Motivating (former) cancer patients to increase their physical activity: The computer tailored OncoActive+ project.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40992

Source
ToetsingOnline

Brief title
The OncoActive+ project.

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
colon/prostate cancer, Malignant neoplasm of colon/prostate

Research involving
Human

Sponsors and support

Primary sponsor: Open Universiteit
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: (Former) Colon/Prostate Cancer patients, Computer tailoring, Health related Quality of Life, Physical Activity

Outcome measures

Primary outcome

Objective physical activity (accelerometer data) en subjective physical activity, specified to work, ADL, sport and leisure time (SQUASH; Wendel-Vos CGW, Schuit AJ, Saris WHM. Reproducibility and relative validity of the short questionnaire to assess Health Enhancing Physical Activity (SQUASH). J Clin Epid 2003,12,1163-9).

Secondary outcome

Health related quality of life, psychosocial feelings, fatigue, mental adjustment to cancer, use of health care, appreciation and use of the intervention.

Study description

Background summary

Cancer and its treatment largely affects life expectancy of individuals and results in an increased level of fatigue, emotional distress, depression and a reduced level of Quality of Life (QoL). The problem is increasing as cancer incidence is expected to rise with 40% to 123.000 new cases per year by 2020. It is important to invest in interventions that reduce the negative effects of cancer and its treatment and help to prevent recurrence of cancer and other (chronic) diseases. Being physically active enough is an important goal in reaching this. Therefore the computer-tailored OncoActive+ project will be developed. The aim of the project is to stimulate physical activity in (former) cancer patients and to support and advise them during this process. The program is individually oriented and largely self-regulated; the patient participates in the program without guidance from caregivers.

Study objective

To develop and evaluate the OncoActive+ project that aims to increase the amount of physical activity of (former) cancer patients. The main goal of this study is to test the effect of the intervention on physical activity behavior, as well as the usability and appreciation of the program, the effect on quality of life and fatigue. The proven effective Active+ program (developed for over fifties) is the base of the OncoActive+ program. Because it is a computer-tailored program, everyone gets personal advise and information, specified to i.a. type of cancer and treatment phase.

Study design

Phase I (not applicable for this METC submission): Preparation and adapting the Active+ into OncoActive+ to the needs of (former) colon/prostate cancer patients, based on literature and interviews with (former) colon and prostate cancer patients, oncologists, physiotherapists, physiologists, oncology nurses, cancer-related PA group coaches.
Phase II (applicable for this METC submission): Small scale pre-test (n=12) and pilot study (n=20) on respectively the material and techniques, and the usability and validity of the adapted OncoActive+ among (former) colon and prostate cancer patients.
Phase III (applicable for this METC submission): The study is a randomized clinical trial. The trial will be carried out to compare the experimental group with the waiting list control group. Outcome measurements are physical activity (accelerometer data), self-reported physical activity, fatigue and quality of life and are taken at baseline, and after 3,6, and 12 months. In total, 428 (former) patients will be initially included by oncologist and oncology nurses of hospitals and radiotherapy centres. The control group will have access to the intervention after the last measurements at 12 months.
Phase IV (applicable for this METC submission): The project ends with a report and distribution of the outcomes, and an implementation inventory for large-scale distribution of OncoActive+.

Outline of the RCT design:

E: M1(Acc1+V1)--> A1-->A2-->M2(V2+PE1)-->A3-->M3(Acc2+V3+PE2)-->M4(Acc3+V4+PE3)
C: M1(Acc1+V1)--> M2(V2)--> M3(Acc2+V3)-->M4(Acc3+V4)

E Experimental group
C Control group
M Measurement (1=baseline, 2= after 13 weeks, 3= after 6 months, 4= after 12 months)
Acc Participants wear an accelerometer in the week before the questionnaires are filled out
V Questionnaires (PA behaviour, quality of life, psychosocial experience,

fatigue, mental adjustment to cancer, and use of health care)
A Advise 1 (after 2 weeks) and 2 (after 8 weeks) based op V1; 3 (after 3 months) based on V2, with ipsative feedback
PE Process evaluation

Intervention

The OncoActive+ intervention consists of several components
- Subjects in the experimental group receive an computer-tailored physical activity advise three times during the 4 months of the intervention. The advise is based on the completed questionnaires in which personal features, physical activity behaviour, and the psychological determinants of physical activity of the subject are processed. Furthermore, the intervention is personalized for environmental determinants by giving advise on possibilities for physical activity and initiatives in the environment.
- Participants will receive a pedometer to set PA goals.
- The intervention will be integrated in a website with further information, a users forum, online physical exercises and the possibility to consult an expert.
The intervention aims to raise awareness on the lack of physical activity, and to stimulate initiation and maintenance of physical activity.

Study burden and risks

There are no risks and detrimental consequences related to the study and intervention. Participants in the experimental group can decide for themselves when and how often they make use of the intervention. The advice texts are developed in cooperation with experts like oncologists, physiotherapists, physiologists, oncology nurses, and cancer-related PA group coaches. Moreover, all the participants (in the experimental group and in the control group) can stop their participation in the study at any time. The burden of filling out four questionnaires and wearing an accelerometer for in total 3 weeks in a period of 12 months is minimal. In addition, expectation is that the use of the intervention will have positive effects on endurance and quality of life. Participants in both groups receive their usual health care. They won*t be refrained from care (including extra professional care they would like to seek). The participants in the control group will receive access to the intervention (the online or written advise, the pedometer and use of the website) at the end of the study period.

Contacts

Public
Open Universiteit

Valkenburgerweg 177
Heerlen 6419AT
NL
Scientific
Open Universiteit

Valkenburgerweg 177
Heerlen 6419AT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Diagnosed with colon/prostate cancer.
-18 years or older
-Able to read and speak Dutch
-The patient needs to be under primary treatment (radiotherapy, chemotherapy, surgery) for prostate or colon cancer, while the former patients need to have successfully completed the main treatment up to one year ago.

Exclusion criteria

-Patients with a serious medical, psychiatric, or cognitive disease that would interfere with participation (e.g. Alzheimer*s Disease, and severe obese (BMI>35)).
-Any operation must have taken place at least six weeks ago.
-Patients in de palliative phase will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2015
Enrollment:	460
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL47678.096.14
Other	NL47678.096.14