E-health in incontinence: from U-Pad to I-Pad

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Urinary tract signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON46957

Source
ToetsingOnline

Brief title
E-health in incontinence

Condition

- Urinary tract signs and symptoms

Synonym
Incontinence, urinary leakage

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW (grant number 837001508)

Intervention

Keyword: e-health, female, general practice, urinary incontinence

Outcome measures

Primary outcome

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 outcome

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.

Facilitators and barriers for the implementation of the intervention.

Study description

Background summary

Urinary incontinence (UI) is a highly prevalent disorder in women affecting an estimated 25%-45% of adult women. Although effective treatments are available, only 30% of women with UI seek help for this 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. 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.

Study objective

This trial aims to study the effects, costs and cost-effectiveness of an App-based program for women 18 years or older with
urinary incontinence (UI) in primary care compared to care delivered by the

general practitioner (GP) according to the guideline on UI of the Dutch college of GPs.

Study design

This is a randomized controlled trial with a non-inferiority design, and a follow-up of four months. Women will be randomized 1:1 to one of two treatment arms: an intervention arm in which an App will be made available to guide the patient during the treatment phase and an arm in which patient will receive standard care provided by their GP.
After completion of the trial phase, a subset of the study population (in both arms, 10 women with the highest score on PGI-questionnaire, and 10 women with the lowest scores on PGI) will enter a qualitative study on expectations and experiences with eHealth-treatment, and on the facilitators and barriers for the implementation of the intervention.

Study burden and risks

Not applicable.

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

- Women, 18 years or older;
- Having access to mobile Apps on smartphone or tablet (Apple or Android platform) * wifi entrance to the internet is sufficient;
- Urinary incontinence (UI), defined as any involuntary loss of urine according to the definition of the International Consultation on Incontinence (ICI), regardless of the subtype (stress UI, urgency UI or mixed type UI). Incontinence episodes should be twice a week or more;
- Wish to be treated;
- Written informed consent.

Exclusion criteria

- Indwelling urinary catheter;
- Urogenital malignancy;
- Previous urethral surgery;
- Being treated for UI in the previous year (pharmacologically or non-pharmacologically);
- Terminally or seriously ill; according to the GP of the patient
- Cognitive impairment or psychiatric disorder;
- Urinary tract infection (dipstick and if negative, dipslide or urine culture);
- Overflow or continuous urinary incontinence;
- Pregnancy or recent childbirth (< 6 months ago);
- Inability to complete a questionnaire in Dutch.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2015
Enrollment:	292
Type:	Actual

Medical products/devices used

Generic name:	Mobile application (App)
Registration:	No

Ethics review

Approved WMO Date:	12-05-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-07-2018
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-03-2019
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
Other	201400359
CCMO	NL51915.042.14