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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Genitourinary tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON31408

Source
ToetsingOnline

Brief title
Urinary incontinence in older women

Condition

- Genitourinary tract disorders NEC

Synonym
involuntary loss of urine, urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMw Programma Doelmatigheidsonderzoek ronde 2008

Intervention

Keyword: elderly women, medical_economics, quality_of_life, urinary_incontinence

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). This index places women in one out of four categories of severity: slight, moderate, severe and very severe. We define success as improvement by at least one category on this index.

Secondary outcome

Secondary outcomes are the combination of severity and impact (ICIQ-score), the number of incontinent episodes (documented in the bladder diaries), the patient*s perception of improvement (GPI), the incontinence specific quality of life measured by the IIQ-7, the general health status (for which the EQ-5d and the MOS SF-20 are used) and the costs of the incontinence. Medical costs will be derived form the case record form (for general practice and hospital-related medical costs) and from patient

questionnaires (use of absorbent pads).

Study description

Background summary

Urinary incontinence is a very common health problem among women. 15%-55% of older women report having experienced involuntary loss of urine. Consequences of incontinence are social isolation, lack of self-confidence, shame and depressive feelings. Urinary incontinence is undertreated. Treatment seeking is often delayed and only 30%- 50% of the affected women ask for help. In most general practices the identification and management of women with leakage of urine is not actively pursuedThe condition can be effectively treated with significant improvement of clinical and quality of life parameters. First line effective treatments are behavioural interventions like pelvic floor muscle training, bladder
training and correction of inadequate voiding patterns.
As urinary incontinence is associated with considerable costs favourable economic effects may also be expected from a strategy that reduces the severity ofincontinence. For this reason we propose a randomized clinical trial to compare the cost-effectiveness of protocolized assessment and evidence-based treatment as compared to usual care in elderly women
with urinary incontinence.

Study objective

The study aims at delivering effective care for older women with urinary incontinence. This condition is underdiagnosed and undertreated, though effective treatments are available to manage urinary incontinence. Therefore, it is important to study if a pro-active approach of the problem improves symptoms and quality of life of elderly women and if this approach is cost-effective.
The main research question is: what are the effects of a protocolized assessment of urinary incontinence problems and an evidence-based treatment advice by a multidiscplinary team on the severity of involuntary urine loss of older women and on their quality of life, as compared to usual care, defined by the NHG guideline.
A second question asks what costs are associated with urinary incontinence in the usual care situation and what the costs and effects will be of the strategy under study. Ultimately, we will answer the question: What are the effects of this approach in terms of incremental cost-effectiveness of a protocolized assessment of urinary incontinence problems and an evidence-based treatment advice by a multidisciplinary team as compared to usual care as defined by the NHG guideline? The primary outcome measure for the economic evaluation will be

the incremental costs per patient that experienced
improvement with regard to her urinary incontinence. Also the incremental costs per QALY gained, and the incremental costs per additional day without urine loss will be estimated.

Study design

The design of the study is a randomized clinical trial. To prevent contamination, GPs will be randomized,
instead of patients. Based on degree of urbanization of the practice area and age and sex of the GP,
matched pairs of GPs will be formed. Within each pair, a GP will be randomly allocated to either
protocolized diagnosis and treatment or to usual care. The GPs in the control group will be blinded for
the intervention protocol.
In the control practices, women will receive standard care, according to the NHG guideline. In the
intervention practices, the results of the baseline assessment of each patient will be reviewed during a
multidisciplinary meeting after which a treatment follows, targeted to the patient. The follow up period is
12 months.

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.

Study burden and risks

The study does not imply any risks for the participants, as all investigations are non-invasive. The burden of the study for the participants consists of filling in questionnaires and keeping a three-day bladder diary. Patients from the intervention group will have to visit the local study centre to have a pelvic examination, including a uroflowmetry, stresstest and post void residu measurement by ultrasound. After a diagnosis has been made, a treatment is advised according to the current state of the art as formulated in the professional protocols. These treatments are non-experimental and have proven effectiveness. The majority of patients will be advised to visit a specialized physiotherapist for pelvic floor muscle exercises and bladder training

Contacts

Public
Academisch Medisch Centrum

Antonius Deusinglaan 1 / Postbus 196
9700 AD Groningen
NL
Scientific
Academisch Medisch Centrum

Antonius Deusinglaan 1 / Postbus 196
9700 AD Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients are eligible for the study if they 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

Patients 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 (according to their GP). In cases of urinary tract infections subjects will be offered treatment and reconsidered at a later date if the incontinence persists.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	246
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL18809.042.07