

Prostate cancer and diet - a randomized controlled trial on the effect of a dietary intervention on the quality of life of men and serum nutrient levels in their blood.

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Being diagnosed with prostate cancer impacts patients quality of life. Besides choosing a treatment strategy that suits patients' values and preferences, they may look for subsequent strategies to cope with their disease. Dietary changes may...

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

Samenvatting

ID

NL-OMON20602

Bron

NTR

Verkorte titel

Prostate cancer and diet - a randomized study

Aandoening

dietary changes, active surveillance, prostate cancer

Ondersteuning

Primaire sponsor: Department of Urology, Erasmus MC

Overige ondersteuning: Gemeente Almere, MVV/Steunfonds Amnestie

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To improve participants' quality of life, as measured by the SF-12 general health domain, by actively engaging in a prostate cancer diet.

Toelichting onderzoek

Doel van het onderzoek

Being diagnosed with prostate cancer impacts patients quality of life. Besides choosing a treatment strategy that suits patients' values and preferences, they may look for subsequent strategies to cope with their disease. Dietary changes may serve as a coping strategy as it can give them the feeling of 'doing something' to help or manage their uncertainty and regaining some control over their disease and their future survivorship.

Onderzoeksopzet

3 months (with three gatherings)

Onderzoeksproduct en/of interventie

A randomized controlled trial including three groups of low-risk prostate cancer patients currently on active surveillance: (I) a control group, (II) a prostate cancer diet-group, (III) a VERS+-group. The two interventions groups (group II and III) will receive a prostate cancer diet and recipes to cook 4 dinner meals per week for a period of 3 months. Furthermore, both groups will receive some coaching on the impact of healthy eating, and how to change and maintain a healthier lifestyle. In addition, the VERS+-group will receive the fruit and vegetables for cooking the meals through a food box. The control group will be informed about healthy eating as described in the guideline from 'het Voedingscentrum - de Schijf van Vijf'.

Contactpersonen

Publiek

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The Netherlands

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Men (aged > 18 years), diagnosed with low-risk prostate cancer defined as T1 or T2a, Gleason 2-6 and PSA level <10 ng/ml, who are currently on active surveillance. Participants must be able to understand and read Dutch. Furthermore they must be able to cook meals or have meals prepared for them.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Men diagnosed with low-risk prostate cancer and treated with radical prostatectomy or radiotherapy (i.e. another type of therapy than active surveillance. Men diagnosed with intermediate- or aggressive prostate cancer. Participants that cannot adhere to the prostate cancer diet. People who are vegetarian, are gluten- or lactose-intolerant, or follow any other kind of diet.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-07-2018
Aantal proefpersonen: 255
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 14-06-2018
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50679
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7076
NTR-old	NTR7274
CCMO	NL62256.078.17
OMON	NL-OMON50679

Resultaten