

Testing the effectiveness of a multi-criteria values clarification methods for patients with localized prostate cancer

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22110

Bron

Nationaal Trial Register

Aandoening

Shared decision making, Values clarification methods, decision aid, analytic hierarchy process, prostate cancer

Ondersteuning

Primaire sponsor: Elisabeth-Tweesteden Hospital

Overige ondersteuning: Stichting Delectus

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Disease-specific knowledge

- Decisional Conflict (special interest: informed subscale) = subjective knowledge

- Value congruence by measuring indicated preferences, changes in preferences

- Decision quality

Toelichting onderzoek

Achtergrond van het onderzoek

The AHP method is a highly appropriate method to gain more insight into patients' values and treatment decisions, by structuring and breaking down the decision into smaller elements for analysis. It encourages a process of pairwise comparisons of potential outcomes, which is needed for a patient to reach stabilized preferences. Furthermore, this VCM is able to explicitly present the calculated treatment option based on the scores that show how well or poorly each treatment option fits with the patients' responses. This will be appropriate for patients who prefer actual treatment advice from the DA.

Currently, the effectiveness of this specific VCM, in addition to the existing DA, on the outcome decision quality, is being evaluated in a prospective cohort study. In that study, decision quality is defined as congruence between well-informed patients' values and the calculated and chosen treatment option. Additionally, results on disease-specific knowledge and preparation for decision making will be compared with a historical control group who only used the existing DA. Health literacy and numeracy will also be assessed to evaluate if the patients with low numeracy and/or low health literacy benefit from the VCM. Furthermore, the VCM will be further evaluated on its usage and patients are able to include additional decision attributes that are not prespecified by the working group but are relevant to them.

Doel van het onderzoek

We hypothesize that the addition of the newly developed web-based VCM to the existing decision aid will improve the support offered to patients in their decision-making process (improvement of disease-specific knowledge, feeling informed, and value congruence) and their decision quality (association between knowledge and value congruence).

Onderzoeksopzet

To evaluate our outcomes we will use questionnaires at 3 timepoints.

T0 = directly after diagnosis and after informed consent is obtained (demographics, health skills, treatment preference)

T1 = After treatment decision is made (treatment preference, decisional conflict, satisfaction,

knowledge, feasibility)

T2 = 6 months after T1 (regret, treatment satisfaction, perceived treatment)

Onderzoeksproduct en/of interventie

The values clarification method (VCM) based on analytic hierarchy process (AHP) is appropriate to generate more insight into the decision making process of patients. AHP is most often used in health care at the policy and health technology assessment level, but AHP is also used as decision support tool in clinical decision making(14). The first step within AHP is to define the decision problem: what are possible treatment options and which considerations and criteria should be used to judge how well the treatment options meet the patient's goal. The selected criteria are used in pairwise comparisons to determine their relative priorities (weights) in the decision. In addition, a second set of pairwise comparisons are used to derive weights for the performance of treatment options on the different criteria. The results can then be combined to create a quantitative measure on a ratio scale that indicates how well each of treatment options can be expected to meet the overall treatment goal. The AHP has been successfully applied to a variety of complex medical decisions, but its use in prostate cancer is limited and focused on prostate cancer screening decisions (15-17) With this method, value congruence can be calculated by measuring the extent of agreement between the preferred treatment calculated by the AHP based VCM, the preferred treatment directly assessed prior to completion of the AHP based VCM, and the final treatment received.

Contactpersonen

Publiek

Erasmus MC/Elisabeth- TweeSteden Ziekenhuis, Urologie

Isabel de Angst
Postbus 90151

Tilburg 5000 LC
The Netherlands

Wetenschappelijk

Erasmus MC/Elisabeth- TweeSteden Ziekenhuis, Urologie

Isabel de Angst
Postbus 90151

Tilburg 5000 LC

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Men that are newly diagnosed with localized early staged prostate cancer. 'Early stage' prostate cancer is defined by a T1c-T2c tumour with a maximum PSA-score of 20 and a maximum Gleason-score of 7.
- Patients are eligible for active surveillance and active treatment.
- Patients who want to use the web-based decision aid.
- Patients have to be able to make use of a computer with internet-access in order make use of the web-based decision aid and the AHP model.
- Patients have to be able to complete a Dutch questionnaire.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with advanced cancer; the decision aid is not suitable for decisions involved in a more advanced stage of the cancer (any score higher than mentioned as inclusion criteria).
- If the urologist judges the patient is not in the right condition to participate, the patient will not be approached.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-09-2017
Aantal proefpersonen:	125
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	09-08-2018
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	NL7223
NTR-old	NTR7422
Ander register	METC Brabant : NW2017-26

Resultaten