

Voorkomen van chronische pijn na borstkankerbehandeling met online ondersteuning

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21960

Bron

Nationaal Trial Register

Verkorte titel

AMAZONE

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: KWF Kankerbestrijding and ESA (European Society of Anaesthesiology)

Overige ondersteuning: KWF Kankerbestrijding and ESA (European Society of Anaesthesiology)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Surviving breast cancer does not necessarily mean complete recovery to a pre-morbid 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 led 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 patients 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 burdened time period.

Study design: The study is designed as a multi-center randomized controlled trial, with an additional control arm. 138 Patients undergoing surgery for breast cancer and scoring high on surgical 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 educational 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 complete 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 cancer patients.

This project is unique in that it intervenes at a time point before persistent pain and other symptoms have established.

Doel van het onderzoek

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 postoperatively in both the randomized patients with high anxiety levels (e-CBT and EDU) and non-randomized participants (TAU) with low anxiety levels.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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H.M.S. Theunissen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	460
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

Data are stored at MUMC+/UM during the active study phase and after study closure in the DataHub infrastructure. A descriptive 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.

Ethische beoordeling

Positief advies	
Datum:	16-12-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten