# WOMEN-UP trial

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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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29615

**Bron**
Nationaal Trial Register

**Verkorte titel**
WOMEN-UP

**Aandoening**

Stress urinary incontinence

### Ondersteuning

**Primaire sponsor:** Academic Medical Centre, Amsterdam
**Overige ondersteuning:** European Committee

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Patient reported improvement of SUI symptoms

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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.

### Onderzoeksopzet

- T-1: Screening visit

- T0: Baseline visit

- T1: 6-8 weeks

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

- T3: 50-52 weeks

### Onderzoeksproduct en/of interventie

Intervention: Pelvic floor muscle training supported by vaginal and abdominal biofeedback, serious games and a web-portal
Control: Usual care pelvic floor muscle therapy

# Contactpersonen

## Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-10-2016 |
| Aantal proefpersonen: | 300 |
| Type: | Werkelijke startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 11-04-2016 |
| 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 | NL5599 |
| NTR-old | NTR5838 |
| Ander register | METC AMC Amsterdam : 2016_132 |

# Resultaten