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Effects of introducing a specialised nurse in the care of community-dwelling women suffering from urinary incontinence

Submission date
16/01/2007

Recruitment status
No longer recruiting

Registration date
16/01/2007

Overall study status
Completed

Last Edited
06/01/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of introducing a specialised nurse in the care of community-dwelling women suffering from urinary incontinence

Study objectives
It is hypothesised that care given by a continence nurse will lead to a reduction in episodes of urinary incontinence and an improvement in quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Ethics Committee of the Atrium Medical Centre on the 28/11/2002, ref: 02-P-46

Study design
Randomised controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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

Interventions
Intervention:
The intervention involved a registered nurse specialised in the care of incontinent patients. Over a period of one year, this nurse advised and guided patients suffering from stress, urge or mixed incontinence. Based on her knowledge and experience, the nurse assessed the patients, using history-taking and post-void residual urine measurement. The nurse advised the patient about the best treatment, guided by a protocol written by a multidisciplinary team.

This protocol presented a management plan including evidence-based interventions for the treatment of stress, urge and mixed incontinence. Also the nurse provided lifestyle and

behavioural interventions tailored to the individual patient as well as information about pads. All patients returned after three, six, and 12 months for follow-up and review of bladder diaries and questionnaires. After each visit, the nurse reported her findings to the patient's GP, who remained responsible for the care of the patient.

Control:
Usual care comprised care delivered by the GP and access to health care workers in the field of continence care (e.g., physiotherapist, urologist). In most cases a physiotherapist gives pelvic floor muscle exercises. Depending on the GP women are asked to return after three or six months for follow up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Number of incontinent episodes: measured by a three-day bladder diary recording the frequency and volume of the incontinent episodes as well as the number of pads used throughout the day and night.

Secondary outcome measures
1. Quality of life: measured with the Incontinence Impact Questionnaire (30 items covering five domains: mobility, emotional functioning, physical activity, social functioning and embarrassment)
2. Amount of bother caused by incontinence is measured by the Urogenital Distress Inventory (19 items covering five domains: discomfort/pain, urinary incontinence, overactive bladder, genital prolapse, obstructive micturition)
3. EuroQol (EQ-5D): a generic questionnaire to measure quality of life (the EQ-5D defines health in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety /depression)
4. Patient satisfaction with care: measured on a ten-point scale ranging from 'very poor' (1) to 'excellent' (10)

Overall study start date
01/05/2003

Completion date
01/03/2005

Eligibility

Key inclusion criteria
1. Women aged 18 years or older
2. Consulting their General Practitioner (GP) with symptoms of stress, urge or mixed incontinence

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
228

Total final enrolment
38

Key exclusion criteria
1. Women suffering from gynecological diseases (e.g., malignancy), dysuria, cystocele, fistula, neurological diseases (e.g., Cerebral Vascular Accident [CVA], Multiple Sclerosis [MS], Parkinson's Disease), urinary tract infection
2. Not being able to fill in the questionnaires or to follow treatment
3. Women who had given birth within three months preceding recruitment

Date of first enrolment
01/05/2003

Date of final enrolment
01/03/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University of Maastricht (UM)
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
University Maastricht (UM) (The Netherlands)

Sponsor details

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Department of Nursing Studies
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Sponsor type
Hospital/treatment centre

Website
http://www.unimaas.nl/default.asp?taal=en

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Other

Funder Name
Central Sickfund (CZ) health care insurance (The Netherlands)

Funder Name
University Maastricht (UM) (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?
Results article	results	01/11/2007	06/01/2021	Yes	No