(Cost-)effectiveness and implementation of a decision aid for patients with prostate cancer

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Patient decision aids (PDA) for prostate cancer have been developed to help patients make a deliberative choice for a treatment option for their disease. Despite proven benefits of PDAs, structural implementation falls short of expectations. To...

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

Samenvatting

ID

NL-OMON21482

Bron
NTR

Verkorte titel
Patient Decision Aid Prostate cancer

Aandoening

Localized prostate cancer

Ondersteuning

Primaire sponsor: Primair: CZ Zorgverzekeraar (Health Insurance)
Secundair: Astellas Pharma B.V.
Overige ondersteuning: Primair: CZ Zorgverzekeraar (Health Insurance)
Secundair: Astellas Pharma B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- PATIENTS
Decisional conflict

- PARTNERS
Effect of prostate cancer in the relationship:
study-specific questionnaire based on the study of Zeliadt

Communication between patient and partner and interaction with HCPs:
Study-specific questionnaire based on the study of Zeliadt

Social contacts and support: Active Engagement Scale (AES)

Toelichting onderzoek

Achtergrond van het onderzoek

For the treatment of localized prostate cancer, several treatment options are available, each with their own side effects. Ideally, a patient should be able to make a choice based on arguments that weigh the most for him. This requires shared decision making, in which patients can make the decision for their treatment in collaboration with their urologist, supported by a patient decision aid (PDA). Despite proven benefits of PDA usage, structural implementation, falls short of expectations. This study was undertaken to implement a PDA and evaluate its effectiveness in a multi-center study. This randomized stepped wedge trial will take place in 18 centers, using a stepped wedge design. All centers start by including only control patients and their partners (i.e. no use of the PDA). Every 3 or 6 months a new cluster of two or four centers will start with the implementation of the PDA, and the inclusion of patients (and their partners) who used the PDA will start. Questionnaires will be send out to patients and their partners, prior to the treatment and after the decision for a treatment is made, 3 months, 6 and 12 months after the treatment. Partners will also be asked to fill in 4 questionnaires. Questionnaires include questions about satisfaction, decisional conflict and quality of life.
The Netherlands

Doel van het onderzoek

Patient decision aids (PDA) for prostate cancer have been developed to help patients make a deliberative choice for a treatment option for their disease. Despite proven benefits of PDAs, structural implementation falls short of expectations. To overcome the hurdles with implementation, we developed a PDA for patients with localized prostate cancer using an iterative participatory approach. In the present study, we aim to investigate (cost-)

effectiveness and implementation of this PDA for patients with localized prostate cancer and their partners. By using a stepped wedge cluster randomized controlled trial, we aim to achieve sustainable implementation of the PDA when proven (cost-)effective.

The PDA will be sequentially implemented in 18 hospitals in the region of Amsterdam, The Netherlands, over a period of 22 months (March 2014 to December 2015). In each hospital, there will be period of 4 to 19 months of including newly diagnosed patients who receive usual care, followed by a period of 3 to 18 months in which the PDA is provided to newly diagnosed patients and their partners. Baseline assessment takes place between the choice for a treatment option and the start of the treatment, with follow up assessments at 3, 6 and 12 months follow-up. The primary outcome measure for patients is reduction of decisional conflict (DCS). Furthermore, for patients a cost-evaluation will be performed (EQ-5D, TIC-P, PRODISQ).
The primary outcome measures for partners are the effect of prostate cancer on the relationship and communication between patient, partner and health care professionals (study-specific questionnaire based on the study of Zeliadt), and social contacts and support (AES).
Patients and partners receiving the PDA will also be asked about their satisfaction with the PDA (study-specific questionnaire based on the study of Légaré).

Outcome measures on implementation include the implementation rate and a questionnaire for health care professionals on determinants of an innovation (the PDA).
We hypothesize that patients using the PDA leads to less decisional conflict in choosing a treatment decision. Sub hypotheses include that patients who use the PDA will choose more active surveillance as treatment option, will perceive more participation, have more realistic expectations of the treatment options, have more knowledge about prostate cancer and will communicate more with their partner about prostate cancer. Furthermore, patients who use the PDA will be expected not to differ from patients who will receive usual care in loss of productivity and need for supportive care.

Onderzoeksopzet

Baseline assessment T0 patients and partners

Between choice and treatment

Assessment T1 patients and partners

3 months after treatment

Assessment T2 patients and partners

6 months after treatment

Assessment T3 patients and partners

12 months after treatment

* After treatment follow up is defined as the last day after irradiation in case of brachytherapy or external beam radiation therapy or the day after the removal of the catheter in case of surgery, or the day after choosing for active surveillance.

MIDI for HCPs: 3 months after implementation in participating hospital

Onderzoeksproduct en/of interventie

Control group: patients with prostate cancer (and their partners), who have a choice for a curative treatment option and who receive care as usual by health care providers in participating centers.

Intervention group: patients with prostate cancer (and their partners), who have a choice for a curative treatment option and who additionally to care as usual by health care providers in participating centers, will receive the PDA.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Newly diagnosed adult patients with localized prostate cancer (and their partners) who have made a decision for a curable treatment option for prostate cancer, but have not undergone this treatment yet

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients (and their partners) younger than 18 years, patients (and their partners) who are not able to understand the Dutch language in speech and in writing, patients who do not have a choice for multiple treatment options for localized prostate cancer. TNM classification: T4, N1, M1

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2014
Aantal proefpersonen:	465

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-05-2015
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	NL5039
NTR-old	NTR5177
Ander register	METc VU medisch centrum : 2013-444

Resultaten