Evaluating the feasibility of a tailored physical therapy program for patients with metastatic breast cancer

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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-OMON45659

Source
ToetsingOnline

Brief title
Tailored physical therapy for patients with metastatic breast cancer

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Metastatic breast cancer; advanced breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Pink ribbon

Intervention

Keyword: breast cancer, metastatic, physical therapy, quality of life

Outcome measures

Primary outcome

Feasibility of the tailored physical therapy program in terms of uptake, safety, and goal attainment. Intervention adherence , and satisfaction of patients and physical therapists will be assessed for possible improvement of the intervention.

Secondary outcome

Activities of daily living (User-P questionnaire), and health related quality of life (EORTC QLQ-C30 questionnaire). Medical data concerning diagnosis, metastases, treatments and comorbidities will be obtained from the medical record only after explicit consent of patients.

Study description

Background summary

Health care services targeted at enhancing physical fitness and physical activity for patients with metastatic breast cancer are often fragmented and standardized rather than tailored to the individual patient. This can result in suboptimal care.

Study objective

Our primary objective is to test the feasibility of a tailored physical therapy program especially designed for metastatic breast cancer patients. As a secondary objective we will evaluate the impact of the program with regard to goal attainment, and maintenance of or improvement in physical and psychosocial outcomes relevant to the patients* goals.

Study design

A single group intervention study, with assessments at baseline and after the intervention program, approximately 6 to 12 weeks after baseline.

Intervention

After a comprehensive intake, a tailored physical therapy program will be provided that consists of elements specifically designed for this population that best target the patients goal(s) related to physical activity and staying fit in order to carry out normal activities of daily living. Dependent on the nature of this tailoring, the program content may differ from patient to patient and may range from specific resistance (e.g. leg press) and/or aerobic (e.g. cycling) exercises, functional exercises (e.g. stair climbing), or relaxation exercises (e.g. progressive muscle relaxation). The combination of exercises can be provided either in person or (partly) via an eHealth platform (Physitrack).

Study burden and risks

Patients who participate will be asked to complete a series of questionnaires pre- and post-intervention and may be asked to perform specific performance-based tests (e.g. 6 minute walk test), when relevant to the goal of the patient. They will subsequently perform exercises that are tailored to their specific goals in a specialized physical therapy practice, at home or a combination of both. All performance-based tests (at the intake) and exercise and relaxation intervention components are evidence-based to the best possible extent, and the literature reports no adverse events from these interventions in patients with metastatic cancer.

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

1) metastatic breast cancer; 2) At least 18 years of age; 3) hose WHO performance score of 0-2; 3) Able to read and write Dutch; and 4) having functional problems with activities of daily living.

Exclusion criteria

1) significant cognitive impairment; 2) symptomatic heart disease; 3) live outside of the greater Amsterdam area; 4) have complex and/or multi-morbid conditions requiring multidisciplinary rehabilitation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	04-05-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	27-02-2017
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

ID: 22708
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60151.031.16
OMON	NL-OMON22708