The effects of involving a nurse practitioner in primary care for adult patients with urinary incontinence.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23496

Source
NTR

Brief title
N/A

Health condition

urinary incontinence

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: ZonMw; The Hague, the Netherlands
Health Care Efficiency Research Programme
Sub-programme: Effects & Costs

Intervention

Outcome measures

Primary outcome

1. Severity of involuntary loss of urine:

measured by the self-completed condition specific International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) which measures frequency, volume and impact on daily life of involuntary urine loss (see supplement for questions and scoring).
The outcome is a sum score of the first two weighted items and the VAS score of impact on daily life.
The questionnaire underwent extensive psychometric testing. It is expected that the International
Consultation on Incontinence (ICI) will rate this questionnaire as Grade A, meaning highly recommendable;

2. Medical costs (the use of diagnostics, treatment and incontinence pads) and non-medical costs (productivity costs, time costs and travel costs): collected using both registration systems and cost diaries during four weeks.

Secondary outcome

1. Quality of life:

Condition specific self-completed quality of life questionnaire: International Incontinence Questionnaire (IIQ): this in Dutch validated 30 items questionnaire measures impact of urinary loss on five domains: ‘mobility’, ‘physical functioning’, ‘social functioning’, ‘emotional health’ and ‘embarrassment’.
b) Generic self-completed quality of life questionnaire;

2. Quantification of symptoms relevant for urinary incontinence (the degree of pad usage times of micturation, voided volumes, incontinence episodes, fluid intake, the degree of urgency, complications, complaints): measured with a self completed bladder diary during 3 consecutive days;

3. Patients satisfaction with provided care by the GP and/or the nurse practitioner for urinary incontinence will be measured with the for urinary incontinence adjusted QUOTE self completed questionnaire;

4. Perceptions of GPs about the availability and involvement of the route via the nurse practitioner: data of a sample of participating GPs will be collected by semi-structured interview and/or questionnaires before, once during the first 2 months and after the study about ideas/expectations, promoting and /or hampering factors for (not) using the nurse practitioner and experiences in relation to quality of care with the nurse practitioner;

5. Perceptions of nurse practitioners: data of participating nurse practitioners will be collected with semi-structured interview and/or questionnaires before, during and after the study about ideas/expectations and experiences in relation to quality of care.

Study description

Background summary

Objective:

Urinary incontinence affects 5% (800.000) of the Dutch population. For most patients (especially those in primary care) with urinary incontinence, guidelines recommend pelvic floor muscle and/or bladder training.

Unfortunately, GPs use this training only incidentally (probably due to its time consuming character) and prescribe incontinence pads. Over 50% of patients get such pads, costing € 90 million each year. Due to ageing of the population a further increase is expected. Several national reports recommend to involve nurse practitioners to support GPs and improve care for patients with urinary incontinence. Overall, this is probably highly cost-effective, as the expected savings in incontinence pads exceed costs for nurse practitioners.

Research question(s):

Does the availability of a nurse practitioner in a new role as substitute for the GP lead to a more efficient care for adult patients with urinary incontinence?
Does it improve quality of life of patients and the satisfaction of patients, GPs and other care providers?

Study design:

in a pragmatic prospective multicenter randomised controlled trial in two Dutch regions the availability and involvement for the GPs of a nurse practitioner is compared with usual care.

Study population:

All consecutive patients consulting their GP within 1 year for urinary incontinence are eligible. Included patients will be followed for 12 months (exclusion criteria listed elsewhere).

Intervention:

the nurse practitioner provides a diagnostic & treatment, based on guidelines and protocols where he/she takes over tasks from the GP. Final responsibility remains at the GP.

Outcome measures:

severity of urinary incontinence (ICIQ-SF quality of life), medical costs (diagnostics, treatment and incontinence pads) and non-medical costs (productivity, time and travel).

Power/data analysis:

based on ICIQ-SF outcome data (â=80%, á=0.05), and given the two-sided H1-hypothesis that the availability of the new nurse practioner improves the effect, the needed number of patients is 350, (with an expected drop-out rate during the trial of 20%: 440).

Economic evaluation:

Cost-effectiveness will be determined using a markov modelling approach, incorporating life time societal costs and effects. Effects will be quantified in incontinence symptom severity adjusted life years, and in (generic) quality adjusted life years.

Time schedule:

study set up: 8 months; trial phase and follow-up: 2 years; analyses/report: 4 months.

Study objective

The involvement of a nurse practitioner will lead to a reduction or even complete disappearance of urinary incontinence in the majority of patients and lead to lower health care costs.

Study design

N/A

Intervention

In this pragmatic trial the intervention is designed as close as possible to treatment options in clinical practice (including ‘cascades’ of patient management choices). This way implementation in the future is easier.

When the patient is allocated to the intervention group the GP has the availability to refer the patient to the nurse practitioner according to a precisely described care protocol.

The main goal of the intervention of the nurse practitioner is to provide a tailored, patient specific diagnostic & treatment plan to all eligible patients, thereby preventing or reducing the use of incontinence pads. Based on guidelines and protocols the nurse practitioner takes over from the GP tasks related to diagnostics, intervention and monitoring of incontinence.

Furthermore, the nurse practitioner supports patients motivation, compliance and adherence both on the short and the long term by monitoring patients over time in a systematic way to ensure that patients will accept, understand, are willing and able to do and actually do and keep doing or following up advices on lifestyle and bladder- and/or pelvic floor muscle training according to a health education model.
Another task of the nurse practitioner is to give adequate information and advice about (when still necessary) the choice and the use of non-curative means like incontinence pads. She/he will always report to the GP and acts as the contact person between the other healthcare providers. In case of unclear pathology, a complex health problem or failure of treatment the nurse practitioner can advice a referral to a specialist or specialised physiotherapist.
In all cases, the decisions for referral is at the GP. Altogether this means that a regular meeting between nurse practitioner and GP to discuss patients is needed.

Contacts

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Eligibility criteria

Inclusion criteria

All consecutive patients consulting their GP within 1 year for symptoms and signs of stress, urge and mixed urinary incontinence (according to the guidelines of the Dutch College of General Practitioners on urinary incontinence are eligible for the study .

Exclusion criteria

1. Excluded will be patients below 18;

2. Women with prolaps degree III or more;

3. Patients with signs of reflex- or verflow incontinence;

4. Patients with tumours in the abdomen;

5. Patients with severe neurological diseases associated with incontinence (multiple sclerosis;

6. CVA;

7. Diabetes, cauda equina syndrome);

8. Actual urinary tract infection;

9. Hematuria without urinary tract infection;

10. Man below 65 with unclear reason for incontinence;

11. Failure after operation or failure of conservative therapy;

12. Severe cognitive problems;

13. Patients not well versed in the Dutch language;

14. Patients who refuse to participate/cooperate;

15. Patients for whom the GP considers the management via the nurse practitioner as impossible/undesired, or unexpected circumstances not related to the trial (such as moving away, sickness).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2004
Enrollment:	350
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2005
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	NL232
NTR-old	NTR269
Other	: N/A
ISRCTN	ISRCTN62722772

Study results

Summary results
N/A