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The effect of a psychological intervention on the recovery of female breast cancer surgery patients

Submission date 17/11/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/03/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/03/2024	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Research over the past decades has demonstrated that psychological factors and health behaviour play a key role in both the development of oncological diseases and the healing process, but the professional evidence is only now beginning to be incorporated into clinical practice. In line with the latest international guidelines, our research group developed a complex multidisciplinary intervention programme for patients recovering from malignant breast cancer, which was evaluated in a randomised controlled trial design for its short- and long-term effectiveness on patients' psychological and physical well-being, starting from the preoperative period and covering a 6-month follow-up period after breast surgery.

Who can participate?
Women aged between 18 and 65 years old who have been diagnosed with primary breast cancer and whose recovery process starts with surgical treatment to remove the breast tumour.

What does the study involve?
The study includes an investigation of the recovery process from breast cancer, covering the impact of multidisciplinary intervention starting before breast surgery, through to 6 months after surgery.

What are the possible benefits and risks of participating?
The possible benefits for the participants are the psychological work with the illness, getting new knowledge about healthy nutrition and getting new knowledge about physiotherapy. Participation is risk-free and can be terminated at any time.

Where is the study run from?
Department of Surgery, Albert Szent-Györgyi Health Centre, University of Szeged (Hungary)

When is the study starting and how long is it expected to run for?
March 2020 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Tünde Lévai, Psychologist, PhD student, levai.tunde.1@med.u-szeged.hu (Hungary)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nill known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Mamma 2020.1

Study information

Scientific Title
A complex study of the impact of multidisciplinary intervention on the recovery of women undergoing surgery for malignant breast cancer. Randomised-controlled trial.

Study objectives
Hypothesis 1: Patients receiving multidisciplinary intervention will be characterised by lower levels of psychological distress and more positive perceptions of illness in the pre- and postoperative periods than the control group.
Hypothesis 2: Patients receiving multidisciplinary interventions will have a higher level of health behaviour in the postoperative period than the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/05/2020, Regional Research Ethics Committee (RKEB) of the University of Szeged, Albert Szent-Györgyi Health Centre (Dugonics tér 13, Szeged, H-6720, Hungary; +3662/545-997; office.rkeb@med.u-szeged.hu), ref: 50/2020-SZTE

Study design
Randomized controlled trial

Primary study design
Interventional

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

Health condition(s) or problem(s) studied
Multidisciplinary intervention on psychological well-being, diet and physical activity in breast cancer patients.

Interventions
In this interventional research, a multidisciplinary intervention will be used for patients recovering from breast cancer. To test the effect of the intervention, there will be an experimental group with intervention and a control group without intervention in a randomised controlled trial design. The study involves patients who start the healing process after surgery for primary breast cancer. The intervention starts 2 weeks before surgery and lasts until the 4th week after breast surgery.

Randomisation is determined by the date of admission of the patient to the surgical ward.
There are three main pillars of intervention: psychological support, dietary advice and physical activity advice in the form of physiotherapy.
Psychological support is provided throughout the intervention, starting 2 weeks before breast surgery, with a total of 4 consultations. In the postoperative period, patients receive a briefing from a dietician, will start physiotherapy in the surgical ward and will receive additional improvement exercises in the form of videos two weeks after the breast surgery.
Members of the control group receive only post-operative physiotherapy in the surgical ward.

Intervention Type
Mixed

Primary outcome(s)
To test the first hypothesis, the following factors are examined:
1. Depression measured using the Beck Depression Inventory-Short Form (BDI), at baseline, 24 hours before breast surgery, 2 weeks, 3 months and 6 months after breast surgery.
2. Trait anxiety measured using the State-Trait Anxiety Inventory (STAI) Trait Anxiety Scale, at baseline.
3. State anxiety measured using the State-Trait Anxiety Inventory (STAI) State Anxiety Scale, at baseline, 24 hours before breast surgery, 24 hours after breast surgery, 2 weeks, 3 months and 6 months after surgery.
4. Positive and negative affectivity measured using the Positive and Negative Affect Schedule

(PANAS), at baseline, 24 hours before breast surgery, 2 weeks, 3 months and 6 months after surgery.
5. Fear of surgery measured using the Surgical Fear Questionnaire (SFQ), at baseline and 24 hours before breast surgery.
6. Perceived stress measured using the Perceived Stress Scale (PSS-10), at baseline, 2 weeks, 3 months and 6 months after breast surgery.
7. Illness perception is measured using a Brief Illness Perception Questionnaire (BIPQ), at baseline, 24 hours before breast surgery, 2 weeks, 3 months and 6 months after surgery.

To test the second hypothesis, the following factor is examined:
Health-promoting lifestyle measured using the Health Promoting Lifestyle Profile II (HPLP II), at baseline, 2 weeks, 3 months and 6 months after breast surgery.

Key secondary outcome(s))
The following secondary outcome measures are measured using the Health Promoting Lifestyle Profile II (HPLP II) at baseline, 2 weeks, 3 months and 6 months after breast surgery:
1. Health responsibility
2. Physical activity
3. Nutrition
4. Spiritual Growth
5. Interpersonal Relations
6. Stress Management

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. Female patients aged between 18 and 65
2. The patients were diagnosed with primary malignant breast cancer
3. The tumour is classified as stage T1-T3/A
4. The tumour is classified as Grade1-3
5. The healing process starts with primary surgery
6. Absence of a pervasive psychiatric or neurological disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
Female

Total final enrolment
80

Key exclusion criteria
1. Presence of a pervasive psychiatric or neurological disease
2. Lack of literacy skills

Date of first enrolment
10/01/2022

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
Hungary

Study participating centre
Department of Surgery, Albert Szent-Györgyi Health Centre, University of Szeged
Semmelweis street 8.
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Sponsor information

Organisation
University of Szeged

ROR
https://ror.org/01pnej532

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Tünde Lévai (levai.tunde.1@med.u-szeged.hu).
During follow-up, the raw data from the six measurement sessions will be shared on request. Participants are anonymised in the research and all subjects have agreed that their data may be used for research purposes.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication