Determinants and Factors of Physical Activity after Oncology Treatments (DEFACTO) in Metropolitan France: Study protocol of a mixed-methods study and intervention

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Abstract

Background: Benefits of physical activity (PA) as supportive care in oncology have been widely demonstrated by the scientific community. However, survivors who have completed chemo-radio-immunotherapy treatments don't achieve PA recommendations. This reinforces the need to identify factors influencing PA level, and to propose a multilevel model (macro-, meso-, micro-level) to better understand what facilitates the adoption and maintenance of active behavior and what hinders it. To date, there is no socio-ecological model explaining this behavior in the post-treatment phase of breast, colorectal, prostate, and lung cancers.

Objective: The objective is to identify factors influencing active behavior in cancer survivorship, and to assess the feasibility of an individualized program targeting the adoption and maintenance of the active lifestyle. Objectives were addressed in three stages. Stage 1 aims to identify factors influencing active lifestyle in cancer survivorship. Stage 2 aims to develop an explanatory model of the factors identified previously to build an individualized health education program targeting the adoption and maintenance of active lifestyle. Stage 3 aims to assess the feasibility and to identify the effects of an individualized health education program.

Methods: First, the exploration of factors influencing PA (Stage 1) will be based on a mixed-methods research, using an explanatory sequential design, supported by a multi-level analysis. The quantitative phase consists in the completion of a questionnaire from a socio-ecological perspective. Then, a subsample of patients will participate in semi-structured interviews to assist in the interpretation of the quantitative results. From this phase, we seek to build a model of the factors influencing active lifestyle and to create an individualized 12-week program in accordance with our previous results (Stage 2).
In phase 3, we will implement our multicenter program for 150 physically inactive cancers survivors throughout Metropolitan France. Program feasibility and transferability will be evaluated. Measured PA level by connected device, and multidimensional variables such as declared PA and sedentary behaviors, PA readiness, motivation, PA preferences, PA knowledge and skills, and barriers and facilitators will be assessed before, during the program, and 52 weeks post-intervention.

Results: The institutional review board approved the mixed-methods study (Phase 1) in April 2020. The intervention (Phase 3) was approved in March 2022. Recruitment and data collection began in April 2022. The implementation of the intervention was concluded in March 2023, data collection and full data analysis are expected to be completed by March 2024.

Conclusions: DEFACTO study aims to better understand, within our socio-ecological model, what facilitates active lifestyle of cancer survivors, and if a tailored intervention based on the model can support an active lifestyle. Clinical Trial: ClinicalTrials.gov NCT05354882; https://www.clinicaltrials.gov/study/NCT05354882

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Protocol

Determinants and Factors of Physical Activity after Oncology Treatments (DEFACTO) in Metropolitan France: Study protocol of a mixed-methods study and intervention

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Abstract

Background:

While the scientific community widely recognizes the benefits of physical activity (PA) in oncology supportive care, cancer survivors who have undergone chemo-radio-immunotherapy treatments struggle to meet PA recommendations. This underscores the importance of identifying factors influencing active lifestyle adoption and maintenance and proposing a multilevel model (micro-, meso-, macro-level) to better understand facilitators and barriers. Currently, no socio-ecological model explains active lifestyle in the post-treatment phase of breast, colorectal, prostate, and lung cancers.

Objective: The objective is to identify factors influencing active lifestyle in cancer survivorship and assess the feasibility of an individualized program targeting active lifestyle. The objectives will be addressed in three stages. Stage 1 aims to elucidate factors associated with the active lifestyle of cancer survivors. Stage 2 involves developing an explanatory model based on previously identified factors to create a tailored health education program for an active lifestyle after oncology treatments.

Stage 3 aims to evaluate the feasibility and the potential effects of this personalized health education program after its national implementation.

Methods: First, the exploration of factors influencing PA (Stage 1) will be based on a mixed-methods approach, employing an explanatory sequential design and multi-level analysis. The quantitative phase involves completing a questionnaire from a socio-ecological perspective. Subsequently, a subset of respondents will engage in semi-structured interviews to aid in interpreting the quantitative results. This phase aims to construct a model of the factors influencing an active lifestyle and develop an individualized 12-week program based on our earlier findings (Stage 2).

In stage 3, we will implement our multicentre, multimodal program for 150 physically inactive and sedentary cancers survivors across Metropolitan France. Program feasibility will be evaluated. Measured PA level by connected device, and multidimensional variables such as declared PA and sedentary behaviors, PA readiness, motivation, PA preferences, PA knowledge and skills, and barriers and facilitators will be assessed before, during the program, and 52 weeks post-intervention.

Results: The institutional review board approved the mixed-methods study (Phase 1) in April 2020 and the intervention (Phase 3) was approved in March 2022. Recruitment and data collection commenced in April 2022, with intervention implementation concluded in May 2023. Data collection and full analysis are expected to be finalized by May 2024.

Conclusion: The DEFACTO study seeks to enhance our understanding, within our socio-ecological model, of factors influencing an active lifestyle among cancer survivors, and to assess whether a tailored intervention based on this model can support an active lifestyle.

Trial registration: ClinicalTrials.gov NCT05354882; https://www.clinicaltrials.gov/study/NCT05354882

Keywords: socio-ecological model, mixed-methods, cancer survivorship, physical activity, sedentary behavior, individualized health education program

Introduction

Background

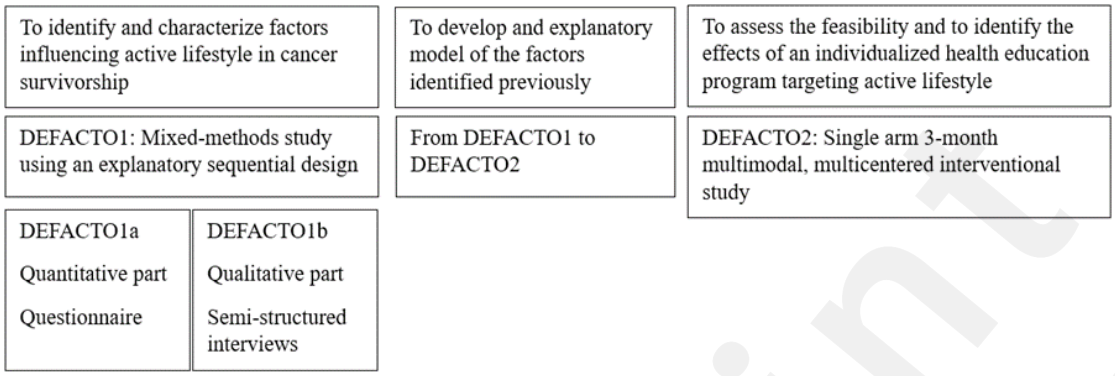
The beneficial effects of physical activity (PA) in oncology have been widely demonstrated by the scientific community [1]. This non-pharmacological intervention [2] is now recognized as a supportive care in oncology in France [3], given its efficacy in improving quality of life [4], reducing cancer-related fatigue [5], and decreasing the relative risk of cancer recurrence [6]. A high level of PA [*i.e.* 600 to 900 Metabolic Equivalent Tasks per hours per week (MET-h/week)] post-diagnosis appeared to be relatively protective against cancer-specific mortality in breast, colorectal and prostate cancers, as well as all-cause mortality in breast, colorectal, lung, and prostate cancers [7].

Despite the documented benefits of PA and the risks associated with sedentary behaviors (SB) defined as any waking behavior in a sitting or lying position, many adult cancer survivors (CS) who have completed chemo-radio-immunotherapy treatments remain insufficiently active and may even engage in SB [8]. While advancements in cancer management have led to a 20% increase in patient survival [9], adverse effects persist long after treatment completion, with a gradual decline observed over 10 to 15 years [10]. The post-treatment period, where the end of treatments marks a break within the “clinical pathway” is particularly crucial to understand. Health promotion is often overlooked during follow-up medical check-ups [11]. Furthermore, individuals who have completed treatment must readjust their daily routines to balance returning to work with family responsibilities while rebuilding their sense of self [12]. Consequently, CS embark on the "care pathway," wherein they grapple with managing their health behaviors [13], including an active lifestyle. For instance, upon returning to work, individuals frequently report feeling more tired, making it challenging to strike a right balance between rest and PA [14].

Prior Work

Studies delineate personal factors (*e.g.* self-efficacy, PA history, motivation) and environmental factors (*e.g.* equipment accessibility, healthcare system) implicated in adherence to PA during and after cancer treatment [15; 16]. French researchers have proposed a conceptual framework for

physio-psychological mechanisms – 3H syndrome – [17] while others aim to propose a psycho-social model [18]. Social-ecological approaches to health education interventions in PA [19] offer a framework for identifying the intricate interrelations between CS and their environment. While



acknowledging the importance of individual factors in behavioral change, such as stage of change, processes of change, decisional balance, self-efficacy, and knowledge, socio-ecological approaches also encompass influences at organizational, environmental, and policy levels. These approaches constitute one of the main pillars of promoting health-enhancing PA [20]. Thus, there is a need to enhance our understanding of active lifestyle in oncology, as highlighted in the French National Cancer Institute report on PA in 2017 [4] and other international reports [21]. To our knowledge, there is no study examining factors influencing PA and SB among breast, prostate, colorectal, or lung CS, utilizing the transtheoretical model (TTM) [22] as a framework and structuring collected data within a socio-ecological model [19].

Exploration and intervention targeting factors associated with active lifestyle – clinical, psychological, cognitive, behavioral, social, or even linked to the clinical pathway and the geographical environment –, can provide insights into the complex behaviors of PA and SB, as well as potential influences on them.

Aims

Three phases of the DEFACTO study can be described (Figure 1 Design of the DEFACTO study):

Figure 1. Design of the DEFACTO study

1. The first phase seeks to identify and characterize the factors that positively and negatively

influence PA and SB among breast, colorectal, prostate, and lung CS, ranging from 3 weeks to 20 years post chemo-radio-immunotherapy treatment. This phase of the study (DEFACTO1) will utilize a mixed-methods approach. Participants' "lifestyle profiles" will be delineated based on their PA and SB levels: 1) high PA/low SB: 2) high PA/high SB; 3) low to moderate PA/low SB; and 4) low to moderate PA/high SB [23; 24].

2. The second phase aims to develop an explanatory model [19] for categorizing the previously identified factors.

3. The third phase is dedicated to assessing the feasibility and potential effects of a multimodal individually-tailored health education program designed in accordance with the model. The program will be specifically tailored for physically inactive and sedentary CS. A verification of the pre-established model will also be conducted.

Methods

Phase 1) Exploratory study using a mixed-methods

The mixed-methods approach of DEFACTO1 adheres to the Good Reporting of A Mixed Methods Study (GRAMMS) recommendations [25]. The sampling, collection and analysis of quantitative (QUAN) and qualitative (QUAL) data, as well as the integration of phases [26] are outlined below.

An explanatory sequential design is employed, beginning with a QUAN phase, followed by a QUAL research phase. Given the multifaceted nature of an active lifestyle, the use of mixed-methods allows for a comprehensive exploration of this complex topic [27]. QUAN data obtained from a self-reported questionnaire are utilized to develop a semi-structured interview guide. Additionally, QUAL data derived from semi-structured interviews aid in interpreting and understanding the QUAN data [28].

Quantitative phase (DEFACTO1a)

The aim is to identify factors influencing active lifestyle among CS. A questionnaire, entitled "DEFACTO questionnaire", was developed between September 2019 and January 2020 from

validated questionnaires on factors influencing PA practice, ranging from the micro-level to the macro-level [29].

Recruitment

The French UNICANCER group on supportive care, the French League Against Cancer, and patient associations are invited to participate in QUAN data collection by distributing the questionnaire to CS (digital or paper survey). To ensure the most representative sample and avoid solely including CS from hospital and associations, information is shared on social networks (*e.g.* Facebook, LinkedIn, and Twitter). Information and consent forms are provided to participants in both digital and paper formats.

Inclusion criteria: Participants in the QUAN study must be aged 18 or older; diagnosed with breast, prostate, colorectal or lung cancer (including 1st, 2nd cancers and recurrences); have completed chemo-radio-immunotherapy treatments within the past 3 weeks and to 20 years; able to read, comprehend, and respond to a questionnaire in French; and have signed the informed consent form for the study.

Exclusion criteria: Subjects are excluded if diagnosed with metastatic cancer; residing outside mainland France to maintain focus on the French context; having an absolute medical contraindication to PA, as this is a known barrier to engagement for these CS and cannot be intentionally change through lifestyle interventions; being pregnant or breastfeeding; being under guardianship, curatorship, or deprived of liberty.

Considering the median age at diagnosis for all cancer types combined in France, projected to be 68 years for women and 70 years for men [30], we aimed to target the broadest possible population during the initial phase of the study. The study encompasses CS ranging from 3 weeks to 20 years post-treatment, recognizing this timeframe as the period during which late effects of treatments may still be experienced [31]. The 3-week threshold corresponds to the point at which CS realize that the end of treatments does not indicate a return to life as it was before diagnosis [32]. The study focuses on the four most common French cancers - breast, prostate, colorectal and lung – for which the benefits of PA are well established [30; 4].

Data collection and assessments

The self-administered DEFACTO questionnaire [29] was developed by integrating validated questionnaires and various other validated scales:

- Estimated PA level through different domains (*i.e.* occupational PA, leisure-time PA, and transport-related PA), and estimated SB are collected by the self-reported Global Physical Activity Questionnaire (GPAQ) [33]. Data collected through the GPAQ are the PA level (in MET-min/week),

the time spent in moderate to high intensity PA in minutes per week (min/week) and the time spent in SB in minutes per day (min/day).

- Variables from the TTM – Stages of change, Processes of change, Decisional balance and Self-efficacy – are collected with the following validated questionnaires: Stages of Change of Exercise Behavior Scale [34; 35]; Exercise processes of change [36]; Decisional balance for exercise [37]; Exercise Confidence Survey [38]. Types of PA motivation are collected through the Motivation Scale for PA for Health Purposes (EMAPS) [39].

- A sub-category of health literacy level is collected using a single question concerning the need of help to understand health information [40]. The idea is not to assess health literacy level but to identify CS with special needs according to this single question.

- Quality of life is assessed by the Short-Form 12 (SF-12) [41].

- Stereotypes related to benefits of exercise are explored through specific items extracted from the Cancer Beliefs and Exercise Scale (items 5, 15, 20, and 30) [42].

- PA barriers already identified in general population are collected with the “Barriers to Being Active Quizz” [43]. This 21-item tool examines 7 areas: 1) Lack of time; 2) Social influences; 3) Lack of energy; 4) Lack of willingness; 5) Fear of getting hurt; 6) Lack of skill sets; 7) Lack of resources. A total score of 6 or above in any area indicates that this is an important barrier to PA for the respondent. The Barriers to Being Active Quizz also gathers data concerning body image, pleasure felt during PA practice, the individual’s environment (*e.g.* home space walkability, sport facilities and equipment), availability of the entourage, all of which are variables identified within the theoretical framework as influencing PA participation [44; 45]. It also explores the PA participation of social and family environments in 3 items (*e.g.* opportunities to practice PA with close circle, other commitments relating to family life, other people’s perception of oneself).

Finally, PA experiences, sociodemographic, anthropometrics, clinical data, and tobacco use are also collected:

- PA experience: Respondents are asked a series of open-ended and closed-ended questions to ascertain whether they have benefited from an Adapted Physical Activity (APA) during their cancer treatment. This includes inquiries into the modalities of the program (*e.g.* type of supervision, location, frequency of meetings) and the satisfaction level, rated from 0 (not satisfied at all) to 10 (very satisfied).

- Sociodemographic data: age (in years); sex (M/F); education level (>College; College; High school; <High school); economic category (<600; [600-1200];]1200-2000];]2000-3000]; >3000 euro/month); professional category (without employment; in sick leave; student; retired; worker); household type (alone; single-parent family; couple without children; couple with children; other configuration); accommodation (flat or house) and area of residence (urban or rural); subscription to a health insurance (yes/no).

- Anthropometric data: weight (kg) and height (cm) are declared by the respondent. Body Mass Index (BMI in kg/m²) is calculated, and CS are classified into normal weight (18.5 and 24.9 kg/m²), overweight (25 and 29.9 kg/m²), and obesity (> 30 kg/m²) categories [46].

- Clinical data related to cancer and comorbidities are assessed using items of the French survey VICAN2 [8]: date of diagnosis (month/year), cancer location, stage, treatments received, time-lapse since the end of treatments (month/year), the presence or not of a second cancer – new primary cancer or recurrence –, and the presence of other pathologies and/or disabilities.

- Tobacco use and consumption are assessed through a closed-ended question. Actual smokers are invited to complete the 2-items the Fagerström questionnaire related to tobacco dependence level [47].

CS complete the whole DEFACTO questionnaire once. All variables are gathered from it.

Data analysis

Descriptive and correlation analyses will be conducted using SAS® software (version 9.4 & SAS/STAT 15.3). CS reaching or not a high PA level (≥ 3000 MET-min/week) [48] and having or

not a high SB (≥ 5 h/day) [23; 24] will be categorized into four lifestyle profiles [23] as follows:

- high PA/low SB: ≥ 3000 MET-min/week & sitting < 5 h/day;
- high PA/high SB: ≥ 3000 MET-min/week & sitting ≥ 5 h/day;
- low to moderate PA/low SB: < 3000 MET-min/week & sitting < 5 h/day;
- low to moderate PA/high SB: < 3000 MET-min/week & sitting ≥ 5 h/day.

Descriptive analysis and multivariate logistic regression will analyze the association between lifestyle profiles of CS and factors identified through the DEFACTO questionnaire. Descriptive and correlation analyses will utilize SAS® (9.4) and the SAS STAT package (15.3), presenting descriptive data as frequencies and percentages and mean ± standard deviation for continuous variables. The Kruskal-Wallis test will compare distributions of Processes of change and PA barriers among lifestyle profiles. The final multiple ordinal logistic regression model will be defined through stepwise selection, examining associations between lifestyle profiles and various parameters from the DEFACTO questionnaire. The ordinal logistic regression will use cumulative probability. Results from the multiple ordinal logistic regression will be reported as Odds ratios (ORs) and 95% confidence intervals, with significance levels set at $p<.05$.

Qualitative phase (DEFACTO1b)

An interview grid will be developed based on significant results from the DEFACTO1a study.

Recruitment

QUAN study respondents who agreed are contacted for the QUAL study. CS are selected according to their lifestyle profile.

Data collection

Semi-structured interviews are carried out by telephone due to the health context related to COVID-19. After patient approval, interviews are recorded and transcribed. According to the mixed-methods' design, interviews' topics correspond to the significant results of the multivariate logistic

regression from the QUAN study.

Data analysis

Transcripts of the interviews will be qualitatively analyzed using the Nvivo® software (version 1.5.1). After the coding of data and the exploration of major themes and topics of the interviews, data interpretation shall be based on the interview grid. Qualitative data will complete quantitative data according to the mixed-methods research design.

Phase 2) Ecological model of PA and SB based on DEFACTO1

The Booth model provides a global vision of factors influencing the initiation and maintenance of an active lifestyle [19]. Other socio-ecological models of PA determinants in overall population have also emerged [49; 50; 51], highlighting microscopic or individual factors (*e.g.* psychological factors, beliefs), mesoscopic factors (*e.g.* family, housing, security), and macroscopic factors (*e.g.* societal, political and legislative influences) [19]. Compared to other socio-ecological models, the Booth model appears to be most adaptable, with its design featuring nested circles that effectively capture the complexity of health behaviors across various environments. Additionally, the model facilitates an understanding of the connections between these environments. To our knowledge, this model has not been previously employed to elucidate factors associated with an active lifestyle among CS in a French context.

The socio-ecological model will be completed with barriers and facilitators to active lifestyle identified during the DEFACTO1 study, and significantly associated with lifestyle profiles of CS.

Phase 3) Health education program (DEFACTO2)

Study design

The DEFACTO2 intervention is a single-arm 3-month health education program, aligning with the typical duration of interventions in this field [52; 53] and the anticipated time needed to establish habits during behavior changes [54]. This multimodal, multicenter intervention is neither randomized nor controlled. Its purpose is to assess the feasibility of implementing an individualized program;

further research is required to evaluate the effectiveness of DEFACTO2 in relation to variations in PA and SB.

Inclusion criteria

Eligible participants are aged between 18 and 75 years old to avoid geriatric oncology [55] and to ensure population homogeneity in the feasibility study. They must be survivors of primary non-metastatic breast, lung, prostate or colorectal cancer (stage I to III, including primary, second cancer, and relapse), have completed chemo-radio-immunotherapy treatments within the past 3 weeks to 20 years, have no contraindications for individual discovery session of Adapted Physical Activity (APA), be willing to commit to the DEFACTO2 3-month program and 12-month follow-up, be physically inactive and sedentary (*i.e.* < 150 min/week of moderate PA or < 75 min/week of vigorous PA, with an average of 5 h/day or more of SB), be proficient in reading, understanding and speaking French, be capable of using the connected device (Garmin Vivosmart® 4) and performing basic operations (*e.g*. pressing a button, charging the battery), possesses a smartphone or a computer to download the Garmin Connect™ application, be able to walk unassisted (to prevent bias in connected device data), reside in France, and have signed the consent form.

DEFACTO2 targets physically inactive and sedentary CS, aiming to increase their PA to meet established guidelines [56; 21]. A total of 145 participants are required to detect a change of 75 minutes of moderate intensity PA per week between before and after the 3-month intervention, with an output of 90% and a 5% risk (two-sided). This calculation is based considering a moderate intensity PA variation of 75 min/week according to the study of Lynch et al. [57]; an average moderate-intensity PA of 50.6 (48.2) min/week in a subset of physically inactive CS from the DEFACTO1 study (not yet published), and a common standard deviation of 140, considering the standard deviation of moderate PA averages observed before and after the intervention in Lynch et al.'s study [57].

Recruitment

Information is disseminated among League Against Cancer committees, with calls for participation in the health education program sent via email. The 15 participating committees inform CS who meet the inclusion criteria, after which interested individuals contact the principal investigator via email or phone to schedule an appointment. Furthermore, calls for participation are distributed nationally to hospitals, patient associations, and social networks to maximize outreach to CS. Ultimately, we anticipated recruiting 10 volunteers per committee, each providing a certificate confirming no contraindication to PA and signing the consent form.

Intervention Design

The primary endpoint of the interventional phase of DEFACTO2 study consists in the feasibility of a health education program aiming to increase moderate intensity PA by 75 min/week in physically inactive and sedentary CS. All participants undergo a 3-month program comprising an APA discovery session, group educational sessions, and 7 or 8 motivational interviews by telephone. The intervention duration follows the guidelines for exercise programs [56].

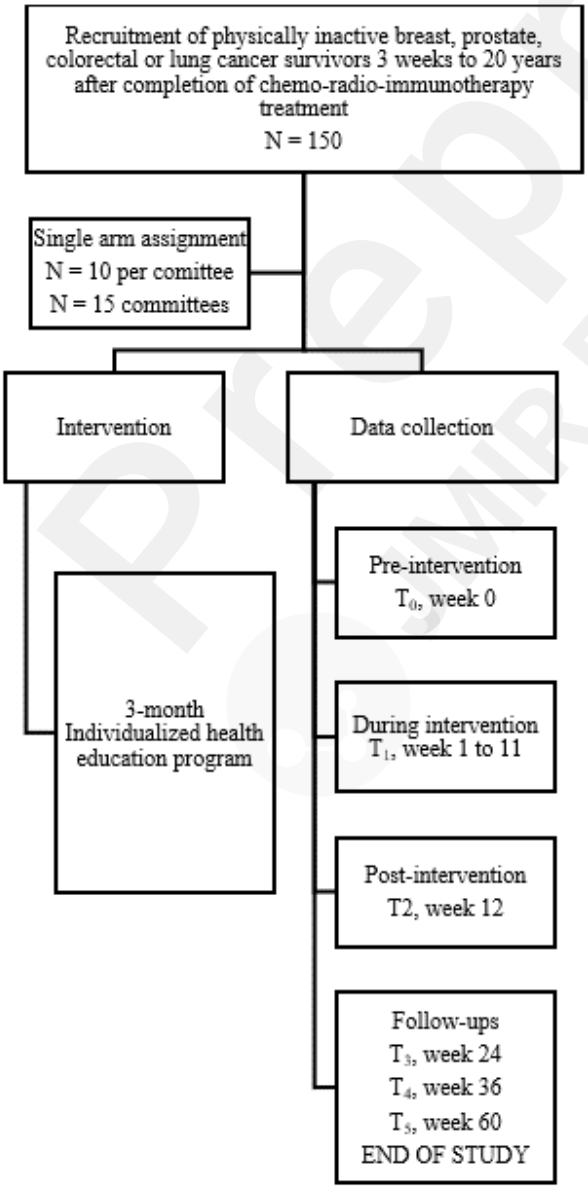
APA individual discovery session will be supervised by a qualified APA professional trained in the DEFACTO approach, with expertise in tailoring APA sessions. Participants will select an activity from a list of several APAs. The content of educational group sessions will be predefined by the research team, reflecting findings from the DEFACTO1 exploratory study. Only APA discovery sessions and educational sessions will be conducted in-person, at the French League Against Cancer departmental committee sites.

Motivational interview is a kind of support strategy used here in a research context [58]. The motivational interview series begin with discussions on participants' expectations and reasons for participation. Then, the content of motivational interviews is tailored based on participant's responses to the DEFACTO questionnaire at inclusion (T_0), focusing particularly on stage of change, processes of change [59], self-efficacy, motivation types, barriers and facilitators data. Motivational

interviews aim to provide practical support for implementing an active lifestyle, addressing individual needs such as balancing PA with work, managing family life, and discovering local PA options or programs, as well as financial support. As motivational interviews progress, an individualized education tool is developed to help participants visualize their barriers and facilitators within a socio-ecological model. The number of motivational interviews is determined based on the average of interventions in similar fields [60].

Participants are followed up 12 months after the intervention (Flowchart for study design (DEFACTO2), Figure 2).

Figure 2. Flowchart for study design (DEFACTO2).



All participants receive a Garmin Vivosmart® 4 connected device to monitor PA and will retain the watch upon completion of the study.

Data collection and assessments

Six data collection periods are taking place (Table 1): prior to the intervention (T_0); continuously during the 12-week intervention (T_1); at the end of the 12-week intervention (T_2); 3 months after intervention for the first follow-up (T_3); and at the 6- and 12-months follow-ups (T_4 and T_5, respectively). From T_2 to T_5, no specific instructions about PA or SB will be provided.

Table 1. Participant assessment and program evaluation (DEFACTO2)

	T_0 – One week before intervention	**T_1 – 12 weeks during DEFACTO Intervention**	**T_2 – End of the 12th week of intervention**	**T_3 – 3 month Post-intervention follow-up**	**T_4 – 6 month Post-intervention follow-up**	**T_5 – 12 month Post-intervention follow-up**
Participant assessments	- PA barriers and facilitators, preferences, self-efficacy, motivation types, knowledge about PA and its link with cancer, subjective PA level & time spent in SB, quality of	- objective PA level (Vivomsart® 4) - punctual and informal feedbacks on experience in the program - Adherence to PA recommendation	- PA barriers and facilitators, preferences, self-efficacy, motivation types, knowledge about PA and its link with cancer, subjective PA level & time spent in SB, quality of life (DEFACTO	- objective PA level (Vivosmart® 4)	- objective PA level (Vivosmart® 4)	- objective PA level (Vivosmart® 4)
Program evaluation		- Adherence to the program - Adverse events declared by the participant	- Satisfaction and experience of participants regarding the individualized program, perception of the intervention's usefulness			

Abbreviations: PA, physical activity; SB, sedentary behavior

DEFACTO questionnaire: Participants will completed the questionnaire at T_0 to develop the individualized education tool, and to tailor the intervention based on TTM processes of change, and PA barriers and facilitators. The questionnaire is completed again at T_2 to identify modifications during the intervention.

PA preferences: Participants' PA preferences will be collected at T_0 through a brief interview for

program individualization.

PA level: Objective PA level will be measured using the Vivosmart® 4 connected watch by Garmin®. Variables required for each Garmin Connect™ account include sex, age (in year), weight (in kg), and height (in cm). These elements are required to calculate variables associated with PA measurement (explained in "Data analysis" part).

Average daily steps, distance traveled (km/day), floors climbed (number of floors climbed/day), heart rate (bpm), and cumulative duration of PA of moderate and vigorous intensities (min/week) will be collected over a 7-day period at T_0, T_2, T_3, T_4 and T_5. Data will be continuously collected from T_0 to T_1, covering a 12-week period [48].

Subjective PA level will be assessed using the GPAQ self-questionnaire [33] at T_0 and T_2.

Adherence: Adherence to the program will correspond to the number of sessions done regarding planned sessions.

Program evaluation

Satisfaction and experience: At T_2, overall satisfaction will be assessed, along with participants' opinion on the individualized health education program. Open-ended questions will allow participants to express any aspects that may have been omitted and that would need to be incorporated into future interventions. Throughout the 3-month program, punctual and informal feedback will be collected, as well as potential adverse events reported by the participants.

Satisfaction of qualified APA professional: An interview will be conducted with all 15 professionals involved in the program at T_2 to gather collective feedbacks on the overall program. The use and practicality of the communication medium used in educational group sessions will be specifically examined.

The feasibility of DEFACTO2 is evaluated based on criteria such as the recruitment process and the capacity to target the intended participants, the appropriateness of procedures and measures in line with study objectives and the study population. The acceptability and fidelity of the intervention are

evaluated by including both open and closed questions in the DEFACTO questionnaire at T_2. Subsequently, the resources and skills of the research team to implement the intervention are assessed, along with the potential effects of the program on active lifestyle [61].***Data analysis***

Data analysis will utilize SAS® software, summarizing the demographic and baseline characteristics of participants at T_0. Continuous variables will be presented as means ± standard deviations, while categorical variables will be reported as frequencies and percentages. Descriptive statistics will detail each component of the DEFACTO questionnaire.

For the primary outcome, both objective PA levels measured by Vivosmart® 4 and subjective data will be considered. Usable data from continuous assessment, *i.e.* when the connected watch is wearied at least 10 h/day and 4 days in a week, will be described through means ± standard deviations. Following verification of data normality, comparative analysis will be conducted using Student-t test between objective PA levels at T_0 and T_2 to evaluate the primary outcome, and between T_2, T_3, T_4 and T_5 to analyze PA maintenance after the 3-month program. The relationship between PA levels measured by Vivosmart® 4 and estimated by self-questionnaire (GPAQ) will be analyzed at T_0 and T_2.

A comparison will be conducted between T_0 and T_2 to assess the evolution of processes of change, self-efficacy, knowledge about PA and its link with cancer, motivation types, barriers and facilitators to PA, declared PA and SB levels, and quality of life.

Results

Ethics and Approval

The Committee for the Protection of Persons (CPP) approved the DEFACTO1 mixed-methods study on April 3, 2020 (CPP SOUTH MEDITERRANEAN II, #2019-A03183-54). The DEFACTO2 intervention was approved on March 7, 2022 (CPP NORTH WEST III, #2021-A01570-41) and registered on Clinicaltrials.gov, on May 2, 2022 (NCT05354882). Free and informed consent was collected before any act related to research.

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Inclusions

DEFACTO1a recruitment and data collection took place between April 2020 and January 2021. A total of 175 cancer survivors completes the DEFACTO questionnaire. From June 2021 to August 2021, semi-structured interviews have been carried out with 18 participants.

DEFACTO2 began in April 2022. The implementation of the intervention was concluded in May 2023, data collection and full data analysis are expected to be completed by May 2024.

Discussion

Overview

DEFACTO employs a mixed-methods approach, utilizing an explanatory sequential design and multi-level analysis. This approach aligns with implementation strategy recommendations and is informed by prior research on needs, barriers, and facilitators [62]. Our tailored and multimodal intervention, grounded in a socio-ecological model, aims to support physically inactive and sedentary CS in adopting and sustaining an active lifestyle. We anticipate this approach to be customizable, feasible, and applicable, fostering lasting behavior change with a broader impact on CS' lifestyles.

Future plans include implementing this program across the 97 departmental committees of the Metropolitan French League Against Cancer. This study will contribute to current research in the field of supportive care in cancer and in public health. Our study addresses several gaps in current scientific studies, such as considering patient's preferences (*e.g.* type of PA proposed), demographic and socioeconomic factors, that remain under-explored and should be investigated more thoroughly [4; 21]. The French context is particular in the field of active lifestyle promotion in the oncology care pathway, as it is not implemented in every country. For example, French physicians can prescribe exercise and a new French decree allows CS to benefit from fitness and motivation assessment, including motivation interview for PA (Decree No. 2020 − 1665 of December 22, 2020, relating to global care pathway after oncology care). Our program could complement current advances in the healthcare system, promoting an active lifestyle that can be incorporated into people's daily lives.

Expected results

The implementation of an individualized active lifestyle program like DEFACTO2 may be influenced by various elements. These elements can either support or impede the program's success. By examining these elements, we can pinpoint the circumstances conducive to implementing such interventions across different settings. This research protocol seeks to offer support based on a modelization to CS encountering challenges in embracing an active lifestyle through an individualized approach. This approach integrates an individual behavior change model with a broader examination of environmental influences on behavior. Additionally, it aims to equip professionals with practical tools to provide effective support to promote an active lifestyle among CS.

Strengths and Limitations

The study has limitations. Firstly, the GPAQ in the DEFACTO questionnaire gathers subjective PA and SB data, potentially leading to inaccuracies [63]. To address this, accelerometer-based PA measurements will be employed in the third phase of the study.

Wearing a connected watch produces a motivating effect for PA, particularly linked to the "awareness" process of experiential change, with direct feedback from exercise [64], and associated with learning to self-measure [65]. The connected watch will serve as both an assessment tool and part of the support provided, as all participants will use it and frequently refer to it.

The DEFACTO questionnaire is not validated but uses validated questionnaires widely used in care pathways.

The committees of the French League Against Cancer have varying ongoing or upcoming projects, motivations, facilities, resources, organization and local policies. Ensuring feasibility across different League Against Cancer committees involves standardizing proposed APA, communication methods, and participant instructions. A toolkit package and one-on-one training is mandatory for professionals involved in DEFACTO2 intervention study.

Conclusions

The findings of this study will have significant implications for the feasibility of implementing tailored interventions promoting PA across the French metropolitan territory. Additionally, they will influence the implementation of PA initiatives in oncology care pathways worldwide. In addition to improving the active lifestyle among CS, such interventions have the potential to provide support to individuals facing difficulties after completing their oncology care pathway, such a better management of priorities and health behaviors.

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Data availability

The data that will be generated during the study will be available from the corresponding author on request.

Authors' Contributions

AA, AMF developed and wrote the study protocol, RG provided the mixed-methods, he also provided feedback on the protocol and this manuscript. All authors (AA, AMF and RG) have written, read and approved the submission of the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

APA: Adapted Physical Activity

CPP: Committee for the Protection of Persons

CS : Cancer Survivors

GPAQ: Global Physical Activity Questionnaire

GRAMMS: Good Reporting of A Mixed Methods Study

MET: Metabolic Equivalent Task

PA: Physical Activity

QUAL: Qualitative

QUAN: Quantitative

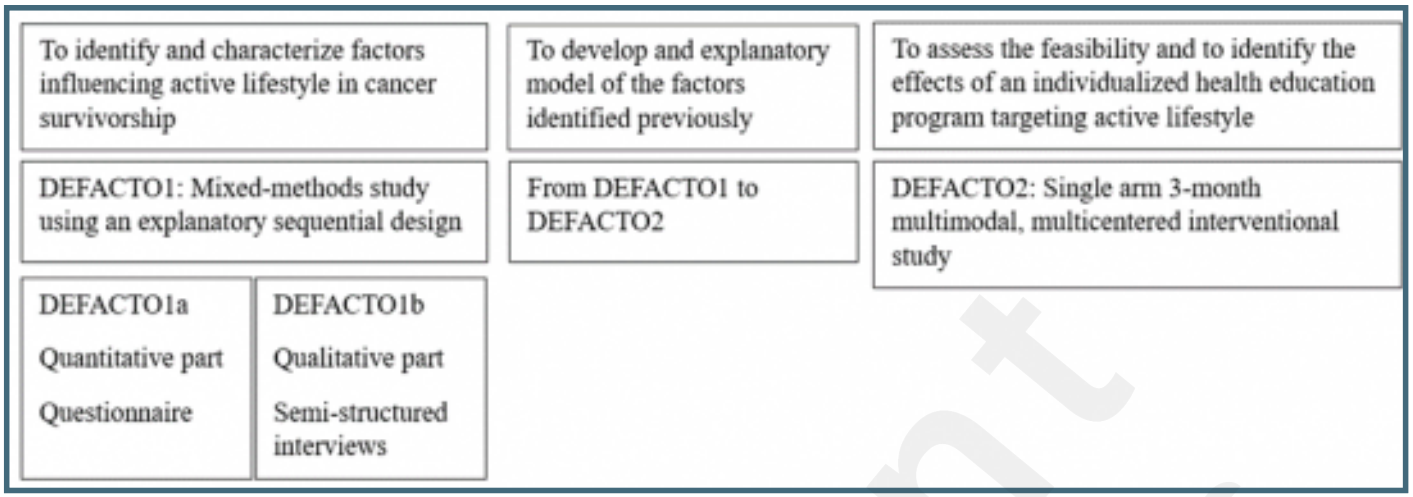
SB: Sedentary Behaviors

TTM: Transtheoretical model

Supplementary Files

Figures

Design of the defacto study.



Flowchart for study design (DEFACTO2).