

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

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

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

Samenvatting

ID

NL-OMON22128

Bron

NTR

Verkorte titel

PCPCC

Aandoening

Prostate cancer, prostaatkanker

Ondersteuning

Primaire sponsor: Tilburg University, St. Elisabeth Hospital

Overige ondersteuning: CZ Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-05-2014
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	01-05-2014
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	NL4432
NTR-old	NTR4554
Ander register	METC Brabant : NW2014-03

Resultaten