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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
16/01/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/01/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/01/2021	Urological and Genital Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms M Du Moulin

Contact details

University of Maastricht (UM)
Faculty of Health Sciences
Department of Nursing Studies
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 1829
m.dumoulin@zw.unimaas.nl

Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

- 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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

ROR

https://ror.org/02jz4aj89

Funder(s)

Funder type

Other

Funder Name

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

Funder Name

Results and Publications

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