Gezamenlijke besluitvorming bij de behandelkeuze voor verzakkingsklachten

Gepubliceerd: 30-10-2016 Laatst bijgewerkt: 15-12-2023

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	Baarmoeder-, bekken- en ligamentum-latumafwijkingen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27378

Bron
Nationaal Trial Register

Verkorte titel
SHADE-POP

Aandoening

- Baarmoeder-, bekken- en ligamentum-latumafwijkingen

Aandoening

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

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Elisabeth TweeSteden Ziekenhuis Tilburg, Universiteit van Tilburg, Zorgkeuzelab
Overige ondersteuning: Same as sponsor

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep
Doel:	Verzorging

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2016
Aantal proefpersonen:	415
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

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

Resultaten

Datum resultaten gemeld: 08-12-2023

Totaal aantal deelnemers: 215

Datum eerste publicatie onderzoek
15-11-2022

URL result
Type
ext
Naam
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