

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.

No registrations found.

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

Summary

ID

NL-OMON20602

Source

NTR

Brief title

Prostate cancer and diet - a randomized study

Health condition

dietary changes, active surveillance, prostate cancer

Sponsors and support

Primary sponsor: Department of Urology, Erasmus MC

Source(s) of monetary or material Support: Gemeente Almere, MVV/Steunfonds
Amnestie

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

(I) To improve participants' feeling of being in control of their disease, as measured with the Prostate Activation Measure (PAM), by actively engaging in a prostate cancer diet. (II) To measure the effect of a dietary intervention with special grown products on the serum nutrient concentrations of participants. (III) To survey the user behavior of both participants and their partners when engaging in a prostate cancer diet. (IV) To test the infrastructure of greenkeepers in the Westland, producing and delivering products for a specific, targeted patient population instead of the general public.

Study description

Study objective

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.

Study design

3 months (with three gatherings)

Intervention

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'.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Control: N/A , unknown

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-07-2018
Enrollment: 255
Type: Anticipated

Ethics review

Positive opinion
Date: 14-06-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50679
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results