Peri-operative slow paced breathing - a non-invasive technique to reduce anxiety in breast cancer surgery patients

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This study aims to examine the effects of guided slow paced breathing performed at induction of anesthesia in patients undergoing surgery for breast cancer on anxiety, scored by Spielberger's State-Trait Anxiety Inventory, State scale (STAI-S...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53189

Source
ToetsingOnline

Brief title
Slow PACE trial

Condition

- Other condition
- Respiratory disorders NEC

Synonym
perioperative tension; perioperative anxiety

Health condition

Stressreductie

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: eigen gelden afdeling Anesthesiologie AvL

Intervention

Keyword: Breast cancer, Breathing, Perioperative, Stress reduction

Outcome measures

Primary outcome

Spielberger's State-Trait Anxiety Inventory, State scale (STAI-S).

Secondary outcome

- mean blood pressure before induction

- need of hypnotics during induction

- post-operative pain and need of opioids

- postoperative nausea and vomiting (PONV)

- patient satisfaction

- compare anxiety trait scored by Spielberger's State Anxiety Inventory

(STAI-T)13 and general anxiety scored by the anxiety subscale of the Hospital

Anxiety and Depression Scale (HADS-A) at baseline

Study description

Background summary

In the perioperative period anxiety for anesthesia and the surgical procedure is common. Breast cancer surgery patients have a higher level of anxiety compared to other patients undergoing (cancer) surgery. Relaxation techniques, like breath focus with deep belly breathing are easy to learn and can have a beneficial effect on postoperative anxiety, pain, and postoperative nausea and vomiting (PONV), but the quality of evidence is low. Slow paced breathing at a frequency of 6 breaths per minute can possibly increase vagal activation,

decrease anxiety, reduce mean blood pressure, postoperative pain and PONV. The beneficial effects of slow paced breathing in the perioperative period have not been examined to date.

Study objective

This study aims to examine the effects of guided slow paced breathing performed at induction of anesthesia in patients undergoing surgery for breast cancer on anxiety, scored by Spielberger's State-Trait Anxiety Inventory, State scale (STAI-S), compared to usual care.

Study design

Single center, two-group, prospective, randomized controlled trial

Intervention

Study groups

Slow PACE group
Participants randomized in the Slow PACE group will receive a link to the study site with a comprehensive instruction video explaining the Slow PACE breathing technique. Furthermore a *kick-off* video-call is planned with an investigator to give additional instructions and to answer any questions regarding the breathing technique. Slow PACE breathing is a simple technique of deep belly breathing in a low frequency (6 breaths per minute), performed in supine position. After the initial instructions participants are asked to practice Slow PACE breathing daily for at least 5 minutes, guided by an audio-guide. Participants will receive a daily email with a reminder and a link in which they can score if they had time to practice the slow-paced breathing the day before.
On the day of surgery, the participant will be asked to start with the Slow PACE breathing technique just before start of induction of anesthesia in the operation room, guided by the investigator and the same audio-fragment as used for training.
Anesthesia and all intra-operative care will be given to all patients as usual.

Control group
Participants in the control group do not have to prepare or train preoperatively. They will recieve all care as usual.

Study burden and risks

There are no risks related to the intervention.
All participants are asked to complete three questionnaires at baseline, and two short questionnaires on the day of surgery and at day 1.

Participants randomized in the intervention group are trained in slow paced breathing after inclusion and asked to practice the technique daily until the day of surgery and to keep score of this daily by email.
We aim to provide everything for the study digitally, so the patient does not have to visit the hospital extra.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Female
- Undergoing surgery for breast cancer in the Antoni van Leeuwenhoekziekenhuis

Exclusion criteria

- Age < 18 years - ASA >= 4 - History of severe pulmonary illness: severe asthma or severe chronic obstructive pulmonary disease (COPD) GOLD III or IV - Known or suspected severe psychiatric disorder - Unable to give written or oral informed consent - Patient refusal - Not able to understand Dutch - No internet access - Visual or hearing impairments interfering with reading and listening to the online material

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2023
Enrollment:	158
Type:	Actual

Ethics review

Approved WMO

Date:	15-09-2023
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL84554.041.23