ISRCTN17036586 https://doi.org/10.1186/ISRCTN17036586

Supporting women with breast cancer: how different psychological approaches can help recovery

Submission date
12/11/2025

Recruitment status
Recruiting

Registration date
27/11/2025

Overall study status
Ongoing

Last Edited
24/11/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effectiveness of different psychological interventions for women recently diagnosed with breast cancer and undergoing surgery. The project, conducted by the Clinical Psychology Unit of ASST Rhodense (Lombardy, Italy), compares standard psychological support (Treatment as Usual, TAU), a psychoeducational intervention, and the EMDR Recent Traumatic Episode Protocol (R-TEP) in reducing distress, anxiety, depression, and post-traumatic symptoms.

Who can participate?
Adult women aged 18–80 years with a first diagnosis of breast cancer, scheduled for mastectomy or quadrantectomy.

What does the study involve?
The study is non-commercial, conducted at the Breast Unit of ASST Rhodense, lasting approximately 12 months.

Eligible participants will be randomly assigned to one of three groups and attend individual psychological sessions twice a week for eight weeks.

What are the possible benefits and risks of participating?
Potential benefits include improved psychological well-being and reduced emotional distress. Risks are minimal and mainly related to temporary emotional discomfort during therapeutic sessions.

Where is the study run from?
Aziende Socio Sanitaria Territoriale (ASST) Rhodense, Italy.

When is the study starting and how long is it expected to run for?
December 2025 to December 2027

Who is funding the study?
ASST Rhodense, Italy.

Who is the main contact?
Dr Livia Emma Ligorio, Clinical Psychology Unit, ASST Rhodense, Italy

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Livia Emma Ligorio

ORCID ID
https://orcid.org/0009-0005-4446-3837

Contact details
Unità di Psicologia Clinica
ASST Rhodense (MI)
Viale Forlanini 95
GARBAGNATE MILANESE (mi)
Garbagnate milanese (MI)
Italy
20024
+39 02994305760
lligorio@asst-rhodense.it

Additional identifiers

Protocol serial number
0059084/25

Study information

Scientific Title
B.R.E.A.S.T. Study: Benefits of R-TEP EMDR protocol in Addressing diStress and Trauma in breast cancer patients - a randomized controlled trial

Acronym
B.R.E.A.S.T.

Study objectives
Background
Breast cancer diagnosis represents a potentially traumatic event for women, often associated with significant psychological distress, anxiety, and depressive symptoms. Research highlights that early psychological interventions are crucial to prevent chronic post-traumatic responses and to enhance patients’ adherence to medical treatment. Psychoeducational and supportive interventions can improve coping, but their efficacy remains limited. Eye Movement

Desensitization and Reprocessing (EMDR), particularly through the R-TEP protocol, has shown promising results in reducing distress and trauma-related symptoms in oncological patients.

Study objectives: This randomized controlled trial (RCT) hypothesizes that the EMDR R-TEP protocol will be effective in improving psychological well-being and reducing trauma-related symptoms in women diagnosed with breast cancer. Specifically:
1. Participants receiving EMDR R-TEP will show clinically and statistically significant improvements over time in anxiety, depression, distress, hopelessness, traumatic impact of diagnosis, psychological well-being, and global symptomatology compared with baseline.
2. The EMDR R-TEP intervention will demonstrate greater efficacy in improving these psychological outcomes compared with both a psychoeducational intervention and treatment-as-usual (TAU)
consisting of standard supportive psychological care.
3. The EMDR R-TEP protocol will produce the most stable and substantial changes over time in post-traumatic symptoms and overall well-being.
The study further hypothesizes that implementing a brief, standardized EMDR protocol within routine oncology care can enhance quality of life, reduce psychological symptom burden, and potentially lower healthcare utilization. By addressing a current gap in psycho-oncological research, this trial aims to generate evidence supporting the integration of trauma-focused psychological interventions into standard cancer care pathways.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/05/2025, Lombardy 3 Territorial Ethics Committee (via Francesco Sforza 28, 20122 Milano, Milan, 20122, Italy; +39 (02) 5503 2982; federica.massacesi@policlinico.mi.it), ref: 5980

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Prevention, Supportive care

Study type(s)
Efficacy, Quality of life, Screening, Treatment

Health condition(s) or problem(s) studied
Prevention of post-traumatic stress symptoms in women with breast cancer

Interventions

The study sample will consist of patients referred to the Breast Unit of the Complex Oncology Department at ASST Rhodense. The sample size was defined based on:
1. a priori power analysis, and
2. the average number of annual admissions to the unit, to ensure realistic feasibility and timely completion of the project.
A priori power analysis was conducted using G*Power v.3.1.9.2 (Faul et al., 2007), adopting a multivariate repeated-measures between–within design, consistent with the protocol, which includes three assessment time points (T0, T1, T2). The between-subjects variable is treatment condition (TAU vs G2 vs G3), whereas time represents the within-subjects factor.
A priori parameters were defined based on previous studies involving comparable interventions, target populations, and constructs:
• Effect size $f^2(V)$ for the global effect: 0.25 (medium)
• $\alpha = 0.05$ (two-tailed)
• Power $(1-\beta) = 0.80$
According to G*Power, a total sample of 98 participants (approximately 33 per group) yields a 95% probability of correctly rejecting the null hypothesis of no significant global effect. Considering the unit's historical patient flow, and to compensate for an expected 20% drop-out rate, the study aims to recruit at least 120 participants, ensuring a minimum of 98 patients with complete data across all longitudinal follow-ups.

This single-centre randomized controlled trial (RCT) includes three arms to evaluate the effectiveness of different psychological interventions for women diagnosed with breast cancer and undergoing surgery. After baseline assessment, participants are randomly assigned (1:1:1) to one of the following conditions using permuted block randomisation with variable block sizes (6 and 9). The sequence will be computer-generated by an independent statistician and allocation concealment will be ensured via a centralised web randomization system.

(1) Control group – Treatment as Usual (TAU):
Standard supportive psychological care routinely provided within the Breast Unit. Individual in-person sessions are held twice weekly (60–90 minutes), focusing on emotional processing, coping enhancement, and treatment adherence, without structured protocols.

(2) Active control group – TAU + Psychoeducation:
Standard psychological support combined with a psychoeducational program addressing the psychological impact of diagnosis, trauma-related reactions, and body image changes. Sessions are conducted twice weekly (60–90 minutes) and include education on emotional regulation and adaptive coping strategies.

(3) Experimental group – TAU + EMDR R-TEP:
Standard psychological support combined with the EMDR Recent Traumatic Episode Protocol (R-TEP), a structured eight-phase intervention targeting distress and trauma associated with cancer diagnosis and treatment. Sessions are conducted twice weekly (60–90 minutes) over eight weeks by trained EMDR psychotherapists.

Intervention Type

Behavioural

Primary outcome(s)

1. Psychological distress measured using the Psychological Distress Inventory – Revised (PDI-R) at baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery, before

randomization), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery)

Psychological distress measured using the Psychological Distress Inventory – Revised (PDI-R) at three time points: baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery, before randomization), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery).

Key secondary outcome(s))

1. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS) at baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery)

2. Post-traumatic stress symptoms measured using the Post-Traumatic Symptom Questionnaire (PTSQ) at baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery)

3. Hopelessness measured using the Brief Assessment of Hopelessness (BAH) at baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery)

4. Body image measured using the Body Image Scale (BIS) at baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery)

5. Overall psychological functioning and well-being measured using the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) at baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery)

Secondary outcome measures include additional psychological domains assessed to evaluate the broader impact of each intervention. Each variable will be measured at three time points: baseline (T0, pre-surgery), post-surgery (T1, within one week after surgery), and post-intervention follow-up (T2, after eight weeks of treatment and within three months after surgery):

Anxiety and depression, measured using the Hospital Anxiety and Depression Scale (HADS)

Post-traumatic stress symptoms, measured using the Post-Traumatic Symptom Questionnaire (PTSQ)

Hopelessness, measured using the Brief Assessment of Hopelessness (BAH)

Body image, measured using the Body Image Scale (BIS)

Overall psychological functioning and well-being, measured using the Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM)

Completion date

31/12/2027

Eligibility

Key inclusion criteria
1. Female participants aged between 18 and 80 years
2. First diagnosis of breast cancer (any stage without metastasis)
3. Scheduled for surgical intervention (mastectomy or quadrantectomy)
4. Good comprehension of the Italian language, sufficient to understand consent procedures and complete psychological questionnaires
5. Ability and willingness to provide written informed consent
6. Voluntary participation and availability to attend all assessment and intervention sessions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Presence of metastatic disease
2. Presence of cognitive impairment that compromises understanding of the informed consent process and/or the completion of assessment instruments
3. Current or past severe psychiatric disorder (e.g., psychosis, bipolar disorder) requiring pharmacological treatment
4. Concurrent participation in other psychological intervention trials that could interfere with study outcomes
5. Inability to attend scheduled sessions or complete follow-up assessments

Date of first enrolment
03/12/2025

Date of final enrolment
03/06/2027

Locations

Countries of recruitment
Italy

Study participating centre
Clinical Psychology Unit - ASST Rhodense (mi)
Viale Carlo Forlanini 95
Garbagnate Milanese (mi)
Italy
20024

Sponsor information

Organisation
Aziende Socio Sanitaria Territoriale Rhodense

ROR
https://ror.org/03gs06p51

Funder(s)

Funder type
Not defined

Funder Name
Aziende Socio Sanitaria Territoriale Rhodense

Results and Publications

Individual participant data (IPD) sharing plan
The data presented will be available on request from the corresponding author Dr Alessandro Alberto Rossi (a.rossi@unipd.it)

IPD sharing plan summary
Available on request