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

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/04/2008	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ron A G Winkens

Contact details
University Hospital Maastricht
Integrated Care Unit (Bze-7)
P.O. Box 5800
Maastricht
Netherlands
6202 AZ
+31 (0)43 3877389
ron.winkens@hag.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This trial received ethics approval from all participating regions:
1. University Maastricht and the University Hospital Maastricht, the Netherlands. Date of approval: 20/04/2005 (ref: MEC 05-002.4/pl)
2. UMC St. Radboud Nijmegen, the Netherlands. Date of approval: 12/07/2005 (AMO nr. 05/041)
3. Medical Ethics Committee (METC-ZWH), the Hague, the Netherlands. Date of approval: 14/12 /2005 (ref: 2005-983; METC-nr: 05-94)
4. Medical Ethics Committee of of QUARTZ, Elkerliek Hospital, Helmond, the Netherlands. Date of approval: 29/06/2006 (PC/hb/06-476)

Study design
Randomissed controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Urinary incontinence

Interventions
Please note that, as of 30/04/2008, the anticipated end date of this trial was amended from 30 /11/2007 to 01/07/2008.

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 and 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.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
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 measures
1. Quality of life: a) 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.

Overall study start date
01/12/2004

Completion date
01/07/2008

Eligibility

Key inclusion criteria
All consecutive patients (both male and female) consulting their GP within one 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).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
350

Key exclusion criteria
1. Patients below 18
2. Women with prolaps degree III or more
3. Patients with signs of reflex- or overflow incontinence
4. Patients with tumours in the abdomen
5. Patients with severe neurological diseases associated with incontinence (multiple sclerosis, CVA, diabetes, cauda equina syndrome), actual urinary tract infection, hematuria without urinary tract infection
6. Men below 65 with unclear reason for incontinence
7. Failure after operation or failure of conservative therapy

8. Severe cognitive problems
9. Patients not well versed in the Dutch language
10. Patients who refuse to participate/cooperate
11. 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)

Date of first enrolment
01/12/2004

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Hospital Maastricht
Maastricht
Netherlands
6202 AZ

Sponsor information

Organisation
University Hospital Maastricht (The Netherlands)

Sponsor details
P.O. Box 5800
Maastricht
Netherlands
6202 AZ
+31 (0)43 3876543
info@azm.nl

Sponsor type
University/education

Website
http://www.azm.nl

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol	15/04/2008		Yes	No