Study on shared decision making in choosing a treatment for pelvic organ prolapse

Published: 30-10-2016
Last updated: 15-12-2023

The use of an interactive web-based Decision Aid reduces decisional conflict and increases patient satisfaction with information and care.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Interventional

Summary

ID

NL-OMON27378

Source
NTR

Brief title
SHADE-POP

Condition

- Uterine, pelvic and broad ligament disorders

Health condition

Pelvic organ prolapse, cystocele, rectocele, enterocele, uterine descent, surgery, pessary, treatment

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth TweeSteden Ziekenhuis Tilburg, Universiteit van Tilburg,

Zorgkeuzelab
Source(s) of monetary or material Support: Same as sponsor

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

The main study endpoints are: satisfaction with treatment decision (making), and satisfaction with information.

Secondary outcome

Secondary endpoints are satisfaction with care and treatment, decisional conflict and decisional regret, quality of life, healthcare providers' evaluation of the (implementation of the) decision aid, and recurring symptomatic POP.

Study description

Background summary

Female pelvic organ prolapse (POP) is a common problem among women worldwide. The prevalence in The Netherlands ranges from 8.4 to 11% in women aged 45-85 years. Pessary or surgical treatment are the two commonly applied treatments. The lack of randomized controlled treatment studies in this field makes recommendations on the best treatment option for individual patients speculative. Choice of treatment depends on both patient and doctor preference. Information on POP provided to patients is not always accurate. This can result in incorrect or incomplete ideas and expectations about the disease and its treatment. Shared decision making (SDM) and the use of a decision aid (DA) are ways to provide patients with sufficient information and improve their knowledge. Furthermore it helps clarify their preferences regarding treatment and improves comfort and participation in the process of decision making, it reduces decisional conflict and makes patients feel more comfortable with their choices. To this end a web-based DA for the treatment of POP was developed. The aim of this study is to investigate the effects of the DA on SDM regarding treatment choice and patient-reported outcomes.

Study objective

The use of an interactive web-based Decision Aid reduces decisional conflict and increases

patient satisfaction with information and care.

Study design

T1: max. 2 weeks after treatment decision, before start treatment

T2: 6 months after T1

T3: 12 months after T1

T4: 24 months after T1

Intervention

In the intervention group, patients will be presented with the decision aid after diagnosis. After completing the web-based decision aid program, patients' preferences will be discussed with the clinician during the next consultation. In the control group patients will receive information regarding treatment options as usual.

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Adults (18-64 years)

Adults (18-64 years)

Inclusion criteria

1. Woman with a symptomatic prolapse

2. Woman for whom a (new) treatment must be chosen. Patients are eligible for at least two treatment options

3. Patients have to be able to make use of a computer with internet access in order to make use of the web-based decision aid and to complete the online questionnaires

4. Written informed consent

Exclusion criteria

1. Patients with a history of gynaecological cancer

2. Patients and clinicians who do not have any access to the internet

3. Patients and clinicians who do not have sufficient knowledge of the Dutch language

4. More than 1 POP-surgery in the past or POP-surgery < 2 years. Anti-incontinence surgery is not considered POP surgery here.

5. In case of a second opinion, the patient will not be included if the first opinion was obtained in one the hospitals involved in the study

6. Patients participating in the PEOPLE study

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Supportive care

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2016
Enrollment:	415
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	18-04-2016
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	NL5795
NTR-old	NTR6070
CCMO	NL55737.028.15

Study results

Results posted:	08-12-2023
Actual enrolment:	215

First publication
15-11-2022

URL result
Type
ext
Naam
Springer.com
URL