Pilot and Feasibility Studies

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Developing and testing the feasibility of a theory-based brief counseling intervention to promote physical activity in breast cancer survivors enrolled in the PAC-WOMAN trial

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Abstract

Background Despite the benefits of physical activity (PA), cancer survivors report engagement barriers, and existing interventions often lack comprehensive solutions. Theory-based interventions using evidence-based behavior change techniques (BCTs) have been shown to be effective in promoting PA for breast cancer survivors, although their feasibility and acceptability lack evidence. The PAC-WOMAN trial is a three-arm randomized controlled trial aimed at promoting short- and long-term PA and improving the quality of life of breast cancer survivors. This study describes the development of a brief counseling theory-based motivational intervention from the PAC-WOMAN trial, assessing its feasibility and acceptability.

Methods A broad search of theory-based interventions for people with chronic diseases was conducted. Key strategies from each intervention helped shape the main components and BCTs used in the eight bimonthly sessions of the PAC-WOMAN brief counseling intervention, which was based on self-determination theory principles and aimed at empowering participants to develop self-regulation resources for PA through basic psychological needs satisfaction. A toolkit and manuals for intervention facilitators and participants were developed. A feasibility study was conducted to monitor implementation fidelity, acceptability, adherence, and participants' experiences (via a focus group).

Results Twelve women (mean age 55.9 ± 6.7 years) participated. Implementation monitoring indicated that the intervention was feasible. The attrition rate was 25%. Focus-group discussion suggested that weekly sessions would increase attendance, highlighted the helpfulness of self-monitoring and the importance of role models for PA, and identified the session on safely exercising at home as key in improving PA levels.

Conclusions This research aims to enhance systematic reporting in intervention development by detailing the specific BCTs used, translating them into implementation strategies, providing comprehensive resources for facilitators/participants, and supporting the implementation, dissemination, and adoption of a theory-based intervention informed by previous research. Feasibility testing suggests that the intervention was well accepted by participants and feasible, although it could benefit from adjustments in format to increase compliance.

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Keywords Physical activity, Self-determination theory, Self-regulation, Intervention development, Pilot testing, Cancer survivors

Key messages regarding feasibility

- What uncertainties existed regarding the feasibility? Despite the recognized benefits of physical activity (PA) for breast cancer survivors, adherence to PA recommendations remains low, attributed to various barriers. Theory-based interventions incorporating evidence-based behavior change techniques and grounded in self-determination theory have shown results in promoting sustained PA adherence and, consequently, leading to improvements in quality of life. However, there is a need for further exploration of the feasibility and acceptability of such interventions in breast cancer survivors.
- What are the key feasibility findings? Data on implementation indicators (e.g., attendance rate, compliance with the intervention protocol, and attrition rate) and qualitative analyses of the focus groups conducted with participants showed that the intervention was well accepted by participants, and that its implementation was proven to be feasible. Suggestions on small changes to some implementation strategies, aiming to improve compliance and long-term adherence to PA, were made and adopted.
- What are the implications of the feasibility findings for the design of the main study? Based on feedback from participants, implementation timings and length between sessions were shortened, some adjustments to group dynamics between participants during the sessions were made, and practical PA exercises were introduced earlier in the intervention.

Background

The global impact of cancer and its increased survivorship rates represent a significant public health concern, increasing the need to understand how modifiable health behaviors, such as physical activity (PA), may help prevent and manage cancer [1]. This increase in cancer survivorship (i.e., from the time of diagnosis to the end of life) has led to new challenges in managing and treating this disease [2]. Coping with the enduring consequences of treatment (e.g., fatigue), increased chances of cancer recurrence, and increased susceptibility to chronic illnesses has adverse impacts on cancer survivors' quality of life (QoL) [3], and consequently, continuous healthcare is imperative long after initial treatment, exerting growing demands on healthcare systems [4].

Despite the reported benefits of PA for health [1, 5, 6], most breast cancer survivors tend not to adhere to PA recommendations [7], reporting several barriers to being physically active (e.g., lack of motivation, accessibility, fatigue, and pain) [8]. Moreover, healthcare systems are strained and lack a comprehensive solution, including PA programs, for breast cancer survivors. This absence of enduring solutions frequently leaves survivors feeling overwhelmed as they navigate the management of treatment side effects on their own [8].

Moreover, providing PA assessment, brief counseling, and referrals as part of routine healthcare has been recommended in the World Health Organization (WHO) Global Action Plan for PA 2018–2030 [9]. Brief interventions, in particular, are recognized by the WHO as effective measures to help people overcome behavioral risk factors, such as a lack of PA [10]. Cost-effectiveness analyses also suggest that it is worth investing in implementing and scaling-up brief interventions to reduce the overall burden of chronic diseases, such as cancer [11].

Interventions grounded in theory and utilizing evidence-based behavior change techniques (BCTs) have proven effective in breast cancer survivors [12, 13], although such interventions remain limited [14]. Furthermore, many interventions lack validated self-regulation tools and fail to explore meaningful connections between PA and participants' values or life aspirations to encourage lasting behavior change [15]. Previous research has indicated that more internally/autonomously motivated (higher quality) forms of motivation play a crucial role in sustaining PA practices and behaviors [16, 17], suggesting the potential validity of self-determination theory (SDT) [18] as a framework for promoting sustained adherence to PA. The significance of SDT in designing and implementing PA interventions is well documented [16, 19, 20], suggesting that a need-supportive intervention climate enhances individuals' well-being and their ability for self-regulation, facilitating the maintenance of behavioral changes [21]. Additionally, self-regulatory skills such as self-monitoring, goal setting, and action planning have been identified as crucial mediators of long-term PA

engagement [22] and as integral components of effective behavior change interventions for breast cancer survivors [13].

Research indicates that PA interventions incorporating BCTs are not only effective for cancer survivors but also more effective than those lacking these components [23, 24]. However, there is a lack of evidence regarding the feasibility and acceptability of brief theory-based interventions (e.g., using SDT), employing evidence-based motivational BCTs (MBCTs), and exploring their efficacy in promoting PA in breast cancer survivors.

Theory needs to be translated into intervention design in a way that facilitates adoption by the intended population and maximizes implementation efforts [25]. Therefore, involving patients or participants in the implementation and dissemination of interventions is a way of gaining feedback and improving intervention design, bridging the gap between research and practice [25, 26]. Given this, feasibility studies, which involve implementing the intervention before a main trial and evaluating participants' feedback, may be useful in the early stages of planning and decision-making, making it easier to assess the practicality, acceptability, and potential success of an intervention [27, 28].

The purpose of this study, embedded in the PAC-WOMAN trial (Physical Activity in Breast Cancer Women) [29], is to (1) describe the development of a theory- and evidence-based brief counseling intervention aimed at promoting a physically active lifestyle and improving QoL in breast cancer survivors and (2) assess its feasibility and acceptability.

Methods

Intervention development

The development of the PAC-WOMAN brief counseling intervention is part of the PAC-WOMAN trial [29]. The trial was approved by the ethics committee of Faculdade de Educação Física e Desporto of Universidade Lusófona (M25C21) and is being conducted in accordance with the Declaration of Helsinki for Human Studies.

The intervention was developed based on a theoretical rationale (SDT), incorporating effective components from prior interventions, and a selection of BCTs proven to be effective in previous behavior change intervention studies.

I. Theoretical rationale

To increase the likelihood of sustained changes in health behavior, it is crucial for interventions to focus on theoretically suggested mechanisms of change and integrate evidence-based strategies for behavior change [30]. Research indicates that interventions based on behavior change theory are more successful than those lacking such background [16, 23, 24]. Theory also plays a crucial role in ensuring a systematic and thorough consideration of determinants linked to evidence [31], making it an integral part of best practices in intervention design [32, 33]. However, there is a need for research that improves the practical application of theory [34].

As stated, SDT has been empirically supported as a valid framework for promoting long-term adherence to PA, providing an understanding of the factors that influence motivation and regulate behaviors [16, 18]. SDT focuses on motivation quality rather than just quantity, proposing that more self-determined, intrinsic, or autonomous forms of motivation, which reflect actions based on an individual's volition, core values, and personal goals, promote better well-being and more sustained adherence to behaviors [18, 35, 36]. In contrast, more controlled or extrinsic forms of motivation, reflecting external or self-imposed pressures for acting as opposed to self-endorsed reasons, are not as sustainable or fulfilling [18, 36]. Within SDT, motivation is understood and assessed as a complex construct with several regulatory styles positioned along a continuum of relative autonomy [18]. The fulfillment of three basic psychological needs—autonomy, competence, and relatedness—is considered essential for self-determined motivation and psychological health [17, 18]. Autonomy refers to the ability to self-regulate one's actions, reflecting a sense of ownership and responsibility over one's behavior, competence reflects the need to master tasks and the experience of being effective, and relatedness concerns feeling socially connected, accepted, and respected by others [17, 18].

The evidence supports the theoretical premises of SDT, namely, that the satisfaction of these basic needs results in self-determined behaviors and increased feelings of vitality and well-being [16, 35]. From an implementation perspective, it is critical to understand how to best promote interventions designed to satisfy these needs. Recent evidence suggests that SDT-informed interventions in the health domain are associated with modest but significant improvements in need support, competence, and autonomy need satisfaction, as well as autonomous motivation [16]. In addition to being a mediator of behavior change, promoting self-determined motivation is also a critical outcome per se, equivalent to enhancing patient well-being and social justice, which are highly relevant to health care [16].

Several SDT-based strategies have been reported to promote need satisfaction and are used in behavior change interventions [16, 34, 36, 37]. These strategies, referred to as BCTs, are defined as discernible, replicable, and essential elements of an intervention design to modify or redirect the causal processes regulating behavior

[38]. The evidence suggests that the use of a combination of such strategies might be necessary to promote need satisfaction [34].

The PAC-WOMAN brief counseling intervention was built upon SDT-based theoretical premises and evidence-based motivational BCTs with the goal of empowering participants to develop self-regulation resources, fueled by psychological needs satisfaction (i.e., autonomy, competence, and relatedness) and autonomous motivation to integrate and sustain PA into their daily lives [29].

II. Mapping previous theory-based interventions: extracting critical components

A broad search of previously implemented interventions aimed at promoting physically active lifestyles for people with cancer or other chronic diseases, based on behavioral or motivational frameworks, and using BCTs was conducted. The target population, brief intervention description, session frequency, program duration, published results, themes, activities, theory/framework, and BCTs used were extracted and compiled in a list (full details in supplementary information file S1).

From this list, relevant components, themes, and activities from each intervention were identified. For example, the BEAT Cancer intervention, an RCT comparing usual care with a 3-month PA behavior change intervention for breast cancer survivors [39], provided patient education materials for each participant at the end of each group session, providing information on the intervention, exercise safety, and goal setting, with additional instructional materials for each addressed topic. This type of supporting material for participants was also reported as being successfully used in other behavior change interventions promoting PA and QoL [39, 40].

After completing this process of mapping the most relevant elements within previous interventions, these were retrieved and informed the design of the PAC-WOMAN brief counseling intervention.

III. Format, length, and contents

The intervention was developed to be implemented in eight bimonthly group-based sessions of 90 min each. Group-based sessions, with other breast cancer survivors, are important for promoting a motivational intervention climate that allows the exchange of experiences, feelings, difficulties, and effective solutions to overcome them in a respectful, nonjudgmental, and supportive environment [41, 42].

Table 1 illustrates the PAC-WOMAN brief counseling intervention main contents for the sessions and how they were informed by previous interventions.

Throughout the sessions and to assist participants' integration of contents, motivation, and self-regulation in a need supportive fashion, SDT-based behavior change strategies were used. These strategies included, for example, identification of reasons for enrollment in the intervention (boosting self-awareness), provision of choice, meaningful rationale, connection between participants' health behavior and deep inner values, goal setting, action planning, self-monitoring through an activity tracker (Xiaomi Mi Band 5) gifted to every participant, coping planning, and weighing the pros and cons of change in the context of held values and life priorities.

Tables 2, 3, and 4 illustrate the mechanisms of action and motivational BCTs used, with examples of session activities and strategies, according to each basic psychological need targeted (autonomy, competence, and relatedness, respectively).

After the intervention design was completed, a detailed intervention manual supporting the delivery of the sessions was produced (see supplementary information files S2 and S3). It details all the components of each of the eight sessions, including (1) goals and components for each session, (2) the importance of each component (the "why"), (3) tips and prompts for implementation (the "how"), (4) the time allocated to each component/task, and (5) the materials needed.

In line with other interventions and as previously stated, a handbook for participants, with a toolbox of resources supporting each session, was also developed. This handbook was handed out at the end of each of the eight sessions and contains a summary of the themes covered during the session; supplementary information on the topics discussed; an "Exercise Booklet" with different exercises that can be performed at home, accompanied by QR codes with complementary instructive videos; and challenges for participants to put in practice in their daily lives until the next session. These challenges included, for example, becoming aware of how many steps they performed each day using an activity tracker provided by the project, setting a SMART goal for increasing the number of daily steps, pinpointing behaviors that could be modified for a more physically active option, identifying role models for practicing exercise, and implementing at home exercise sessions.

Feasibility and acceptability of the intervention

The developed PAC-WOMAN brief counseling intervention was implemented in a group of 12 breast cancer survivors recruited through physician referrals (recruitment processes of the PAC-WOMAN trial are described elsewhere [29] and, for this study, occurred between January 10, 2022, and March 31, 2022), to test its feasibility and acceptability. The feasibility study occurred between April 12, 2022, and July 21, 2022. Lessons learned from it were then incorporated in the ongoing main

Table 1 PAC-WOMAN brief counseling intervention sessions and contents

Session number	Themes	Informed by previous interventions and informational guides
1	Reasons for change and related types of motivation The importance of self-monitoring strategies	Phys-Can [43] EuroFIT [40] Move More guide [44] PA brief counseling guides [45]
2	Benefits of physical activity Types of physical activity and sedentary behaviors SMART goal setting	BEAT Cancer [39] Phys-Can [43] Shape-Up [46] BOOST [47] ENRICH [48] EuroFIT [40] Exercise for Health guide [49] Move More guide [44] Moving Through Cancer [50] PA brief counseling guides [45]
3	Exercising safely and independently at home	BEAT Cancer [39] BOOST [47] ENRICH [48]
4	How to integrate physically active behaviors in daily life The importance of social support	BEAT Cancer [39] ENRICH [48] Shape-Up [46] EuroFIT [40] Exercise for Health guide [49] Move More guide [44] Moving Through Cancer [50] PA brief counseling guides [45]
5	Barriers and facilitating factors for including physical activity into daily routines Planning and dealing with barriers and setbacks Action and coping planning	BEAT Cancer [39] Phys-Can [43] ENRICH [48] EuroFIT [40] Moving Through Cancer [50] PA brief counseling guides [45]
7	Medical factors in managing cancer adverse events and physical activity	BEAT Cancer [39] Move More guide [44]
6	Boosting body image and self-acceptance and physical activity	ReBIC [51] Accepting your Body After Cancer [52] The Body Image Workbook [53]
8	Reassessing goals and long-term action plans	BEAT Cancer [39] Phys-Can [43] ENRICH [48] EuroFIT [40] PA brief counseling guides [45]

PAC-WOMAN trial protocol. After confirming the eligibility criteria and interest to enroll in the intervention, the participants were asked to sign a written informed consent form.

Intervention facilitators, who all had background education on exercise and health promotion, received training by a certified trainer on motivational counseling skills beforehand, congruent with a person-centered, SDT-based approach, completed initial training sessions, and performed mock counseling encounters with participants concerning the sessions to be delivered. Then, all eight bimonthly group-based sessions were subsequently implemented in accordance with the intervention manual. A monitoring logbook was filled out weekly by the intervention facilitators to aid in feasibility testing, including monitoring of session attendance, deviations from the implementation of each session component, adverse effects of the intervention, unexpected events, and additional comments.

After the end of the 4-month intervention, a semistructured qualitative online focus group with participants was conducted, which lasted approximately 45 min. This focus group was delivered by two of the intervention facilitators, and all participants were invited to participate. The semistructured question guide for this focus group (see supplementary information file S4) targeted overall experiences with the program, the perceived importance of session themes, proposed activities, and resources (such as the use of a self-monitoring device provided by the project, the importance of setting

Table 2 Developing an autonomy-supportive intervention climate

Basic psychological need	Key processes targeted (mechanisms of action)	Motivational and behavioral change techniques (active ingredients)	Session activities (examples)
Autonomy	Raise self-awareness regarding different types of reasons for behavior change/maintenance	Identify reasons to engage in the program and try to classify them in more external/internal [BCT 13.4; MBCT 1 and 5]	In session 1, asking participants for their reasons to enroll in the project
		Identify reasons to stay in the program, compare them, and reflect on differences [BCT 1.5; MBCT 5 and 12]	Reflecting, at the end of the project on session 8, if reasons for wanting to change behavior are different from the one listed at the beginning
	Increase autonomous motivation for PA and reduce the relative importance of controlled motives	Prompt participants to link PA-related behavior changes to other important values/goals [BCT 7.1; MBCT 7]	As a challenge for session 1, participants were asked to think about parts of their day where they could have an "active choice" (choosing to change a behavior to a more physically active option)
		Reflect on potential sources of pressure to act in certain ways and develop plans to cope with that [BCT 1.2, 11.2, and 13.2; MBCT 2 and 21]	In session 6, a discussion was led with participants about societal norms for body image and how can they be challenged, focusing on what our bodies allow us to do and how we feel in them instead of how they look
	Increasing personal value and meaning by encouraging the selection of self-relevant goals	Allow participants to set their own goals/changes based on individual preferences and coherent with current lifestyles [BCT 1.1 and 1.3; MBCT 17]	Participants were asked to set SMART (specific, measurable, attainable, relevant, and time-bound) goals for PA in session 2
		Discuss the rationale for each potential behavior change [BCT 4.1, 5.1, 6.1, and 9.1; MBCT 5]	In session 2, the different PA types (aerobic exercise, strength training, flexibility and balance exercises, daily life PA, and sedentary behavior) and their benefits, as well as their personal relevance, were discussed with participants
	Provide choices around how participants make changes	Provide a menu of options within a set of behaviors [BCT 1.5, MBCT 6]	When setting goals in session 2 and revising them in session 8, participants chose which type of PA they wanted to engage with (walking, structured exercise, dancing, etc.) and was personally relevant

Table 3 Developing an intervention climate rich in structure (supporting competence)

Basic psychological need	Key processes targeted (mechanisms of action)	Motivational and behavioral change techniques (active ingredients)	Session activities (examples)
Competence	Set optimal challenges	Assist participants in identifying the level of change they are ready or realistically able for (changes that can be readily mastered and not overly stressful or demanding) [BCT 1.1, 1.3, and 1.6; MBCT 17]	When setting SMART PA goals and action plans, in session 2, the need for them to be personally relevant and achievable for each participant was emphasized
		Focus on process/progress and not outcomes per se [BCT 1.5, 1.7, and 2.3; MBCT 10 and 20]	At the end of the intervention, on session 8, participants were encouraged to frequently review their goals
	Prompt the use of self-regulatory skills	Handing out a participant handbook, exercise booklet, self-monitoring device [BCT 2.3, 2.6, 4.1, 6.1, 8.1, and 8.7; MBCT 6, 7, and 20]	All participants were offered an activity tracker for self-monitoring PA in the first session
	Identify sources of instrumental support	Explore sources of social support outside the program [BCT 1.4 and 3.1; MBCT 14 and 19]	During session 4, participants were asked to draw a map with their daily activities and spaces they visit often and think about how they can seek support from someone else in each of those contexts
	Prompt vicarious and experiential learning	Stimulate within group exchanges on new experiences or barriers (and how to overcome them) related to behavior change [BCT 1.2, 3.1, 12.1, 12.2, and 12.3; MBCT 15, 19, and 21]	Identifying potential barriers to practicing PA and having participants, as a group, try to come up with solutions was an activity from session 5

Table 4 Developing an intervention climate rich in interpersonal involvement (supporting relatedness)

Basic psychological need	Key processes targeted (mechanisms of action)	Motivational and behavioral change techniques (active ingredients)	Session activities (examples)
Relatedness	Increase sense of connection and acceptance	Make activities within the group interactive, stimulating discussions around participant's perspectives on changes [BCT 3.1 and 6.2; MBCT 6, 7 and 8]	During session 4, participants were encouraged to share personally relevant change tips and tricks for being more active, which helped other participants think of ways of adapting the same behavior to their daily life
		Create a genuine, warm, and nonthreatening environment where all perspectives around change are acknowledged and accepted [BCT 3.1; MBCT 6, 8, 10, 11, and 12]	All discussions during sessions were held in group, allowing every participant to share their experiences
	Increase sense of belongingness	Facilitate empathy within a group with the same characteristics [BCT 3.1; MBCT 11 and 12]	The group comprised of breast cancer survivors undergoing hormonal therapy, being able to share similar experiences
		Support/testimonials from role models [BCT 6.1 and 6.2; MBCT 14]	For sessions 3, 5, and 7, other breast cancer survivors, who underwent similar treatments to the participants, were invited to give their testimony on why and how they practice regular PA

Table 5 Sociodemographic characteristics of the study participants ($n = 12$)

Characteristic	Number (n)
Age	
40–49 years	3
50–59 years	4
> 60 years	5
BMI	
18.5–24.9 kg/m^2	1
25–29.9 kg/m^2	6
> 30 kg/m^2	5
Marital status	
Married	10
Divorced or separated	1
Single	1
Education level	
Incomplete primary school	2
Complete primary school	2
Highschool	3
Bachelor's degree	4
Postgraduate education	1
Time since breast cancer diagnosis	
1–2 years	5
3–4 years	3
> 5 years	4
Time under hormonal therapy	
1–2 years	7
3–4 years	1
> 5 years	4

SMART goals, the utility of reflecting on the health benefits of PA, the importance of role model testimony, and the utility of the participants' handbook). Feedback on session length and frequency and suggestions for future implementation of the program were also addressed.

The focus group was recorded, with participants providing informed consent, and the data were transcribed verbatim. Participants' names were anonymized. Coding was applied to the qualitative focus group data, based on the themes of the questions asked during the discussion. Coding was independently conducted by two researchers, and the research team then reviewed and agreed upon the category names arising from the research data. The transcript was translated into English from Portuguese.

Results

Participants

A total of 12 women referred by their oncology doctor participated in the feasibility study, with a mean age of 55.9 years (SD ± 6.7 years) and an average BMI of 29.8 kg/m^2 (SD ± 4.6 kg/m^2). The time since breast cancer diagnosis and time under aromatase inhibitor therapy varied between 10 years and 1 year prior to enrollment. All had medical clearance to engage in regular PA. Table 5 presents more detailed sociodemographic characteristics of the study participants.

Feasibility

Three trained exercise and health professionals delivered the intervention, attending all the sessions. After each session, a logbook was completed to check whether all the components stipulated for the session were delivered as planned in the implementation manual. In this regard, no major deviations occurred, and all the sessions were implemented according to the intervention manual for both the format and contents of the intervention to be delivered. The time allocated for each activity was mostly met, with only the activity about the implementation of the "Exercise Booklet" (with examples of exercises to do at home) taking more time than stipulated. The length of the sessions (90 min) was deemed adequate for the activities planned for each session.

Attendance to sessions was acceptable, since 9 out of 12 participants (75%) completed half or more sessions (4 or more out of the 8 sessions). None of the participants was able to attend all eight sessions; one person only missed one session, and four participants attended six sessions. The dropout rate was 25%, with three participants dropping out of the intervention: one for professional reasons (i.e., could not attend sessions due to work schedule), one for personal/family reasons (i.e., carer for family member and could not attend sessions), and one participant become uncontactable after only attending the first session. No adverse or unexpected effects related to the sessions were reported. Unrelated to the intervention, one participant missed one session due to severe sciatica pain, a recuring symptom already reported before enrollment.

Acceptability of intervention contents, tools, and format

The semi-structured focus-group discussion conducted after the end of the intervention revealed that, in general, participants' experience with the intervention was positive and helpful in gaining knowledge on how to have a more physically active lifestyle. Some participants shared the following:

> *I know it had an impact on my life (…). Really, there is a link between what you have been teaching us and what we have been reflecting on. I think it was all important. It had a very good impact on me.; It was positive on all aspects; I was happy to be in this group.*

Reasons for joining the PAC-WOMAN project were explored at the beginning of the focus group, as most participants noted that those reasons changed

throughout their experience. At first, their enrollment in the intervention was due to pressure from oncology doctors and an overall sense of wanting to help scientific advancements to improve the QoL of breast cancer survivors. However, during the sessions, those feelings started to change, and the participants felt that they could gain knowledge and learn tools useful for themselves.

> *In the beginning, there was a feeling of almost providing a service to the community and helping the research, wasn't there? And then, as the program progressed, it became more personal and useful for me…*

In the first session, *a self-monitoring* activity tracker was provided for every participant, and its use was encouraged as one of the main components of the intervention. This was very well received by the participants and resulted in the formation of a habit of using this self-monitoring device. The participants reported using the tracker every day to monitor PA, steps per day, sedentary time, and sleep quality.

> *I do not think I have let go of it since it was given to us… I use it every day and sleep with it too; Sometimes we're concentrated, and we do not realize how long we have been sitting… And now the tracker ends up telling me, look, you have been sitting too long, maybe you need to do something. And (the tracker) has the function not only of monitoring my activity but also of helping me to reach my goals.*

Setting SMART goals and reviewing them regularly were one of the tasks asked of the participants throughout the intervention. One participant reported going from being active but not having set goals for that activity to setting daily step goals and having to increase this goal throughout the intervention.

> *I had another activity tracker before the intervention, but only used it for counting the time when I went for a walk, I did not even look at the day-to-day… Since I started this program and you gave me this one, then every day I see the things I have already done and if I already completed at least eight thousand steps. However, now I need to change this goal, because eight thousand steps per day is not enough for me now.*

However, other participants reported feeling frustrated when they could not reach their daily goals.

> *It is a bit frustrating when we look at the end of the day and there are so few steps…*

One of the sessions of the intervention was about how to safely exercise at home, and participants were given the "Exercise Booklet," with prompts, photos, and videos of exercises. The participants reported that this booklet was a very useful resource, allowing them to understand what kind of exercises they could perform at home when walking or exercising outside was not possible. Nevertheless, they reported not using this resource as much as they wanted due to the weather, as they found it would be more useful during the winter months than during the summer months when outdoor exercise was possible.

> *I think it is fantastic! I strongly advise you to watch the videos and truly use it, because it is very easy to use, I loved it. (…) It was also good to know what we can do at times when it is not possible to walk outside. The only thing is I think this was given to us at a bad time, during the warmer months. However, at least I have this goal of doing it in the winter, at least I'm sure that is when I will get the most use out of this tool.*

One participant even reported not using the "Exercise Booklet" on their own yet but being enthusiastic about the health benefits felt by other participants who were using it.

> *Mind you, there was a colleague who said in one of the sessions that because she used these tools, and she gave an example, she could even move her arm better when she went to sleep… Just this feedback gets me exited to use it, but I confess that I have not done anything…*

In the same session, a *role model*, another breast cancer survivor of a similar age to the participants and with a very active lifestyle, was invited to give her testimony about how she manages to incorporate exercise into her daily life and served as a model for demonstrating the proposed exercises during the session. This testimony was one of the key drivers of change for the participants, as they described.

> *It was really important for me to see someone who is my age, who went through a situation like this at a much younger age, and how she turned it around… And obviously the fact that she's a person who you look at and see is in very good physical shape, is very motivating, is it not?; I think it was a very strong testimony… It is something I will not forget, truly.*

At the halfway point of the intervention, *reflecting on barriers for* exercising and having coping plans was one of the themes explored in the session. This reflection proved particularly enlightening for some participants, who described this session as especially useful for their

daily life, not only in the context of overcoming barriers for practicing PA.

> *That session was very useful for me, not only because of the issue of physical activity, but it even helped me to understand other things that I often do in other aspects of my life, like making excuses for not doing things… That session was very well thought out.; This session showed me that it is always possible (doing exercise), even if it means waking up earlier. And the thing is, lack of time is no excuse. It is not; it cannot be. This is a priority.*

The feedback from the *session with oncology doctors* about medical considerations in managing cancer adverse events and PA was positive overall, but fewer positive aspects were pointed out by the participants. The session was considered important and relevant to the intervention but slightly unproductive, as some participants monopolized the time allowed for questions with the doctors with particular problems somewhat unrelated to the intervention.

> *I think it was important, but I think it could have been more productive… The session became a little slow, so to speak and I think we lost a lot of time with personal issues of some colleagues…*

A discussion about the *overall format* of the intervention and implementation revealed that one of the identified reasons for attrition, as shared by some participants' testimonials, was related to the wide length of time between every two sessions, which took place every other week. The participants reported that it would be easier to create the habit of attending the sessions and comply with the intervention if the sessions were delivered on a weekly basis instead.

> *I think the fact that the sessions were every 15 days was a bit of a hassle for me. I think it would be easier for someone to know that for two months, every Tuesday, they're going to have a session…*

One other aspect raised by participants was the need to have more physically active moments during the intervention. For example, having more sessions exploring the "Exercise Booklet" would have helped participants incorporate those exercises into their routine more often.

> *I think that if this program had something more practical, it would be easier for people to become more aware…; Maybe having a more theoretical session one week, then a more practical session the next week, perhaps would help to incorporate everything we were learning and all the information we received… And more time to practice what we learn might be important to really know how to apply it all.*

However, the participants shared that the intervention was a very positive experience and had a real impact on their lives by changing their habits, behaviors, and perceptions of PA.

> *I mean, all the knowledge I have acquired over this time is going to help a lot… And now I'm really determined, not just to continue what I have already done, but to do more. And so, for me, it has been truly a transformative thing.; I know it had an impact on my life and feel a sort of connection with what you have been teaching us and what we have been reflecting on.*

Some participants even described feeling less pain and improvements in their QoL, even in such a short amount of time.

> *I feel that when I do exercise regularly, I feel much better. I have a lot of pain, and I notice that when I do exercise classes, they help me a lot, and I want to do it again. and I'm not very disciplined, but I do what I can… Essentially, I'm aware of the importance of everything we have talked about, and it is about putting it into practice, and realizing that when I do it regularly, I feel much better, and I think that is the greatest demonstration of why it is important to do it (exercise).*

Discussion

The aim of this paper was to describe the development and feasibility of a theory-based brief counseling intervention, which is part of the PAC-WOMAN trial, aimed at increasing PA levels, reducing sedentary behavior, and promoting QoL in breast cancer survivors.

The potential of theoretically informed interventions to increase the effectiveness of PA promotion in breast cancer survivors is recognized [54]. Studies focusing on PA and behavior change for cancer survivors often lack a robust application of theory, failing to clearly establish connections between theoretical frameworks and intervention design, implementation, and evaluation [54, 55]. This research aims to address this need for systematic reporting and increased transparency in intervention development to advance understanding and facilitate intervention replication [54–56]. Furthermore, the development of this intervention was also informed by previous research and intervention models with proven results (such as [39, 40, 47, 48]), as well as well-studied BCTs [36, 37], strengthening its potential efficacy.

In this study, the intervention contents were described through specific BCTs that were then transformed into practical delivery methods and activities and covered in

the intervention manual for intervention facilitators and in the handbook of resources for participants, thus enabling easier implementation, dissemination, and adoption of the intervention. This process addresses the reported need for sufficiently detailed intervention descriptions and precise reporting of used BCTs, which is critical for assessing the effectiveness of interventions and correct coding of BCTs [56–58].

Brief interventions have been shown to be sufficient in promoting small changes in PA behavior that last beyond intervention completion in cancer survivors [13], indicating promising PA outcomes of brief counseling interventions in this population. Despite these positive results in promoting PA behavior, there is a lack of evidence regarding the feasibility and acceptability of these types of interventions to breast cancer survivors, which would promote their uptake.

This study relied upon voluntary participants recruited through oncology doctor, and as described in previous research, recruitment to exercise trials among cancer survivors is challenging [59]. However, to assess the feasibility of an intervention, a minimum sample size of 12 participants is suggested as a reasonable guideline [60]. Given this study aimed to test the acceptability and feasibility of the PAC-WOMAN brief counseling intervention, the used sample size proved to be sufficient. Moreover, this feasibility study will allow for further testing of the intervention with a larger sample, within the PAC-WOMAN trial [29].

Withdrawal from PA trials is common among cancer populations [61, 62]. In PA interventions for patients with cancer, the average attrition rate is reported to be 24% [63], although it varies widely between interventions, reaching as high as 30–45% [61, 64]. In this feasibility study, the attrition rate was 25%, which was within the reported rates from other interventions and so was considered acceptable.

With respect to implementation, interventions promoting PA in cancer patients and survivors, with eight counseling sessions lasting 90 min each, are common [46, 48, 51]. Information from the monitoring logbook, filled by intervention facilitators at the end of each session, showed this intervention to be feasible, with an appropriate number and length of sessions (eight sessions of 90 min), as well as a suitable amount of time and type of activities proposed for each session.

Furthermore, evaluating the implementation of the intervention, not only through quantitative measures (such as the attendance rate, compliance with the intervention manual, and attrition rate) but also on the basis of the subjective experiences of the participants (collected in focus groups), is a major strength of this study, providing the opportunity to receive detailed insights into participants' opinions and feedback of the intervention and thus informing and refining the final implementation of the main PAC-WOMAN trial. Feasibility studies are important, as they can offer substantial methodological evidence regarding the design, planning, and justification of a trial [27, 28]. While they are often conducted to inform aspects of the main trial design, they can also be employed to mitigate or eliminate issues that limit the successful implementation of trials [27, 28].

Data from focus group indicated an overall positive experience with the intervention from participants, with BCTs such as "self-monitoring," "action planning," and "modelling of the behavior" through a role model, highlighted as the most useful in adopting a more active lifestyle. This focus group also emphasized some issues related to implementation strategies:

i) The bimonthly design of the sessions, leading to a 15-day interval between sessions, was considered too long. The participants mentioned increased planning effort to attend, which potentially increased the probability of absence from the sessions. The participants mentioned that having weekly sessions at the beginning of the program would be good for creating the habit of attending. Based on this feedback, the implementation was amended to contemplate four initial weekly sessions and then four bimonthly sessions. Even though the drop-out rate for this feasibility study was deemed acceptable, the change in intervention session delivery timings generated by its findings is expected to assist in the reduction of drop-out rates in the main PAC-WOMAN trial implementation. Having participant's preferences in consideration is essential in trial implementation, especially in this type of population, as the main reported barriers for cancer survivors' participation in exercise trials are patient-centric (for example, time constraints and other prior commitments) [59].
ii) The session with oncology doctors was highlighted as somewhat unproductive, due to the dynamic of the Q&A section of the session (i.e., being dominated by some participants). To avoid this barrier, the final PAC-WOMAN implementation was amended and upgraded with group dynamic strategies, such as participants writing the questions in small papers picked at random by the implementors, ensuring that every participant becomes involved.
iii) The last feedback concerned the suggestion of the participants of having more active and practical moments during the sessions to promote better uptake of the proposed exercises. The implementation manual was changed accordingly so that the "Exercise

Booklet" session, where participants learned and performed exercises to do at home, would appear sooner within the intervention timeline, promoting earlier adoption of this behavior. Additionally, another active moment exploring different exercises proposed in the "Exercise Booklet" was added to session 5, in line with the participants' suggestions.

Given the promising results of this feasibility study, future PAC-WOMAN trial implementation will involve a larger sample size of breast cancer survivors, to assess the generalizability and short- and long-term effectiveness of the intervention. Future research should also compare the PAC-WOMAN brief counseling intervention with other established PA interventions for cancer survivors to better understand its relative effectiveness and identify specific elements that contribute most to its success, exploring different session structures and formats to optimize participant engagement and reduce drop-out rates. Future studies could also explore how to further personalize the intervention based on individual preferences, goals, and challenges, tailoring the intervention to each participant's specific context and potentially enhancing engagement and outcomes.

Conclusions

This paper aimed to describe the development and testing of the feasibility and acceptability of a brief theory-based intervention to promote a physically active lifestyle and improve QoL in breast cancer survivors. Detailed information on the contents and BCTs used by the session, the intervention climate promoted, and the manuals developed was provided. Data on implementation indicators and focus groups with participants showed that the intervention was well accepted by participants, and that its implementation was proven to be feasible, allowing for further testing with a larger sample within the PAC-WOMAN trial.

Abbreviations

BCTs	Behavior change techniques
MBCTs	Motivational behavior change techniques
PA	Physical activity
QoL	Quality of life
SDT	Self-determination theory
WHO	World Health Organization

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

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Authors' contributions

SF, EVC, and MNS, conceptualization and methodology; SF and IN, data curation and formal analyses; SF, EVC, IN, BR, VI, and MNS, project administration; SF, writing — original draft; all authors, writing — review and editing and visualization; EVC, BR, and MNS, funding acquisition; and EVC and MNS, supervision. All the authors read and approved the final manuscript.

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Data availability

All data generated or analyzed during this study are included in this article and its supplementary information files. A full verbatim transcript of the focus group is available upon request.

Declarations

Ethics approval and consent to participate

The trial was approved by the ethics committee of Faculdade de Educação Física e Desporto of Universidade Lusófona (M25C21) and is being conducted in accordance with the Declaration of Helsinki for Human Studies. All participants signed a written informed consent form.

Consent for publication

All participants signed a written informed consent form.

Competing interests

The authors declare that they have no competing interests.

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