

Self-management as a first-line treatment prior to GP consultation for men with lower urinary tract symptoms

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To assess the effectiveness and cost-effectiveness of providing an online personalized self-management program as a first-line intervention to men with lower urinary tract symptoms (LUTS) compared to care as usual (CAU).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Urinary tract signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON50755

Source

ToetsingOnline

Brief title

Urincontrol4men

Condition

- Urinary tract signs and symptoms

Synonym

lower urinary tract symptoms, voiding complaints

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: eHealth, General practice, LUTS

Outcome measures

Primary outcome

Outcomes will be assessed at 6 weeks and 3 and 6 months. The primary outcome measure will be the Patient Global Impression of Improvement after 6 months.

Secondary outcome

The secondary outcome measures will be the differences in cost-effectiveness, ICIQ-MLUTS score, quality of life, medical consumption, and productivity losses.

Study description

Background summary

The prevalence of moderate-to-severe lower urinary tract symptoms (LUTS) in men is 20%-25% and increases with age. Most guidelines on male LUTS recommend promoting self-management and lifestyle changes as the first-line option, especially for patients with mild complaints. In the Netherlands, many of these patients will first visit a general practitioner (GP). However, the lack of clinic time to explain self-management means that GPs are more likely to prescribe medication, with around half of all men who visit their GP being prescribed an alpha-blocker. In 2018, over 300,000 Dutch men were prescribed alpha-blockers for LUTS; unfortunately, despite being the first-line drug treatments, their effects are small and may not even reach the level of minimal important difference. It may therefore be preferable to provide patients with a valid alternative that can be trialed before attending the GP and receiving unnecessary medical care. LUTS are highly amenable to self-management thanks to their mixed etiology, uncertain and generally favorable clinical course,

lack of cure, and status as a social and professional challenge. Although self-management can be difficult to implement because it is time-consuming to explain, it has proven effective when a pathway to implementation can be found. For this reason, our study group developed an online intervention that can be used at home by men with LUTS, giving tailored advice to each case. For this, men complete questions about symptom severity, lifestyle (e.g., coffee and alcohol consumption), height, and weight, plus a frequency-volume chart, and appropriate advice is presented. This tool was developed based on available literature and the opinions and experiences of Dutch GPs and urologists, and it has been piloted among men with uncomplicated LUTS in secondary care. Feasibility testing has also continued in primary care [data to be published]. The intervention is also suitable for people with low literacy levels because all information is presented in video and audio formats. Self-management is ideally given in primary care or before people seek help, indicating that the intervention could be made available to men in the community. However, we must first study the cost-effectiveness of the online self-management program in terms of the healthcare-seeking behaviors of men with LUTS in primary care, specifically targeting those who are considering visiting a GP.

Study objective

To assess the effectiveness and cost-effectiveness of providing an online personalized self-management program as a first-line intervention to men with lower urinary tract symptoms (LUTS) compared to care as usual (CAU).

Study design

A pragmatic non-inferiority randomized controlled trial in the general population.

Intervention

Six weeks of access to an online program offering personalized self-management advice compared to care as usual

Study burden and risks

Participants in both intervention arms can directly benefit from the treatment they receive. Risk of both treatments are negligible. Results of the study can

have long term benefits for men with LUTS as in the case of non-inferiority of the eHealth intervention they can benefit from a treatment that is easy accessible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Men with LUTS

Exclusion criteria

Nocturnal incontinence

Inability to void despite urgency
Sudden onset or worsening LUTS
Treatment from a pelvic physiotherapist, GP, or urologist at any point in the previous year for LUTS
A history of prostate cancer, bladder cancer, or urinary tract surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	07-04-2022
Enrollment:	698
Type:	Actual

Medical products/devices used

Generic name:	Urincontrol4men (online lifestyle intervention)
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	24-03-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved	

Date:	20-07-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	14-09-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL79018.042.21