

# IMPROVING CARE OF EARLY BREAST CANCER (EBC) PATIENTS IN EUROPE

Investigators  
Meeting

Vienna, AT  
12 March 2025



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# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: a new tool to promote patients' empowerment in their healthcare process

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# State of the Art

## PATIENT DECISION AIDS FOR BC PATIENTS:



A tool that might be used by patients either before or within a consultation with physicians



Informing patients about the main treatments for a BC by focusing on both pros and cons of each option



Comparing available treatment options



Eliciting patients' preferences and values about the main treatment options for BC



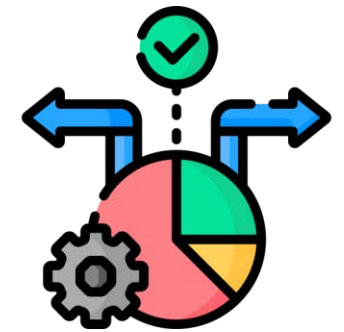
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### Patient Decision Aid (PDA)

- Providing information
- Clarifying preferences
- Fostering discussion with clinicians

### Shared Decision Making

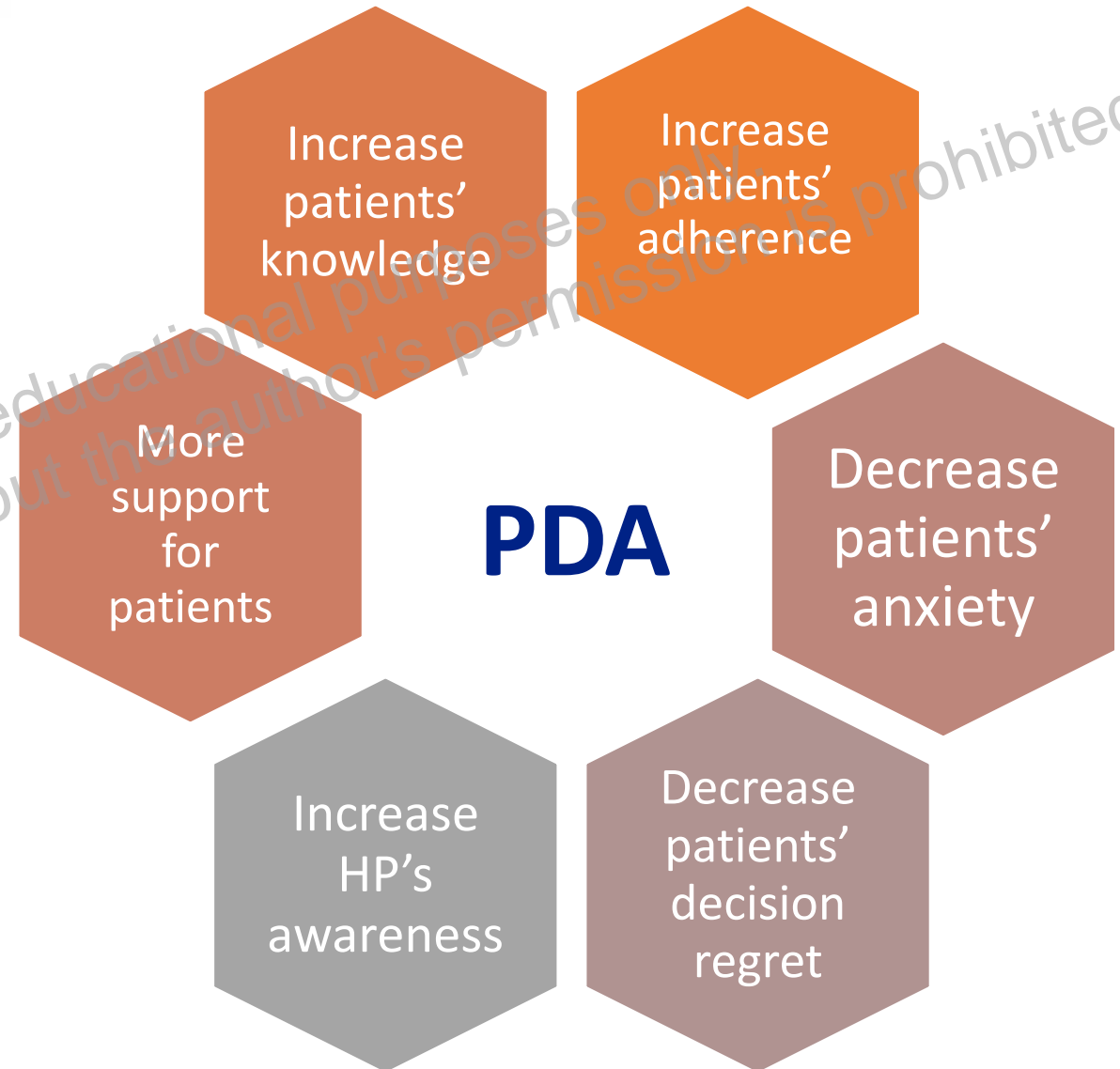
- Simultaneous participation of physicians and patients in all phases of treatment decision-process
- Increased empowerment and engagement in patients and therefore more adherence to treatment
- Aiding physicians during consultations



# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Aim of the project

Favour the encounter between patients and clinicians by:

- Providing support and knowledge to patients while also decreasing their distress levels;
- Increasing Healthcare Professionals' awareness on patients' needs and preferences



# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Methodology and timetable

WP1	WP2	WP3	PILOT
Systematic review	1° draft is sent to 20 patients	2° draft sent to 30 patients	Prospective study
Semi-structured interviews with 20 patients	Semi-structured interviews <b>QUALITATIVE MEASURES</b>	Questionnaires: Attrakdiff, SUS, e-heals, 38-item study-specific <b>QUANTITATIVE MEASURES</b>	N= 150; Randomly assigned to Control Group and Experimental Group
Semi-structured interviews with 30 physicians			Questionnaires: SDM; QLQ23; QLQ30; STAI; PH9; Distress Thermometer (at T0, T1, T2)

*1° DRAFT*

*2° DRAFT*

*3° DRAFT*

6 months

12 months

21 months

September 2024

August 2026





# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Status of the project

## WP1

Systematic review



*The impact of decision tools in treatment decision-making for women with early-stage breast cancer: A systematic review*

Serena Sdinami, Lorenzo Conti, Benedetta Capetti, Valeria Sebri, Roberto Grasso, Paola Zagami, Carmen Criscitiello, Giuseppe Curigliano, Gabriella Pravettoni

*Submitted at BMC Journal – Medical informatics and Decision-Making*



### Aim

Gather as much information as possible regarding current, available PDAs, what is considered to be useful and acceptable by both patients and healthcare professionals

### Methods

26 included studies:

- Different study designs
- Qualitative, Quantitative and Mixed Methods outcomes
- Lower Socio-Economic Status and lower health literacy populations

6 months



September 2024

March 2025

# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Status of the project

## WP1

Systematic review



*The impact of decision tools in treatment decision-making for women with early-stage breast cancer: A systematic review*

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## Results

**PDA has positive impact on:**

1. Providing information (knowledge scores increased)
2. Improving the quality of decision-making process and satisfaction
3. Not increasing levels of depression and/or anxiety in patients
4. Lower SES/health literacy populations

## Barriers

**Challenges of PDA development:**

1. Easy-to-use PDA for HP professionals
2. Implementation issues at the national and international level





# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR

## Early BC:

### Status of the project



Age Range: from 25 to 60 years old

Education level: at least bachelor degree

#### Investigated areas:

- Socio-demographic information
- Diagnosis and treatment choice
- Consultations with physicians: did the patient experience SDM?
- Received social support (family, friends, caregivers)

6 months

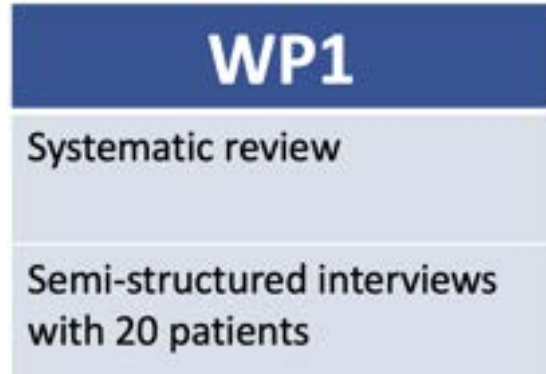


September 2024

March 2025

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# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Status of the project



**Age Range:** from 25 to 60 years old

**Education level:** at least bachelor degree

**Outcomes:**

- Difficulty absorbing information during consultations due to high anxiety levels;
- Difficulty communicating with physicians due to time constraints and/or lack of medical knowledge;
- Difficulties with managing side effects of treatments at home;
- Wanting to reach out to other patients and experiences;
- Difficulty explaining their journey to caregivers, family and close friends.

6 months



September 2024

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# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC:

## Status of the project



6 months



September 2024

March 2025

**Interviews with:** Oncologists, Radiologists, Radiotherapists, Surgeons

**Investigated areas:**

- Socio-demographic information;
- Clinical information regarding breast cancer, staging, diagnosis and treatments available;
- Medical consultations: how does a standard consultation take place? (eg. does it follow a script or is it adapted to the individual physicians are talking to?)
- What are the medical concepts that most patients struggle to understand?
- «Would you use a PDA during your consultations? Do you foresee any implementation issues?»

# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Status of the project

WP1
Systematic review
Semi-structured interviews with 20 patients
Semi-structured interviews with 30 physicians



6 months



September 2024

March 2025

## Oncologists:

- Difficulty grouping BCs in clear treatment categories, also due to contrasting literature results;

## Radiologists:

- Difficulty for the patients to fully comprehend the «next steps» after having found a mass on the breast;

## Surgeons:

- Difficulties in choosing between breast conserving surgery and mastectomy (when possible);

## Radiotherapists:

- Misconceptions about the treatment and side effects (radioactivity!);

Difficulties in efficiently answering to patients' email and questions in a timely manner due to work overload → BURDEN ON HP

# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Status of the project

WP1
Systematic review
Semi-structured interviews with 20 patients
Semi-structured interviews with 30 physicians

Starting from the outcomes of the WP1 we developed a first draft of the PDA.

1. Meets both Healthcare Professionals and patients' needs
2. Assesses the barriers emerged during our systematic review

**1° DRAFT**



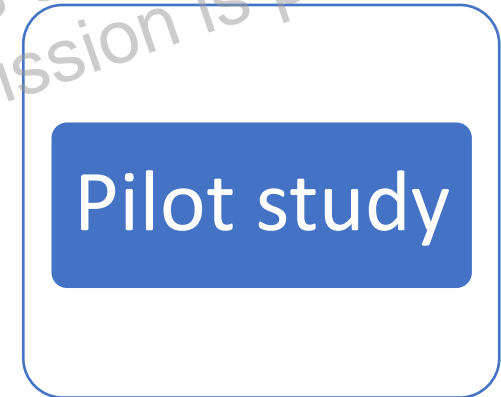
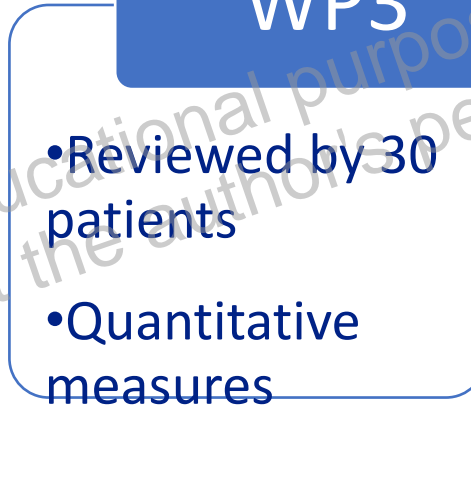
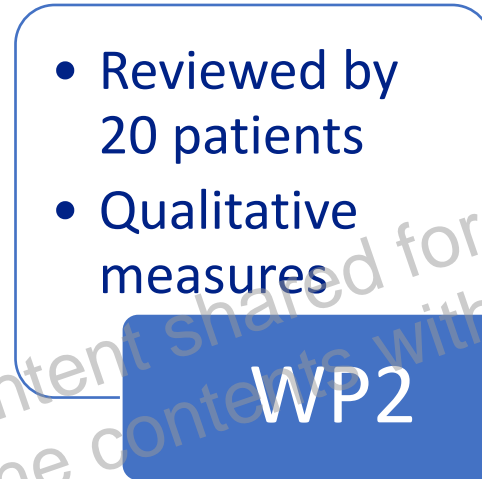
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# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: Status of the project

1° DRAFT

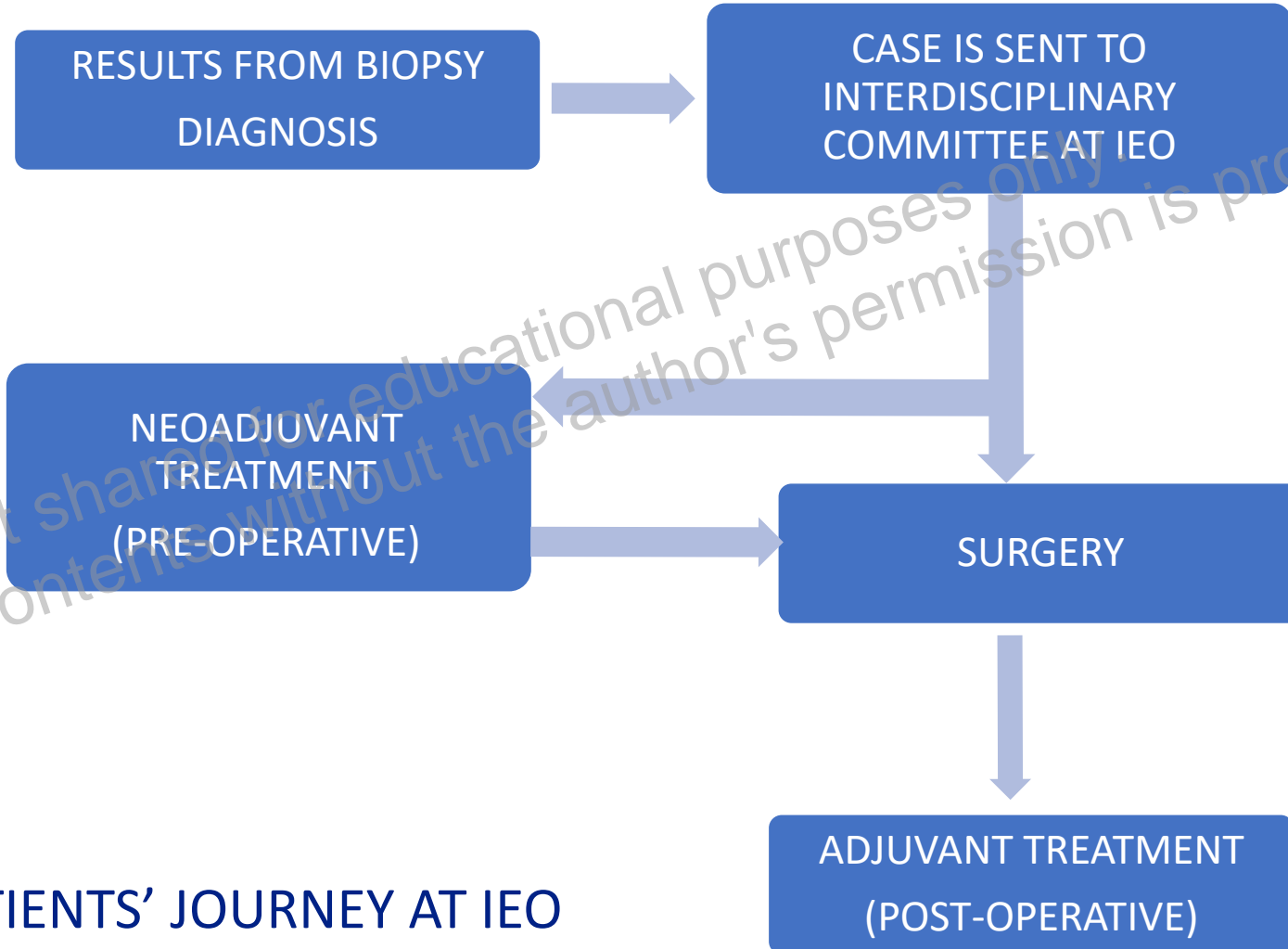


From now on, we will move on to WP2 and WP3, in order to develop a PDA in line with the International Patient decision Aid Standard Collaboration (IPDAS) before starting our Pilot Study.

# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: WHAT NEXT?

**PILOT**

Prospective study  
N= 150;  
Questionnaires



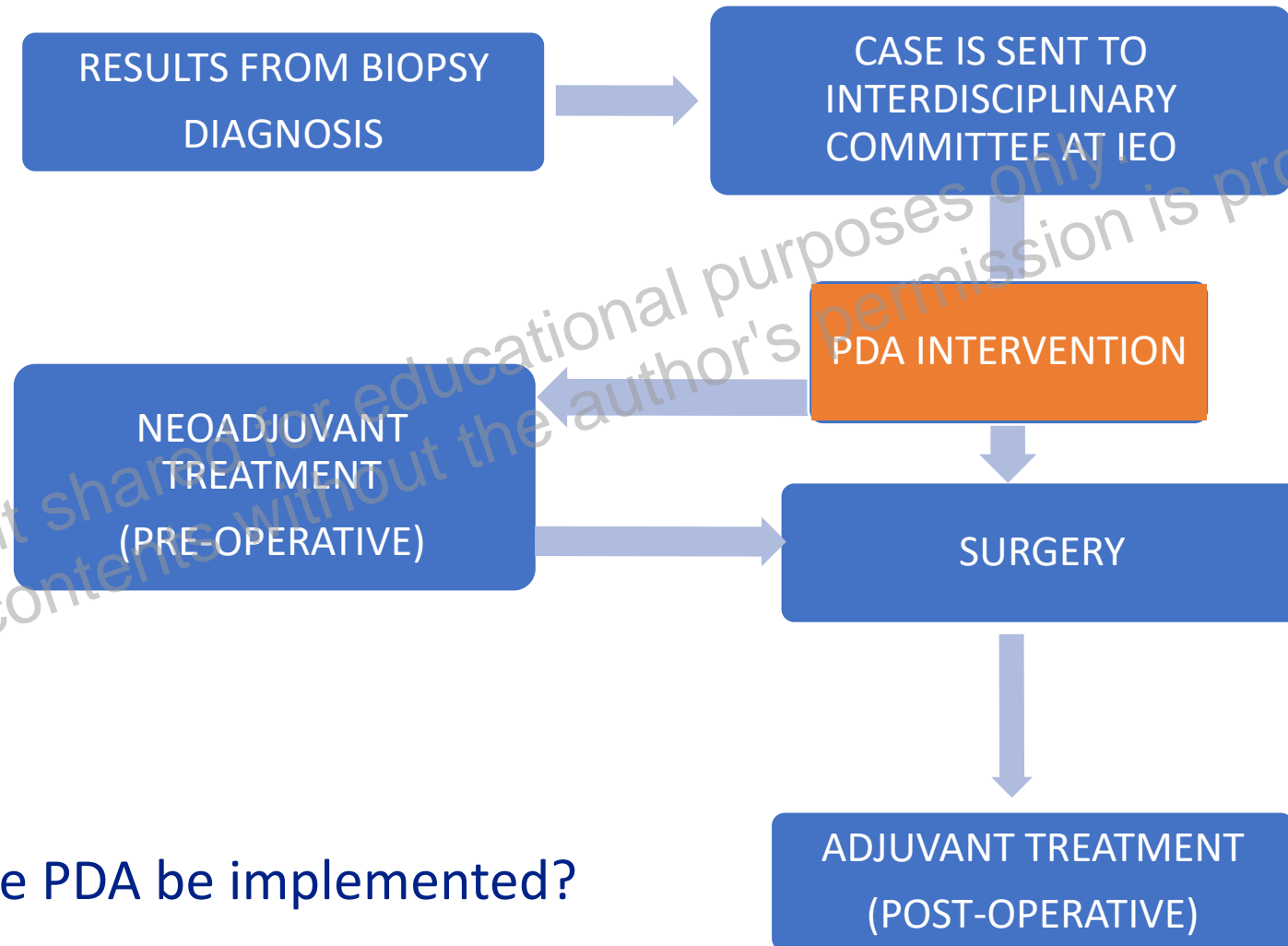
STANDARD PATIENTS' JOURNEY AT IEO

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# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: WHAT NEXT?

**PILOT**

Prospective study  
N= 150;  
Questionnaires



When will the PDA be implemented?

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# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: WHAT NEXT?

## PILOT

Prospective study

N= 150;

Questionnaires

## RANDOMIZATION INTO CONTROL GROUP OR EXPERIMENTAL GROUP

- N=75 Standard Care (Control Group)
- N=75 Standard Care + PDA (experimental group)

## QUESTIONNAIRES

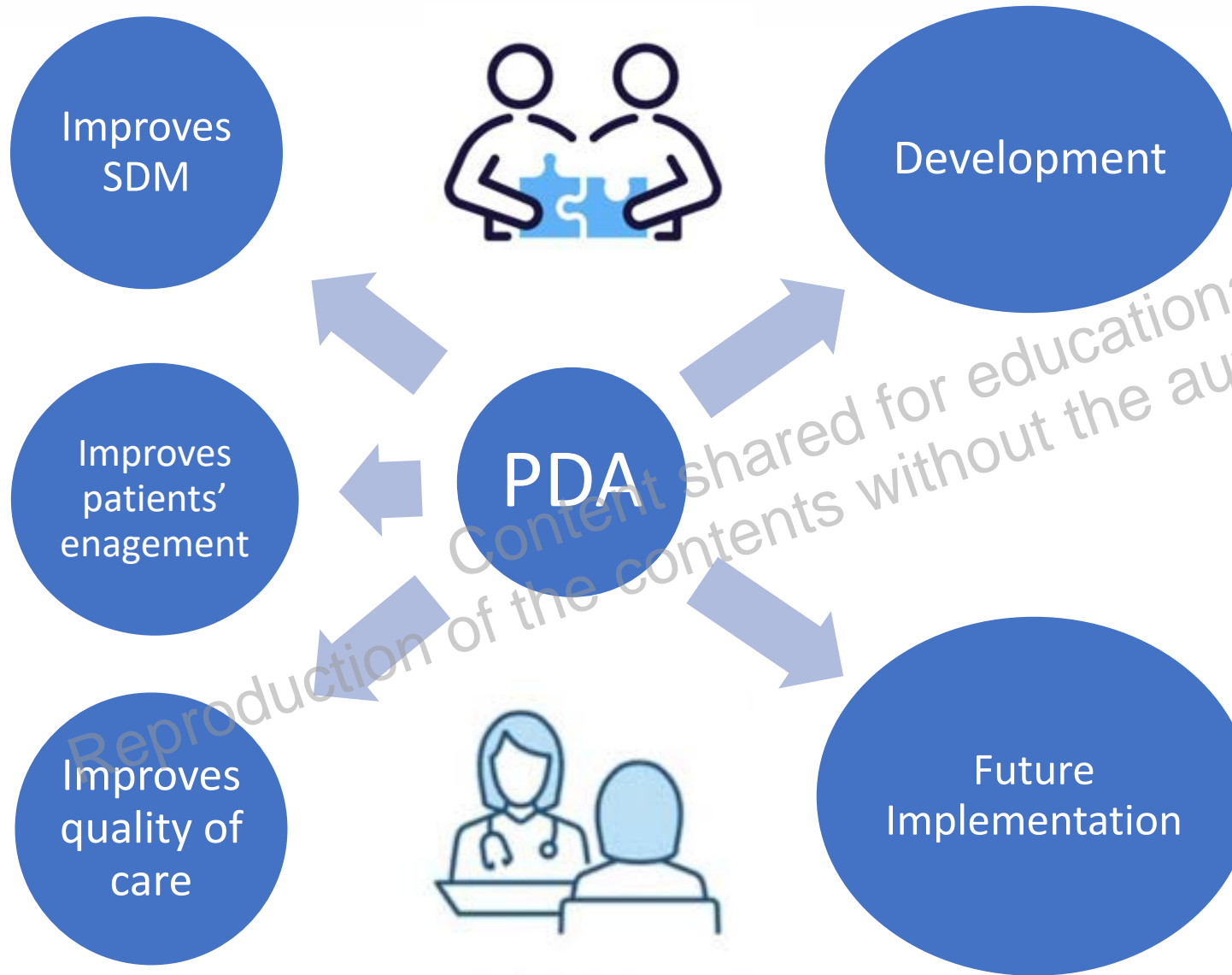
- SDM for shared decision making
- QLQ23 and QLQ30 for Quality of Life in oncological patients
- STAI for state and trait anxiety
- PH9 for depression
- Distress Thermometer for distress

Will be administered at:

- T0: one week after the first medical consultation
- T1: one month after the first medical consultation
- T2: three months after the first medical consultation



# DEVELOPMENT AND TESTING OF A Patient Decision Aid FOR Early BC: What do we know so far and what needs to be done



During Development Phase: Focus on patients' needs and what is beneficial, useful, helpful for them

During future Implementation Phase: Focus on systemic gap that may influence PDA's effectiveness

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# Recommended readings

## Evidence update of PDA efficacy in oncological decision-making

- [https://www.cochrane.org/CD001431/COMMUN\\_patient-decision-aids-help-people-who-are-facing-decisions-about-health-treatment-or-screening](https://www.cochrane.org/CD001431/COMMUN_patient-decision-aids-help-people-who-are-facing-decisions-about-health-treatment-or-screening)

## Sources for PDA content development

- <https://interactiveguidelines.esmo.org/esmo-web-app/toc/index.php?subjectAreaID=8&loadPdf=1>
- <https://www.aiom.it/linee-guida-aiom-2023-carcinoma-mammario-in-stadio-precoce/>

## PDA DEVELOPMENT – guidelines (updated)

- <https://decisionaid.ohri.ca/IPDAS/>
- Stacey D, Volk RJ. The International Patient Decision Aid Standards (IPDAS) Collaboration: Evidence Update 2.0. Medical Decision Making. 2021;41(7):729-733. doi:10.1177/0272989X211035681
- Witteman HO, Maki KG, Vaisson G, et al. Systematic Development of Patient Decision Aids: An Update from the IPDAS Collaboration. Medical Decision Making. 2021;41(7):736-754. doi:10.1177/0272989X211014163



# IEO Project Team



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# Thank you



**Sharing Progress in Cancer Care**

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