The impact of Module Continence Aids on costs and quality of life in patients with urine incontinence

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23307

Source
Nationaal Trial Register

Brief title
Module CH

Health condition

Urine-incontinence

Sponsors and support

Primary sponsor: ZonMW
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

- Use of continence aids
- Functioning of the patient

- Costs related to urine incontinence

Secondary outcome

N/A

Study description

Background summary

To improve tailored prescription of continence aids, involved parties (patient associations, suppliers, pharmacists, health insurers) have developed a protocol: the Module Continence Aids (Dutch abbr.: Module CH). This module is recorded in the Generic Quality Framework for Medical Devices in the Register of the National Health Care Institute and will be introduced from 2018 onwards. It is unknown whether using the Module CH has an actual influence on the functioning of users, the extent of the use of incontinence aids and the associated costs. The factors that can improve or obstruct implementation are unknown as well. We want to investigate this in an observational care evaluation study in primary care, consisting of a before-after comparison. During the baseline measurement we collect information about the current functional status of users of absorbent incontinence aids, the use of continence aids and the costs associated with urine incontinence. Subsequently the Module CH is applied. The follow-up include the same measurements as used during the baseline measurement. In addition, we identify the factors that can improve or obstruct implementation using interviews with involved healthcare providers.

Study objective

Implementation of Module CH leads to better tailored care, improved functioning of the user and more efficient use of absorbent incontinence aids.

Study design

- Baseline measurement
- Follow up after 3 months
- Follow up after 6 months

Intervention

N/A

Contacts

Public
UMCG
Miranda Schreuder

N/A
Scientific
UMCG
Miranda Schreuder

N/A

Eligibility criteria

Inclusion criteria

Patients who already use continence aids, provided by the pharmacy (or national operating supplier).

Exclusion criteria

- Patients with fecal incontinence as only kind of incontinence.
- Patients who already have had a prescription according to the new Module CH.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	600
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL7560
Other	METc UMCG : METc2018/551

Study results