A randomised controlled trial comparing the clinical and cost-effectiveness of pelvic floor muscle exercise versus TVT(O) procedure for female moderate to severe stress urinary incontinence

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To compare the clinical and cost-effectiveness of pelvic floor muscle training versus TVT/TVT-O surgery as primary treatment of moderate to severe female urinary incontinence.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20079

Bron
Nationaal Trial Register

Verkorte titel
PORTRET Trial

Aandoening

stress urinary incontinence, SUI, TVT, TVT-O, PFMT

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: ZonMw The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Complete cure on objective and subjective parameters

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE: To compare the clinical and cost-effectiveness of pelvic floor muscle training versus TVT-O)-surgery as primary treatment of moderate to severe female urinary incontinence.

STUDY DESIGN: Multi-centre randomised controlled trial.

STUDY POPULATION: Women with moderate to severe, predominantly stress, urinary incontinence,
who have not received specialised PFMT or previous anti-incontinence surgery.

INTERVENTIONS: Women will be assigned to either PFMT by a specialised physiotherapist for a standard of 9-18 session in a period of 6 months, or TVT(O)- surgery.

OUTCOME MEASURES: Objective cure will be assessed from history and clinical parameters. Subjective improvement will be measured by generic and disease-specific quality of life instruments. A prediction model for a successful outcome will be developed.

SAMPLE SIZE CALCULATION / DATA ANALYSIS: In order to observe a significant difference insubjective improvement, 65% in PFMT and 80% in TVT®, with a power of 0.9, a total of 200 women have to be assigned by randomisation to each group.

ECONOMIC EVELUATION: The short term (1 year) incremental cost-effectiveness in terms of costs per additional year free of urinary incontinence and costs per QALY gained will be estimated. As the vast
majority of relevant outcomes will have occurred by one year this period appears sufficient. Uncertainty will be evaluated using bootstrap techniques (1000 replicates) on the individual patient data. A CEA plane will be used to depict the dispersion of the estimates of incremental costs and effects of TVT(O) compared to PFMT, thus allowing a direct inference with regard to the certainty of one treatment having a more favourable balance between costs and effects over the other.

TIME SCEDULE: We estimate
that the inclusion will be finished within 18 months. PFMT may take up to 6 months to be regarded as optimal, leaving 12 months for follow-up after treatment ending.

Doel van het onderzoek

To compare the clinical and cost-effectiveness of pelvic floor muscle training versus TVT/TVT-O surgery as primary treatment of moderate to severe female urinary incontinence.

Onderzoeksopzet

0= randomisation

2 months

4 months

6 months

12 months

18/24 months

Onderzoeksproduct en/of interventie

Women will be assigned to either PFMT by a specialised physiotherapist for a standard of 9-18 session in a period of 6 months, or TVT(O) surgery.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All women aged 35-80 years who present with symptoms of moderate to severe, predominant stress urinary incontinence.

2. Moderate to severe stress incontinence according to the Sandvik severity index. The index is calculated by multiplying the reported frequency (four levels, 1 to 4) by the amount of leakage (two levels, 1 and 2). The resulting index value (1-8) is further categorized into slight (1-2), moderate (3-4) and severe (5-8)

3. Objective confirmation of stress urinary incontinence by either examination, stress-test or urodynamics.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A post voiding bladder volume of more than 100 ml.

2. History of anti-incontinence surgery.

3. PFMT exercises by a specialised physiotherapist for urinary incontinence in the previous 6 months.

4. Genital prolapse Stage 2 or more according to the POP-Q classification.

5. Probability of future pregnancy and childbirth present.

6. Co morbidity which is associated with increased surgical risks, for instance women with ASA 3 or 4 classification.

7. History of recurrent lower urinary tract infection (> 3 times/year).

8. Insufficient knowledge or understanding of the Dutch language.

9. Use of medication interacting in bladder function.

10. History of or current major psychiatric illness.

11. History of chronic neurological disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2008
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2008
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	NL1203
NTR-old	NTR1248
Ander register	ZonMw : 80-82310-98-08203
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A