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

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

Samenvatting

ID

NL-OMON26828

Bron
Nationaal Trial Register

Verkorte titel
URINO

Aandoening

Urinary incontinence (NLD: incontinentie voor urine).

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: Zon-MW, The Netherlands Organisation for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2008
Aantal proefpersonen:	246
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

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

Resultaten

Samenvatting resultaten
N/A