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Protocol for the development and testing of a web-based patient decision aid for early-stage breast cancer patients within a cancer centre care: a mixed-method approach

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ABSTRACT

Introduction Early breast cancer (BC) detection enhances survival, with treatment options influenced by cancer stage, pathological characteristics and patient preferences. Patient decision aids (PDAs) promote shared decision-making (SDM), enhancing patients' engagement, adherence to treatment and satisfaction. However, few PDAs for early-stage BC patients exist in the Italian context.

Methods and analysis A first developmental phase will include a systematic review on current PDAs and semistructured interviews with patients and healthcare professionals. Outcomes will be used to develop a first draft of PDA. Following international guidelines, the PDA will be sent to patients to gather first qualitative feedback and subsequently quantitative feedback regarding the attractiveness, usability and comprehensibility of the tool and patients' health literacy. Once having reached a final version of PDA, a pilot randomised controlled trial study will be implemented: a control group will receive standard care (n=75) and an experimental group (n=75) will receive standard care and the PDA. Depression, anxiety, SDM, quality of life (QoL) and distress levels will be assessed through validated questionnaires in both groups at three different time points. Measures will include attractiveness, usability and comprehensibility of the PDA as well as efficacy measures assessed through evaluation of patients' levels of anxiety, depression, distress and QoL.

Ethics and dissemination This protocol was approved by the ethical committee Comitato Etico Territoriale Lombardia 2 of the Istituto di Ricovero e Cura a Carattere Scientifico European Institute of Oncology (L2-253; approved in November 2024). All participants will be given written and verbal information, and informed consent will be obtained from all participants across all phases of our project. Participation in the study will be fully voluntary. All the methodologies mentioned in this protocol will be carried out according to both national and international declarations, guidelines and regulations compliant with proper ethical research involving human subjects. Results will be published in peer-reviewed journals, through traditional academic pathways. This protocol study has been registered on clinicaltrials.gov in January 2025 (Identifier: NCT06762496).

Trial registration number NCT06762496.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ *Rigorous multiphase development process:* This study follows internationally recognised IPDAS guidelines and uses a mixed-method approach to ensure methodological robustness;
⇒ *Strong patient-centred approach*: This protocol integrates patients' perspectives at multiple stages, collecting both quantitative and qualitative data directly from patients, increasing the likelihood that the patient decision aid (PDA) will be relevant to patients' needs.
⇒ *Interdisciplinary collaboration*: The involvement of oncologists, radiologists, radiotherapists, surgeons and any other healthcare professional involved in breast cancer care will ensure clinical relevance; the collaboration with information technology specialists will also ensure seamless integration into clinical workflows.
⇒ *Single-centre design*: Conducting the study only within the European Institute of Oncology may limit generalisability of the results, as institutional routines and patient characteristics may differ across other national and/or international oncological centres.
⇒ *Digital literacy challenges*: Despite mitigation strategies, older adults or patients with lower eHealth literacy may struggle to use a web-based PDA, reducing its reach and inclusivity.

INTRODUCTION

Breast cancer (BC) is the most common cancer among women worldwide.[1 2] Based on the cancer stage and pathological characteristics, different prognoses can be identified.[3] The implementation of screening

programmes has demonstrated that diagnosing BC at earlier stages improves optimal prognoses and survival.[4] Early BC treatments include both local and systemic therapies; surgery and radiation can be applied as local treatments, while systemic treatments include hormone therapy, chemotherapy, targeted drug therapy and immunotherapy.[4] In this regard, treatment choice is usually driven by the tumour's expression of biomarkers, specifically hormone receptors and Human Epidermal growth factor Receptor 2 (HER2) expression. However, in the presence of limited evidence, uncertainty of outcomes or equipoise, treatment choice increasingly relies on patients' preferences, which can vary widely among people.[5 6] These decisions are considered preference-sensitive, as they typically involve multiple reasonable options and require a trade-off between risks and benefits.[6] Accordingly, shared decision-making (SDM) is becoming increasingly popular.[7] SDM can be defined as a collaborative approach between healthcare professionals and patients, improving decision-related outcomes.[8–10] Evidence shows that enhanced communication in clinical consultations between patients and physicians, as well as physicians educating, commenting with and orienting patients, enhances adherence to treatment and satisfaction, increasing patients' empowerment in their healthcare process.[11–13] Additionally, according to the literature, patients' involvement in treatment decision-making, discussing treatment options and their related side effects, fosters their psychological well-being.[14 15] In the oncological context, literature demonstrated that if treatment options have similar survival rates, patients' preferences carry even more weight in treatment decision-making.[16]

However, effectively implementing SDM in clinical practice is not always straightforward because of time constraints, complexity of medical information and emotional distress. In this context, decision aids were developed to promote SDM in the patient-healthcare professional dyad. Patient decision aids (PDAs) are tools designed to support the discussions between physicians and patients during deliberations about treatment decisions.[17] They could be relevant in patient-healthcare professional communication during consultations about treatment decisions.[17–19] PDAs can take various formats, from leaflets to videos or interactive multimedia websites, and aim to provide information about the disease, available treatments and side effects while clarifying patients' personal values through preferences assessment. A solid amount of evidence supports the use of a PDA in early-stage BC patients, as it improves patients' knowledge levels about their disease and available treatments, by providing clinically accurate and reliable information. Furthermore, they can also have a beneficial impact on the quality of decision-making, by turning patients into more informed decision-makers, as well as on the satisfaction with the decision made.[14 20–23] In accordance with the PDAs' implementations, evidence shows that women with BC usually prefer to have an active role during medical consultations.[14 24 25] Moreover, women who experience a higher level of SDM are usually more satisfied with decision-related outcomes and less depressed.[26 27] All this evidence, taken together, points to PDAs being useful and non-invasive tools to improve SDM.

Given the aforementioned framework, and the lack of such tools in the Italian context, it becomes necessary to develop a PDA specifically related to early BC patients within an Italian cancer centre care. Therefore, this contribution aims to develop and test a PDAs' protocol for early-stage BC Italian women who receive the diagnosis for the first time. The PDA will be jointly developed by a team of healthcare professionals with experience in research; patients will be included through every step of the developmental process, to monitor the acceptability of the intervention before, during and after the implementation. In so doing, we will be able to thoroughly assess acceptability from different perspectives, as suggested by the Theoretical Framework of Acceptability.[28]

Additionally, the PDA will support SDM by providing healthcare professionals with an easy-to-use tool for standard care and medical consultations, enabling them to better understand patients' attitudes, preferences and needs. Finally, the PDA will be developed as a cross-cultural resource, regularly updated to reflect new emerging oncological therapies for early BC patients based on new scientific findings.

AIMS

The present protocol aims to present a study designed to develop and test a PDA for women who receive a diagnosis of early-stage BC for the first time. Specifically, the primary objective of the study is to evaluate the effectiveness of the PDA in increasing patients' knowledge about early-stage BC treatment options, and in enhancing the alignment between patients' values and their treatment choices. The secondary objective is to explore the impact of the PDA on patients' active engagement during medical consultations, particularly with regard to their perception of involvement in decision-making, satisfaction with the decision-making process and confidence in the choice made. In so doing, we also aim at decreasing patients' levels of anxiety and depression, while improving their quality of life (QoL) and decreasing their perceived distress.

Lastly, the study aims to assess the feasibility and acceptability of the PDA among both patients and healthcare professionals, with attention to its potential for integration into standard oncology care pathways.

METHODS

This protocol study has been registered on clinicaltrials.gov in January 2025 (Identifier: NCT06762496). To develop and test a PDA for women with early-stage BC, different methodologies will be applied. More specifically, the development phase of the PDA will follow a multiphase and mixed methods approach, as suggested

by the guidelines for PDA development supported by a solid amount of literature and recognised by the International Patient Decision Aid Standards Collaboration.[29–32] In particular, the present protocol will be based on a developmental phase, divided into three steps, and an implementation phase, which will include a pilot study.

Patient and public involvement

A multidisciplinary team worked towards the development of this protocol. Psycho-oncologists, healthcare professionals with different expertise and physicians specialised in different aspects of early-stage BC care took part in research design and planning.

Patients' involvement will be fundamental throughout the development and implementation of the PDA in a standard clinical setting. During recruitment, all participants will be informed of study objectives and dissemination plans. Patients will also be asked to review drafts of the PDA at different points in time, focusing on PDA's content, layout and user interface, while providing feedback on clarity, tone and usability.

Developmental phase

Step 1

The first step will be focused on gathering various fundamental information for the development of the PDA. For this purpose, a systematic review will be conducted on currently available PDAs for early-stage BC patients. Moreover, semistructured interviews will be carried out with both patients and healthcare professionals.

In order to investigate these areas of interest, the final research question will be focused on detecting currently available PDAs for early-stage BC patients. During the screening phase, psycho-oncologists with experience in clinical research will include any relevant work regarding PDAs' efficacy and its long-term effects on patients' distress, anxiety, knowledge levels and general well-being. Researchers will also gather data regarding the content, acceptability, feasibility and possible implementation issues and barriers of currently available PDAs for a population of early-stage BC. During the data extraction phase, researchers will put special focus on detecting which are the main variables used to evaluate the efficacy of PDAs across literature. Outcomes from lower socio-economic status and lower health literacy populations will also be included, in order to ultimately develop an inclusive PDA based on the newest findings in this regard. At least three databases will be searched for studies that meet the following inclusion criteria: include females with early-stage BC as a cohort; investigate the impact of a PDA; assesses its acceptability; were published in English; participants did not suffer from any neurological or psychiatric diseases. Qualitative, quantitative and mixed methods studies are going to be included in this systematic review to provide a more comprehensive view on the content and implementation of PDAs in oncological settings.

Simultaneously, we will collect information through semistructured interviews with both patients and healthcare professionals. More specifically, we will interview patients who satisfy eligibility criteria shown in table 1, as well as healthcare professionals who satisfy eligibility criteria shown in table 2. All patients taking part in the semistructured interviews will be under the care of our institution: this will enable us to detect through medical records patients who suffer from psychiatric or neurological disorders and to exclude them. The semistructured interview will take place at the European Institute of Oncology and/or via online platforms (eg, Google Meet, Teams, Zoom) and will last 15–20 min each. Semistructured interviews with patients will focus on the following domains: sociodemographic background; clinical history; treatment decision-making process; social support; level of involvement perceived during medical consultations; advice and words of support they want to share with other women going through an early BC diagnosis for the first time; patients' opinions on the introduction of a PDA in their oncological journey. The semistructured interviews with healthcare professionals will explore: the main features of early-stage BC, available treatments and main side effects; the standard counselling process; treatment decision-making process; patients' engagement and physicians' perceptions of patients' interests regarding illness details. A detailed overview of the semistructured interviews' questions is reported in online supplemental material 1.

Table 1 Eligibility criteria for patients involved in the developmental phase of the study

Inclusion criteria	► Female (assigned female at birth); ► 18 or older; ► At least one diagnosis of resectable early-stage breast cancer (BC) (0–2A); ► Patients treated or undergoing oncological treatment for early-stage BC (0–2A) at the time of the developmental phase; ► Absence of psychopathological features; ► BC patients who are willing and able to provide written informed consent for participation.
Exclusion criteria	► BC patients who showed physical or psychological issues, cognitive impairments, neurological or psychiatric disorders that may compromise the patients' ability to take part in the study; ► BC patients with distant metastases from BC or locally advanced/unresectable diseases; ► Known substance abuse or psychiatric disorders that would impact the cooperation with the requirements of the participation.

Table 2 Eligibility criteria for healthcare professionals taking part in the developmental phase of the study

Inclusion criteria	► Healthcare professionals working at the European Institute of Oncology; ► Healthcare professionals with at least 5 years of expertise in treating breast cancer; ► Healthcare professionals who consent to take part in the study.

The number of participants for each group will be defined by data saturation, defined as the point at which no new information or themes emerge from the dataset; to determine data saturation information redundancy will be evaluated, while also detecting the diminishing emergence of new themes from the semistructured interviews with both healthcare professionals and patients.[33 34] We expect to reach data saturation at the end of no more than 30 semistructured interviews with healthcare professionals and 20 semistructured interviews with patients. In spite of estimating a maximum number of 50 semistructured interviews, it is possible we will reach data saturation before that. Each interview will be conducted by a psychologist expert in the psycho-oncological field. The interviews will be audio recorded and transcribed, so as not to miss any relevant information and to enable us to conduct a thematic analysis.[35 36] More specifically, all transcriptions will be anonymised: at least two independent researchers with experience in clinical thematic research will go through the content in order to become familiar with the data. Subsequently, they will identify initial codes to highlight segments of interest, following a bottom-up approach derived straight from the data. Therefore, themes and subthemes will be identified during the process of thematic analysis: codes will be aggregated into subthemes and then into main themes. Any discrepancy in coding and/or identification of main themes will be resolved through discussion and an external researcher, excluded from the initial data analysis phase, will validate the themes so identified.

At the end of Step 1, a first draft of PDA will be developed. The contents will be drawn from data collected from the systematic review and the semistructured interviews, considering evidence-based and recent information regarding early BC and available treatments. Moreover, the contents will be revised by expert healthcare professionals who were not involved in the previous research phase. A first draft will be developed in collaboration with an information technology (IT) company with expertise in implementing digital solutions for the healthcare system.

Step 2

The second step will focus on qualitatively evaluating the usability and comprehensibility of the first version of the PDA. 20 patients who satisfy the eligibility criteria shown in table 1 will be contacted and, if consent is obtained, they will receive via mail the PDA in its first version for them to consult. Patients will be asked to take notes of any misleading, unclear and/or missing content, along with its limits and strengths. Afterwards, semistructured interviews will be conducted in person or online by a psycho-oncologist to discuss the PDA's features and provide feedback on any helpful or misleading/unclear characteristics. For a detailed overview of semistructured interviews' questions, see online supplemental material 2. As for Step 1, the interviews will be audio recorded and transcribed. At the end of the semistructured interviews, a thematic analysis will be conducted to identify the main topics of interest.[35 36] If data saturation is not reached after 20 semistructured interviews, more early-stage BC patients will be recruited. Data gathered from this second step will allow us to revise the first draft of the PDA and obtain a second one, which will be evaluated in the third step.

Step 3

This phase will investigate the usability and comprehensibility of the second draft of the PDA through a mixed methods approach consisting of both qualitative and quantitative evaluations. 30 early-stage BC patients who satisfy the eligibility criteria shown in table 1 will be recruited and, if consent is obtained, they will receive the second draft of the PDA. In addition, participants will be asked to fill in a Qualtrics link with socio-demographic questions, open-ended questions and self-administered standardised questionnaires to assess the second version of the PDA. Specifically, data will be collected regarding:

- The attractiveness of the PDA in terms of usability and appearance. This measure will be taken through the AttrakDiff,[37 38] a questionnaire consisting of 32 7-point bipolar items that represent opposite qualities (eg, good-bad) and measures the following dimensions: pragmatic quality; hedonic quality—identity; hedonic quality—stimulation; attractiveness. Since this questionnaire has not yet been validated for the Italian population, we will ask an English mother-tongue expert in assessment tools to back-translate the already-validated English version.
- The subjective assessment of the usability of the PDA, through the System Usability Scale,[39] a simple 10-item scale which investigates the complexity or intuitiveness experienced while navigating through the tool;
- The information's effectiveness, comprehensibility, usability and value through a 38-item specific questionnaire to measure satisfaction with the PDA, adapted from Petersen *et al*.[40]
- Knowledge, comfort and perceived skills at finding, evaluating and applying electronic health information to health problems. This domain will be evaluated through the eHealth Literacy Scale (eHEALS),[41] an eight-item measure of e-health literacy and the perceived ability to distinguish between reliable and unreliable online information.

Table 3 Eligibility criteria for patients involved in the prospective experimental study

Inclusion criteria	► Female (assigned female at birth); ► 18 or older; ► A diagnosis of resectable early-stage breast cancer (BC) (0–2A) for the first time; ► Absence of psychopathological features; ► Provide written informed consent for participation.
Exclusion criteria	► BC patients who show physical or psychological issues, cognitive impairments, neurological or psychiatric disorders that may compromise the patients' ability to take part in the study; ► BC patients with distant metastases from BC or locally advanced/unresectable diseases; ► Known substance abuse or psychiatric disorders that would impact the cooperation with the requirements of the participation.

All questionnaires can be viewed in detail in online supplemental material 3. Data collected during this third step will be included in the development process of the third and final version of the PDA, which will be tested in a pilot study.

Implementation phase

The last and final step will involve a pilot study to assess how using the PDA will impact SDM, patients' QoL and emotions. After a screening phase, patients who satisfy the eligibility criteria shown in table 3 will be recruited. 150 patients will be randomly assigned to 1 of 2 different groups: intervention group, in which 75 participants will go through the final version of the PDA right before their encounter with the physician and then receive via mail a Qualtrics link with a battery of questionnaires; control group, in which other 75 participants will only receive via mail the online link with the battery of questionnaires without having envisioned the PDA. Both groups will receive this email after the diagnosis and before the medical consultations with physicians. Both groups will be asked to complete the online battery of questionnaires three times: 1 week after the first medical consultation (T0), 1 month after the first medical consultation (T1) and 3 months after the first medical consultation (T2). If participants do not complete the questionnaires, an automatic reminder will be sent 1 week after the initial email and 2 weeks after the first reminder. The questionnaires will be as follows:

- Patient-Health Questionnaire for Depression (PHQ-9), a nine-item self-report scale which investigates and evaluates the severity of depressive symptoms[42];
- State-Trait Anxiety Inventory (STAI), a validated 20-item self-report assessment tool that investigates both state anxiety and trait anxiety[43];
- Shared Decision-Making Questionnaire—9 (SDM-Q-9), a nine-item self-report assessment tool which investigates the level of SDM experienced in the clinical setting[44];
- Distress thermometer, a screening tool which investigates and assesses psychological distress in oncological populations[45];
- EORTC-QLQ-C30 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire),[46] a 30-item tool developed by the European Organization for Research and Treatment of Cancer to assess QoL in oncological patients;
- EORTC-QLQ-BR23,[46] a five multi-item scale developed by the European Organization for Research and Treatment of Cancer used on BC patients to assess body image, sexual functioning, systemic therapy side effects, breast symptoms and arm symptoms.

PDA contents and implementation procedure

We will base the content of our PDA on findings from our systematic review regarding current and already available PDAs for early-stage BC population. However, we do expect the content of our PDA to focus on information regarding medical examinations necessary for diagnosis, the different biomarkers used for diagnosis and staging procedure, the different possible treatments and side effects, surgery options and related differences. We also expect the PDA to include other patients' experiences and to provide a space for patients to write down their thoughts, doubts and questions they can then ask their healthcare professionals at their next appointment.

1. Standard care procedure for early-stage BC patients within our Institute is usually structured in three different steps, defined as follows:
2. Patients underwent a radiological examination (either within our Institute or at another hospital), from which a dubious mass appeared;
3. Patients undergo a biopsy to determine the mass's histological characteristics, which determines the malignancy of the tumour;

At this point, patients are informed regarding their diagnosis and first appointments with healthcare professionals (usually oncologists) are scheduled. Simultaneously, the multidisciplinary committee assigned to each case convenes on the best course of action and an oncological care plan is formed, which will be delivered to the patient in person during the first consultation.

Our intervention will take place within the third step, after patient have been informed of their diagnosis and before their scheduled meeting with their healthcare professional. More specifically, after having obtained a list of eligible participants directly from healthcare professionals involved in the process of diagnosing, psycho-oncologists with experience in clinical research will contact eligible participants and ask for their consent to

take part in the study. If consent is obtained, each participant will be randomised to the intervention or the control group. Participants randomised in the intervention group will be given access to the web-based PDA before their first consultation, as to familiarise with the patient journey and promote SDM during the first consultation.

The web-based PDA will be developed through a collaboration with an IT company with expertise in implementing new technologies within clinical care. More specifically, the IT company will collaborate with our Institute's informatics team in order to set up a data server and a website created specifically to access the PDA from our institute's Wireless Local Area Network (W-LAN). Psycho-oncologists in charge of recruiting participants for our randomised control trial will log onto the website as admins, generate a unique username and password for each new participant and provide them to recruited patients. In so doing, we will ensure data security, privacy and anonymisation to all participants. Any data regarding PDA consultation (duration of visit, interactions with various subheadings) will be available only to healthcare professionals who were in charge of recruiting patients.

RANDOMISATION, SAMPLE SIZE AND STATISTICAL ANALYSIS FOR THE PILOT STUDY

The primary analysis will consider the following endpoints at T0, T1 and T2 (respectively, 1 week, 1 month and 3 months later the first medical consultations):

- Depression scores, as measured through the PHQ-9;
- Anxiety scores, as assessed through the STAI;
- SDM levels, as measured through the SDM-Q-9;
- Psychological distress levels, as assessed through the distress thermometer;
- QoL scores, measured through the EORTC-QLQ-C30 and the EORTC-QLQ-B23.

The difference between T1 and T0 and T2 and T0 will be calculated for each endpoint. These differences are assumed to follow a normal distribution. Should deviations from normality be observed (assessed graphically via Q-Q plots), a suitable transformation will be applied to approximate normality. Since two follow-up time points (T1 and T2) are considered relative to the baseline (T0), a mixed-effects model will be implemented to evaluate the mean effect of PDA over time, accounting for both fixed effects of the intervention and random effects due to individual variability. To account for multiple testing, the p-value associated with the intervention for each evaluated endpoint will be adjusted using a Bonferroni correction. Specifically, an effect will be considered statistically significant if its p-value is less than 0.05 divided by six (ie, p<0.0083).

In the sample size calculation, the effect size is used to quantify the magnitude of the intervention's impact for each of the specified endpoints. An effect size of 0.5 is assumed for each endpoint, indicating a moderate impact of the intervention. Effect size is a standardised measure reflecting the difference between groups, allowing for comparison across endpoints. This means we expect the mean change due to the intervention, when compared with the mean change expected without intervention, to be at least half the pooled SD of the change. Additionally, an intra-patient correlation coefficient of 0.5 (moderate correlation) is assumed between the changes from baseline (T0) to follow-up time points (T1 and T2). This correlation is accounted for in the sample size estimation. Under these assumptions, a total sample size of 150 early-stage BC patients (75 assigned to the PDA group and 75 assigned to the control group) is needed to reject the null hypothesis (effect size=0) with an 80% power when the alternative hypothesis (effect size=0.5) holds. This calculation also accounts for the predefined threshold for rejecting the null hypothesis, set at 0.0083 (Bonferroni correction for six tests to control the overall type I error rate at 0.05).

The power calculation was carried out by means of a simulation study. The main analysis will be conducted using the PROC MIXED procedure in SAS (Mixed Procedure within the Statistical Analysis System), fitting a single linear mixed-effects model for each endpoint that jointly analyses the two change scores (T1–T0 and T2–T0) per subject. The model includes a fixed effect for treatment and a random intercept for each subject to account for within-subject correlation across time points. The model is specified as:

$$\text{Change}_{ij} = \beta_0 + \beta_1 \times \text{TRT}_i + u_i + \varepsilon_{ij}$$

where Change_{ij} is the change from baseline score for subject i at time point j (j=1 for T1–T0, j=2 for T2–T0); β_0 represents the mean change in the control group; β_1 represents the average treatment effect across the two time points; TRT_i is the treatment group for subject i (0=control, 1=PDA); u_i is a random intercept for subject i; ϵ_{ij} is the residual error.

As a secondary analysis, the potential effect of time on the PDA effect will be evaluated by including the time variable and its interaction with intervention among the fixed effects in the mixed-effects models.

The randomisation list for the pilot study aimed at testing the efficacy of PDA intervention will be prepared by the study's statistician, and a block randomisation scheme will be used to randomly assign patients to the control group or the experimental group. The block size will vary from 4 to 8. The 'blockrand' R package will be used to generate the randomisation list[47] (Blockrand: Randomisation for block random clinical trials R package V.1.3 http://CRAN.R-project.org/package=blockrand).

ETHICS AND DISSEMINATION

This protocol was approved by the ethical committee Comitato Etico Territoriale Lombardia 2 of the Istituto di Ricovero e Cura a Carattere Scientifico European Institute of Oncology (L2-253; approved in November 2024). Written and verbal information will be provided and informed consent will be obtained from all participants,

both patients and healthcare professionals, across all phases of our project. Participation in the study will be fully voluntary. No fees will be charged to the participants, and no payments will be made. All the methodologies mentioned in this protocol will be carried out according to both national (ie, GCPs (Good Clinical Practice)) and international declarations (ie, Declaration of Helsinki), guidelines and regulations compliant with proper ethical research involving human subjects. Dissemination plans involve traditional academic pathways, and results will be published in peer-reviewed journals or conference abstracts.

Data statement and protection

Patient data will be anonymised and treated with confidentiality, ensuring that it cannot be associated in any way with the individual. For this purpose, a sequential identification number will be assigned to each patient registered in the trial. All data gathered from this project, including the identification number and patients' names, will be stored along with all clinical data related to the state of health. Only the authorised parties will be able to access these data. Any publications derived from the study data will be written by the investigator and co-investigators of the study and published in a peer-reviewed scientific journal.

EXPECTED OUTCOMES

This project started in September 2024 and is scheduled to be completed by August 2026. The main results will be published following data analysis and after this study has reached its primary objective. Since the developmental phase of our proposal is based on internationally recognised standards for the development of a PDA, together with up-to-date clinically accurate information gathered both from clinical experts in the field and scientific findings, we aim at developing a reliable, clear and useful tool, easy to be implemented in daily clinical practice and well-accepted by both patients and physicians. By taking care of patients' sociodemographic characteristics, we also aim to develop a tool that would be inclusive both cross-culturally and with regard to lower health literacy populations. More specifically, during all phases of our PDA development, patients' sociodemographic characteristics such as level of education, age and region of origin will be gathered, in order to control for sociocultural differences and preventively act on any possible disparities while developing the PDA. Since we will initially implement our newly developed PDA within our institute based in Milan, Italy, we expect the majority of patients to be Italian speakers. Nonetheless, in order to make it available to international patients, we will be making the PDA available also in English. Whether non-Italian, English-speaking eligible patients will consent to take part in our study, we will gather data regarding PDA's efficacy using the English version of the assessment tools listed in the previous sections. This will ensure us the possibility to gather relevant data on which we will conduct further research on cross-cultural development of our tool, as to ultimately validate our tool across different cultures. Moreover, our newly developed PDA will be adapted to new advancements in oncological treatments for early-stage BC. Given the highly patient-centred development of our PDA, we expect to receive high scores on the questionnaires assessing the acceptability, usability, comprehensibility and attractiveness.

Additionally, based on the solid amount of literature supporting the use of PDAs in oncological settings, we expect to find significant differences between the intervention and control group. Particularly, we will be looking into depression and anxiety levels, SDM experienced by patients during medical consultations, psychological distress and QoL in patients with early-stage BC. We expect that the intervention group experiences less anxiety, depression and psychological distress due to the exposure to PDA's informational content. At the same time, we expect the experimental group to experience higher levels of SDM and a generally better QoL, compared with the control group. Furthermore, we expect different patterns between the two groups across the three different assessment periods (T0, T1, T2). For instance, we expect anxiety levels, depression levels and psychological distress levels to drop more rapidly among patients from the intervention group when confronted with outcomes from the control group.

The joint collaboration between healthcare professionals from different expertise (radiologists, radiotherapists, oncologists, surgeons, psycho-oncologists and other relevant roles) will be fundamental to the development of PDA's content. Such collaboration will guarantee a collection of strongly reliable and accurate information coming from all different parts involved in the oncological journey of an early-stage BC patient.

However, the present protocol also shows some limitations. First, the PDA resulting from the present protocol will be tailored to the specific needs of patients and healthcare professionals within the European Institute of Oncology. However, given that few PDAs are currently employed in Italian oncological care contexts, such newly developed PDAs for early-stage BC patients may have a significant impact on our community also at regional and national level and might therefore be of use to implement also outside the European Institute of Oncology. Nonetheless, before rendering it available to other hospitals both at the regional and national levels, further research might be needed regarding other care centres implementation policies and standard care, in order to develop a tool that is cross-cutting across different institutes.

Moreover, literature shows that older oncological patients experience issues in using online platforms to seek health information and prefer obtaining information from paper-based resources and/or physicians. In fact, despite reporting that web-based information is highly accessible and easily consultable, older oncological patients showed difficulties in using online

resources, displayed less online Health Information Seeking Behaviour (HISB) than younger patients and had problems interacting with navigational elements.[48–51] In order to ease PDA's consultation for all ages, when developing the PDA, particular attention will be given to older patients' feedback about the online drafts: whether navigating difficulties may arise, a simplified layout or a consultation guide will be implemented.

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Contributors SS wrote a first draft of this submission, together with VS. DM and VB reviewed and implemented the first draft. RG reviewed the final version, together with CC and PZ. GP is the principal investigator, the guarantor of this project and supervises the work together with GC.

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Competing interests None declared.

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