RUTI-FREEDOM: Recurrent Urinary Tract Infections in Females Receiving Effective Education, Digital Outreach & Management - a multicenter prospective randomized controlled trial in the Netherlands

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON57320

Source
ToetsingOnline

Brief title
RUTI-FREEDOM

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
recurrent urinary tract infections, rUTI

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Innovatie & wetenschapsfonds Isala

Intervention

Keyword: Digital coaching, eHealth, rUTI, telemedicine

Outcome measures

Primary outcome

The primary outcome measure is the number of symptomatic culture-proven urinary

tract infections over a 12-month period.

Secondary outcome

Secondary outcomes are:

- the number of prescribed and used antibiotic treatments

- the number of telephone consultations and outpatient clinic visits

- healthcare costs

- quality of life

- cost-effectiveness

Study description

Background summary

Recurrent urinary tract infections (rUTIs) rank among the most prevalent bacterial infections globally. In the Netherlands, approximately 20,000 women are referred to urologists for this condition annually. Our previous research demonstrated that these referrals have limited added value, despite high expectations. The Dutch Healthcare Institute (Zorginstituut Nederland or ZIN) outlines three pillars for improving care for this patient group in the

"Verbetersignalement Urineweginfecties" (2021): enhancements in decision-making through shared decision-making, reduction of unnecessary diagnostics, and minimizing antibiotic usage. ZIN reports that many patients are willing to wait for spontaneous recovery from an infection but are often unaware of this possibility. Additionally, our own research reveals that 25% of women lack awareness, and 50% have limited knowledge of preventive measures. The majority express a need for more information about their condition and preventive treatment options. While a greater information supply could improve patient knowledge, it proves challenging for healthcare providers to deliver and for patients to retain in practice. There is a lack of access to information for patients, insufficient time for counseling, and a shortage of healthcare providers. Digital coaching may provide a solution to address these deficiencies.

Study objective

A pilot study on digital coaching in rUTI at the Urology Department of Isala tested an app-based treatment additional to standard care.[8] The app provides information on rUTI aetiology, lifestyle recommendations, treatments, and the value of additional diagnostics. Besides interactive education, the app establishes a digital communication channel with the hospital, demonstrating increased patient knowledge and positive lifestyle changes. Patients were very content with the additional accompaniment for their condition.
The efficacy of app-based rUTI treatment in reducing diagnostics, hospital visits, and antibiotic usage remains uncertain. This randomized controlled trial (RCT) seeks to ascertain whether app-based intervention enhances rUTI healthcare compared to standard Dutch care.

Study design

: Multicenter Randomized Controlled Trial in women suffering from rUTI. Patients will be randomized in a 1:1-ratio to either intervention group or control group. Total follow-up will entail 12 months.

Intervention

Participants in the intervention group will have access to a digital application, which enables patients to educate themselves, to monitor their symptoms and lifestyle, to assess their symptoms by filling in a digital questionnaire and to contact the outpatient clinic. Access to this application is provided as an addition to the care as usual from the urology outpatient departments, which is the same care as usual in both the intervention group and the control group.

Study burden and risks

Participating in the study requires a time-investment from patients. Patients in the intervention group will be asked to complete a series of educational e-learnings. Also, they will be asked to complete a bi-monthly digital questionnaire. Furthermore, all participants will be asked to complete several questionnaires at 4 months, 8 months and 12 months. The risks for participating are minimal due to the additional nature of the intervention.

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

Female sex
Aged 18 or older
new referral to urologist for rUTI

possession of smartphone/tablet/PC with internet connection

Exclusion criteria

- Subjects with an indwelling catheter or performing clean intermittent catheterization
- Subjects suffering from urogenital malignancy or having had urogenital malignancy in the past
- Subjects having had prior surgery to urinary tract
- Subjects suffering from active urolithiasis
- Active pregnancy
- Subjects suffering from terminal illness
- Subjects suffering from dementia or other psychiatric illnesses.
- Subjects with insufficient command of the Dutch language, which precludes them from following study instructions or completing study questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	210
Type:	Anticipated

Medical products/devices used

Generic name:	Luscii Vitals
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-01-2025
Application type:	First submission
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	NL86740.042.24