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

Gepubliceerd: 08-09-2005 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON23496

Bron
NTR

Verkorte titel
N/A

Aandoening

urinary incontinence

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: ZonMw; The Hague, the Netherlands
Health Care Efficiency Research Programme
Sub-programme: Effects & Costs

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

University Hospital Maastricht,
Integrated care unit (Bze-7),
P.O. Box 5800
Ron A.G. Winkens
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3877389

Wetenschappelijk

University Hospital Maastricht,
Integrated care unit (Bze-7),
P.O. Box 5800
Ron A.G. Winkens
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3877389

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 .

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2004
Aantal proefpersonen:	350
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2005
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	NL232
NTR-old	NTR269
Ander register	: N/A
ISRCTN	ISRCTN62722772

Resultaten

Samenvatting resultaten
N/A