Sharing Progress in Cancer Care

QUALITY OF CARE IMPROVEMENT IN MBC PATIENTS INVESTIGATORS MEETING

Lisbon - 8 November 2023

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“Enhancing therapy adherence among metastatic breast cancer patients”

Sharing Progress in Cancer Care

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SPORE DATA

IEO Istituto Europeo di Oncologia

QUALITY OF CARE IMPROVEMENT IN MBC PATIENTS
INVESTIGATORS MEETING

Sharing Progress in Cancer Care

Pfizer

METASTATIC BREAST CANCER DISEASE

Epidemiology aspects

More than **281.550 new cases** of invasive breast cancer have been reported in the 2021.

Around **3%-6%** of the breast cancer patients have **metastatic disease** at the time of diagnosis.

10%-30% of patients with early breast cancer later develop systemic recurrence.

METASTATIC BREAST CANCER (MBC) INCIDENCE

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ADHERENCE TO ORAL ANTICANCER TREATMENTS

A Journey into the Complexity

- **MBC** is an **incurable disease** and medications are focused on deferral disease progression and symptoms mitigation.

- **MBC patients** present pain and fatigue, and an increased difficulty with physical, social, and emotional functioning.

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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

ESMO Expert Consensus Statements on Cancer Survivorship: promoting high-quality survivorship care and research in Europe

I. Vaz-Luis[1,2*], M. Masiero[3,4], G. Cavaletti[5], A. Cervantes[6,7], R. T. Chlebowski[8], G. Curigliano[3,9], E. Felip[10], A. R. Ferreira[11,12], P. A. Ganz[13], J. Hegarty[14], J. Jeon[15], C. Johansen[16], F. Joly[17], K. Jordan[18,19], B. Koczwara[20], P. Lagergren[21,22], M. Lambertini[23,24], D. Lenihan[25], H. Linardou[26], C. Loprinzi[27], A. H. Partridge[28], S. Rauh[29], K. Steindorf[30], W. van der Graaf[31,32], L. van de Poll-Franse[33,34,35], G. Pentheroudakis[36], S. Peters[36] & G. Pravettoni[3,4]

Contents lists available at ScienceDirect

The Breast

journal homepage: www.journals.elsevier.com/the-breast

Progression-free survival and quality of life in metastatic breast cancer: The patient perspective

Shirley Mertz [a], Christine Benjamin [b], Charis Girvalaki [c], Antonella Cardone [c], Paulina Gono [c], Suepattra G. May [d,*], Erin Comerford [e], Kyi-Sin Than [d], Kelly Birch [d], Meaghan Roach [d], Sky Myers [d], Medha Sasane [e], Liat Lavi [e], Anna Cameron [e], Fatima Cardoso [f]

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(Mertz et al., 2022; Yerrapragada et al., 2021)

ADHERENCE TO ORAL ANTICANCER TREATMENTS

A Journey into the Complexity

Call to Action for Improving Oral Anticancer Agent Adherence

Laura A. Levit, JD[1]; Shaily Arora, PharmD[2]; Paul G. Kluetz, MD[3]; Allison Magnuson, DO[4]; Atiqur Rahman, PhD[3]; and R. Donald Harvey, PharmD[5]

Journal of Clinical Oncology®
An American Society of Clinical Oncology Journal

Original Investigation | Oncology

October 13, 2022

Factors Associated With Patients Not Receiving Oral Anticancer Drugs

Sahil D. Doshi, MD[1]; Morgan R. L. Lichtenstein, MD[2,3]; Melissa P. Beauchemin, PhD, MSN, CPNP[3,4]; et al

Author Affiliations | Article Information

JAMA Netw Open. 2022;5(10):e2236380. doi:10.1001/jamanetworkopen.2022.36380

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- The clinical advancements achieved in anticancer treatments have increased the **5-year survival rate** around **38%**.
- **Oral anticancer treatments** (OATs) have changed the oncology treatment landscape, accounting for 40%–50% of new cancer treatments in development.
- Notwithstanding, **adherence to OATs is suboptimal** (ranged 30%-85%), declining over time since treatment initiation.

ADHERENCE TO ORAL ANTICANCER TREATMENTS

Adherence a Multicomponent Model

Psycho-cognitive and social variables
(e.g., psychological wellbeing, social support)

Socio-demographical
(e.g., socio-economic status)

Disease and treatment-related characteristics
(e.g., prognosis, dosage, side-effects)

Attitudes, beliefs, and values

Healthcare-system-related factors

Health literacy and knowledge

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ADHERENCE TO ORAL ANTICANCER TREATMENTS

New Challenges

Given the **impact of non-adherence on clinical outcomes** and the associated economic burden for the healthcare system, finding **effective ways to increase treatment adherence** is particularly relevant.

MBC patients need support in managing oral therapies and overcoming individual and systemic barriers and roadblocks.

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RISK-PREDICTIVE MODELS AND DECISION SUPPORT SYSTEMS

Engines to reduce the complexity of medication non-adherence to OATs

Machine Learning Models

Decision Support System (DSS)

Clinicians OUTCOMES

- Inform about the **specific risk factors** associated with non-adherence;
- **Earlier identification of MBC patients** with poor adherence;

MBC Patients OUTCOMES

- Provide evidence-based information;
- **Recognize and clarify their personal** values, and increase participation in care decision;
- Facilitate communication by providing information and a platform to **encourage substantial interaction**.

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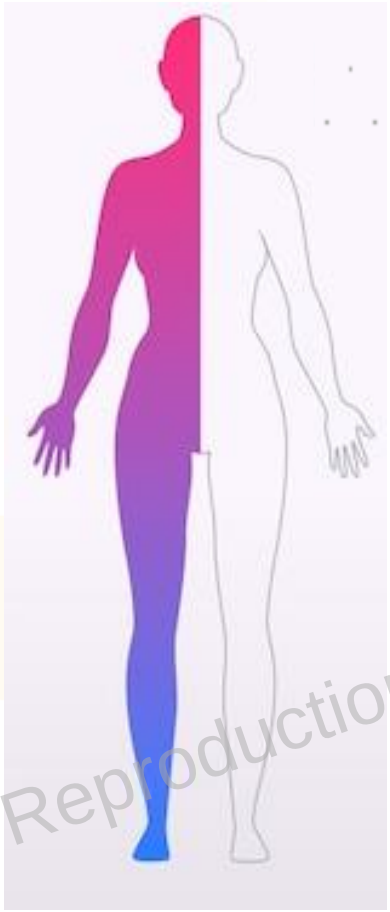
PFIZER PROJECT

Enhancing Therapy Adherence Among Metastatic Breast Cancer Patients



The goal of the **Pfizer Project** is to develop a predictive model of non-adherence and associated shared decision support system (DSS) and guidelines to foster patients' engagement and enhanced therapy adherence among MBC patients.

- **Retrospective Study** (N=2750) provides a preliminary version of the predictive model of non-adherence.

- **Prospective Study** (N=100) assesses the effectiveness and usability of DSS web-based and will improve the predictive power of the machine learning model.

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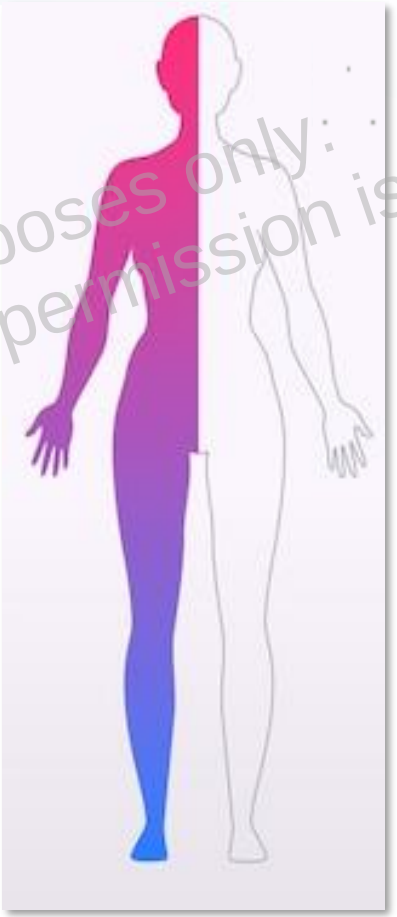
PHASE 1°- RESTROSPECTIVE STUDY



RETROSPECTIVE STUDY

Method

Multi-modal retrospective data has been retrieved from the **Patient Electronic Health Records** (EHR) using the **Natural Language Processing (NLP)** in a sample of **2.750 MBC** patients (from 2010 to 2020). The mean age was 58.3 (SD=11.7).

- **Overall variables included:**
  Sociodemographic variables, diagnosis, biochemical and medical tests, procedures and medical history, treatment programs, treatment side effects, comorbidities, and familiarities.

- **Adherence variables included:**
  Initiation of the treatment, interruption of treatment, and skipped treatment doses.

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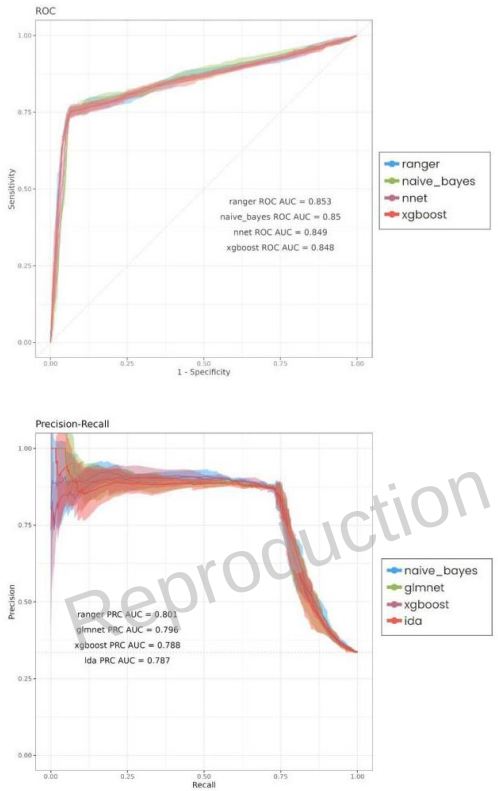
RETROSPECTIVE STUDY

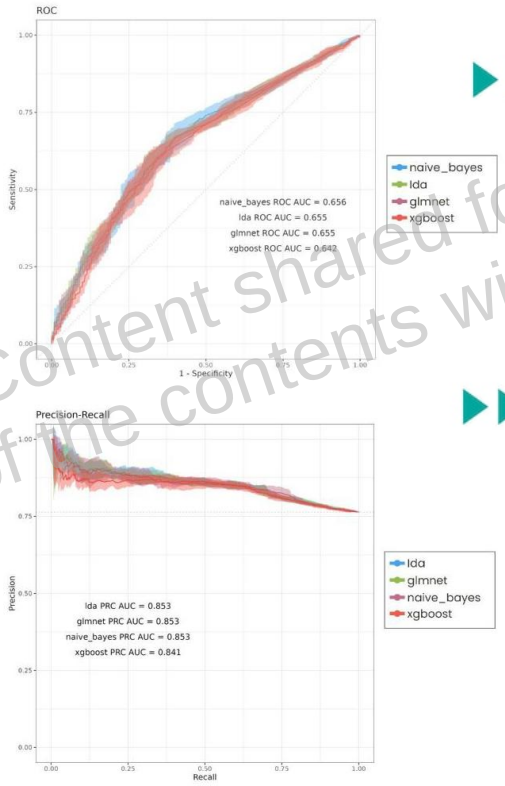
Method

A machine learning application was developed on models to predict adherence risk factors and used data extracted from the EHR of the European Institute of Oncology (Milan, Italy).

Physical status and comorbid conditions



Short and long term side effects



- The machine learning models focused on two outcomes: **short and long-term side effects,** as well as **physical status and comorbid conditions.**

- The models were integrated into a web application built using the **Shiny open-source framework** for the R statistical language.

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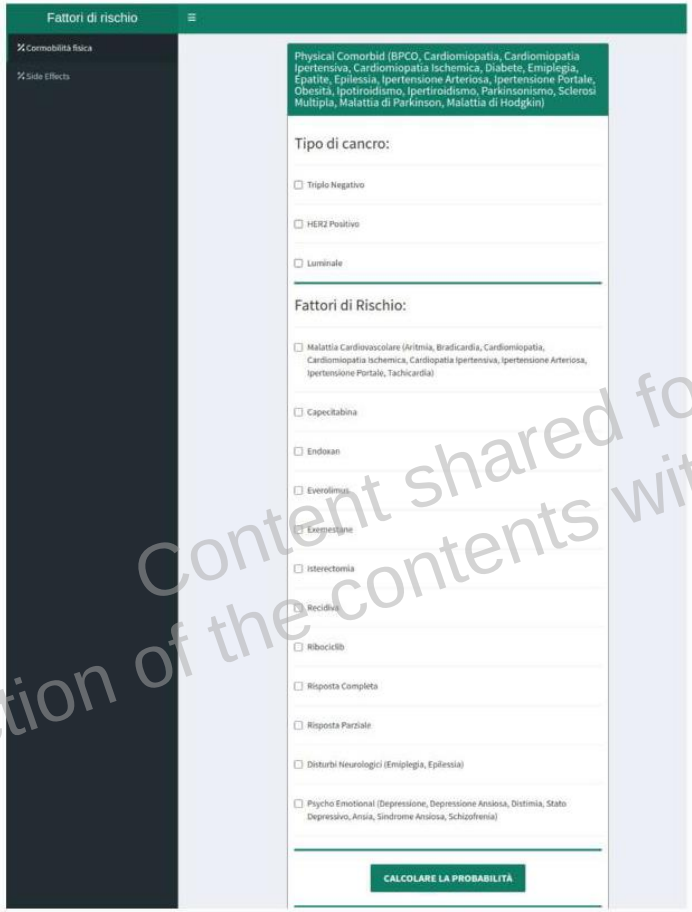
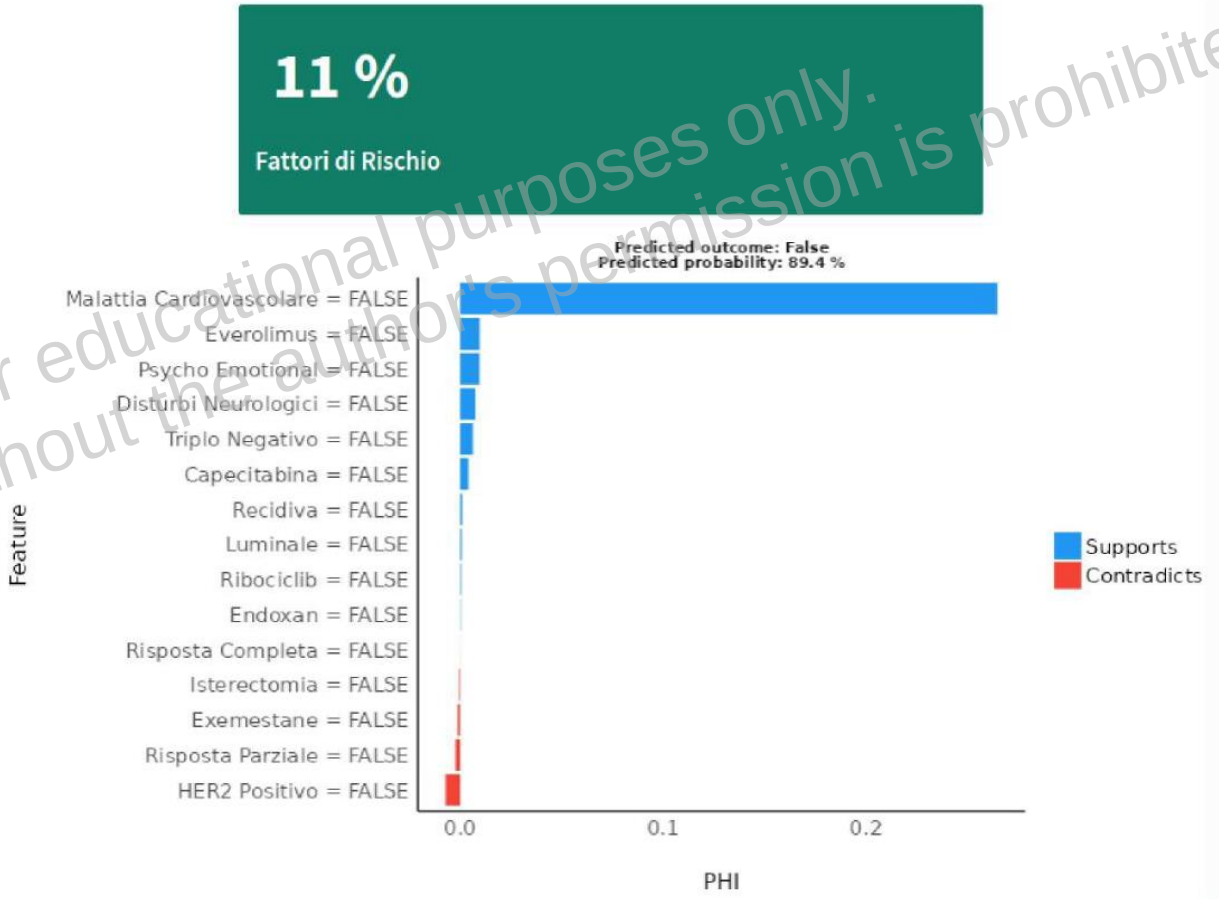
RETROSPECTIVE STUDY

Results

Shiny application





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PHASE 1°- DECISION SUPPORT SYSTEM

PFIZER PROJECT

Decision Support System: Design and Development

Identification of the key issues: OATs in MBC, non-adherence, resources and barriers (psycho-social *vs*. contextual *vs*. organization) and interventions.

Preiliminary Mockup of the DSS using Wikimedia technology

Final Contents of the DSS

STEP 1 Literature Analysis

STEP 2 Qualitative Study

STEP 3 Version 1.0 DSS

STEP 4 Experts' Revision

STEP 5 DSS

Focus Group (19 MBC patients - M_{age}= 55. 95 SD_{age}= 6.87 min. 46 – max 70).

All contents of the DSS were revised, and checked by an expert group (clinicians, psychologists and technical experts).

Ensuring focus on PATIENT PARTICIPATION and ENGAGEMENT

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PFIZER PROJECT

TREAT - "TREatment Adherence supporT"

Metastatic Breast Cancer

a. Disease
b. Features, and symptoms
c. Available Therapies
d. Side-effects
e. Psychological Impact

MAGGIORI INFORMAZIONI

Possibility to link to evidence-based sources (**ESMO guidelines**)

Adherence to Cancer Therapies

a. The meaning of non-adherence
b. Incidence and consequences of non-adherence in MBC
c. Causes of non-adherence

Promoting Adherence

a. Resources
b. Barriers
c. Interventions to support adherence
d. Self-manage strategies to boost adherence.
e. A goal-setting protocol

My Adherence Diary

a. free-text diary reporting doubts, concerns, thoughts, and behaviors related to their disease and therapies

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PHASE 2°- PROSPECTIVE STUDY

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Prospective Study

DSS TREAT

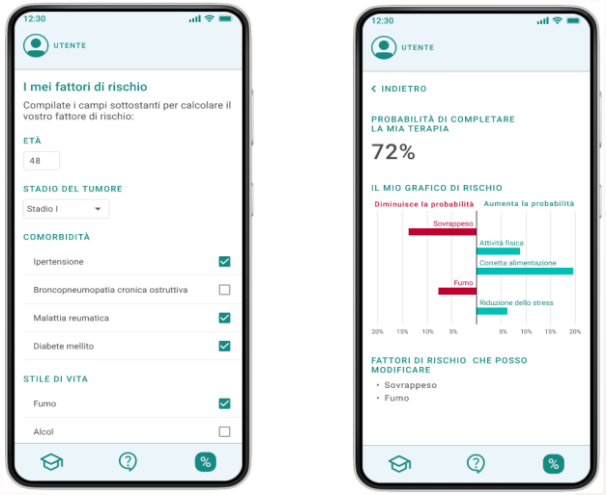
Primary endpoint

To assess the effectiveness of a **DSS web-based solution** in promoting adherence to oral anticancer treatments in a sample of MBC patients.

Secondary endpoint

To collect a set of new physical, psychosocial, behavioral, and QoL variables that will be used to tune **and refine the preliminary version of the machine learning models** to predict patients' adherence behavior.

Risk Predictive Models



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Study Design

Randomized Controlled Trial

Sample

A sample of 100 MBC patients admitted to the European Institute of Oncology at the Division of Medical Senology are enrolled.

Experimental Group: 50 MBC patients exposed to the DSS.

Control Group: 50 MBC patients not exposed to the intervention.

MEASURES

International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Medication Compliance and Persistence Work Group

- Adherence Medication Diary
- Adherence Attitude Inventory (AAI)
- Morisky Medication Adherence Scale (MMAS-8)

- State-Trait-Anxiety Inventory (STAI-Y)
- Beck Depression Inventory-II (BDI-II)
- Cancer behavior Inventory CBI Short form (CBI-B/I)
- Sense of Coherence (SOC-13)
- Brief Pain Inventory (BPI)
- European Organization for Research and Treatment of Cancer Quality of Life questionnaire (EORTC-QLQ-C30)/ QLQ-BR23
- Big Five Inventory
- System Usability Scale (SUS)

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(Morisky et al.,2008, Berlowitz et al., 2017, Bress et al., 2017)

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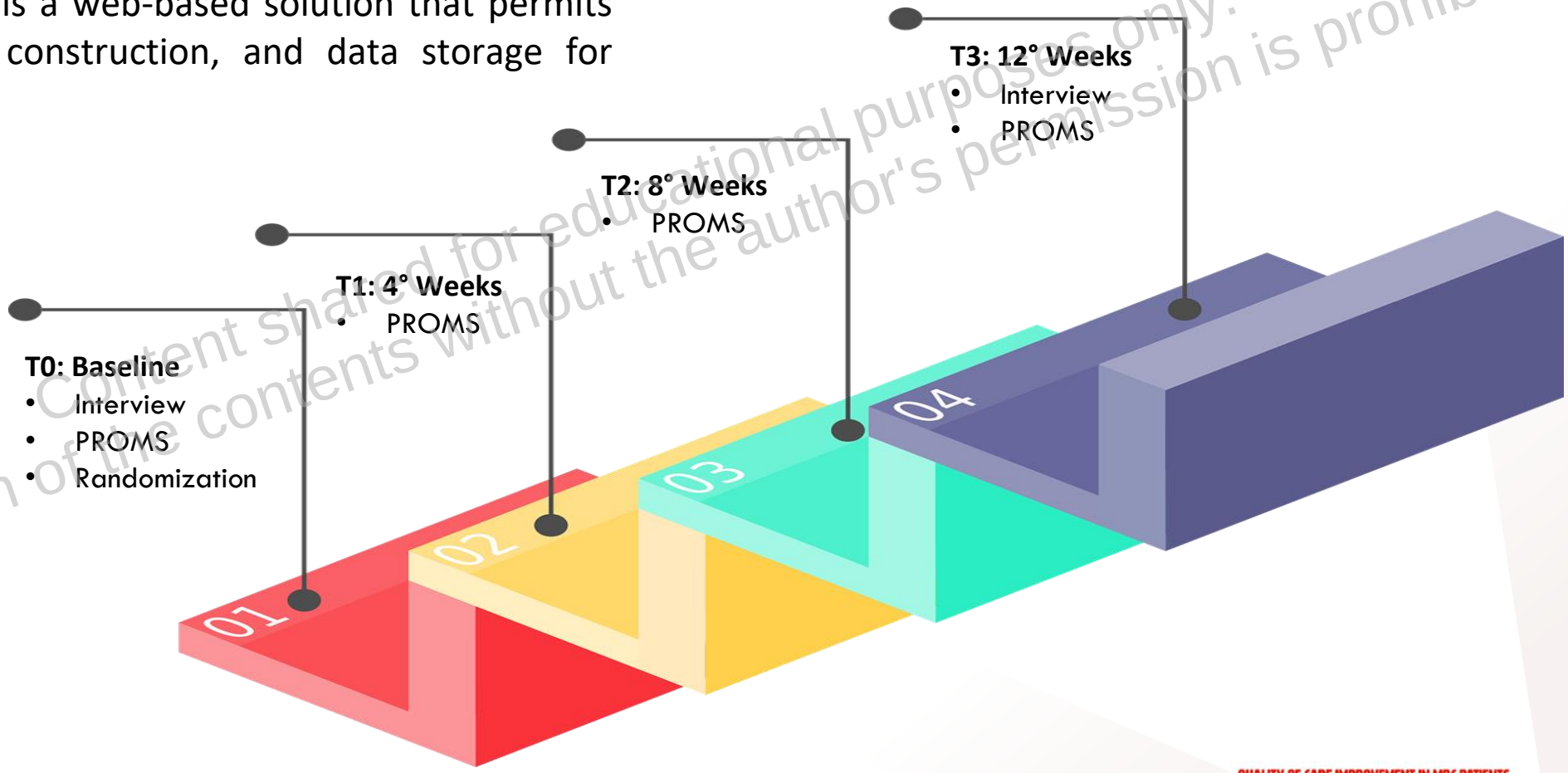
Timeline

Daily Adherence Diary
(12 weeks)

An internal database was created using the **REDCap** Platform of the IEO. The **REDCap** is a web-based solution that permits data collection, survey construction, and data storage for research aims.



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DIARIO SETTIMANALE DI ADERENZA ALLA TERAPIA ORALE dal 23-05- **al** 28-05

Giorno Settimanale	Data (gg/mm)	Ho assunto la terapia (sì/no/parziale)	Effetti collaterali (Descrivi i tuoi sintomi se presenti)	Intensità (0 per nulla intenso - 10 molto intenso)	Pensieri (Descrivi brevemente le tue riflessioni)	Emozioni (Descrivi brevemente il tuo stato d'animo,)	Comportamen (Descrivi brevement tua condotta di aderenza o non aderenza)
Lunedì							
Martedì	23/05	SI	STOMATITE PICCOLI SCARICHI DI DIARREA	5	OGGI VISITA ONCOLOGICA SEMBRA CHE LA TERAPIA NON FUNZIONI	AMAREGGIATA	NESSUN PRO NELL'ADEGUA A NUOVI ORAR LA NUOVA TER
Mercoledì	24/05	SI	STOMATITE IN TRATTAMENTO	3	SOLITA ROUTINE LAVORO X APP. AGENDA SALUTE	MENO AMAREG	
Giovedì	25/05	SI	LIEVE STOMATITE (IN TRATTAMENTO)	1	LAVORO OBBLIGO DI ESSERE SERENA	TRANQUILLA (SE NESSUNO FA DOMANDE)	SHOPPING CON AMICHE
Venerdì	26/05	SI	STANCHEZZA	2			PASSEGGIATA
Sabato	27/05	SI	/	1		CERCO DI PENSARE POSITIVO!!	SOLITO QUOTIDIANO
Domenica	28/05	SI	BRUCIORE DI STOMACO E PICCOLO ATTACCO DIARREA (IMODIUM)	1	SOLITE COSE		"

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Adherence Weekly Diary

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Sample

69 MBC patients (M_{age}=55 SD_{age}=20.5 min. 30 - max. 75) admitted to the Division of Medical Senology of the IEO were enrolled.

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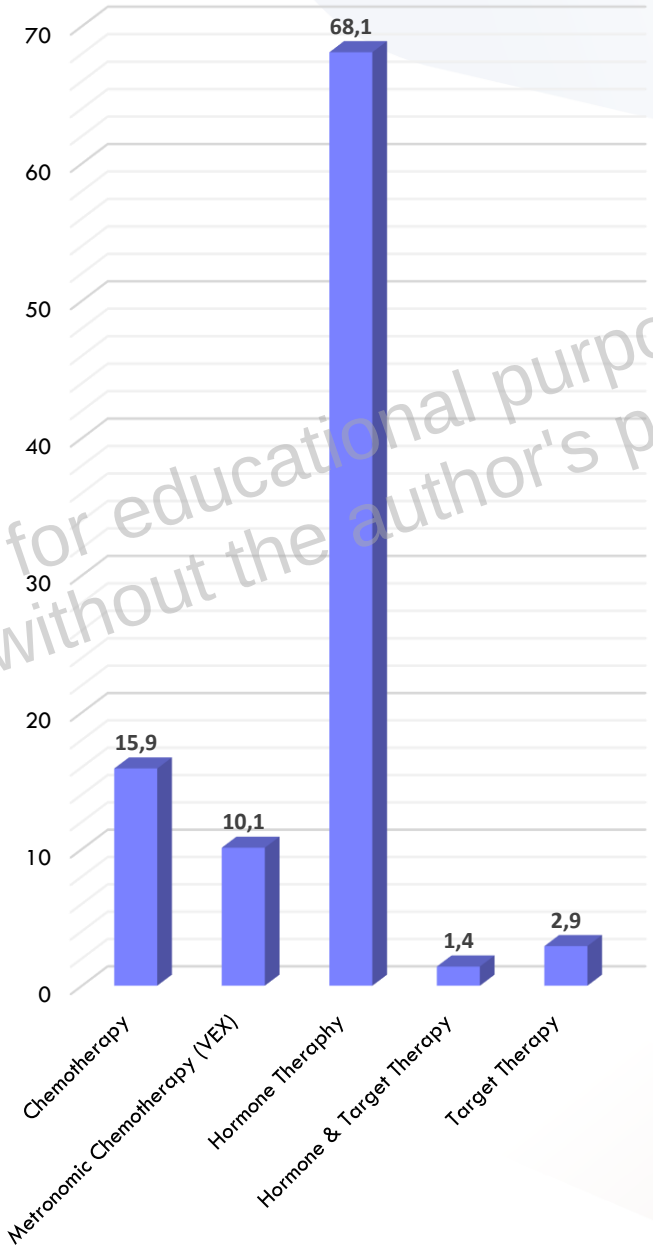
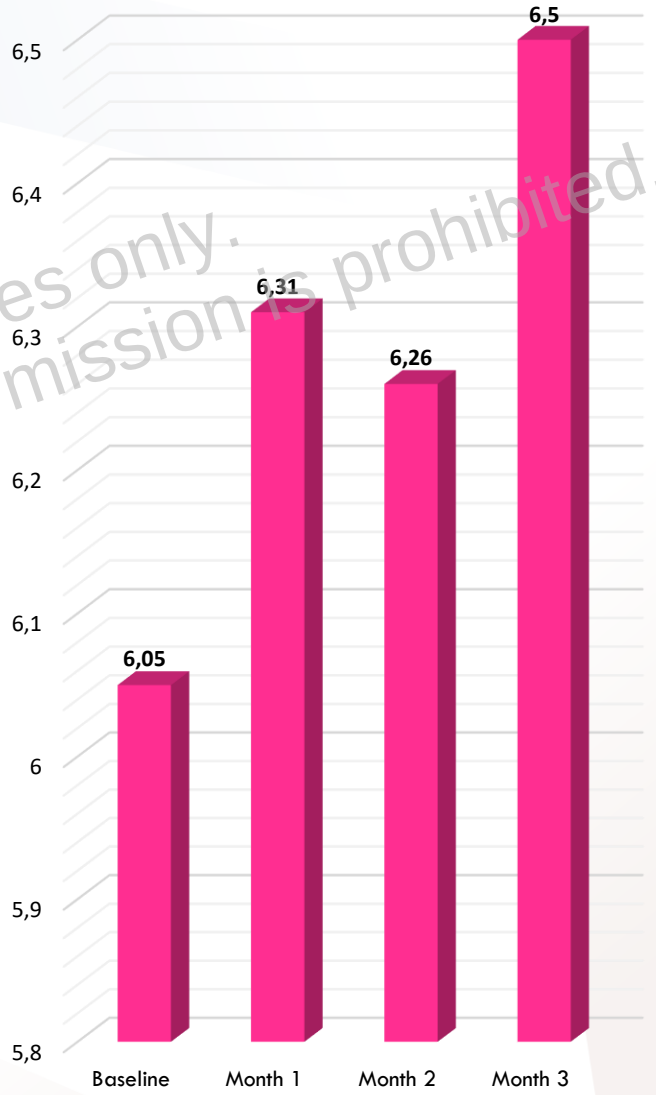
Treatments



Adherence



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INVESTIGATORS MEETING

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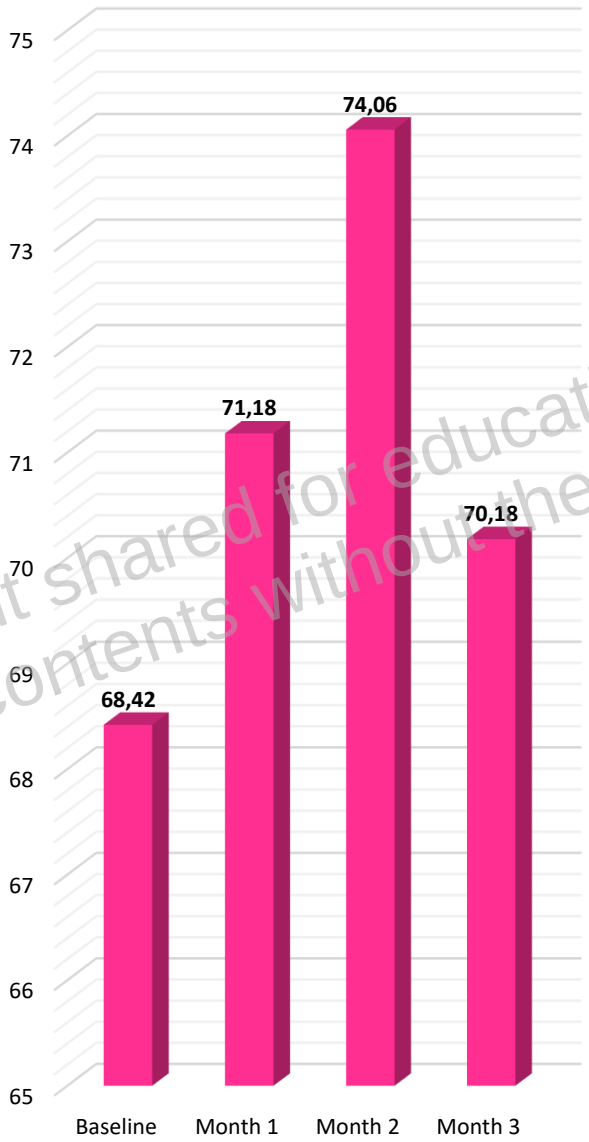
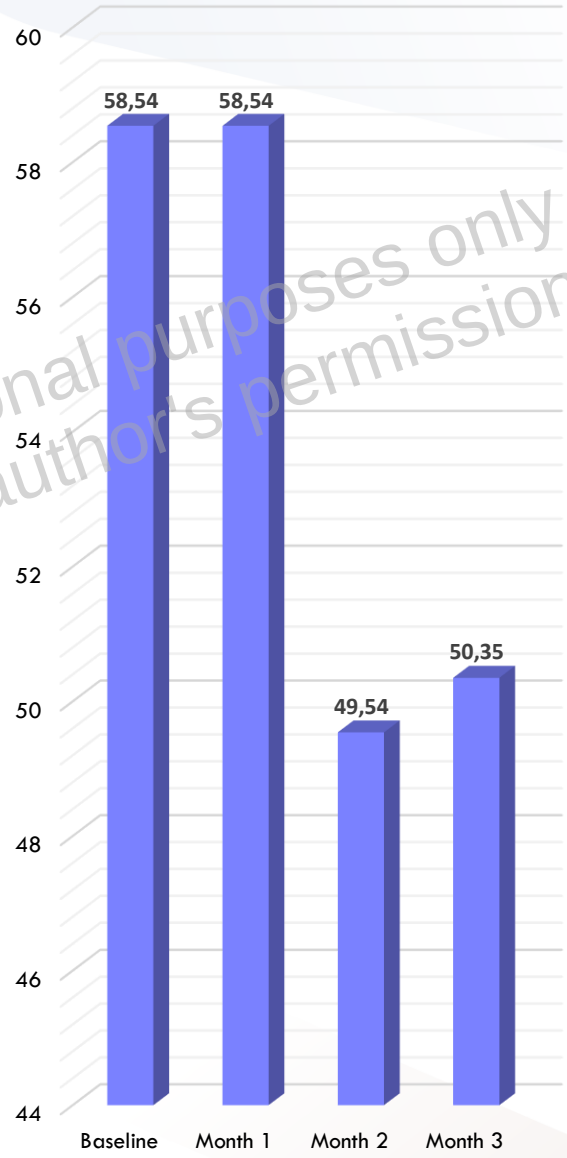
EORTC-QLQ-C30)/ QLQ-BR23

Global Health Status



Future Perspective



$p < .025$

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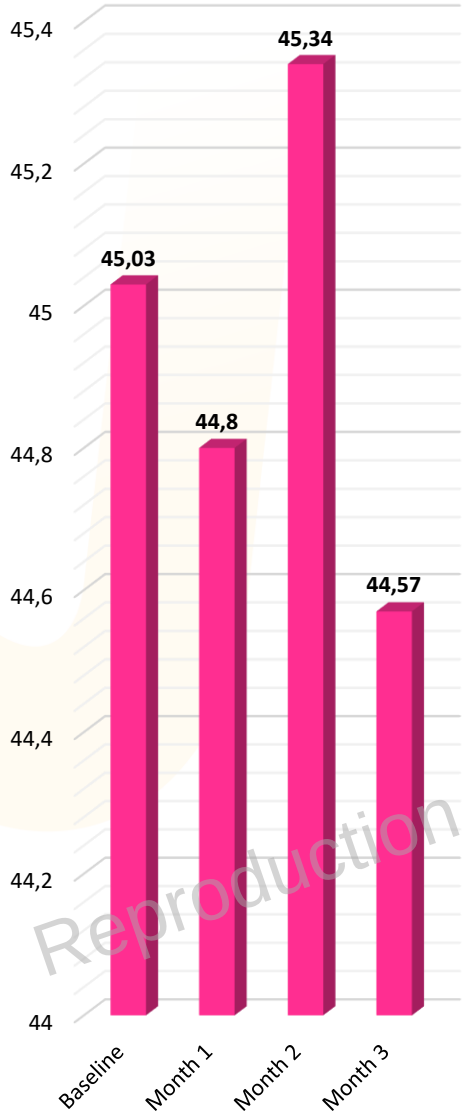
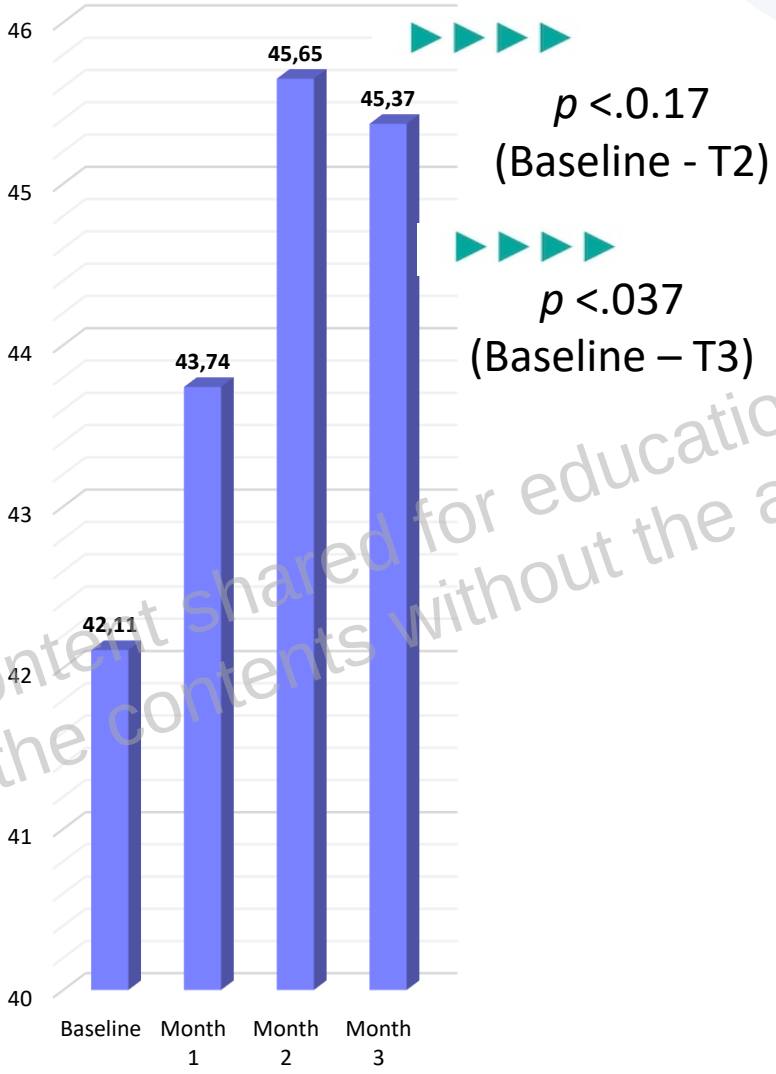
Self-Efficacy



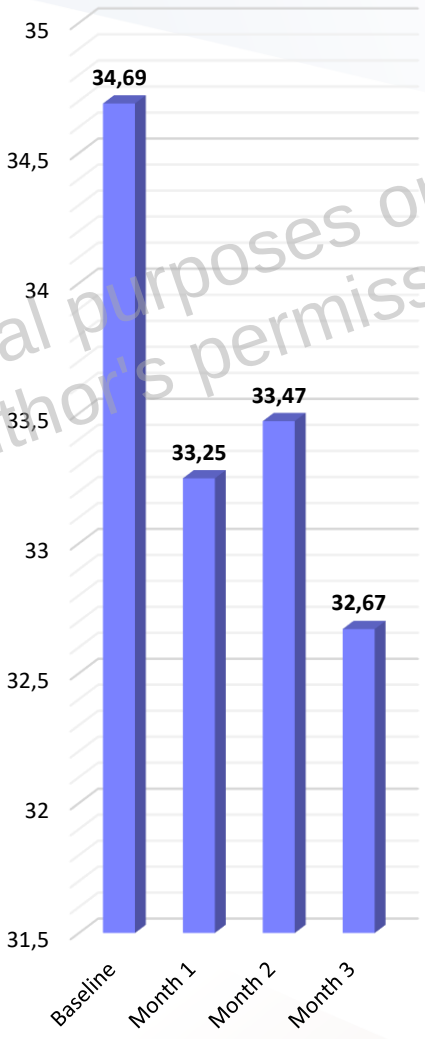
Commitment to Adherence



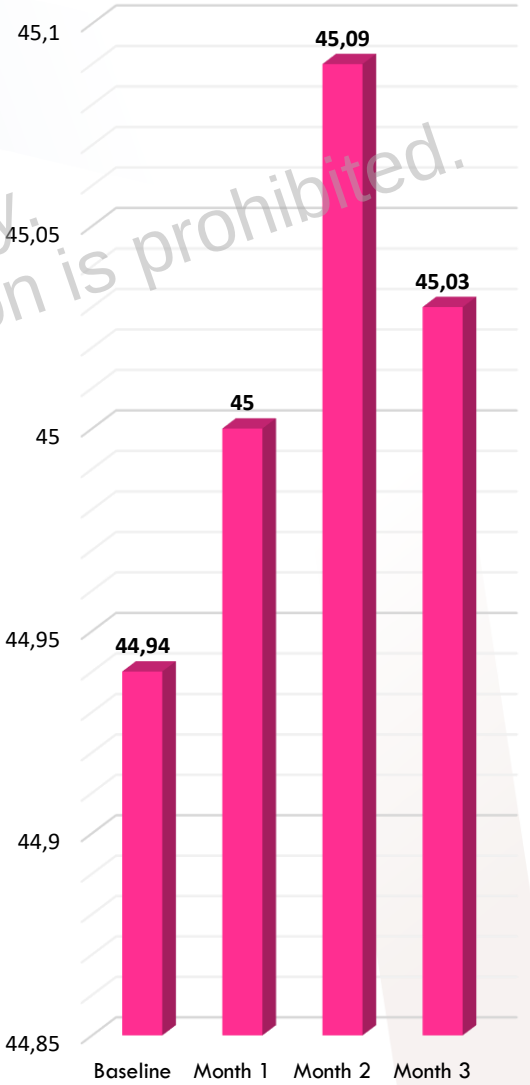
p <.0.17
(Baseline - T2)

p <.037
(Baseline – T3)

Patient and Providers Communication



Cognitive Functions



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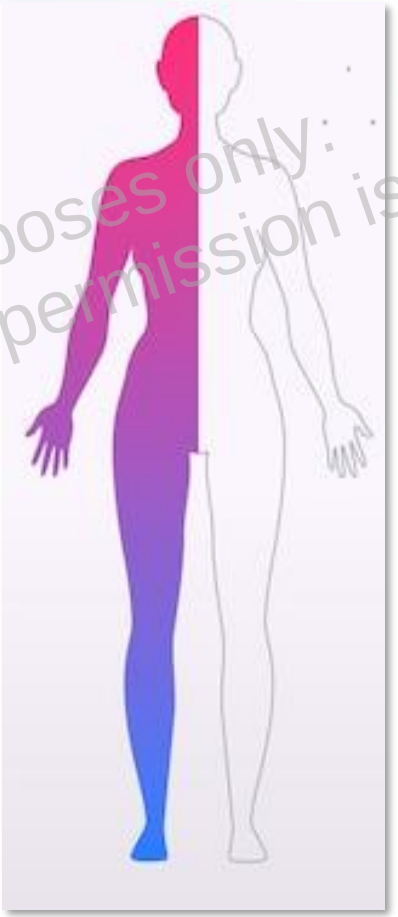
CONCLUSION



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Expected Results

Refining the initial risk-predictive model of adherence will inform about specific predictors of adherence behavior.

Identifining patients with poor adherence will permit the development of tailored psychological and behavioral interventions.

Implementing a shared and integrated DSS might be an essential strategy for MBC patients to enhance understanding of medication non-adherence.

Supporting oncologists' treatment decisions, allowing them to better understand the hindered reasons behind a complex adherence trajectory.

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THANK YOU

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