FeAsibility of a PReoperative, multimodal lifestyle InterventiOn in patients with breast cancer ReceivIng neoadjuvant chemotherapy (APRIORI-study)

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

Summary

ID

NL-OMON56667

Source
ToetsingOnline

Brief title
APRIORI-study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, mammary cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Nationaal Fonds tegen Kanker

Intervention

Keyword: breast cancer, multimodal lifestyle intervention, neaoadjuvant chemotherapy, prehabilitation

Outcome measures

Primary outcome

The primary endpoint of the study is the feasibility of the multimodal lifestyle intervention with respect to recruitment, adherence, drop-out, safety and acceptance.

Secondary outcome

Secondary outcome parameters are Fatigue (Multidimensional Fatigue Index, MFI-20), cardiorespiratory fitness (WRpeak on modified Steep Ramp Test), Muscle Strength (1-Repetition Maximum on leg press, chest press, abdominal crunch and lateral pulldown strength equipment), and nutritional status (Patient Generated Subjective Global Assessment (PG-SGA) short form, weight (kg), height (cm), energy and protein intake, energy and protein requirements, circumference of upper arm and waist).

Study description

Background summary

Breast cancer is the most common type of cancer among women. The disease and treatment are associated with an increased risk of deterioration in physical fitness, muscle strength, nutritional status, mental well-being, and health-related quality of life (HRQoL) and fatigue. To improve health outcomes, modifiable factors should be intervened as early as possible. The preoperative period during which patients receive neoadjuvant chemotherapy seems ideal to offer a multimodal lifestyle intervention, but is currently hardly used for

this purpose. During the preoperative period, nutritional status can be optimised through guidance from a dietician and self-monitoring of nutritional intake via a digital food diary. Additionally, offering a moderate-intensity endurance training (MIET) exercise programme during neoadjuvant intravenous chemotherapy infusion enables supervised exercise at a time when patients would otherwise be inactive. It may also improve tumour perfusion, thereby increasing the effectiveness of cytostatic uptake into the tumour and counteracting resistance to cytostatic drugs. The last six weeks prior to surgery can be used to further optimise cardiorespiratory fitness and muscle strength through a high-intensity interval training (HIIT) and strength training programme. Before the effect of a preoperative, multimodal lifestyle intervention in breast cancer patients receiving neoadjuvant chemotherapy can be investigated, its feasibility needs to be investigated first.

Study objective

The primary objective of this study is to investigate the feasibility of a multimodal prehabilitation programme consisting of MIET during neoadjuvant intravenous chemotherapy infusion, HITT and strength training during the last six weeks prior to surgery, and optimising nutritional intake throughout the total preoperative period in patients with breast cancer with respect to recruitment, adherence, dropout, safety and acceptance. The secondary objective is to provide a preliminary evaluation of participant responses to a preoperative multimodal lifestyle intervention, on cardiorespiratory fitness, muscle strength, nutritional status, and fatigue in patients with breast cancer receiving neoadjuvant chemotherapy.

Study design

A prospective, single-centre, longitudinal mixed-methods feasibility study.

Intervention

The multimodal lifestyle intervention consists of three modalities. Patients are asked to complete 11 sessions of MIET during intravenous chemotherapy infusion, 8 sessions of HIIT and strength training in the last six weeks prior to surgery, and 4 consultations with a dietician throughout the preoperative period. The MIET training sessions consist of 45-50 minutes training programme on a cycle ergometer during the chemotherapy infusion. The physiotherapist will additionally advise patients to adhere (or build up to) the Nederlandse Norm Gezond Bewegen (NNGB) on remaining weekdays. The HIIT training sessions consist of a 25 minutes training programme performed on a cycle ergometer, followed by four muscle-strengthening exercises. During the consultations with the dietician, patients* energy and protein intake are evaluated and advice is given on how to achieve the calculated energy and protein requirements. To improve patient self-management and empowerment, patients are also advised to

use a free digital food diary.

Study burden and risks

The risks of participating in the multimodal lifestyle intervention are considered minimal. The performance tests (Steep Ramp Test, 1-Repetition Maximum) are safe and feasible for this population. However, patients could experience some discomfort (exhaustion, muscle fatigue) due to the performance tests or exercise programs. Study related adverse events, related to exercise or nutritional changes will be closely monitored and managed by the physiotherapist and dietician. Participation in study will take approximately 17,5 to 20 hours per patient. This time includes two consults with a physiotherapist, 8 sessions of HIIT and strength training, 4 consultations with a dietician, filling in the digital food diary and one semi-structured interview with the researcher to investigate acceptance of the multimodal lifestyle intervention and study procedures as perceived by patients and healthcare professionals. Patients are asked to complete questionnaires on fatigue and nutritional status on five different occasions.

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

Inclusion criteria:
• Patients diagnosed with stage I-III breast cancer eligible for neoadjuvant intravenous chemotherapy at the Maastricht University Medical Center
• Aged >=18 years
• Eastern Cooperative Oncology Group (ECOG) Performance Status Scale grade 0-1 (Table 1) [40,41]
• Enough understanding of the Dutch language

Exclusion criteria

Exclusion criteria:
• Human Epidermal growth factor Receptor 2 (HER2) - positive tumour
• Scalp cooling
• Recurrent breast cancer
• Conditions that seriously hamper physical exercise
• Incapacitated subjects as reported by the attending medical specialist in the medical record. When any doubt arises, the patient will not be considered eligible.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2024
Enrollment:	11
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	12-03-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT06266312
CCMO	NL85719.068.23