A decision aid for the treatment of Benign Prostatic Hyperplasia

No registrations found.

Ethical review Positive opinion **Status** Recruiting

Health condition type -

Study type Interventional

Summary

ID

NL-OMON27217

Source

Nationaal Trial Register

Brief title

BPH DA

Health condition

DA BPH

Sponsors and support

Source(s) of monetary or material Support: Stichting Delectus

Intervention

Outcome measures

Primary outcome

value congruence and regret

Secondary outcome

decisional conflict, SCIP-B, SDM-Q-9, EORTC-info-25, knowledge

Study description

Background summary

a prospective cohort study to investigate the effect of a decision aid for benign prostatic hyperplasia compared to a historical control cohort.

Study objective

Patients who have used the decision aid for making the treatment choice for benign prostatic hyperplasia: feel more informed, have more knowledge about the disease, feel more involved in making the decision, make a more value congruent choice, have less regret,

Study design

T1: after using decision aid

T2: 3-6 months after treatment choice

Intervention

using a BPH decision aid

Contacts

Public

Fieke van der Wijden [default] The Netherlands

Scientific

Fieke van der Wijden [default] The Netherlands

Eligibility criteria

Inclusion criteria

New patient with a LUTS caused by benign prostatic hyperplasia who have the choice

between:

- waiting OR start medication
- continue (other) medication OR operation

Exclusion criteria

- -absolute operation indication (example: persistent urinary retention)
- speak not good enough dutch to understand the DA or questionnary
- cannot use a computer

Study design

Design

Study type: Interventional

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: N/A, unknown

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 12-09-2016

Enrollment: 200

Type: Anticipated

Ethics review

Positive opinion

Date: 12-09-2016

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 NL5926 NTR-old NTR6106

Other METC Brabant : NW2014-21

Study results