WOMEN-UP trial

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29615

Source
NTR

Brief title
WOMEN-UP

Health condition

Stress urinary incontinence

Sponsors and support

Primary sponsor: Academic Medical Centre, Amsterdam
Source(s) of monetary or material Support: European Committee

Intervention

Outcome measures

Primary outcome

Patient reported improvement of SUI symptoms

Secondary outcome

1. Patient reported cure of SUI symptoms

2. Incontinence related quality of life

3. Generic quality of life / Utility

4. Indication for SUI-surgery during follow-up

5. Patient satisfaction

6. Resource use / Costs

7. Performance of pelvic floor

8. Adherence to treatment

9. Treatment-related adverse events

10. Serious Adverse Device Events (SADE’s)

Study description

Background summary

Randomized controlled trial, hypothesizing that pelvic floor muscle training supported by vaginal and abdominal biofeedback, serious games and a web-portal is non-inferior to pelvic floor muscle training alone.

Study objective

Pelvic floor muscle training supported by vaginal and abdominal biofeedback, serious games and a web-portal is non-inferior to pelvic floor muscle training alone.

Study design

- T-1: Screening visit

- T0: Baseline visit

- T1: 6-8 weeks

- T2: 12-14 weeks (end of treatment)

- T3: 50-52 weeks

Intervention

Intervention: Pelvic floor muscle training supported by vaginal and abdominal biofeedback,

serious games and a web-portal
Control: Usual care pelvic floor muscle therapy

Contacts

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Eligibility criteria

Inclusion criteria

- Women between 18 and 75 years old

- Symptoms of mild or moderate stress urinary incontinence more than once a week (ICIQ-IU-short form index score ranging from 1 to 12).

Exclusion criteria

1. Mixed urinary incontinence (MUI) with a predominance of urge urinary incontinence.

2. Subjects who are not able to give informed consent, due to legal incapability or history or

current major psychiatric illness (as subjectively assessed by a physician).

3. Subjects who are pregnant

4. Subjects who underwent specialized pelvic floor muscle training (PFMT) for urinary incontinence in the previous 12 months

5. Subjects with genital prolapse more than 1 cm beyond the plane of the hymen (simplified POP-Q stage stage 3 or more, ICS-IUGA classification)

6. History of recurrent lower urinary tract infection (>4 times/year)

7. Insufficient knowledge or understanding of the Dutch / Spanish / Finnish language

8. Insufficient score on the IT-knowledge questionnaire (Appendix Q)

9. Woman unable to contract her pelvic floor muscles (Oxford = 0 or EMG-measure)

10. History of chronic neurological condition, like spinal cord injury, multiple sclerosis, cerebro-vascular incidents.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2016
Enrollment:	300
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-04-2016
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	NL5599
NTR-old	NTR5838
Other	METC AMC Amsterdam : 2016_132

Study results