The OncoActive+ project.

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The developed OncoActive+ intervention will be an easily accessible physical activity intervention for (former) colon and prostate cancer patients as the user defines when and how to be physically active. OncoActive+ has the potential to easily...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25964

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

(Former) colon and prostate cancer patients, computer tailoring, physical activity, health related quality of life.

(Voormalige) darm en prostaat kanker patienten, computer tailoring, fysieke activiteit, gezondheid gerelateerde kwaliteit van leven.

Ondersteuning

Primaire sponsor: The research will be executed at the faculty of Psychology of the Open Universiteit, in cooperation with Maastricht University.
Overige ondersteuning: KWF Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Objective physical activity (accelerometer data) en subjective physical activity, specified to work, ADL, sport an leisure time (SQUASH).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

The OncoActive+ project aims to increase the amount of physical activity of (former) colon and prostate cancer patients. The proven effective Active+ program (developed for over fifties) is the base of the OncoActive+ program. OncoActive+ tries to stimulate physical activity through personal advises and information, specified to i.a. type of cancer and treatment.

Subjects in the experimental group receive an physical activity advise three times during the 4 months of the intervention. The advise is based on the completed questionnaires in which personal characteristics, physical activity behaviour, and the psychological determinants of physical activity of the subject are processed. It aims to raise awareness on the lack of physical activity, and to stimulate initiation and maintenance of physical activity. Participants will receive a pedometer to set PA goals. The program is individually oriented and largely self-regulated; the patient participates in the program without guidance from caregivers.

The main goal of this study is to test the effect of the intervention on physical activity behavior (accelerometer, self-reported). Secondary goals are to test the usability and appreciation of the program, and the effect on quality of life and fatigue. The primary and secondary outcomes will be measured at baseline, after 3 months, after 6 months and after 12 months.

Doel van het onderzoek

The developed OncoActive+ intervention will be an easily accessible physical activity intervention for (former) colon and prostate cancer patients as the user defines when and

how to be physically active. OncoActive+ has the potential to easily reach broad patient populations with low (personnel) costs, and it is therefore low in demand of health care providers. If proven effective, the feasibility of the intervention will be examined among relevant organizations in order to come up with an end product that is useable in practice. In the future OncoActive+ might also be useful for other cancer types

Onderzoeksopzet

Both primary and secondary measurements will be measured at baseline, after 3 months, after 6 months and after 12 months.

Onderzoeksproduct en/of interventie

Before the intervention will be tested for effectiveness with a randomized controlled trial (RCT), the intervention already effective proven Active+ program will be adapted through a literature review and interviews with experts and (former) prostate and colon cancer patients. Intervention material will be tested, and a pilot study will be executed. During the RCT subject in the experimental group receive an physical activity advise (either online or through written letters) three times during the 4 months of the intervention. The advise is based on the completed questionnaires in which personal characteristics, physical activity behaviour, and the psychological determinants of physical activity of the subject are processed. It aims to raise awareness on the lack of physical activity, and to stimulate initiation and maintenance of physical activity. Furthermore, the intervention is personalized for environment determinants by giving advise on possibilities for physical activity and initiatives in the environment. The intervention will be offered both online and written. In addition, a website with further information will be developed, as well as an users forum and the possibility to consult an expert. Participants of the control group 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 and use of the website) after the end of the study period.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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 survivors need to have successfully completed the main treatment up to one year ago.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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. When operations are planned in the future, patients only can be included when the operation has taken place at least six weeks ago.

- Patients in de palliative phase will be excluded.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-12-2013
Aantal proefpersonen:	450
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-11-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4028
NTR-old	NTR4296
Ander register	KWF Kankerbestrijding (funding source) : NOU 2012-5585
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

Golsteijn RHJ, Bolman C, Volders E, Peels DA, de Vries H, Lechner L. OncoActief: een gerandomiseerd onderzoek naar de effectiviteit van een computer-getailorde interventie ter bevordering van fysieke activiteit bij (voormalige) prostaat- en darmkankerpatiënten. Nederlands Tijdschrift voor Oncologie 2015;12:84-88.