

# 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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Primary objective: to improve participants\* quality of life, as measured by the SF-12 general health domain, by actively engaging in a prostate cancer diet. Secondary objectives: - To improve participants\* feeling of being in control of their...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Reproductive and genitourinary neoplasms gender unspecified NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON50679

### Source

ToetsingOnline

### Brief title

Prostate cancer and diet - a randomized study.

### Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Prostatic disorders (excl infections and inflammations)

### Synonym

Prostate cancer, prostate carcinoma

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Gemeente Almere;MMV/Steunfonds Amnestie en EPEMED en Erasmus MC Foundation

## Intervention

**Keyword:** Dietary intervention, Prostate cancer, Quality of life, Serum nutrient levels

## Outcome measures

### Primary outcome

For the VERS+-group we expect an improved quality of life as measured with the SF-12, general health domain (improvement of  $\pm 5$  points).

### Secondary outcome

- For the VERS+-group an improved Patient Activation Measure (PAM) score is expected. Because the use of the PAM is still scarce in prostate cancer patients, it is difficult to quantify the expected score increase.
- An increase in the nutrient levels measured in the blood of participants in the two intervention groups after 3 weeks (t2) and 3 months (t3) of following a prostate cancer diet.
- To survey the user behaviour of both participants and their partners when engaging in a prostate cancer diet.
- 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

## **Background summary**

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 objective**

Primary objective: to improve participants\* quality of life, as measured by the SF-12 general health domain, by actively engaging in a prostate cancer diet.

Secondary objectives:

- 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.
- To measure the effect of a dietary intervention with special grown products on the serum nutrient concentrations of participants.
- To survey the user behaviour of both participants and their partners when engaging in a prostate cancer diet.
- 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 design**

A randomized controlled trial including three groups of prostate cancer patients who are currently being treated (including active surveillance) or have been treated for prostate cancer in the past; (1) a control group, (2) a prostate cancer diet-group, and (3) a VERS+ -group.

## **Intervention**

The two intervention groups (prostate cancer diet-group and the VERS+ group) will receive a prostate cancer diet and recipes to cook 4 dinner meals per week for a period of 3 months, as well as a few suggestions for breakfast and lunch meals. 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\*.

Throughout the study period of 3 months, study participants will attend 3

meetings (at baseline (t1), after 3 weeks (t2) and after 3 months (t3)) for which they will be requested to fill-out quality of life questionnaires and a food frequency questionnaires upfront. Prior to the three meetings blood will be drawn (vena puncture). Blood will be drawn during the meetings using finger prick blood (Dried Blood Spot Technique). Six and 12 months after the start of the study, participants will receive follow-up questionnaires to see whether they have been able to continue the dietary changes made during the three month study intervention period.

### **Study burden and risks**

The prostate cancer diet is in accordance with the guidelines of \*Het Voedingscentrum\* and the World Cancer Research Fund. Participants will have to invest time and be perseverant in cooking the recipes and adapting a healthier lifestyle. Participants off all three groups (individual meetings per group) are invited to attend three meetings which will last between 1-2 hours per meeting. In anticipation of the meetings, participants are requested to complete quality of life questionnaires and a food frequency questionnaire. Prior to the three meetings blood will be drawn (vena puncture). Risk of vena puncture is negligible, idemque the burden.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40  
Rotterdam 3015 GD  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40  
Rotterdam 3015 GD  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Male, age  $\geq 18$  years.
- Diagnosed with prostate cancer.
- Currently being treated for prostate cancer (including active surveillance).  
Has been treated for prostate cancer in the past.
- Able to understand and read Dutch

### Exclusion criteria

- Unable to understand and read Dutch.
- Unable to invest time in cooking according to the provided prostate cancer diet.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-07-2018
Enrollment:	255
Type:	Actual

## Ethics review

Approved WMO

Date: 14-06-2018

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 12-07-2019

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 13-10-2020

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 25-09-2023

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20602

Source: NTR

Title:

### In other registers

**Register**

CCMO

OMON

**ID**

NL62256.078.17

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