Randomized controlled trial in adult women with urinary incontinence comparing treatment delivered through a mobile application versus standard care.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25754

Source
NTR

Brief title
URinControl

Health condition

Urinary incontinence, Stress-incontinence, Urge-incontinence

Sponsors and support

Primary sponsor: Department of General practice
University Medical Centre Groningen
University of Groningen
Source(s) of monetary or material Support: ZonMw: The Netherlands Organization for Health Research Development

Intervention

Outcome measures

Primary outcome

The change in symptoms score, measured with the International consultation on Incontinence Questionnaire on UI Short Form (ICIQ-UI-SF), 4 months after randomization

Secondary outcome

All secondary endpoints are assessed 4 and 12 months after randomization.

- Patient-reported Global Impression of Improvement;

- Condition-specific quality of life;

- Generic health related quality of life;

- Number of incontinence episodes per day

- Sexual functioning

- frequency, severity and impact of incontinence (every month during first 4 months)

- Costs at 12 months

- Process evaluation: Evaluation of user friendliness and acceptability of patients and health-care workers.

Study description

Background summary

BACKGROUND Urinary incontinence (UI) is a highly prevalent disorder in women. Despite available treatment options only 30% of women seek help for the problem. The availability of an easy-to-use, evidence based App for the treatment of UI may reduce the necessity of face-to-face contacts and increase continence rates and quality of life. Especially, the possibility to receive frequent reminders would enable patients to perform the necessary training, as forgetting is the most important reason why adherence can be lacking. This will help women with UI to have a better quality of life and it will considerably reduce health care costs.

OBJECTIVE To study the effects and cost-effectiveness of a App-based treatment program for

women with urinary incontinence (UI) compared to standard care delivered by the general practitioner.

STUDY DESIGN AND POPULATION: Randomized controlled trial with non-inferiority design with non-pregnant women aged 18 years or older, who visit their general practitioner (GP) for symptoms of UI are eligible. They will be recruited from general practices in the northern part of the Netherlands.

INTERVENTION: The intervention consists of a treatment program on a mobile application for tablet or smartphone without face-to-face contact (App URinControl). The active control treatment is the standard care delivered by the GP

OUTCOME MEASURES: The primary outcome is the score on the International consultation on Incontinence Questionnaire on UI Short Form (ICIQ-UI-SF), which measures symptoms and impact of the UI on daily life. Secondary outcomes are the perception of improvement by the patient, number of UI episodes, condition- specific and generic health related quality of life sexual functioning and costs. Also, a process

evaluation will take place.

Study objective

A treatment program for urinary incontinence (UI) in adult women delivered through a mobile application is not inferior to the standard way of treating patients, in primary care regarding its effects, it is less expensive and more cost-effective.

Study design

Three assessments will be performed, at baseline, after 4 months and after 12 months.

Intervention

Intervention group: Mobile application (App)
After randomization patients will receive access to the URinControl-App. In the App, basic information is provided in a video fragment. Next, participants will learn how to use their pelvic floor. Then the participants will start with a training program tailored to their type of incontinence. Women with stress (predominant) UI will start with pelvic floor muscle training (PFMT); women with urgency

(predominant) UI will start with bladder training and PFMT will be added later in the program. All exercises will be supported by animations. All information will be available through a bibliography within the app.
During the program patients are asked to fill out the number of incontinence episodes, as well as the intensity with which they performed the exercises. Treatment will be reinforced by regularly sending 'push' notifications to stimulate treatment adherence.
The content of the app is a translation of the recommendations of the guidelines on the treatment of UI of women in primary care. In the letter with instructions which will be advised to contact their general practitioner (GP) if
the progress of the treatment is unsatisfactory.

Control group: Standard Care
Patients in the standard care group will be diagnosed and treated according to NHG-guideline on UI (PFMT in case of stress UI, bladder training and PFMT for urgency UI). GP's can instruct patients themselves, or refer them to a practice nurse or a specialized pelvic physiotherapist. In case of urgency incontinence, they can also choose to prescribe medication.

Contacts

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Eligibility criteria

Inclusion criteria

Subject must meet all of the following criteria:

- Women, 18 years or older;

- Access to mobile Apps (iOS or Android);

- Urinary incontinence (UI), defined as any involuntary loss of urine according to the definition of the international Consultation on Incontinence (ICI), regardless of subtype (stress-, urgency- or mixed type UI). Incontinence episodes should be twice a week or more;

- Wish to be treated;

- Written informed consent.

Exclusion criteria

Potential participant who meets any of the following criteria will be excluded from study:

- Indwelling urinary catheter;

- Urogenital malignancy;

- Previous urethral surgery for incontinence or prolapse;

- Being treated for UI in the previous year (pharmacologically or non-pharmacologically);

- Terminally or seriously ill;

- Cognitive impairment or psychiatric disorder;

- Urinary tract infection;

- Overflow or continuous UI;

- Pregnancy or recent childbirth (< 6 months ago);

- Inability to complete a questionnaire in Dutch.

- Prolapse POPQ ≥ stage IIb

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2014
Enrollment:	240
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-01-2015
Application type:	First submission

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	NL4948
NTR-old	NTR5052
Other	- : Protocol ID 837001508

Study results

Summary results

Loohuis AMM, Wessels NJ, Jellema P, Vermeulen KM, Slieker-Ten Hove MC, van Gemert-Pijnen JEWC, Berger MY, Dekker JH, Blanker MH. The impact of a mobile application-based treatment for urinary incontinence in adult women: Design of a mixed-methods randomized controlled trial in a primary care setting. Neurourol Urodyn. 2018 Sep;37(7):2167-2176. doi: 10.1002/nau.23507. PMID: 29392749 https://doi.org/10.1002/nau.23507

Van der Worp H, Loohuis AMM, Flohil I, Kollen BJ, Wessels NJ, Blanker MH. Recruitment through media and general practitioners resulted in comparable samples in an RCT on incontinence. Journal of Clinical Epidemiology (online first: https://doi.org/10.1016/j.jclinepi.2019.12.001)