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Using intervention mapping to facilitate and sustain return-to work after breast cancer: protocol for the FASTRACS multicentre randomized controlled trial

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Abstract

Background Women with breast cancer face many barriers to return to work (RTW) after their cancer. The main objective of the FASTRACS-RCT is to evaluate the impact of the FASTRACS (Facilitate and Sustain Return to Work after Breast Cancer) intervention on the sustainable RTW of breast cancer patients, 12 months after the end of active treatment.

Methods FASTRACS-RCT is a prospective, national, multicentre, randomized, controlled and open-label study. A total of 420 patients with early breast cancer scheduled for surgery and (neo)adjuvant chemotherapy, will be randomly assigned (1:1 ratio) to: (i) the intervention arm comprising four steps over 6 months : Handing over the intervention tools; transitional medical consultation with the general practitioner (GP); pre-RTW visit with the company's occupational physician (OP); catch-up visit with a hospital-based RTW expert (if sick leave > 10 months) (ii) the control arm to receive usual care. The design of the FASTRACS intervention was informed by intervention mapping for complex interventions in health promotion planning, and involved patients and representatives of relevant stakeholders. Specific tools were developed to bridge the gap between the hospital, the GP, the OP and the workplace: a toolkit for breast cancer patients comprising a theory-based guide; specific checklists for the GP and the OP, respectively; and a theory-based guide for workplace actors (employer, manager, colleagues). The primary endpoint will associate sustainable RTW (full-time or part-time work at 50% or more of working time, for at least 28 consecutive days) and days off work. It will be assessed at 4, 8 and 12 months after the end of active oncological treatment. Secondary endpoints will include quality of life, anxiety, depression, RTW self-efficacy, physical activity, social support, job accommodations, work productivity, job status, and the usefulness and acceptability of the intervention's tools.

Discussion FASTRACS-RCT will be supplemented by a realist evaluation approach aimed at understanding the influence of context in activating the intervention's mechanisms and effects. If the expected impact of the

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intervention is confirmed, the intervention will be adapted and scaled-up for other cancers and chronic diseases to better integrate healthcare and work disability prevention.

Trial registration NCT04846972 ; April 15, 2021.

Keywords Breast neoplasms, Cancer survivors, Intervention studies, Theory-driven evaluation, Work disability prevention, Return to work, Intervention mapping, General practitioner, Occupational health physician, Self-efficacy

Background

Breast cancer (BC) is the most common cancer in women globally, with an estimated number of 1.7 million women diagnosed each year [1]. It accounts for 27.8% of all cancer diagnoses in women in Europe [2] and 31% in the United States [3]. In France, 61,000 new cases of breast cancer are reported yearly [4]. Despite a good prognosis with a five-year survival rate of 87% in France, the impact of breast cancer on job retention is significant. Overall, about 40% of BC survivors are estimated to be of working age, a proportion expected to increase with the raising of the retirement age [5]. A meta-analysis showed that the unemployment rate is higher after breast cancer than after other cancers (35.6% versus 31.7%) [6]. In the CONSTANCES cohort in France, among women with BC who were active before their diagnosis from 2012 to 2018, only 73.2% returned to work within 2 years after diagnosis [7].

The factors influencing the rate of return to work and the length of time off work are related to the disease (prognosis, treatment, symptoms), workplace factors (physical and cognitive demands, social support at work), and social and demographic factors (age, level of education and income) [8–10]. Disease-related factors include pain, fatigue, cognitive difficulties, upper limb joint limitations, hot flushes, lymphoedema, and psychological distress. The influence of chemotherapy on the sick leave duration is significant particularly when combined with trastuzumab [11].

Different psychological factors are known to influence the RTW process and outcomes after breast cancer, such as anxiety and depression [7]. The experience of breast cancer can change life priorities and the value attributed to work [12, 13], thus influencing the RTW perspectives.

Beyond medical and health factors, the social environment of patients is determining. Social support at work and job accommodation are likely to facilitate RTW and job retention [14]. Conversely, self-reported workplace discrimination increases the probability of job loss by 15% [15]. The lack of appropriate information from healthcare professionals and their lack of knowledge is pointed as a barrier to RTW after breast cancer [16]. Marital and family dynamics can have a positive or negative influence on the RTW trajectory of BC patients [13].

Despite the good level of descriptive evidence on the factors determining RTW after cancer, the results of the proposed interventions are disappointing [10, 17–19]. These failures are attributed to a lack of conceptualisation and the over-medicalised view of a problem that is essentially social, complex and cross-sectoral [20]. A recent review of interventions aimed to support return to work in women after breast cancer, identified only one intervention based on a theory related to return to work [17]. More than 80% of the interventions were provided by healthcare professionals, and only 38% were oriented towards the workplace and offered other activities, such as coordination of services, information, and instructions for developing a return-to-work plan [17].

Given the variety of factors that determine RTW and the number of stakeholders involved, RTW interventions must be considered as complex interventions with a high risk of theoretical and implementation failures [20, 21]. This type of intervention needs explicit theoretical foundations blended with the field expertise of relevant stakeholders [21]. Interventions developed with participatory approaches are believed to be more relevant, acceptable, effective and sustainable. In this respect, the intervention mapping protocol [22] has been used for several years to develop, implement and evaluate health promotion programs, notably in the field of cancer [23] and in work disability prevention [24].

The main objective of the FASTRACS-RCT is to evaluate the impact of the FASTRACS (Facilitate and Sustain Return to Work after Breast Cancer) intervention on the sustainable RTW of breast cancer patients, 12 months after the end of active treatment.

Methods/design

Study design

FASTRACS-RCT is a prospective, multicenter, randomized, controlled, open-label study. The study protocol was approved by the French ethics committee CESREES on November 19, 2020 (reference number: 2551836) and the study database was authorized by the National Commission for Data Protection and Liberties (CNIL) on April 9, 2021 (reference number: DR-2021-101). The study is registered on http://www.clinicaltrials.gov (NCT04846972).

Aim of the study

The main objective of the FASTRACS-RCT is to evaluate the impact of the FASTRACS intervention on the sustainable RTW of patients with breast cancer, 12 months after the end of active treatment as defined in Table 1,

Table 1 End date of active treatment according to patient's treatment *

Patient's treatment	End date of heavy treatment
Neoadjuvant chemotherapy + surgery, without adjuvant chemotherapy or radiotherapy	Date of surgery
+/- Neoadjuvant chemotherapy + surgery + adjuvant chemotherapy	Date adjuvant chemotherapy completed
+/- Neoadjuvant chemotherapy + surgery + adjuvant chemotherapy + radiotherapy	End date of radiotherapy
Neoadjuvant chemotherapy + surgery + radiotherapy	End date of radiotherapy

* For the purposes of this study, capecitabine and TDM-1 (trastuzumab emtansine) are considered as chemotherapy, whereas pembrolizumab, trastuzumab, pertuzumab, abemaciclib, and olaparib are not

compared with a control group receiving usual care. Secondary objectives are to assess the impact of the intervention on health-related quality of life, health-related utility, anxiety, depression, job status, work functioning, RTW self-efficacy, working conditions, social support, physical activity, and healthcare. Other objectives are to assess the difference between the employment rate in managerial and in operational occupations 12 months after the end of oncology treatment, and to compare the adverse events in the intervention group and the control group.

Study population

In order to participate, women have to meet all of the following eligibility criteria: (1) aged between 18 and 60 years, (2) with a diagnosis of invasive breast carcinoma of stage cTNM or pTNM I to III (UICC 8th edition), confirmed by histological examination, (3) treated by intravenous adjuvant or neoadjuvant cytotoxic chemotherapy, (4) breast surgery +/- of the axillary area, carried out within 3 months preceding the start of adjuvant chemotherapy, or scheduled after neo-adjuvant chemotherapy, (5) in salaried employment at the time of diagnosis, (6) affiliated to the French social healthcare insurance, (7) reading, understanding and writing the French language, (8) not opposing the collection of data.

Patients are not eligible in case of (1) in situ carcinoma alone, (2) distant metastases, (3) history or co-existence of another primary cancer (apart from a basal cell cancer of the skin and / or a non-mammary cancer in complete remission for more than 5 years), (4) recurrence or second breast cancer, (5) without employment contract; self-employed or supported contract, (6) cannot be followed for the duration of the study, for medical, social, family, geographic or psychological reasons, (7) deprived of liberty by court or administrative decision.

Recruitment

Participants are recruited in 14 cancer centres, public hospitals or private clinics in France. The study is proposed to eligible breast cancer patients at the postoperative or pre-chemotherapy consultation by the oncologist or the surgeon. In practice, the investigator checks all eligibility criteria, explains the objectives of the study to the women and then proposes her to participate. Information is given orally and on a leaflet.

Randomization

At the first visit of the study, participants are randomly assigned (1:1 ratio) by the research assistant using EnnovClinical® software (i) to receive the FASTRACS intervention or (ii) to receive routine care. Randomization is stratified using a dynamic minimization algorithm with three factors: centre of inclusion, age (≤ 50 y / > 50 y), and socioprofessional category (management/execution).

Intervention arm

Patient and public involvement statement

A partnership was established between the research team and a committee bringing together the various stakeholders: breast cancer patients and associations, employers, healthcare professionals, and representatives of the health, labour and social security authorities. This intersectoral strategic participatory committee (ISPC) includes 35 participants who were involved in all phases of the research to assess needs, develop and test intervention tools, and implement the intervention [25]. A partnership charter [additional file 1] [26] was drawn up to provide a long-term structure for the mutual commitment of researchers, patients, and the various stakeholders.

Intervention development

The intervention mapping protocol [22] was used to develop the FASTRACS intervention to facilitate and sustain RTW after breast cancer. The intervention was developed in partnership with the ISPC using participative methods, following the six steps in the intervention mapping (IM) protocol. IM-Step 1 : The ISPC was established and partnership charter was drawn up [26]. A needs assessment allowed to formulate a logic model of the problem including behavioural and environmental factors and their determinants [27]. IM-Step2: A logic model of change was defined including matrices of change objectives for patients, employers, and healthcare professionals. IM-Step 3: Theory-based methods were chosen to develop and test the tools used in the intervention [28]. IM-Step 4 : The intervention process (logic model of use) was defined to precise who does what,

when and where [25]. IM-Step 5: The implementation was completed. IM-Step 6 : The evaluation is currently under way by means of a realist randomised controlled trial (RCT) [29] which combines an RCT to evaluate the effects of the intervention (FASTRACS-RCT) associated with a realistic evaluation approach [30] (RECOVA-FASTRACS) to document the mechanisms, implementation and acceptability of the intervention and its tools. This article describes the FASTRACS-RCT protocol.

Intervention tools

Four tools were developed with the ISPC and pre-tested with a panel of participants: a guide for patients [28], a checklist for GPs, a checklist for OPs, and a guide for employers [25]. The patient's guide is designed to prepare them to interact with their GP, their OP, their employer and their colleagues [28]. The checklists for GPs and OPs are designed to help them structure their overall assessment and patient-centered care [31]. The employer's guide is designed to facilitate the patient's reintegration into the workplace and the adaptation of her workstation [32]. The structure and purpose of these tools are detailed in [additional file 2].

Intervention process (logic model of use)

The logic model of use for the FASTRACS intervention formulates who does what, when and where [33]. It comprises four successive steps represented in Fig. 1 and described in more details in the [additional file 3]. (FASTRACS-Step 1) Handing over the intervention tools: A nurse from the oncology day hospital or a research assistant gives the patient a kit containing the four intervention tools, and explains how to use them. (FASTRACS-Step 2) A transition visit (from hospital to community care) with the GP is scheduled for the month following the end of active treatment. This step is designed to ensure that the patient's needs are assessed and cared for as a whole, and to discuss the RTW project. (FASTRACS-Step 3) Pre-RTW visit with the company's OP is recommended in order to assess the patient's functional abilities and limitations, and to define a return to work strategy. (FASTRACS-Step 4) Catch-up visit with a hospital-based RTW expert. This last step is planned only for patients who have not returned to work 10 months after inclusion.

Control arm

Participants randomized in the control group receive usual care. They have the same follow up as participants of the intervention arm.

Evaluations

Modalities

The measures and timing of study outcome are summarised in Table 2. All patients benefit from two face-to-face baseline assessments by a research assistant when attending the participating hospital centre for their regular oncology follow-up visit: at inclusion before the randomization (T0), and before the end of the active treatment (T1). For the rest of the follow-up period (T2, T3, T4), patients in both groups receive a questionnaire by email (online questionnaire: eCRF Clinsight) or by post (prepaid return envelope), depending on the mode chosen by the woman at inclusion. The research assistants contact the patients if they have not completed the questionnaires whether online or by mail, and offer to complete the questionnaires by telephone.

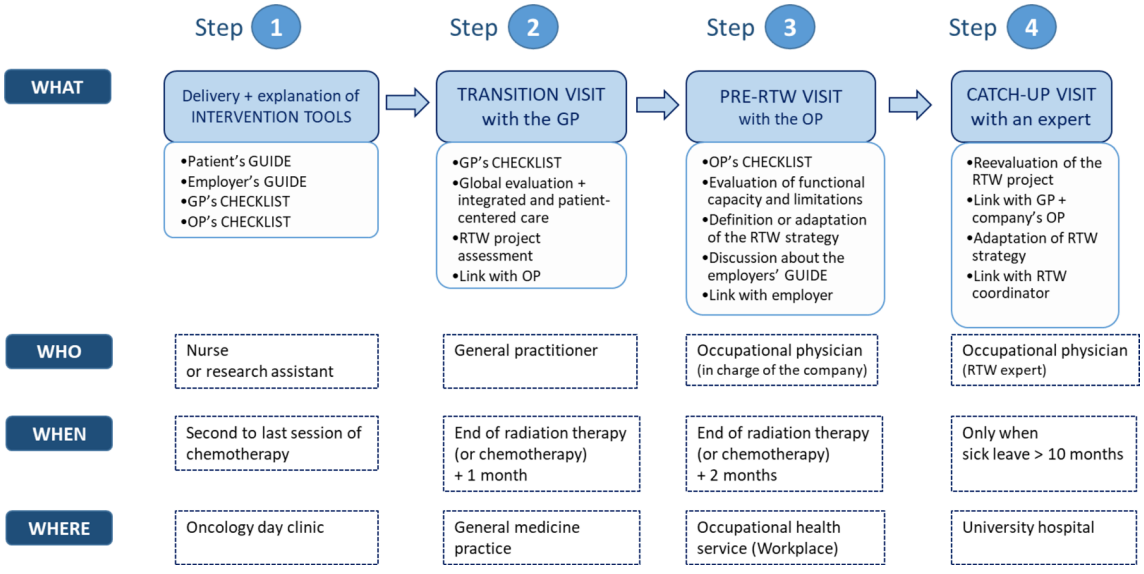

Fig. 1 Logic model of use for the FASTRACS intervention. GP (general practitioner); OP (occupational physician); RTW (return-to-work)

Table 2 Timing of the data collection and steps of the intervention

Timing of the data collection (T) Steps of the intervention	**T0 – inclusion + randomization (Both groups)**	**T1 (Both groups)**	**(Intervention group only)**	**(Intervention group only)**	**(Intervention group only)**	**T2 (Both groups)**	**(Intervention group only)**	**T3 (Both groups)**	**T4 - final (Both groups)**
Timing\ Data collected	**Between the 1st and penultimate course of CT or dedicated visit before the end of active treatment**	**3rd to penultimate CT session or dedicated visit if CT stopped or dedicated visit before end of active treatment if late inclusion**	**Penultimate to final CT session or dedicated visit if CT stopped or dedicated visit before end of active treatment if late inclusion**	**End of active oncology treatment + 1 month (+/- 14 days)**	**End of active oncology treatment + 2 month (+/- 14 days)**	**End of active oncology treatment + 4 month (+/- 14 days)**	**End of active oncology treatment + 5 month (+/- 14 days)**	**End of active oncology treatment + 8 month (+/- 14 days)**	**End of active oncology treatment + 12 month (+/- 14 days)**
Information and enrolment	X								
Job physical exertion score, age, occupation, history	X								
Socio-demographic and professional data		X							
EQ-5D 5 L + QLQC30 + BR23, HAD, RTW-SE-11, IPAQ	X					X		EQ-5D 5 L alone	X
Handing over the intervention tools			**Intervention STEP 1**						
Social support		X				X		X	X
Sustainable RTW and days off work						X		X	X
Care pathway						X		X	X
Transitional medical consultation with the GP				**Intervention STEP 2**					
Pre-RTW visit with the company's OP					**Intervention STEP 3**				
Catch-up visit with a hospital-based RTW expert (if sick leave > 10 months)							**Intervention STEP 4**		
Work productivity (WRF questionnaire)									X

Table 2 (continued)

Timing of the data collection (T) Steps of the intervention	**T0 – inclusion + randomization (Both groups)**	**T1 (Both groups)**	**(Intervention group only)**	**(Intervention group only)**	**(Intervention group only)**	**T2 (Both groups)**	**(Intervention group only)**	**T3 (Both groups)**	**T4 - final (Both groups)**
Timing\ Data collected	**Between the 1st and penultimate course of CT or dedicated visit before the end of active treatment**	**3rd to penultimate CT session or dedicated visit if CT stopped or dedicated visit before end of active treatment if late inclusion**	**Penultimate to final CT session or dedicated visit if CT stopped or dedicated visit before end of active treatment if late inclusion**	**End of active oncology treatment + 1 month (+/- 14 days)**	**End of active oncology treatment + 2 month (+/- 14 days)**	**End of active oncology treatment + 4 month (+/- 14 days)**	**End of active oncology treatment + 5 month (+/- 14 days)**	**End of active oncology treatment + 8 month (+/- 14 days)**	**End of active oncology treatment + 12 month (+/- 14 days)**
Job status									X
Utilization of the patient's guide and the employer's guide (Intervention group)						X	X	X	X
Medical data (treatments…)									X

CT [chemotherapy] ; EQ-5D 5 L [Euroquol 5 dimensions] ; QLQC30 + BR23 [Quality of Life Questionnaire – Core 30 items + breast extension – 23 items] ; HAD [Hospital Anxiety Depression scale], RTW-SE-11 [Return to Work Self Efficacy – 11 items], IPAQ [International Physique Activity Questionnaire]; WRF [Work Role Functioning]; GP [general practitioner] ; OP [occupational physician]

Data collection

A complete data collection timetable is provided in Table 2. All data are filed out in an electronical case report form (e-CRF).

Demographic and clinical data

Demographic data, including, living situation, employment status, education, socio-professional level, job type and working conditions are collected by self-reported questionnaires at T0 and T1.

Medical data

Medical data on the cancer (tumour histology, hormone receptor status, stage at diagnosis), and the dates and types of treatment (surgery, chemotherapy, radiotherapy, targeted therapies, hormone therapy) are collected via the medical file by the research assistant at T4.

Endpoints

Sustainable return-to-work and days off work (primary outcome)

For this study, sustainable RTW is defined as a return to full-time or part-time work (50% or more of working time) for at least 28 consecutive days. Sustainable RTW and the cumulative number of days off work is measured with specific questions to the patients (on a declarative basis) [34, 35] at T2, T3 and T4 corresponding to the period between the end of the active oncology treatment and the following 12 months.

Health-related quality of life

Health-related quality of life, symptoms and adverse events are measured with the European Organization for Research and Treatment of Cancer (EORTC) Quality-Of-Life Questionnaire (QLQC30) [36] and 13 targeted questions from its specific module for breast cancer (BR23) [37, 38] at T0, T2 and T4. QLQC30 questionnaire consists of 30 items to evaluate five functioning domains (physical, role, emotional, cognitive, and social). Higher scores represent better functioning, better global health-related quality of life, and greater symptom burden.

Health-related utility

Health-related utility is measured with the European Quality of Life-5 dimensions-5 levels (EuroQoL EQ-5D 5 L) questionnaire [39] at T0, T2, T3, T4. EQ-5D is a generic instrument for describing health outcome. It contains five dimensions i.e. mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. This version includes five levels of impairment in each of the existing five dimensions.

Anxiety and depression

Anxiety and depression are measured with the Hospital Anxiety and Depression Scale (HADS) questionnaire [40] at T0, T2 and T4.

Return-to-work self-efficacy

Return-to-work self-efficacy is measured with the RTW-SE questionnaire [41, 42] at T0, T2 and T4. Self-efficacy is a cognitive mechanism reflecting an individual's expectations and beliefs about being able to carry out the necessary actions in order to achieve a specific goal [43]. This determinant has been shown to be highly predictive of a return to work in the event of chronic illness [44].

Physical activity

Physical activity is measured with the short version of IPAQ questionnaire [45, 46] at T0, T2 and T4. This measure assesses the types and intensity of physical activity that people do as part of their daily lives.

Perceived social support

Social support received is measured with questions covering four dimensions (emotional, material, informational, and support to restore the patient's self-confidence) at T1, T2, T3 and T4. The measurement of informal help is assessed on the basis of information gathered using an adaptation of the RUD (Resources Utilization in Dementia) questionnaire [47, 48], an instrument for resource use data collection, enabling comparison of costs of care across countries with differing health care provisions.

Work productivity

Work productivity is measured with the WRF questionnaire [49] at T4. The Work Role Functioning Questionnaire is an outcome measure linking a persons' health to the ability to meet work demands within five dimensions (work scheduling demands, output demands, physical demands, mental and social demands, and flexibility demands).

Working conditions and job accommodation

Working conditions and job accommodation are measured with specific questions (work tasks, working hours, technical aids and human aids) at T4. Whether accommodations are voluntary (accepted) or involuntary (imposed) are explored.

Employment status

Employment status is measured with specific questions at T4.

Healthcare

Information on the number and timing of consultations with physicians (GP, OP, others), paramedics and other professionals is collected through specific questions at T2, T3 and T4.

Process evaluation

The acceptability and use of intervention tools are measured with specific questions at T2, T3 and T4. These quantitative indicators will be used in a complementary realist evaluation [29, 30] by qualitative approaches (individual interviews, focus groups) with patients, GPs, OPs and employers to document their use of the intervention tools.

Statistical analysis

Statistical methods

Primary analysis

The main analysis will be a combined analysis of the two primary endpoints based on the assessment of the Net Benefit of the intervention, estimated through generalised pairwise comparisons extended to several outcome measures [50]. In this analysis, the included outcomes need to be ordered in successive priorities. The first priority binary endpoint will be sustainable return to work and second priority endpoint will be the number of days off work during the first year, analysed as a continuous criterion). Pairwise comparisons require consideration of all possible pairs of patients, one patient taken from the intervention group, and the other taken from the control group. The outcomes of these two patients are first compared according to the first priority outcome. Pairs of patients that can not be classified as wins or losses (ties), will be analysed based on the number of days off work during the first year (second priority outcome) using a threshold for the minimum clinically relevant difference between two patients set at 1 day [51].

Secondary analyses

Secondary analyses will include exploratory analyses of the efficacy of the intervention on the secondary endpoints and on each primary endpoints analysed separately. The endpoints will be described using standard statistics and compared between groups using fixed-effect or mixed-effect models to take account of randomisation stratification variables as adjustment variables (centre random effect and fixed effects for binary factors). The group will be tested as a fixed effect (intervention versus control) and if statistically significant, the interaction effects with the adjustment variables will be tested.

The models will be linear for the scores calculated from the questionnaires (scores from 0 to 100) and the number of days off work, logistic for the binary criteria or adapted according to the distribution of the data for the number of medical visits. For exploratory analyses, the significance threshold will be set at 0.05 and will not be adjusted for multiple comparisons.

The difference between the employment rate in managerial occupations and in operational occupations 12 months after the end of oncology treatment will be compared between the groups in a logistic model in which the variable to be explained will be employment at 12 months (binary) and the explanatory variables will be occupation (managerial vs. operational), group (intervention vs. control) and their interaction. Age and type of occupation (operational/managerial) strata will be introduced as adjustment variables.

The number, type and grade of side events (according to the CTCAE grid) will be compared in the intervention group and the control group at T0 and T4 using a chi2 test or an exact test.

Care pathway and consumption (medical and paramedical consultations or consultations with other professionals, hospital admissions, consumption of analgesics, antidepressants, anxiolytics and hypnotics) at T2, T3 and T4 will be described by group using standard statistics.

The software used will be SAS version 9.4 or later (Copyright (c) 2002–2003 by SAS Institute Inc, Cary, NC, USA.) and R version 3.6.3 or later (R Core Team (2012). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-project.org/.)

Sample size

We assumed that 75% of patients in the control group would return to work permanently [10] and that among these patients, the average number of days off work in the first year would be 60 days. The number of days off work was simulated using a beta distribution. The study was calibrated to detect an improvement in the FASTRACS intervention group, with 85% of patients returning to work permanently, including a reduction in the average number of days off work for medical reasons to 55 days. 5000 trials were simulated with "R" 3.3.1 software to evaluate the expected performance of our study according to these hypotheses. The results showed that an enrolment of 400 patients would make it possible to demonstrate a statistically significant net benefit at a two-sided alpha risk of 5%, with a power of over 80%. Assuming a 5% attrition rate, 420 patients would need to be randomised (210 patients per group).

Data monitoring

The randomization and database for clinical data use EnnovClinical® software and the access is secured (personal ID and password required) with different levels of security depending on the role of the investigator.

Discussion

Originality and strength of the study

Whereas most interventions for returning to work after cancer focus on the patient (improving physical, psychological or cognitive functional capacities) [10, 17, 19], the FASTRACS intervention aims to modify the determinants of the return to work situated in the patient's environment, in line with the paradigm of population health intervention research [52]. The aim is to empower women as individuals, while encouraging the actors in their environment to adopt behaviours that will help them to return to work. This corresponds to an ecological perspective of the social determinants of health [53] as recommended for health promotion [22] and complex interventions [21].

Strong emphasis was placed on the participatory process throughout the study, from the initial needs assessment [27], through to the development of the intervention, its implementation and evaluation. This involvement of all the stakeholders is a particular strength of the study given the shortcomings noted in the literature, whether in the field of cancer [23] or job retention [24]. The integration of the experiential knowledge of the stakeholders with the scientific expertise of the researchers is expected to lead to an intervention that is more relevant, feasible, effective and ultimately sustainable [21].

The role of workplace actors in the FASTRACS intervention is particularly important, compared with published studies where this is rarely the case [17, 19]. Employers, managers and colleagues need support to make it easier for an employee to return to work after cancer [32, 54, 55]. The employer guide was developed to answer the unmet needs of managers and colleagues in the RTW process [32, 56].

Another strength of the study is the elaboration of a theoretical logic model of change underlying the FASTRACS intervention [22]. The stages and tools of the FASTRACS intervention were based on different theories of behaviour change according to the results of the initial needs assessment [27]. An ecosystemic and processual model of RTW was developed to provide a theoretical basis for the intervention, based on the trans-theoretical model of change [57], The bioecological model of muman development [58], and the arena model in work disability prevention [20]. The objectives of behaviour change on the part of women, healthcare professionals and workplace actors were explicitly formalised, as were the determinants of these behaviours to be modified by the intervention [59]. This approach responds to a number of shortcomings identified in the literature [17, 23, 24] and will guide a theory-driven evaluation [60] of the FASTRACS intervention with a realist perspective [61]. This methodological pluralism combines an interventional epidemiology paradigm for the evaluation of effects, and a realist evaluation paradigm for the evaluation of the context and mechanisms that produce them. This meets the most recent recommendations for the evaluation of complex interventions by the Medical Research Council in the UK [21].

Limits of the study

Patients without chemotherapy are not included, even though they might nevertheless have problems returning to work. This choice was made in view of the specific additional difficulties caused by chemotherapy [11].

Patients with metastatic cancer cannot take part in the study. Given that recent therapeutic advances have significantly prolonged the duration and quality of life of patients with metastatic disease, it would probably be appropriate in the future to include such patients in this type of study aimed at returning them to work.

Non-employed patients are not included in the study. As they do not have an occupational physician in the French healthcare system, they cannot follow the intervention's logic model. Yet these people have specific needs for which there is no satisfactory response. If the FASTRACS intervention is successful, it will be necessary to adapt its modalities to enable these patients to benefit from it.

Inclusion in the study is limited to oncology departments delivering chemotherapy. These constraints are both logistical (number of centres participating in the study) and methodological (participation of patients who are sufficiently homogeneous to be able to compare the outcome of the intervention). In everyday practice, women with breast cancer may need help to return to work at later stages of their treatment, for example in radiotherapy centres or with their occupational health service.

There is no specific training or monitoring mechanisms to ensure that GPs, OPs and patients' employers use the intervention tools as planned. This may result in uneven fidelity in the implementation of the intervention, leading to variations in its results. These variations will be assessed in the realistic component of the evaluation by identifying the context-mechanism-outcome configurations of the intervention.

Expected impact of the intervention

The expected impact at the individual level of the participants is an improvement in their sustainable return to work 12 months after the end of active oncological treatment. This improvement is likely to enhance their general and work-related quality of life, their financial independence and their social participation. At workplace level, it is expected to improve the social climate and social image (inclusion of vulnerable workers), as well as reducing the costs associated with absenteeism. From a health

insurance perspective, it is possible that the intervention will lead to a reduction in the duration of sick leave and the associated costs. From a societal perspective, it is expected to reduce social inequalities in returning to work after breast cancer.

If the favourable results of the intervention are confirmed, the intervention methods could be extended to working-age population groups with other cancers, or other chronic diseases. The Intervention Mapping protocol used for the first time in France to develop the FASTRACS intervention could be promoted to develop other health promotion programmes contributing to cancer prevention, in areas such as smoking prevention, promotion of physical activity, cancer screening and other health-promoting behaviours.

Abbreviations

BC	Breast cancer
CESREES	Comité éthique et scientifique pour les recherches, les études et les évaluations dans le domaine de la santé
CNIL	Commission Nationale de l'Informatique et des Libertés
CT	Chemotherapy
eCRF	Electronic case report form
EORTC	European Organisation for Research and Treatment of Cancer
EQ-5D 5L	Questionnaire EUROQOL 5 dimensions
FASTRACS	Facilitate and Sustain Return to Work after Breast Cancer
GP	General Practitioner
HAD	Hospital Anxiety and Depression scale
HRQol	Health-related quality of life
IPAQ	International Physical Activity Questionnaire
ISPC	Intersectoral Strategic Participatory Committee
ITT	Intention-to-treat
OP	Occupational Physician
PA	Physical Activity
QLQ	Quality of life questionnaire
RCT	Randomized Controlled Trial
RTW-SE-11	Return-To-Work Self-Efficacy – 11 questions
RUD questionnaire	Resources Utilization in Dementia questionnaire
UICC	Union for International Cancer Control
WRF	Work Role Functioning

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12885-024-12796-4.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions

JBF, BF, LG, MLB, LL, SR, PS and JP designed the trial. JBF, BF, LG, MLB, LL, JP and PS obtained funding. JBF, BF, LG, MLB, LL and JP are involved in the patient recruitment and data collection. All authors developed the intervention with specific input : Occupational health and medicine (JBF), Health psychology and behaviour change (GB, JC), Oncology (JP, BF), Methodology (JBF, BF, LG, MLB, LL, JP), Public health (LG), Patient and public engagement (JBF, MLB, LG), General practice (MLB, LL), Work psychology and social psychology (PS, SR).All authors reviewed the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the French ethics committee CESREES on November 19, 2020 (reference number 2551836) and the study database was reported to the National Commission for Data Protection and Liberties (CNIL) (reference number: DR-2021-101). The study is registered on http://www.clinicaltrials.gov (NCT number: NCT04846972). According to French regulations, all participants expressed their informed consent and non opposition.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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