Effect of a physical activity promotion program offered online or via blended care on physical activity level in breast and prostate cancer survivors: The PABLO Trial

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Objective: This study will evaluate the effectiveness of IPAS, with and without additional support, for enhancing objectively measured PA levels. We expect that IPAS will increase levels of PA more than usual care (UC), with a larger expected effect...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON46574

Source
ToetsingOnline

Brief title
Promotion of physical activity in breast and prostate cancer survivors

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
breast carcinoma / breast cancer; prostate carcinoma / prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Breast and Prostate cancer, Ehealth, Physical activity, RCT

Outcome measures

Primary outcome

The primary outcome measure is change in minutes of weekly moderate to vigorous physical activity from baseline to 6 and 12 months as assessed by accelerometer.

Secondary outcome

secondary outcomes are: Self-reported physical activity (IPAQ). Stage of change, fatigue (MFI), mood (POMS), HRQOL (SF-36 and EQ5D) will be assessed by questionnaires.At baseline, 6 and 12 months. Medical consumption (iMCQ) and productivity costs (iPCQ) will be measured at 6 and 12 months by questionnaire.

Study description

Background summary

Rationale: Many breast and prostate cancer survivors experience negative physical and psychosocial consequences of the disease and its treatment. There is compelling evidence that physical activity (PA) counteracts many of these consequences. Yet, cancer survivors often do not meet the recommended level of PA. Therefore, we have developed an internet-based program (IPAS) to encourage PA in an accessible way. As some studies suggest that supervised programs may be more effective, we added minimal remote supervision that consists of structural and on-demand telephone contact with a physical therapist to one of the intervention arms.

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Study objective

Objective: This study will evaluate the effectiveness of IPAS, with and without additional support, for enhancing objectively measured PA levels. We expect that IPAS will increase levels of PA more than usual care (UC), with a larger expected effect for IPAS + support. We also expect to demonstrate cost-effectiveness of the interventions, compared to UC. Secondary outcomes are self-reported PA, stage of change, fatigue, mood, and health-related quality of life (HRQOL). Finally, moderators and mediators of the outcome will be studied in exploratory analyses.

Study design

Study design: In this three armed randomized controlled trial patients will be randomized to IPAS with or without additional support or to a usual care control group.

Intervention

Intervention (if applicable): IPAS consists of 6 months of noncommittal use and provides automated, algorithm-based tailored information on PA and PA assignments along with feedback on current PA level in relation to existing guidelines, using patient input obtained via questionnaires. Added support in the second intervention arm consists of structural and on-demand telephone contact with a physical therapist.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients who participate will be asked to wear an accelerometer for seven days at three time points and fill out a series of questionnaires pre and post intervention. Patients in intervention groups will be encouraged to be more physically active in a way that suits their situation capabilities and interests best. It is anticipated that the program will have direct benefit in terms of improvement of patients* fatigue and HRQOL, and will help them in reaching their goals regarding PA. As patients with contraindications to participating in unsupervised exercise are excluded, and advices are directed at enhancing levels of daily type activities, risks of participation are minimal.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Histologically confirmed primary breast or prostate cancer (stages: T1 - T4, N0 - N3 and M0)
- Primary treatment should have been completed a minimum of 3 months and a maximum of 36
months prior to study entry.
- Should not have signs of recurrence or progression at time of study entry.
- Should have access to the internet in their home environment.
- Should have basic proficiency in using online applications.
- Should have a DIGID authentication code (to log into the program), or willing to obtain it.
- Patients may currently be receiving adjuvant (anti)hormonal therapy.

Exclusion criteria

- Patients who are unable to or cannot safely perform unsupervised exercise at the at the recommended levels
- Patients who lack basic proficiency in Dutch.
- Patients who have serious cognitive or psychiatric problems that would preclude them from following the intervention or completing the study questionnaires.
- Patients participating in concurrent studies or rehabilitation programs containing psychosocial
and/or exercise interventions.
- Patients who already meet the PA guideline of >150 min/week of moderate to vigorous PA for
longer than six months (patients in the maintenance stage according to TTM). To take into account a *30% overestimation of self-reported PA, we will be excluding patients who report > 200 min/week MVPA for longer than 6 months.

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):	21-12-2017
Enrollment:	246
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2017

Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	15-02-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-06-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-09-2018
Application type:	Amendment
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	NL62269.031.17