A randomized clinical trial of urinary incontinence in older women: cost-effectiveness of protocolized assesment and evidence-based treatment.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26828

Source
Nationaal Trial Register

Brief title
URINO

Health condition

Urinary incontinence (NLD: incontinentie voor urine).

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: Zon-MW, The Netherlands Organisation for Health Research and Development

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the reduction in the severity of involuntary loss of urine after 12 months according to the Incontinence Severity Index (ISI).

Secondary outcome

Secondary outcomes are the combination of severity and impact, the number of incontinent episodes, the patient's perception of improvement, the incontinence specific quality of life, the general health status and the costs of the incontinence.

Study description

Background summary

Objective:

To study the effects and cost-effectiveness of protocolized diagnosis and treatment of urinary incontinence in older, community-dwelling women, compared to standard care according to the guidelines of the Dutch College of General Practitioners (NHG).

Design:

A prospective randomized clinical trial in general practices. To prevent contamination, general practitioners (GPs) are randomized, instead of patients. After matching for age, sex and degree of urbanization of the practice region, GPs will be divided at random into two groups.

Study population:

All female patients registered in 26 general practices and 55 years of age or older will receive a short postal questionnaire on symptoms of involuntary loss of urine. If they answer positively and are willing to participate, they will be included in the study, after informed consent.

Intervention:

The intervention will consist of a protocolized assessment of urinary incontinence and an evidence-based treatment, targeted to the patient. In the control group, women will receive standard care.

Outcome:

The primary outcome measure will be the change in the severity of the incontinence 12 months after inclusion in the trial and measured according to the Incontinence Severity Index (ISI). Secondary outcomes will be the number of incontinent episodes per day, global perception of improvement, quality of life and costs.

Sample size:

We expect an improvement by at least one category on the ISI in 65% of the patients in the intervention group. To be able to reliably assess a clinically relevant difference of 25% between intervention and control group we will need 123 patients in both groups. This number takes into account loss to follow-up and randomization on GP-level.

Analysis:

The intervention group will be compared to the control group regarding the proportion of patients that experience improvement. Adjustment for cluster randomization will take place.

Economic evaluation:

Outcome measures will be the number of patients that experience improvement, the incremental costs per QALY gained and per extra day without loss of urine.

Study objective

The primary potential effect of the intervention is a reduction of the severity of urinary incontinence in the participating women. Secondary expected effects are improvement of the quality of life of incontinent women and reduction of the costs of urinary incontinence.

Study design

Follow-up measurements will be done at three and twelve months and includes self-report questionnaires an a three-day bladder diary. In addition, patients will be asked to complete a small monthly questionnaire.

Intervention

All included women will be interviewed about their clinical history and asked to complete a three-day bladder diary and to fill in self-report questionnaires.
The additional assesments for the intervention group consists of a urogynaecological examination. A fresh urine sample will be examined for bacteria to detect urinary tract infections. A provocation stress test will be performed to detect stress incontinence. With a full bladder subjects have to cough in lying and standing positions to detect urinary leakage when the abdominal pressure is raised. After performing this test, uroflowmetry will be done to measure maximal flow and voided volume. After voiding, an ultrasound measurement of the post void residual volume will take place. The last part of the evaluation consists of an examination of the abdomen and the external and internal genitalia with standardized assessment of pelvic organ prolapse and the pelvic floor muscle function.

The results of the assessment of each patient will be reviewed during a multidisciplinary meeting with participation of a general practitioner, urologist, gynaecologist and a pelvic floor physiotherapist. The multidisciplinary team will formulate a reccomendation on the management of the incontinence problem, taking into account the type and possible causes of the incontinence, the evidence on the effectiveness of different treatment modalities, the functional status and co-morbidity of the patient, the motivation and cooperation of the patient and her prognosis and life expectancy.
Summarized, all patients will we interviewd and asked to fill in self-report questionnaires, but only the intervention group will be urogynaecological examined and treated according to the advice of the multidisciplinary team.

Contacts

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Eligibility criteria

Inclusion criteria

The source population consists of women aged 55 or older who are registered in the practices of 26 general practitiones in the northern part of The Netherlands. Patients are eligible for the study if the have symptoms of involuntary loss of urine, if they are able to fill in a questionnaire in Dutch and if they have given informed consent.

Exclusion criteria

Patient will be excluded if they have urinary tract infections or overflow incontinence, are suffering from malignancies, are currently treated for urogynaecological conditions, have an indwelling catheter or are severely demented or in a poor physical condition.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	246

Type:	Anticipated

Ethics review

Positive opinion

Date:	15-01-2008
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	NL1139
NTR-old	NTR1181
Other	University Medical Center Groningen (UMCG), The Netherlands : ZonMW projectnr 80-82310-98-08204
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A