Serious game-enhanced biofeedback supported self-management versus standardized pelvic physiotherapy in women with mild to moderate stress urinary incontinence - A multinational, non-blinded randomized controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47256

Source
ToetsingOnline

Brief title
WOMEN-UP

Condition

- Other condition

Synonym
involuntary loss of urine, stress urinary incontinence

Health condition

stress-urine-incontinentie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Europese Commissie

Intervention

Keyword: biofeedback, pelvic floor muscle therapy, self-management, stress urinary incontinence

Outcome measures

Primary outcome

Subjective improvement of SUI symptoms

Secondary outcome

1. Objective cure of SUI symptoms

2. Incontinence related quality of life

3. Generic quality of life

4. Indication for SUI-surgery during follow-up

5. Patient satisfaction

6. 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

Urinary incontinence is a common problem with a prevalence ranging from 25.0% (EPINCONT study) 1 to 51.1%2, and can be divided into three different types: stress urinary incontinence (SUI, involuntary leakage on effort or exertion, sneezing or coughing), urge urinary incontinence (UUI, involuntary leakage accompanied by or immediately preceded by urgency) and mixed urinary incontinence (MUI, involuntary leakage associated with urgency and also exertion, effort, sneezing or coughing). One study, conducted in several European countries, showed a predominance of MUI (42%), followed by SUI (38%) and UUI (18%)3. The prevalence of urinary incontinence is known to reach a peak around midlife (50-54 years), followed by a slight decrease and stabilization around 65 years. After this stabilization the prevalence encounters a steady rise1. Stress urinary incontinence in particular can lead to women stopping to participate in physical exercises and social activities, negatively affecting her confidence, self-perception and overall quality of life.

There a several treatments for SUI, ranging from conservative treatments (lifestyle interventions or pelvic floor muscle therapy) to surgery (midurethral sling surgery). In a systematic review, pelvic floor muscle therapy (PFMT) has proven to be a reliable primary conservative therapy in stress urinary incontinence, especially in patients with a mild severity. However, this review was based on articles with a generally short follow-up duration4.

A recent randomized controlled trial has shown that women with moderate-to-severe stress urinary incontinence have significantly better subjective and objective outcomes at 12 months after midurethral sling surgery than after pelvic floor muscle therapy. Furthermore, a high crossover rate (49.0%) from PFMT to sling surgery was reported5.

The main problem of PFMT is that women do not adhere to the intervention and stop performing their exercises. It has been proven that adding feedback to physiotherapy improves the outcome6 and it seems that the role of the physiotherapist is more to motivate and provide feedback, rather than controlling the exercise as such. Requiring a physiotherapist makes the intervention relatively expensive. In addition, PFMT is not accessible everywhere in the world. In less populated areas, patients may have to travel far to find a physiotherapist. Because of these flaws of the intervention, investigators have searched for innovative ways to make pelvic floor muscle exercises accessible to more patients.

The WOMEN-UP consortium has developed an intervention combining biofeedback and

motivating tools in a self-support ICT-system in order to reduce visits to the physiotherapists, thus making treatment of stress urinary incontinence more accessible. This self-support system consists of a vaginal and abdominal biofeedback device (based on improvements of existing vaginal biofeedback devices), an application for smartphone/tablet containing serious games and an online platform on which the patient can upload her training results and interact with her health care provider. It is hypothesized that the self-support treatment via a decision support system and a secure remote medical supervision is not inferior compared to PFMT with conventional biofeedback supervised by a therapist in clinical setting.

Study objective

The objective is to compare the intervention to standardized care PFMT in terms of clinical, economic and satisfaction outcomes.

A secondary objective is to develop a prediction model to identify suitable patients who will benefit the most from the intervention.

Study design

The study will be a multicenter, multinational, non-blinded, randomized controlled trial

Intervention

Holistic self-support system including:
1. Pelvic floor muscle training
2. Portable vaginal biofeedback device
3. Application for smartphone / tablet including serious games, intended to facilitate training
4. An online platform intended to stimulate patients* adherence, check progress, monitor adverse events and interact with her therapist.

Study burden and risks

During the trial patients will be asked to complete disease specific and generic QOL questionnaires at four different timepoints. They undergo a pelvic examination at 4 months after randomization which would not happen outside of study conditions.

The only risk involved with the intervention is overtraining, leading to complaints of vaginal pain during exercises or during coitus. Overtraining will be noticed by the health care professional either by the answers on the short questions after each exercise (self-support system) or by mention of the patient during the weekly visit to the health care professional (standardized

PFMT group). If overtraining is noticed, the health care professional will temporarily halt the training schedule for a period of at least a week. After one week, training can recommence if the complaints have subsided.

Other risks are negligible

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 between 18 and 75 years old
- Symptoms of mild or moderate stress urinary incontinence

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 therapy (PFMT) for urinary incontinence in the previous 12 months
5. Subjects with genital prolapse beyond the hymen (Baden-Walker grade 3 or 4). prolapse stage 2 or more according to the POP-Q 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
9. Woman unable to contract her pelvic floor muscles (Oxford = 0)
10. History of chronic neurological condition, like spinal cord injury, multiple sclerosis, cerebro-vascular incidents.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2018
Enrollment:	110
Type:	Actual

Medical products/devices used

Generic name:	vaginal biofeedback device;application on smartphone/tablet and online platform
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-08-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL56562.018.16