the data, indicating that additional data collection would be unlikely to yield further understanding. Saturation was achieved after conducting four focus groups comprising a total of 20 participants, at which stage the data were considered sufficiently comprehensive to address the research questions.

2.3. Focus Groups Procedures and Data Collection. We used qualitative research methodology based on focus groups following a predefined guide developed with the input of multidisciplinary stakeholders (see Supporting Information 1). Between May and November 2022, four virtual focus groups were conducted by an experienced qualitative researcher (EM, PhD). Following a brief introduction to the study and its objectives, EM facilitated the discussions using focus group guides created by an interdisciplinary team. The same guide was used for all the focus groups. Each focus group session lasted approximately 90 min.

During the focus group, participants were encouraged to share their personal experiences following their involvement in the MEDEA study. The discussions were structured to address key themes such as barriers and facilitators to intervention uptake and adherence, participant satisfaction, and suggestions for improving the weight loss program. Spontaneous feedback was also welcomed. All focus group sessions were audio-recorded, transcribed verbatim, and anonymized. A brief questionnaire was administered to participants after each focus group to collect sociodemographic information. In the interest of transparency, we used the Consolidated Criteria for Reporting Qualitative Studies (COREQ) to ensure comprehensive and thorough reporting of our study, following the 32-item checklist that covers the necessary components of the study design [42].

2.4. Analysis. A thematic analysis was performed by two researchers using NVivo 12 software, following a six-step process [43] to identify main themes and subthemes. Analytic procedures involved:

1. Familiarization with the data (reading and re-reading transcripts of audio recordings and field notes and organizing materials)
2. Generation of initial codes (line-by-line coding of the materials)
3. Recognition of overarching themes
4. Comprehensive examination of themes in accordance with Braun and Clarke's guidelines [44]
5. Systematic categorization of themes (defining the name of each theme and subtheme and the narratives they are conveying)
6. Compilation of the final report (describing the content of each theme and subtheme, selecting exemplifying quotes, and discussion with other members of the team to finalize the reporting).

Descriptive statistics were used to characterize the study participants.

2.5. Ethics. Prior to enrollment, all participants provided written informed consent. To maintain anonymity, the analysis excluded any identifiable information, such as names or ID numbers. The study protocol of MEDEA received approval from the national personal data protection committee in February 2020, with an amendment in July 2020 (CPP: 2019-A02374-53).

3. Results

Overall, 20 patients with an average age of 58 years (range: 38–76) participated in four focus groups. Most participants had at least a high school degree or higher, were married, and lived in an urban environment (medium-sized towns or large cities). Participants' characteristics are described in Table 1, and the composition of the focus groups is described in Table 2. The first focus group comprised seven patients, the second five, and both the third and fourth groups included four patients each. The main themes emerging during the focus groups are summarized in Figure 1, as well as in Tables 3 and 4. Participants reported mostly positive experiences with the MEDEA intervention (Table 3) citing perceived objective benefits, including weight loss but also reduction of their symptoms including emotional distress, and a general increase in their wellbeing. Furthermore, participants saw the intervention as a catalyst for sustainable behavior change in nutrition and physical activity, and they valued greatly increasing their knowledge about food composition and healthier alternatives, debunking preconceived ideas, and generating motivation to be active again and to develop new habits. Finally, participants underscored not only the convenience of remote, phone-based intervention but also the human aspect, which made them feel supported while also granting a sense of "safety" from

TABLE 1: Participants' characteristics.

Characteristics	Total (N = 20)
<i>Age (years)</i>	
Mean	58.0
< 40	2
40–49	4
50–59	5
60–69	6
≥ 70	3
<i>Highest education level</i>	
Primary school	1
Secondary school	1
Professional education	2
High school	3
< 5 years after high school	6
≥ 5 years after high school	7
<i>Occupational categories</i>	
Working	11
Retired	8
Unemployed	0
On disability	1
<i>Family situation</i>	
Single	4
In a relationship	3
Married	11
Divorced	1
Widowed	1
<i>Type of town</i>	
Village	3
Small town	5
Medium-sized town	5
Large city	7

judgment which allowed them to speak more truthfully. All patients were enthusiastic with their coach and expressed the desire to meet them in person or via video call to “put a face to a name.”

Despite having mainly positive representations about the MEDEA trial and its intervention, participants also underlined several barriers to uptake and engagement in the study and made valuable suggestions for improvement (Table 4). The ongoing request for tools to sustain engagement came into sharper focus. Patients not only asked for some form of longer follow-up coaching but also for ways to enable and facilitate self-monitoring. Patients also highlighted the interest of having a wider array of healthy eating recipes to facilitate incorporation in their everyday life. The need for a multidisciplinary weight management team also emerged, specifically with the desire for psychological support, as patients expressed that some of their questions and concerns would be better tackled by a mental health professional than by a dietitian. Another common point that emerged in the focus groups was the cultural rift perceived by the participants regarding the MEDEA intervention. Patients mentioned that the relationship toward food in France and the U.S. can be significantly different, with some patients rejecting meal replacement supplements or portion control. Indeed, patients sometimes felt the intervention as being “too American” and wished for more

adapted content, which considered their pre-existing habits and usual food. It is also worth remarking that some participants also brought up relevant points regarding the trial itself. In particular, participants brought attention to the complexity of some patient-reported instruments used in MEDEA for patient-reported data collection during the trial and advocated for a more patient-friendly research ecosystem. More specifically, they wished for a greater focus on the selection of pertinent patient-reported outcome measures to reduce the length or avoid redundancy by increasing communication with participants throughout the study and by receiving continuous feedback such as preliminary results of the study. Finally, they also wished for a greater sense of community experience during the trial, sharing their desire to meet other participants and share their views and experiences.

4. Discussion

This qualitative analysis among participants in the intervention arm of the MEDEA randomized clinical trial explored acceptability, satisfaction, and suggestions of improvement to inform future implementation of telephone-based weight loss interventions among survivors of early-stage breast cancer. Participants reported positive experiences with the intervention, particularly highlighting (1) a sense of satisfaction with the intervention, citing a perceived objective benefit; (2) the intervention as a catalyst to sustainable behavior change; and (3) the convenience of telephone-based format. In addition, some barriers as well as the need for optimization were cited, including (1) the need for tools to sustain engagement; (2) the need for additional cultural adaptation; and (3) the need for a more patient-centered research ecosystem.

Qualitative research can contribute in numerous ways to the development and implementation of health interventions, both by facilitating patient engagement and by providing researchers and caregivers a deeper and more complete understanding of patients' perspectives, which standardized questionnaires might overlook. An increasing number of randomized controlled trials are adopting an integrated approach by including some qualitative component such as exit interviews [45, 46]. Nevertheless, to our knowledge, no sizable, randomized trial investigating weight loss in BC has included qualitative interviews apart from the BWEL Trial (Alliance A011401) [28], whose qualitative data to date is yet to be published.

In 2016, Fazzino et al. published a qualitative evaluation of a phone-based weight loss trial on 186 obese BC survivors in the American Midwest [34]. They highlighted the convenience of adopting and maintaining the diet with protein shakes and prepackaged entrees, but perceived greater difficulty in self-monitoring and pursuing physical activity. Beckenstein et al. also collected analogous feedback in 2020, with participants appreciating the food-provisioning aspect, albeit expressing initial difficulty at consuming unfamiliar food [32]. Contrary to Fazzino's results, we found our patients to be satisfied with the MEDEA intervention, especially regarding their ability to easily integrate the learnings

TABLE 2: Sociodemographic composition of the focus groups.

Alias	Age	Level of education	Work situation	Family situation	Place of residence
Ludmila	58	High school	Working	Married	Small town
Sabine	58	Professional education	On disability	Married	Large city
Madeleine	75	≥ 5 years after high school	Retired	Single	Medium-sized town
Catherine	62	Secondary school	Working	Married	Medium-sized town
Irène	57	< 5 years after high school	Working	Married	Small town
Colette	66	< 5 years after high school	Retired	Married	Large city
Fernande	65	≥ 5 years after high school	Retired	Married	Small town
Mylène	68	Professional education	Retired	Widowed	Small town
Adeline	42	≥ 5 years after high school	Working	Married	Large city
Monique	71	< 5 years after high school	Retired	Married	Village
Armelle	43	≥ 5 years after high school	Working	Married	Small town
Flore	58	Primary school	Working	In a relationship	Medium-sized town
Aurélié	39	< 5 years after high school	Working	Single	Large city
Lucie	49	≥ 5 years after high school	Working	Single	Village
Elodie	38	≥ 5 years after high school	Working	In a relationship	Medium-sized town
Claudette	68	High school	Retired	Married	Medium-sized town
Fabienne	68	High school	Retired	In a relationship	Village
Sylvie	54	≥ 5 years after high school	Working	Married	Large city
Blanche	76	< 5 years after high school	Retired	Divorced	Large city
Maxine	44	< 5 years after high school	Working	Single	Large city

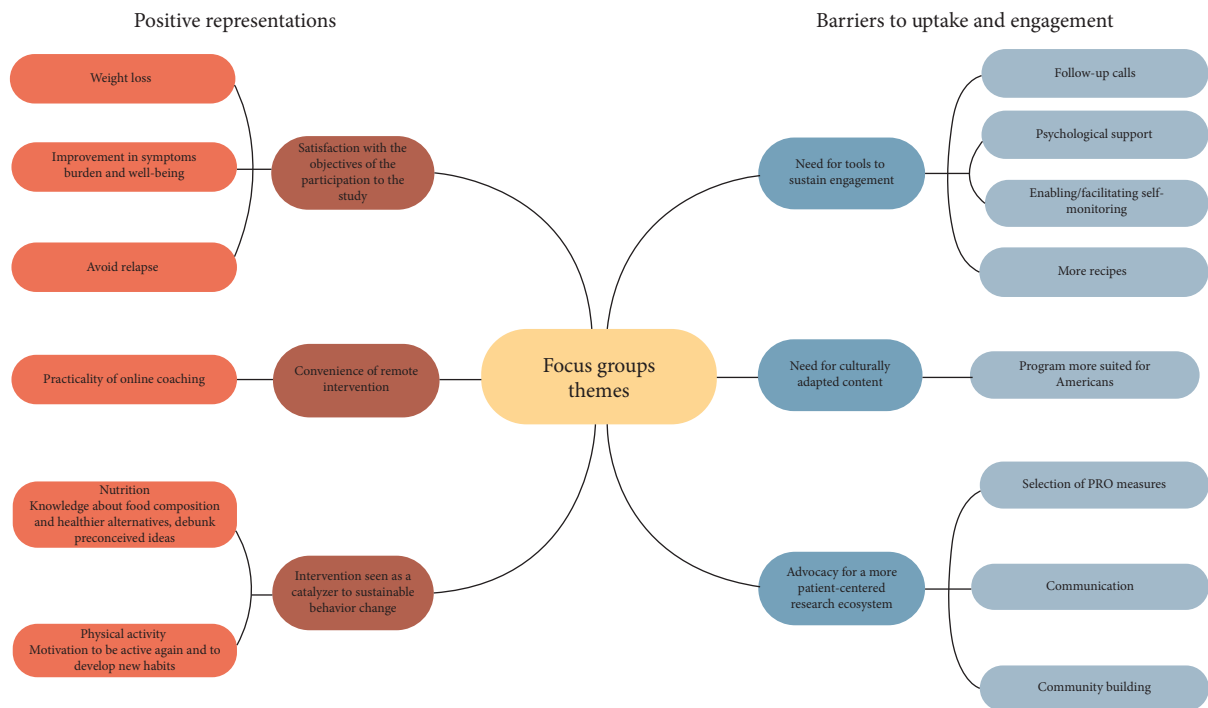


FIGURE 1: Conceptual diagram summarizing the key representations that emerged from participants.

of the program regarding caloric restriction, healthy eating habits, and improving activity levels into actions in their daily life.

This discrepancy might be explained by the type of intervention chosen by Fazzino et al. but is also related to the recruitment of only obese patients, while MEDEA also included overweight patients, who may experience less discomfort in daily physical activity and therefore be more open towards it [47]. Furthermore, a strength of the MEDEA

intervention was its toolbox approach which allowed for tailored remote and community-based strategies for increasing physical activity levels to the need of each participant, thereby lessening the issue of scheduling conflicts or lack of interest toward structured sportive activities which emerged from other qualitative studies [32, 34]. This is particularly relevant in minority communities, that have been found to be particularly at risk for low adherence to lifestyle modification intervention due to work and family

TABLE 3: Positive representations about the intervention that emerged from participants.

Themes	Subtheme	Exemplifying quotes (after each citation, we present the alias and the age of the participant)
Satisfaction with the objectives of the participation to the study	Improvement in symptoms burden and wellbeing Weight loss Avoid relapse	<i>"I'm very satisfied with the weight loss, with the starting sport again, but also because I had the impression that I was acting against cancer. Because I had an aggressive cancer and there's always a sword of Damocles hanging over me, but by losing weight and doing sport I have the impression that I'm acting, and that's great"</i> (Irène, 57 years old)
		<i>"Since this program was all about weight loss, I was ecstatic. It's incredible to be at home, on the phone, they guide you and you lose weight. It's amazing."</i> (Claudette, 68 years old)
		<i>"My self-image improved. When you look at yourself with the kilos off, it's really nice. [...] Personally, I find that I'm much more toned, I'm more energetic, I can run after my grandchildren. Before, with all those kilos, it was more complicated. [...] And I have less pain. I sleep better."</i> (Sabine, 58 years old)
		<i>"The fact of having lost a lot of weight, of putting back on clothes I hadn't worn for I don't know how many years [...] It's a real change, not just a change of diet but a real change of life."</i> (Lucie, 49 years old)
		<i>"The study was proposed to me, in relation to a weight loss and especially with an objective of perhaps avoid relapse, it is what motivated me. [...] I was interested in the follow-up, being monitored for a year by the dietician."</i> (Fernande, 65 years old)

TABLE 3: Continued.

Themes	Subtheme	Exemplifying quotes (after each citation, we present the alias and the age of the participant)
Intervention seen as a catalyzer to sustainable behavior change		"It helped me a lot because it made me understand that I was eating too much of some food categories and not enough of others. And it allowed me to balance my meals." (Blanche, 76 years old) "What I really liked about MEDEA was the cancer-targeted aspects of nutrition that challenged a lot of the preconceived ideas I'd seen on the internet. It was interesting to have something that was somewhat adapted to cancer, like: be careful, it's not that it's dangerous, but it's better not to eat too much of that." (Adeline, 42 years old) "It brought me a lot of good things because I learned to eat well. I learned about certain things I didn't know. I didn't know the difference between hunger and the desire to eat; I was confused about all that, so I learned a lot of things." (Claudette, 68 years old) "It gave me new eating habits, because I thought I had excellent eating habits and in the end not so much. We changed all that with the coach and it's not so bad, I've developed new eating reflexes." (Armelle, 43 years old)
	Nutrition Knowledge about food composition and healthier alternatives, debunk preconceived ideas Physical activity Motivation to be active again and to develop new habits	"I didn't have that motivation anymore. I had a huge lassitude and she [the coach] really coached me, she taught me again to feel like it, to boost myself, to walk, to go for a walk with the dog and now I've become an addict. I do two and a half hours of sport a day. I've completely changed and completely changed my life." (Sabine, 58 years old) "On terms of physical activity, yes, I've changed completely because before I didn't do anything (at least not much), and during MEDEA I was doing sport every day. I started with active walking because I was aching all over because of the hormonal treatment (joint and muscle pain). [...] In anticipation of going back to work full-time, I bought myself an elliptical trainer." (Elodie, 38 years old) "What I also found good in the study was that it wasn't necessarily doing "sport". It's having a physical activity like walking or something else. It's not necessarily sport, sport, I don't know like training, jogging. So I've integrated it in my life [...] I go to work biking, when I'm teleworking I'll walk for an hour in the morning or a little at lunchtime." (Sylvie, 54 years old)

TABLE 3: Continued.

Themes	Subtheme	Exemplifying quotes (after each citation, we present the alias and the age of the participant)
Convenience of remote intervention	Practicality of phone coaching	<i>"It's much better over the phone because it would have been a constraint to free up time to go to physical meetings and everything, it would have really been a constraint I think."</i> (Maxine, 44 years old)
		<i>"I thought there was something really nice about this telephone relationship too. I thought it was really nice to be able to rely on your word and your word alone. I feel like I've been able to speak more truthfully than when I was face to face with someone."</i> (Aur�lie, 39 years old)
		<i>"For me, when you're working, it's ideal. Because otherwise I'd never have been able to free up the time to go to a place, to have the consultation, in other words, to have the face-to-face exchange. So I found the telephone flexible and easy."</i> (Sylvie, 54 years old)

TABLE 4: Barriers to uptake and engagement in the study and suggestions for improvement.

Themes	Subtheme	Exemplifying quotes (after each citation, we present the alias and the age of the participant)
Need for tools to sustain engagement	Follow-up call Psychological support Enabling/facilitating self-monitoring More recipes	"That might be a small criticism I could make, if we had a call from the dietitian at 6 months [after the 1 year intervention], it would perhaps help to keep the momentum on which we started." (Irene, 57 years old)
		"I don't know if a psychologist could be included in MEDEA, but in any case it would be a good thing or that the coaches refer to psychologists to work on a certain number of questions that are more of a psychological nature." (Aur�lie, 39 years old)
		"I would have liked to have a summary of my weight loss. A small conclusion on a diagram to see the evolution." (Irene, 57 years old)
		"I would have liked to have more recipes to make things easier for me at the start. I'm 71 years old, so I've got eating habits, I've got culinary habits, and to completely change the way you cook ... It's hard at first. I would have liked a little more help in that direction." (Monique, 71 years old)
Need for culturally adapted content	Program more suited for Americans	"For me, it was more like an American-style method, in terms of food. The menu planning, all that, it's not very French." (Blanche, 76 years old)
		"There was a whole chapter on meal replacements and portion control, and then she lost me. I said to her, 'What the hell is this? I'm not on a diet to eat cereal bars or anything like that.' [...] Replacing meals with substitutes was out of the question." (Elodie, 38 years old)
Advocacy for a more patient-centered research ecosystem	Selection of PRO measures Communication Community building	"The food questionnaire is horrible to fill out! Oh, and by the way, you made me think of it, the last one, it must be 2 months ... I still haven't fill it, because it annoys me so much that I forgot." (Madeleine, 75 years old)
		"The quality of life questionnaire is fine, but the food questionnaire is really complicated. Every time I ask myself how it works, the portion per week. ... It's complicated. It's both very long and very complicated to fill in." (Adeline, 42 years old)
		"I think it would be interesting to have some of the results of the study." (Elodie, 38 years old)
		"What's missing is an announcement of the results of the study. [...] If we were regularly kept up to date a little on the progress of this study, to know what it was becoming, that would be good." (Catherine, 62 years old)
		"I would have liked to meet the women who did the same program, to talk to them." (Adeline, 42 years old)

responsibilities [48, 49]. Similarly, a motivational effect may be related to the comprehensive and thorough guidance of the coaches across the study period. In fact, every patient participating in the qualitative analysis had positive remarks regarding the work of the MEDEA coaches.

Participants in our study broadly expressed positive representations about the study, especially remarking on positive changes in their self-image, increased motivation, and knowledge about food composition and healthier alternatives. The perceived value regarding the delivery of targeted nutritional educational and self-management advice observed in our data also emerged in the studies reported by Beckestein et al., which respectively emphasized the increased confidence and motivation gained through such strategies and the lack of knowledge and information regarding weight management delivered by the healthcare professionals at the time of diagnosis [32, 49]. The convenience of the remote intervention was also highlighted in our study, consistent with findings previously reported in literature [34, 50]. Indeed, a 2015 systematic review evaluating the evidence behind remote-based lifestyle interventions in cancer survivors found that across all delivery modalities, 20 out of 27 studies reported statistically significant improvements in physical activity and/or dietary behavior outcomes and/or weight [51]. Specifically, phone-based trials have demonstrated in both the U.S. and Australia both wider reach [52] and greater weight loss maintenance with individual phone counseling compared to mail [53, 54], email, and web-based interventions [55–57].

Although the MEDEA trial failed to demonstrate a significant impact in its primary endpoint of improving self-reported cancer-related fatigue measured by the EORTC QLQC30 [58], in our qualitative study, patients highlighted that weight loss held a relevant effect in the amelioration of symptoms like fatigue, insomnia, and musculoskeletal pain. These data are aligned with the results of previous trials such as the POWER-Remote which reported a correlation between symptom severity and weight loss [27].

While an overall positive perception of the MEDEA trial emerged from the focus groups, valuable insights can be gained from the reported barriers and observed shortcomings. Indeed, while in a North American context, the convenience of meal replacements and protein shakes was appreciated [34], their French counterparts felt stifled by the reduced dietary choices and suggested recipes proposed during MEDEA. Interestingly, similar complaints were highlighted in another European study: an analogous desire for food demarcation rather than outright deprivation emerged from Perperidi et al.'s work with Greek breast cancer survivors [59]. These barriers highlight the need for future researchers to account for the different cultural approaches with regard to food, especially as clinicians may find themselves in contact with an ever more diverse population in routine practice. This study suggests that cultural context plays a key role in shaping the acceptability and effectiveness of weight loss interventions among European breast cancer survivors. What emerges is that beyond dietary preferences, participants' responses revealed culturally rooted attitudes toward food as a source of identity,

pleasure, and social connection, factors that may conflict with standardized, restrictive dietary protocols. These insights underscore that successful implementation in foreign settings requires more than translation; it calls for meaningful cultural adaptation that respects local values, expectations, healthcare context, and everyday practices.

Participants also highlighted the need for continued support, not only in the form of follow-up nutritional coaching calls and tools to facilitate self-monitoring, but also through the offering of psychological support. In consideration of the profound link between weight gain, and pathological relationships with food as a whole, and psychological distress, this point is particularly relevant and emerged in other studies as well [59]. While a longer follow-up nutritional coaching was indeed present in the original BWEL study and could have fulfilled the unmet need of sustained engagement, to our knowledge the only large, randomized study to include the option of psychological support was SUCCESS C, that provided limited psychological support, "in case of severe psychological problems of participants" [60].

Finally, participants disliked some of the research questionnaires used and expressed their desire for a more patient-centered research environment, with more pertinent and succinct PROs and the creation of a tighter, supportive, and engaging community between participants. These findings are consistent with studies such as the Stepping STONE trial [33], wherein patients similarly expressed a desire for greater interaction with other group members. Some data does exist supporting a group-based approach, provide social support and a feeling of accountability [34, 61], which should be taken into account in future research. Digital tools could potentially help facilitate a more convenient and democratic collection of PROs and providing real-time encouraging feedback for completing research procedures, as well as connect study participants [62]. In addition, such tools could encourage patients to self-advocate in the course of their care and research through the participation of digital crowdsourcing or digital community boards across the study lifecycle to inform specific research questions, adapt study materials to their needs, and aid in the design and implementation of healthcare interventions [63].

It is to be acknowledged that participants of this qualitative analysis likely did not include sufficient diversity in terms of income levels, as most were highly educated women living in urban environments. Socioeconomic deprivation has indeed been shown to alter the efficacy of different weight-loss interventions in nononcological patients [64]. Future efforts should therefore aim to take into account how perception of nutrition is interwoven with social, cultural, and economic factors. Furthermore, a relatively small sample size and the absence of focus groups in the control arm might have biased our results, not giving a voice to the experiences of patients' undergoing the standard nutritional program. Additional selection bias may be present, as patients who had a negative experience with the intervention might be less likely to agree to participate in qualitative investigations.

5. Conclusions

Patient acceptability of the MEDEA intervention was generally positive, suggesting possible applicability of the North American BWEL approach in Europe, which should, however, be tailored to match the different cultural milieu to provide patients with the highest quality personalized care.

Including qualitative research efforts in clinical trials investigating lifestyle interventions is important in order to provide a complete understanding of the barriers to initial weight loss and the maintenance of a healthier lifestyle, especially taking into account the different ways in which culture, education, and socioeconomic aspects influence nutrition.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Disclosure

Partial findings of this work were presented in the form of a poster at the 2024 San Antonio Breast Cancer Symposium (P2-05-12). The role of the sponsoring institution is limited to data collection and management.

Conflicts of Interest

Maria Alice Franzoi: Research Funding: Resilience (Institution); Gilead Sciences (Institution), Speaker honoraria: Novartis (Institution). Barbara Pistilli: Consulting fees: Astra Zeneca (institutional), Seagen (institutional), Gilead (institutional), Novartis (institutional), Lilly (institutional), MSD (institutional), Pierre Fabre (personal), Daiichi Sankyo (institutional/personal), Olema (institutional) Research funding (to my institution): Astra Zeneca, Daiichi Sankyo, Gilead, Seagen, MSD Travel support: Astra Zeneca; Pierre Fabre; MSD; Daiichi Sankyo, Pfizer. Stefan Michiels: outside the scope of the submitted work: fees for scientific Committee Study member Roche; Data and safety monitoring member of clinical trials: IQVIA, Kedrion, Biophytis, Servier, Yuhan. Ines Vaz-Luis: Honoraria: Amgen (institutional), AstraZeneca (institutional), Pfizer/Edimark (institutional), Novartis (institutional), Sandoz (institutional), Chugai Pharmaceutical (institutional), Servier Monde (institutional), Institut de recherches internationales Servier (institutional), Doctaforum Medical Marketing SL (institutional), Research Funding: Resilience Care (Institution). Travel: Novartis. The remaining authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. (*Supporting Information*)

Supporting Information 1: MEDEA—Focus group guide.

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