Evaluating feasibility and preliminary effects of a patient portal on empowerment of breast and lung cancer patients and survivors

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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-OMON38681

Source
ToetsingOnline

Brief title
Patient portal: feasibility and effects

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer and lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek

Source(s) of monetary or material Support: KWF kankerbestrijding (via Alpe d'Huzes stichting onderdeel van KWF)

Intervention

Keyword: cancer survivor, empowerment, physical activity, quality of life

Outcome measures

Primary outcome

To study feasibility and acceptability as well as the effects of the patient

portal on patient empowerment, physical activity, communication, dyspnea (lung

cancer) and quality of life

Secondary outcome

NA

Study description

Background summary

There is an increasing population living with physical and psychosocial consequences of breast and lung cancer during and after cancer treatment. Patients are often left guessing what to expect when treatment ends. That's why the Institute of Medicine (IOM) recommended the incorporation of survivorship care plans (SCP*s) into oncology practice to address the specific needs of these people. One important aspect of survivorship care is the screening for psychosocial needs. This could be done by self-reported outcome measures (PRO*s) such as health-related quality of life (HRQL) instruments. Despites the many reported benefits of incorporating PRO's into daily practice, routine use of PRO's to date is not part of usual care in many oncology hospitals, which leaves them missing out a great opportunity. In addition it is also clear that physical activity levels among cancer survivors in general are low. Therefore most cancer survivors lack the many beneficial effects of physical activity. Integrating physical activity promotion programs in survivorship care plans will facilitate the uptake in usual care. Currently a relatively basic information website (*voorlichting op maat*; VOM) is offered to breast and lung cancer patients in our hospital which contains digital leaflets with information about disease and treatment. This site however has no interactive features, such as online PRO*s, physical activity assessment and feedback or an

elaborate survivorship care plan. We propose that a combination of a SCP with integrated PRO's and physical activity support will be a feasible and effective way to empower cancer survivors to take charge of their health and health behaviours.

Study objective

Our objective is to test the feasibility and preliminary effects of a web-based patient portal containing a survivorship care plan, online questionnaires for symptoms and HRQL with personalized feedback and a physical activity support programme that is tailored to the status and preferences of the patient. All with the overarching goal to enhance knowledge and motivation of patients to be actively involved in their health care (patient empowerment).

Study design

A sequential cohort design with a control group and an intervention group following each other in time.

Intervention

Patients in the control groups will receive care as usual which includes access to a basic information website (VOM) without any interactive features. Patients in the intervention groups will be given access to the enriched and interactive patient portal.

Study burden and risks

The patient portal will help patients to be better informed about their disease, treatment and follow up. Furthermore it is expected that they will be empowered to actively influence their health status in a positive way by engaging in regular physical activity and by monitoring their symptoms and quality of life. The risks of participation in the study are minimal and might include anxious feelings toward information about disease and treatment. All content of the portal however will be provided by health care professionals working at the Antoni van Leeuwenhoek and will be subsequently edited by both the health education centre (*voorlichtingscentrum*) and the public relations department of the Antoni van Leeuwenhoek, thus greatly minimising this risk. The content will also be extensively pilot tested throughout 2013 in small groups of selected patients to thoroughly evaluate the patients* perceptions of all the content.

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

Patients with a histologically confirmed breast cancer or non-small cell lung cancer who will be treated with curative-intent (including lung cancer patients receiving concurrent chemo- and radiation therapy).

Exclusion criteria

-Significant cognitive impairment (such as post stroke, dementia etc.)
-Presence of metastases

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2013
Enrollment:	320
Type:	Anticipated

Ethics review

Approved WMO Date:	30-08-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-02-2014
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	NL44192.031.13