Promotion of physical activity in breast and prostate cancer survivors

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26518

Source
Nationaal Trial Register

Brief title
The PABLO Trial

Health condition

Breast and Prostate Cancer
Physical Activity
Fatique
Mood
Health related Quality of life.
Borst en Prostaatkanker
Fysieke activiteit
Vermoeidheid
Stemmingsklachten
Gezondheidsgerelateerde kwaliteit van leven.

Sponsors and support

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

Intervention

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

The secondary outcomes are: self-reported physical activity (IPAQ). Stage of change, fatigue (MFI) mood (POMS), HRQOL (SF-36, EQ5D) and 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

Introduction: A higher level of PA is associated with beneficial effects on physical and psychosocial functioning of cancer survivors after treatment. However, cancer survivors often do not meet the recommended level of PA. The Netherlands Cancer Institute (NCI) created an internet-based program to support PA.

Aim: To investigate the effectiveness of an online PA promotion program or blended care on PA levels in breast and prostate cancer survivors.

Methods: This multicenter trial will randomize participants into 3 study groups (N=82 per group) of men and women with histologically confirmed primary breast or prostate cancer (T1 – T4, N0 – N3, M0), who completed their treatment within 3 till 12 months at the NCI, Rijnstate or UMCU. One intervention group will receive access to the 6-months online intervention. The intervention is based on the Trans Theoretical Model and includes personal activity advice, information documents, video’s and assignments. Every month, the participants complete a short questionnaire online, which determines the stage of behavioral change regarding PA. Based on these results, a tailored and interactive program with assignments about goals, barriers and successes regarding PA of the participants will be provided. The second intervention group will receive access to the online intervention as well

as to additional support by a monthly phone call of a physiotherapist. The control group will receive usual care and a leaflet with PA guidelines. The total study duration is 12 months. At baseline, 6 months and 12 months, the primary outcome PA will be objectively measured during 7 days by an accelerometer. The secondary outcomes; self-reported PA (IPAQ), Fatigue (MFI), Mood (POMS) and Health-Related Quality of Life (HRQoL) are measured by online questionnaires.

Analysis: The group differences for primary outcome PA and secondary outcomes; self-reported PA, fatigue, mood and HRQoL will be analyzed by linear mixed models.

Results are expected in 2020.

Study objective

This study will evaluate the effectiveness of IPAS, with and without additional support, to improve objectively measured PA levels. We expect that IPAS will raise the level of PA more than normal care (UC) with a higher expected effect for IPAS + support. We also expect that cost effectiveness of the interventions is demonstrated in relation to UC. Secondary outcomes are self-reported PA, stage of change, fatigue, mood and health quality of life (HRQOL). Finally, explorers and mediators of the outcome will be studied in exploratory analyzes.

Study design

Baseline, T1 (after 6 months) and T2 (after 12 months).

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.

Contacts

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Eligibility criteria

Inclusion criteria

-Histologically confirmed primary breast or prostate cancer (stages: T1 - T4, NO - N3 and M0)

-Primary treatment should have been completed a minimum of 3 months and a maximum of 12 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 (anti)hormonal adjuvant 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 per week of moderate to vigorous PA for longer than six months (patients in the maintenance stage according to TTM).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2018
Enrollment:	246
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-12-2017
Application type:	First submission

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
NTR-new	NL6733
NTR-old	NTR6911
Other	Nederlands Kanker Instituut : 2015-7904

Study results