A randomised controlled trial comparing the cost-effectiveness of pelvic floor muscle exercise versus the 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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON33716

Source
ToetsingOnline

Brief title
PORTRET study (Physiotherapie OR Tvt Randomised Efficacy Trial

Condition

- Urinary tract signs and symptoms

Synonym
Urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw doelmatigheidsonderzoek

Intervention

Keyword: Female, Incontinence, Pelvic floor muscle training, Tension-free Vaginale Tape

Outcome measures

Primary outcome

Primary outcome is complete cure of stress incontinence

Secondary outcome

1. Subjective improvement (Qulaity of life)

2. Costeffectiveness

3. Development of prediction model

4. Complications

Study description

Background summary

Stress urinary incontinence is a common condition affecting approximately 20% of adult women causing substantial individual (quality of life) and economic (119 million Euro/year spent on incontinence pads) burden. Pelvic floor muscle training (PFMT) is regarded as first line treatment, but only 15-25% of women will be completely cured. Approximately 65% will report that their condition improved, but long term adherence to treatment is problematic. In addition, at longer term (2-15 years) follow-up 30-50% of patients will end up having surgery. From 1996 a minimal invasive surgical procedure, the Tension-free Vaginal Tape (TVT) has rapidly became the gold standard in surgical treatment of stress urinary incontinence. With TVT 65-95% of women are cured. However, approximately 6% of women will develop symptoms of an overactive bladder, resulting in reduced quality of life. Because of its efficacy the TVT appears to be preferable over PFMT but both treatments and their costs have not been compared head-to-head in a randomised clinical trial.

Study objective

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.

Study design

Multi-centre randomised controlled trial

Intervention

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. TVT(0) surgery consists of performing a small incision under de midurethra through which a 1 cm broad polypropylene tape is placed. Either behind the pubic bone, or through the obturator foramen. The tape is placed without tension and after this the wound and skinwounds are closed. The whole procedure takes about 15 minutes to perform.

Study burden and risks

Women in both treatment arms will receive a non-experimental treatment. Both treatment options are recognized as part of standard care. The burden associated with participation is limited to a total of 3 extra visits to the hospital for data assessment. There are no specific risks involved in participating.

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

A. All women aged 35-80 years who present with symptoms of moderate to severe, predominant stress urinary incontinence. This severity is established by means of the so called Sandvik index.
B. The predominance of stress urinary incontinence is assessed with the Stress/Urge Incontinence Questionnaire (S/UIQ). Two questions are asked. *How many times in the last seven days have you had an accidental leakage of urine onto your clothing, underwear, or pad*.
- During an activity such as coughing, sneezing, laughing, running, exercising or lifting? Symptom of stress urinary incontinence (SUI).
- With a sudden strong need to pass water that you could not reach the toilet in time? Symptom of urge urinary incontinence (UUI).
For predominant stress urinary incontinence the number of SUI events should outnumber the number of UUI.
C. Moderate to severe stress incontinence according to the Sandvik severity index.[15] 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 (6-8).

Exclusion criteria

1. No confirmation of stress urinary incontinence during gynaecological examination or on a stress test with at least 300 ml bladder filling
2. A post voiding bladder volume of more than 100 ml, as determined by bladder catheterisation or ultrasound (Bladderscan®)
3. History of anti-incontinence surgery
4. PFMT exercises by a specialised physiotherapist for urinary incontinence in the previous 6 months

5. Genital prolapse Stage 2 or more according to the POP-Q classification. (ref)
6. Patients desire for future pregnancy and childbirth.
7. Co-morbidity which is associated with increased surgical risks, for instance women with ASA 3 or 4 classification. Up to the physician to decide.
8. History of recurrent lower urinary tract infection (> 3 times/year).
9. Insufficient knowledge or understanding of the Dutch language.
10. The use of drugs that affect bladder function
11. History of or current major psychiatric illness as subjectively assessed by the physician.
12. History of chronic neurological disease, like spinal chord injury, multiple sclerosis, cerebro-vascular incidents.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2008
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	05-02-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-07-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	14-04-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-08-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-10-2009
Application type:	Amendment
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	NL20330.041.07