Prehabilitation and rehabilitation in breast cancer surgery patients: a pilot study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON51627

Source
ToetsingOnline

Brief title
BREHAB

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breast cancer, breast malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Chirurgie
Source(s) of monetary or material Support: Stichting Borstkanker Onderzoek Rotterdam

Intervention

Keyword: breast cancer, prehabilitation, quality of life, rehabilitation

Outcome measures

Primary outcome

Pilot study parameters

- To estimate patient recruitment/consent rate to the prehabilitation/rehabilitation group Enrolment logs will be recorded for all patients who meet the eligibility criteria. Reasons for non-participation will be recorded and data entered into an excel spreadsheet. We define a success criterion of 40% of the total number of participants invited to be recruited to the research evaluation.

- To estimate patient attendance,measured by the number of sessions attended out of 10, reasons for non-attendance will be collected and withdrawals tracked. We will consider an attendance rate of 80% satisfactory.

- To estimate patient adherence monitored with the aid of the wearables. Adherence is defined as at least 150 min of moderate intensity exercise and at least two strength training sessions per week. Exercise instructions are based on the Health Council's exercise guidelines. We will consider an adherence of 70% as satisfactory.

- To estimate the number of withdrawals, defined as the proportion of patients who quit the intervention before reaching the primary endpoint (HRQOL at six months after surgery). Information about the reasons for withdrawal will be collected and entered into an excel spreadsheet.

- To estimate patient satisfaction with the programme assessed during three

interviews: at four weeks, at three months after surgery and at the end of the study. Satisfaction is defined as: satisfaction with the lifestyle coach, satisfaction with the duration of the intervention, satisfaction with the physical training programme. Patients will be given room for their own input to improve the intervention.

- To investigate likely changes in the primary outcome measure HRQOL measured with the EORTC-QLQ-30 questionnaire at six months after surgery.

- To investigate likely changes in the secondary outcome measures:

- BMI (kg/cm2) measured at baseline, the day before surgery and at six months after surgery.

- Functional capacity measured using the 6-minute walking test (6MWT) at baseline, one day before surgery and at six months after surgery.

- The number of postoperative complications after 30 days measured with the Comprehensive Complication Index (CCI).

- Smoking status measured at baseline and at six months after surgery.

- Mean score of the different BREAST-Q scales.The questionnaire will be administered at enrolment and at six months after surgery.

- Mean scores of quality of life by means of the EORTC-BR23 questionnaire, which will be administered at enrolment and six months after surgery.

- Mean scores of the different EORTC-QLQ-30 scales which will be administered at enrolment
and six months after surgery.

Other study parameters:

o Patient age

o Tumor characteristics (ER, PR, HER2NEU receptors, size, BR grade,TNM

classification)

o Type of surgery

o Type of (neo)adjuvant systemic treatment

o Type of radiotherapy

o Type of targeted therapy

o Professional status

o Exercise habits

Secondary outcome

Not applicable

Study description

Background summary

Breast cancer is the most common malignancy in women; one in seven women will develop breast cancer in her lifetime. The diagnosis and treatment of breast cancer, of which surgery is the cornerstone, have a severe impact on both physical and mental well-being. Most patients experience a variety of complaints, such as fatigue, pain, weight gain or loss, anxiety and/or depressive symptoms, which have a major impact on HRQOL. Moreover, impact of these complaints is variable.
The benefits of lifestyle interventions, especially multimodal ones, have been demonstrated by several studies. Diet, exercise and psychological counselling have positive effects on weight, fatigue, fitness, quality of life and perioperative outcomes such as post-operative complications and length of hospitalisation. Multimodal interventions seem to be the most effective. However, existing rehabilitation and prehabilitation programmes generally investigate the impact of one specific intervention in relation to one or a few specific outcomes. This knowledge is often insufficient to create a personalized treatment plan, given that rehabilitation needs are complex

because patients exhibit a wide range of symptoms with varying impact, and thereby have specific needs and goals that vary across individuals. Therefore, a systematic approach to provide individualized rehabilitation is warranted.

Research direction
Standard of care for patients with breast cancer is surgery and (neo)adjuvant treatment (radiotherapy, chemotherapy, immunotherapy, anti-hormonal therapy). To decrease the morbidity related to diagnosis and treatment of breast cancer, an intervention should, in our opinion, be individualized and patient-friendly in order to achieve better quality of life and satisfaction and a better prognosis than standard of care. The personalized approach of lifestyle coaching is ideally suited to the individual needs of patients with breast cancer.
A pilot study can be used to evaluate the feasibility of recruitment, assessment procedures, retention, safety and implementation aspects of lifestyle coaching as an intervention. Inclusion of a control group allows for a more realistic examination of recruitment, and estimation of effect sizes and quality of life. A pilot study is also designed to investigate the possible effects of lifestyle coaching that may be worth following up in a subsequent larger study. If lifestyle coaching proves to be safe and feasible, and the methodology (after eventual modifications) is repeatable on a larger scale, the next step will be to perform a randomised controlled trial to demonstrate the effectiveness of lifestyle coaching.
Objective of the study: Klik voor meer informatie
The objectives of the BREHAB pilot study include both process and research objectives. Analysis of the process objectives will enable the feasibility of a larger RCT to be assessed. They focus on the feasibility of prehabilitation and rehabilitation through lifestyle coaching, the acceptability of the intervention and the ability to both recruit and retain participants in the research evaluation.
This pilot study serves as preparation for a future randomised controlled trial. Endpoints of the pilot study are: recruitment rate, attendance rate, adherence, withdrawals, overall satisfaction, evidence of selection bias and likely changes in primary and secondary outcome measures (HRQOL, BMI, fysical fitness, complications, smoking status, different domains of the BREAST-Q and EORTC-BR23 questionnaire and other domains of the EORTC-QLQ-30 questionnaire)

Study objective

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Study design

This study is designed as an open label pilot trial with two arms: an intervention group and a control group. The interventional arm will receive lifestyle coaching. The control arm will receive usual care according to the Dutch breast cancer guideline.
A pilot study is an essential first step in investigating a new intervention. A pilot study can be used to evaluate the feasibility of recruitment, assessment procedures, retention, safety and implementation of lifestyle coaching as an intervention. Inclusion of a control group allows for a more realistic examination of recruitment and randomization. It is also designed to search for possible effects of lifestyle coaching that may be worth following up in a subsequent larger study. If lifestyle coaching proves to be safe and feasible, and the methodology (after eventual modifications) is repeatable on a larger scale, the next step will be to perform a randomised controlled trial to demonstrate the effect of lifestyle coaching.
The study population consists of adult women undergoing surgery for breast cancer. All eligible patients will consecutively be included and randomised. Participant*s involvement in the trial is 7 months for patients who do not undergo neo-adjuvant treatment or 9 months for patients who do undergo neo-adjuvant treatment. Analysis of clinical outcomes will be undertaken at the six months follow-up point after surgery for all patients.

Intervention

The intervention consists of prehabilitation and rehabilitation through an individualised lifestyle coaching programme, starting from diagnosis up to 6 months postoperatively.
Lifestyle coaching will be performed by a lifestyle coach certified by the official Dutch association of lifestyle coaches (in Dutch: BLCN: Beroepsvereniging Leefstijlcoaches Nederland). In addition, the lifestyle coach has advanced experience in the treatment of patients with breast cancer. Lifestyle coaching will be conducted in a private consulting room or in home environment, according to the patients preference.
The aim of lifestyle coaching is to outline all aspects of lifestyle (such as nutrition, exercise, smoking, alcohol consumption, stress and sleep) and determine which aspects can be improved for the patient. The patient is guided in making her own choices without imposing choices.

Study burden and risks

Additional interventions that will be performed comprise the investigational treatment (within 1-2 week[s] after diagnosis), which includes lifestyle coaching. Potential burden and risks: discomfort, physical injuries (low risk) or barriers due to physical exercise.

Contacts

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Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Woman with a confirmed breast cancer diagnosis
2. Planned surgical treatment of breast cancer
3. Age 18 years or older
4. Provision of written informed consent

Exclusion criteria

1. Severe mental retardation, which limits the ability to follow instructions independently
2. Severe psychiatric problems, which limits the ability to follow instructions independently
3. Legal incapacity
4. Language barrier: If we cannot find a lifestyle coach who speaks the patient's language, unfortunately we cannot offer the lifestyle coaching in its entirety, and this option will be omitted for the patient.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2022
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	03-11-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL82852.100.22