The reproducibility and sensitivity of a new scoring system for pelvic floor muscle function

Published: 04-12-2007
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To examine the reproducibility and sensitivity of a new scoring system for pelvic floor muscle function

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30445

Source
ToetsingOnline

Brief title
New scoring system for pelvic floor muscle function

Condition

- Other condition

Synonym
pelvic floor dysfunction, urogynaecological dysfunction

Health condition

bekkenbodemaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Alant Vrouw
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Pelvic floor muscle function, Scoring system, Validation

Outcome measures

Primary outcome

The main endpoint of the study is to observe the intra- and interpersonal

reproducibility of the pelvic floor muscle function scoring system (PFMS)

Secondary outcome

1. The correlation of PFMS with urogenital symptoms

2. Internal and constructy validity

3. The sensitivity to change of PFMS

Study description

Background summary

Pelvic floor muscle training is one of the cornerstones in the treatment of women with a variety of urogenital symptoms. For instance, in urinary stress incontinence it is the first line of treatment. The training can be based on increasing muscle strength in one, but other women may benefit from relaxation and coordination. Recently the International Continence Society proposed a scoring system to facilitate the communication between different carers in the field of pelvic floor pathology. Before starting to use a new scoring system, the system has to be reliable and reproducible, meaning that a study on the inter- and intraobserver variety is necessary.

Study objective

To examine the reproducibility and sensitivity of a new scoring system for pelvic floor muscle function

Study design

Observational study

Study burden and risks

In routine practice all patients fill in the same questionnaire as used in our study. Also a pelvic floor muscle examination is routinely performed at first visit. The majority of patients will be scheduled for additional diagnostic procedures. At this second visit they will have an additional pelvic floor musle examination by the two examiners. Those women who will be scheduled for a pelvic floor rehabilitation program will be invited for an extra visit to our clinic before starting this therapy. The patients mostly do not have to come for an extra visit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Women with urogynaecological symptoms
- Good understanding of the Dutch language in word and writing

Exclusion criteria

- History of sexual abuse
- History of urogynaecological surgery
- History of connective tissue or muscle disease
- History of neurological disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	130
Type:	Anticipated

Ethics review

Approved WMO

Date:	04-12-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL14313.041.06