Evaluation of information provision and treatment decision making for men with early-stage prostate cancer.

No registrations found.

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

Summary

ID

NL-OMON22128

Source
NTR

Brief title
PCPCC

Health condition

Prostate cancer, prostaatkanker

Sponsors and support

Primary sponsor: Tilburg University, St. Elisabeth Hospital
Source(s) of monetary or material Support: CZ Fonds

Intervention

Outcome measures

Primary outcome

Decisional conflict (short term),
decisional regret and treatment satisfaction (long term). All measured by questionnaires.

Secondary outcome

Decision making role, knowledge about prostate cancer, statisfaction with information, preparation for decision making, health-related quality of life, and personality (anxiety, depression, optimism) and skills measures (self-efficacy, health literacy, numeracy). All measured by questionnaires.

Study description

Background summary

At an early stage, prostate cancer patients are often eligible for more than one treatment option, including active surveillance. In terms of long-time survival no treatment option is superior. To choose the most suitable treatment, a patient has to weigh his personal preferences against the risk involved to the cancer and the occurrence of side-effects from treatment. To stimulate shared decision making between a patient and his physician, decision aids (DA's) have proven to be a valuable tool but routine use in clinical practice is lagging behind. For this study an existing prostate cancer treatment DA is adjusted to Dutch context for use at minimal effort and optimal support in clinical consultation. This has resulted in an innovative, web based DA. The aim of this study is to investigate the effectiveness of this tool as well as implementation in clinical practice.

Country of recruitment: The Netherlands

Study objective

We expect that the decision aid will support patients in deciding about prostate cancer treatment by decreasing decisional conflict and regret. We also expect and an improvement of treatment satisfaction and health-related quality of life.

Study design

T0: Registration; after diagnosis, but before a treatment decision is made (no questionnaire).

T1: After treatment decision making (approximately two weeks after registration)

T2: Follow-up after 6 months

T3: Follow-up after 12 months

Intervention

The control group will receive usual care; information provision and provided decisional

support will be given according to the hospital standards.

In addition to usual care, the intervention group will be granted access to an online decision aid, providing patients with structured information on the risks and benefits of the different treatment options and offer value-clarification tasks. A summary is obtained to discuss with their physician during the following consultation.

Contacts

Public
Tilburg University
Social and Behavioral Sciences
PO Box 90153
M. Cuypers
Tilburg 5000 LE
The Netherlands
+31 13 466 28 55
Scientific
Tilburg University
Social and Behavioral Sciences
PO Box 90153
M. Cuypers
Tilburg 5000 LE
The Netherlands
+31 13 466 28 55

Eligibility criteria

Inclusion criteria

- Men that are newly diagnosed with early stage prostate cancer;

- Tumour stage T1 or T2;

- Maximum PSA-score of 20;

- Maximum Gleason-score of 7;

- Patients who are eligible for at least two treatment options;

- Patients (in the intervention arm) have to be able to make use of a computer with internet-

access in order make use of the web-based decision aid.

- Patients have to be able to read and understand Dutch language.

Exclusion criteria

- Patients with advanced cancer;

- If the urologist judges the patient is not in the right condition to participate;

- In the case of a second opinion when the other involved hospital also uses a decision aid from this or an other study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2014
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-05-2014
Application type:	First submission

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
NTR-new	NL4432
NTR-old	NTR4554
Other	METC Brabant : NW2014-03

Study results