Voorkomen van chronische pijn na borstkankerbehandeling met online ondersteuning

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21960

Source
NTR

Brief title
AMAZONE

Health condition

Breast cancer

Sponsors and support

Primary sponsor: KWF Kankerbestrijding and ESA (European Society of Anaesthesiology)
Source(s) of monetary or material Support: KWF Kankerbestrijding and ESA (European Society of Anaesthesiology)

Intervention

Outcome measures

Primary outcome

Persistent pain after breast cancer treatment (PPBCT), six months after breast cancer surgery

Secondary outcome

- Pain intensity scores (intercept and slope) during the first postoperative week (Pain Diary)
- Cessation of postoperative opioid use (no. of days)
- Mean pain intensity in the operated area at 2, 6 and 12 months (NRS)
- Neuropathic pain (DN4)
- Pain interference at 2, 6 and 12 months as measured with the BPI
- Quality of life before surgery and at 6 and 12 months (EORTC-QLQ – BC)
- Unspecific symptoms, before surgery and at 6 and 12 months (hot flushes (EORTC-QLQ – BC23), concentration problems, sleeping problems (added to BC23)
- Depression, before surgery and at 2, 6 and 12 months (PROMIS short form 4A)
- Pain sensitivity preoperatively and at 1 week and 6 months and post-surgery assessed with quan-titative sensory testing (QST) and a conditioned pain modulation algorithm (CPM)
- Shoulder function operated side, before surgery and at 6 and 12 months (DASH)

Potential mediators
- General anxiety (HADS-A)
- Pain catastrophizing (PCS)
- Fear of cancer recurrence (CARS) before surgery and at 2, 6 and 12 months

Procedure related parameter
- Compliance with intervention

Baseline and surgery parameters

Study description

Background summary

Rationale: Surviving breast cancer does not necessarily mean complete recovery to a premor-bid state of health. In the past decade it became clear that cancer survivorship is a new diagnosis for patients with complex patterns of somatic and psychological distress requiring continuing complex medical care. Amongst these, persistent pain after breast cancer treatment (PPBCT) with a prevalence of 15-65% is probably the most invalidating, increasing survivor’s symptom burden and negatively affecting mood, sleep, daily activities, and quality of life. Once chronic, PPBCT is difficult to treat and requires a complex individualized multidisciplinary approach. Multiple individual and cancer treatment related risk factors for PPBCT have been identified in the past decades. Studies aiming to prevent PPBCT by modifying its somatic risk factors have not yet lead to a significant reduction of PPBCT prevalence. Virtually NO studies have been performed to modify psychological distress before surgery with the aim of preventing persistent pain, even though for years studies about prevention persisting pain after surgery in general and PPBCT in particular have been suggesting the necessity for such an approach.
Objective: This study is designed to examine the preventive effect of pre- and postoperative cognitive behavioral therapy (CBT) on the development of PPBCT, specifically targeting pa-tients with high levels of anxiety and/or pain catastrophizing. Treatment will be offered online, increasing accessibility and feasibility of participation in an emotionally and physically

bur-dened time period.
Study design: The study is designed as a multi-center randomized controlled trial, with an ad-ditional control arm. 138 Patients undergoing surgery for breast cancer and scoring high on sur-gical or cancer-related fears, general anxiety or pain catastrophizing will be randomized to e-CBT (Intervention) or education (SHAM intervention). Patients not scoring high for anxiety or fears (n=322) will undergo treatment as usual (Control). All patients are followed for 12 months.

Study population: Women undergoing unilateral surgery for breast cancer, aged above 18 years.

Intervention: Five sessions of internet-based cognitive behavioural therapy (e-CBT) or 5 sessions of education (EDU) starting one to two weeks before surgery until six weeks after surgery.

Main study parameters/endpoints: Prevalence of significant PPBCT (NRS ≥3) at six months

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients scoring high for anxiety will be randomized to either an education-al intervention consisting of information about surgery and a healthy lifestyle (EDU group) or a psychological intervention aimed at reducing anxiety and negative cognitions (e-CBT group). As the interventions are web-based, patients can use them wherever they are and also repeat sessions at their own discretion.
The low anxiety control group will receive treatment as usual (TAU) and will be asked to com-plete web-based questionnaires. In addition all randomized and non-randomized participants will be asked to participate in pre- and postoperative pain sensitivity testing (QST/CPM).
The burden consists of filling in online questionnaires (4 x 20 min), participating in QST/CPM assessments (2 x 90 minutes, 1 x 30 minutes) on a voluntary basis and for the intervention groups of the use e-CBT or web-based education in the perioperative period (5 x 60 minutes) and three short appointments with a therapist of 20-30 minutes each.
Benefit for patients in the e-CBT condition is a charge free psychological therapy potentially lowering the risk of persistent pain and other complications of breast cancer treatment.
If the treatment is effective, the developed web-based treatment can be offered to all breast can-cer patients.
This project is unique in that it intervenes at a time point before persistent pain and other symp-toms have established.

Study objective

1. Primary: To investigate the effect of internet-based cognitive behavioral therapy (e-CBT) in patients with high levels of preoperative anxiety and/or pain catastrophizing, on the risk of PPBCT six months after breast cancer surgery. e-CBT will be compared with an educational intervention consisting of information about surgery and a healthy lifestyle.
2. Secondary aim is to examine the hypothesis that e-CBT exerts its effects via a reduction of central sensitization and decrease of nociceptive signal transmission. Herefore skin sensitivity and the efficiency of endogenous pain modulation will be assessed at baseline and postopera-tively in both the randomized patients with high anxiety levels (e-CBT and EDU)

and non-randomized participants (TAU) with low anxiety levels.

Study design

Baseline; Day of surgery; POD 1-7; 2-6-12 Months postoperative

Intervention

1. Cognitive behavioral therapy (e-CBT) or 2. Educational intervention consisting of information about surgery and a healthy lifestyle (EDU). 3. The third, non-randomized group receives treatment as usual (TAU).

Contacts

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Eligibility criteria

Inclusion criteria

for both groups
- Women undergoing surgery for breast cancer
- Age ≥ 18 years old
Inclusion criteria for the randomized group
- Women scoring ≥ 8 on the HADSa, ≥ 3 on the Surgical fear item, ≥ 5 on the CARS, or ≥ 18 on the PCS, will be included in the RCT.
Inclusion criteria for the non-randomized group
- Women scoring < 8 on the HADSa, < 3 on the Surgical fear item, < 5 on the CARS, or < 18 on the PCS will be included as a control group, receiving treatment as usual.

Exclusion criteria

for both groups
- Preventive breast surgery
- Bilateral surgery
- Not able to understand Dutch
- No internet access
- Visual or hearing impairments interfering with reading and listening to the online material
- Known or suspected severe psychiatric disorder
- Current litigation procedure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2021
Enrollment:	460
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data are stored at MUMC+/UM during the active study phase and after study closure in the DataHub infrastructure. A descripteve dataset will be forwarded from Datahub to DataverseNL. A Unique Persistent Identifier (PID) is automatically generated for this dataset. Patient data will not be accessible.

Ethics review

Positive opinion

Date:	16-12-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9132
Other	METC azM/UM : METC20-086

Study results