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

No registrations found.

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

Summary

ID

NL-OMON21482

Source
NTR

Brief title
Patient Decision Aid Prostate cancer

Health condition

Localized prostate cancer

Sponsors and support

Primary sponsor: Primair: CZ Zorgverzekeraar (Health Insurance)
Secundair: Astellas Pharma B.V.
Source(s) of monetary or material Support: Primair: CZ Zorgverzekeraar (Health Insurance)
Secundair: Astellas Pharma B.V.

Intervention

Outcome measures

Primary outcome

- 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)

Secondary outcome

- PATIENTS

Quality of life (EORTC QLQ-C30 and PR25)

Treatment preferences (study-specific questionnaire)

Experienced participation and approach to decision making (study-specific questionnaire based on the Perceived Participation of Deber)

Expectations of the treatment (SETS pre-treatment)

Outcome of the treatment (SETS post-treatment)

Subjective and objective knowledge about prostate cancer (based on DQI knowledge, Karen Sepucha (Massachusettes General Hospital) and PCA 0915 of Carrie Levin)

Communication between patient and partner (study-specific questionnaire based on the study of Zeliadt)
The need for supportive care (SCNS SF-34 and prostate module)
Decision regret (DRS)
COST-EVALUATION
Quality of life for the benefit of cost analysis (EQ5D)
Registration of aftercare (TiC-P)
Productivity Costs (PRODISQ)

SATISFACTION WITH INTERVENTION
Use of the PDA (study-specific questionnaire)
Appreciation for the PDA (study-specific questionnaire)
Satisfaction with the use of the PDA (SCIP-B)
Preparation for decision making (Prep-DM)
Promoting and impeding factors using the PDA (study-specific questionnaire based on the study of Légaré)

- PARTNERS
Quality of life of partners (SF-12)
Treatment preferences (study-specific questionnaire)
Experienced participation and approach to decision making (study-specific questionnaire based on the Perceived Participation of Deber)
Role as caregiver (CSI)
SATISFACTION WITH INTERVENTION
Use of the PDA (study-specific questionnaire)
Appreciation for the PDA (study-specific questionnaire)
Promoting and impeding factors using the PDA (study-specific questionnaire based on the study of Légaré)

MODERATING FACTORS PATIENTS AND PARTNERS
Socio-demographic questionnaire with clinical variables
Monitoring and blunting coping styles

IMPLEMENTATION

IMPLEMENTATION
Implementation rate number of participating hospitals and proportion participating HCPs per hospital as a proportion of total number of all HCPs treating prostate cancer patients, and approximate proportion of patients provided with the PDAs as a proportion of total number of eligible patients per participating hospital (retrieved from the Netherlands Cancer Registry).
Measurement instrument for determinants of innovation (MIDI) among HCPs

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2014
Enrollment:	465
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-05-2015
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	NL5039
NTR-old	NTR5177
Other	METc VU medisch centrum : 2013-444

Study results