Validation of pelvic floor related symptom and Quality of Life questionnaires in Dutch patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22262

Source
Nationaal Trial Register

Health condition

urinary incontinence, erectile dysfunction, pelvic organ prolapse, fecal incontinence

Sponsors and support

Primary sponsor: Erasmus Medical Center, the Netherlands, department of Urology
Source(s) of monetary or material Support: Erasmus Medical Center, the Netherlands, department of Urology

Intervention

Outcome measures

Primary outcome

Questionnaires' Psychometric Properties:

1. Reliability: internal consistency;

2. Reproducibility: test-retest reliability;

3. Validity: convergent validity;

4. Responsiveness: sensivity of change.

Secondary outcome

N/A

Study description

Background summary

The objective of this study is to validate the Dutch versions of Pelvic Floor Related Questionnaires (Urogenital Distress Inventory Short Form: UDI-6; Incontinence Impact Questionnaire Short Form: IIQ-7, International Index of Erectile Function short form: IIEF-5, Pelvic Floor Distress Inventory Short Form: PFDI-20, Pelvic Floor Impact Questionnaire Short Form: PFIQ-7, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire Short Form: PISQ-12, Fecal Incontinence Quality of Life Scale: FIQL, Fecal Incontinence Severity Index: FISI).

The linguistic validation of the questionnaires will be performed through a multistep process: backward and forward translations coordinated by clinical investigators, followed by a pretest. The final versions will be administered to a larger sample of patients, aged 18 years or older, with complaints for at least 3 months. To evaluate test-retest relaibility, patients will be re-rated after 1 week. To test the questionnaires' capacity to discriminated patients with or without symptoms (cases and controls, respectively) a sample of 50 healthy patients will be enrolled.

To test for convergent validity, a voiding diary, defecation diary, SF-12 and EuroQol-5 will be used.

To measure the sensitivity of change; questionnaires will be filled out 3 months post therapy.

Hypothesis: Pelvic floor related symptom and Quality of Life questionnaires (IIQ-7, UDI-6, IIEF-5, PISQ-12, PFIQ-7, PFDI-20, FISI, FIQL) in Dutch are valid instruments, which can be used reliably in daily practice and clinical research.

Study objective

Pelvic floor related symptom and Quality of Life questionnaires (IIQ-7, UDI-6, IIEF-5, PISQ-12,

PFIQ-7, PFDI-20, FISI, FIQL) in Dutch are valid instruments, which can be used reliably in daily practice and clinical research.

Study design

1. Baseline;

2. +1 week;

3. Three months after therapy.

Intervention

Dutch version of the questionnaires:

1. Incontinence Impact Questionnaire Short Form (IIQ-7);

2. Urogenital Distress Inventory Short Form (UDI-6);

3. International Index of Erectile Function short form (IIEF-5);

4. Pelvic Floor Distress Inventory Short Form (PFDI-20);

5. Pelvic Floor Impact Questionnaire Short Form (PFIQ-7);

6. Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire Short Form (PISQ-12);

7. Fecal Incontinence Quality of Life Scale (FIQL);

8. Fecal Incontinence Severity Index (FISI).

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Eligibility criteria

Inclusion criteria

1. Aged 18 years or older;

2. Urinary incontinence and/or pelvic organ prolapse (stadium 2 or higher) and/or erectile dysfunction and/or fecal incontinence for at least 3 months.

Exclusion criteria

1. Malignancy;

2. Demention;

3. Mental retardation.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	650
Type:	Actual

Ethics review

Positive opinion

Date:	28-05-2010
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	NL2229
NTR-old	NTR2355
Other	METC / CCMO : 2008-376 / NL25341.078.08 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A