Aims of course/workshop
The aim of the workshop is to give an overview of eHealth solutions with focus on mobile applications for treatment of pelvic floor disorders. Furthermore, we aim to discuss research methods and implementation of eHealth. The discussion will focus on possibilities and difficulties that may occur during study and implementation period with examples from our own research. The workshop will be interactive and we ask participants to bring their smartphones, iPads or PC tablets to the workshop.

Learning Objectives
After this workshop participants should be able to:
1. eHealth for pelvic floor disorders has the potential to increase access to care and empower patients.
2. It is important for patients and caregivers to know if Health Apps are effective before use.
3. Study methods, possibilities for data collection and patient monitoring in eHealth trial differ from trials in other fields. There are also certain difficulties with eHealth trials.

Learning Outcomes
1. To recognize women’s experiences from internet and app treatment of urinary incontinence
2. To identify the difficulties in quality assessment of existing mobile apps for pelvic floor disorders
3. To identify possibilities and difficulties with eHealth trials and implementation of mHealth (mobile technologies)

Target Audience
Urologists, Gynaecologists, General Practitioners, Continence advisors, Physiotherapists, Nurses, Researchers

Advanced/Basic
Basic

Conditions for learning
Interactive moments (bring your smartphone, laptop, PC tablet, iPad)

Suggested Reading
- Björk AB, Sjöström M, Johansson EE, Samuelsson E, Umeåfjord G. Women's Experiences of Internet-Based or Postal Treatment for Stress Urinary Incontinence: Qual Health Res. 2014; Apr;24(4):484-93

Eva Samuelsson
From research to implementation
eHealth is the transfer of health resources and health care by electronic means. mHealth is the use of mobile technologies to support health information and medical practices (1). It is a challenge for every country to deliver high quality, effective and safe care at an affordable cost. Health apps and medical apps provide new possibilities. The four most common barriers for implementation of mHealth in Europe found in 2015 (1) were funding, cost-effectiveness, legal issues and priorities. Only 23% of EU member states have an entity that is responsible for the regulatory oversight of the quality, safety and reliability of mHealth applications.
When a medical app is released for free use we do not know if it will be used in the way the developer expected. Mobile applications bring new opportunities to follow the use and the result of treatment and we will give you examples of this from our own research.

Within the eContinence project, we developed the medical app Tät® for first-line treatment of stress urinary incontinence (SUI). The app has information about SUI and features a pelvic floor muscle-training programme along with reminders and user statistics. We demonstrated its efficacy for symptom severity (ICIQ-UI SF) and disease specific quality of life (ICIQ-LUTS qol) in a randomised controlled study (RCT) that included 123 women with SUI ≥1/week (2).

During the workshop we will demonstrate different methods of collecting data after release of the app for free. We will discuss the results from the implementation study; the improvements in symptom severity were clinically relevant even in an unselected population and app treatment seem to be an easily accessible and effective first line treatment for stress urinary incontinence.

Take home message
mHealth gives new possibilities to collect data. Treatment of SUI with the support of an app gives improvements that are clinically relevant even in an unselected population

1. From innovation to implementation. eHealth in the WHO European region. WHO 2016 http://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf

Anne Loohuis
From cool tool to evidence based medicine (study design)
- Which methods are appropriate for the studies on the effects of eHealth interventions?
- Do methods differ from standard RCT methodology?
- The app URinControl

As Eysenbach already said in 2001: eHealth is an emerging field in the intersection of medical informatics, public health and business (1). Also in pelvic floor disorders, there are many applications available to inform, monitor and treat patients and to support care-providers in everyday practice. The possibilities seem endless and the development of new applications is moving fast. Development is important, however, it is equally important to evaluate these new applications. Before using it in daily practice, we need to be sure of the applications effectiveness, cost-effectiveness and patients- and caregivers preferences and experiences. It is important to ensure the quality of the eHealth application is equally or better compared to standard care. Furthermore, we need to have input from patients and caregivers to prepare successful implementation. Therefore, we need to do research.

Since eHealth is an emerging field, there is no golden standard for a research design to evaluate a new application. Which methods are appropriate to study eHealth interventions? Do methods differ from other interventions? According to the ‘Centre of Evidence-Based Medicine’ (http://www.cebm.net/) the highest level of evidence can be found by using a randomized controlled trial. However, there are some pro’s and cons for using a RCT in eHealth-research (2).

In this workshop, we will discuss the use of a RCT and good alternatives. We will use an example of our own, the URinControl-App, an app for the treatment of urinary incontinence in adult women in general practice. With this example we will consider different research designs and their pros and cons. There is room for questions and attenders of the workshop can bring their own ideas or applications to the table to discuss the best design with the room.

Take home message
There is no golden standard for a research design to evaluate a new application

(2) Liu JL, Wyatt JC. The case for randomized controlled trials to assess the impact of clinical information systems. Am Med Inform Assoc. 2011;18(2:173-80)

Ina Asklund
How do women describe their experiences of internet and app treatment?
A qualitative study about internet-based treatment of SUI

250 women with SUI were randomized to treatment via internet or via a brochure. There was no face-to-face contact during the study. After 3 months, both groups had improved significantly regarding symptoms (ICIQ-UI SF) and disease specific quality of life (ICIQ-LUTS qol) (1). 21 women were then interviewed about their experiences of the treatments. The experiences were categorized into three main categories:

1. “Hidden but present” – life with incontinence
Adjustments in everyday life, lack of knowledge about treatments available, guilt about not doing PFMT, not taken seriously, high barrier for seeking help.

2. “At a distance but close” – the relationship to the care provider
A relationship to the urotherapist, negative stress, helped motivation more in the Internet than in the brochure group.

3. “By myself but not alone” – the sense of empowerment
Increased knowledge and awareness led to empowerment.
To summarize, a core category was found: “Acknowledged but not exposed”
Women with incontinence might feel alone and exposed. Participating in a treatment made them feel acknowledged, supported and more in control.

**A qualitative study about mobile app treatment of SUI**
123 women with SUI were randomized to treatment with a mobile app or to a control group. After 3 months both groups were followed-up and the results showed that women using the app had improved significantly regarding symptom severity and QOL compared to the control group (2). 15 women in the app group were interviewed about their experiences. In the preliminary results the experiences are summarized in three main categories:

1. An effective and simple/easy treatment
The app was informative, it gave support, reminders and increased motivation to treatment.
2. New technique changes attitudes
App treatment gave a feeling that the problem was prioritized and less taboo.
3. Confident and capable to perform the treatment independently
Women felt competent to perform the treatment without face-to-face contact.
To summarize, women experienced the app treatment as an easily available, effective and modern treatment option that was possible to perform independently.

**Conclusions from the two studies:**
Qualitative studies are important to understand why and how a new treatment works. The interviews increase our understanding of how women experience treatment programmes via an app or the internet. This knowledge has led to improvements of the app and the internet programme and also helps us in the development of future treatment programmes.

**Possibilities:** Easily accessible and lower the barrier for health seeking. Smartphones and apps are part of everyday life. Reminders increase motivation.

**Difficulties:** How to keep the motivation up? How to support and confirm progress? How to give advice if the treatment doesn’t work?

**Take home message:**
Treatment programs for SUI delivered via a mobile app or the internet are effective and appreciated. Women experience these treatment programs as easily accessible first-line options that can support and motivate them in their self-management of SUI.


**Marco Blanker**

**Survey of available Apps**
We have searched the App store and Google Play for available apps, which can be used for the treatment of urinary incontinence. This search yielded 38 different Apps, mainly focusing on the treatment of UI in women.
For only one of these Apps we could find supportive publications in PubMed. We have sent all App-providers a short survey, in which we ask for the evidence base of the Apps, as well as information about the target population, available languages, and number of downloads.
During the workshop Marco Blanker will present the results of this survey and discuss the evidence base of available Apps.

W 8 E-health in Pelvic Floor Disorders

While you are waiting for W 8 to start........
1. Grab your phone, laptop, PC tablet or iPad
2. Go to www.menti.com
3. Enter the code 49 10 77 and vote

W8
E-health in Pelvic Floor Disorders

Eva Samuelsson, Sweden (chair)
Marco Blanker, the Netherlands
Anne Loohuis, the Netherlands
Ina Asklund, Sweden

eHealth is the use of information and communication technologies (ICT) for health

mHealth is the use of mobile technologies to support health information and medical practices

- More than 2 billion smartphone users globally in 2016 - a quarter of the world
- Rapid growth in developing countries

Eva Samuelsson

Affiliations to disclose:
The name Tät (mobile application) and the logo Tät.nu are registered as Trademarks by The Swedish Patent and Registration office for E Samuelsson at Umeå university

Funding for speaker to attend:
- Self-funded
- Institution (non-industry) funded
- Sponsored by:

eHealth and pelvic disorders WS 8

Schedule
13.30-13.35 Introduction Eva Samuelsson
13.35-14.10 From cool tool to evidence based eHealth (& survey of available apps) Anne Loohuis and Marco Blanker
14.10-14.30 From research to implementation of eHealth Eva Samuelsson
14.30-14.45 How do women describe their experiences of internet and app treatment? Ina Asklund
14.45-15.00 Discussion
Quiz 1

1. Go to www.menti.com
2. Enter the code 49 10 77 and vote

Have you ever recommended the internet or apps for patients with urinary incontinence?

- Yes, the internet or apps without specification
- Yes, specified websites or apps for information
- Yes, specified websites or apps for assessment (questionnaires or bladder diary)
- Yes, specified websites or apps for treatment
- No
From cool tool to Evidence Based mHealth (& Survey of available apps)

ICS 09-2016 Workshop “eHealth in Pelvic Floor Disorders”

Marco H. Blanker, MD PhD
General practitioner & epidemiologist
University of Groningen, University Medical Center Groningen, The Netherlands

Anne M.M. Loohuis, MD
General practitioner trainee & PhD candidate
Department of General Practice
University Medical Center Groningen, The Netherlands

Content

Topics next 35 minutes

- "Cool tool"
- Evolution of research in mHealth
- Survey of available apps
- Reasons to perform research in mHealth
- How to perform research in mHealth
- URinControl-App
- Discussion/Questions/Experiences

“Cool tool”

It starts with:

- a healthcare problem
- a healthcare professional
- a promising idea
Problem in daily practice: Incontinence
- Help-seeking behaviour (shame)
- Instructions take time
- Adherence variable
- High costs

Promising idea: App “Bekkenbodem” (= “pelvic floor”)

Marijke developed and implemented the App in her own practice and online.

After 3 years:
- 10,000-50,000 downloads
- Ratings of patients and professionals pretty good

Marijke Slieker-Ten Hove, Pelvic Floor Physiotherapist, The Netherlands

"Cool tool"

How about:
- Harms & benefits/ Effectiveness/ Costs/ Adherence/ Help-seeking behaviour/ Experiences
- Comparison to Usual Care

Definition of success?
- Ratings/ Number of downloads/ Other parameters?

How to compare with other Apps?
- When is App A better than App B?

No evaluation: We just don’t know

Success story?

Cool tools available

Total number of medical Apps (2015): 165,000

Patient Adoption of mHealth. Report by the IMS Institute for Healthcare Informatics. August 2015

Evolution of eHealth research

Number of articles mHealth 1993-2014:

Conclusion: No evidence of effectiveness for majority of medical apps

Evolution of eHealth research

300 Registered mHealth trials at clinicaltrials.gov (2015)
Versus 165,000 Medical Apps in 2015

Survey of available apps

165,000 Medical Apps – only few scientific reports

What about Apps for Urinary Incontinence?

Survey
- Search
- Online questionnaire

Survey - search

App Store and Google Play

Search July 2016
- Hand search using Incontinence as main search term (English, German, Finnish, French, Norwegian, Polish, Portuguese, Spanish, Swedish, and Turkish)
- “comparable Apps” and “other users also installed these apps” options
- Both stores searched in duplicate
- Results combined
- Contact person invited for online survey

Survey - questionnaire

Questionnaire
- Self-designed (no validated questionnaire available)
- Aim of app
- Development (e.g. involvement of patients and health care professionals; evidence base)

Survey – Results

131 different Apps
- 12 no contact information
- 119 invitations sent
  - 3 bounced (wrong e-mail)
  - 23 responses (8 not intended for prevention/treatment of UI)
- So results of 15 apps available (no statistics applied)

Available languages

<table>
<thead>
<tr>
<th>Language</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
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</tr>
<tr>
<td>Spanish</td>
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</tr>
<tr>
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<tr>
<td>Norwegian</td>
<td></td>
</tr>
<tr>
<td>Russian</td>
<td></td>
</tr>
</tbody>
</table>

What is the intention of the App?

1 - Prevention of UI
8 - Treatment
6 - Prevention and treatment
Survey – Results

Type of incontinence addressed in App

<table>
<thead>
<tr>
<th>Urgency</th>
<th>Stress</th>
<th>Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔✔✔</td>
<td>✔</td>
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</tbody>
</table>

Survey – Results

Content of Apps (n=15)

- Information about UI – 10
- Graphics – 7
- Pictures – 5
- Animations – 9
- Exercises (treatment) – 10
- Exercises (prevention) – 9

- 10/12 kegel
- 1/12 bladder training
- 1/12 dr Swann
- 1/12 hypopressive
- 1/12 other (not defined)

Survey – Results

Development of content – which sources were used?

- Doctors / PT / patients (5)
- Scientific literature (4)
- Wikipedia / internetsources (3)
- Personal experience (2)
- ‘common knowledge’ (1)
- ‘alternative healing methods from all over the world’ (1)

Survey – Results

Development of content – who were involved?

- Patients (7)
- PT (7)
- Urologist (5)
- (uro)Gynaecologist (4)
- GP/PCP (3)
- Software engineers (3)
- Other (psychiatrist, midwives, health care manager, psychologist) (all 1)
- “my family and I”

Survey – Results

Development of content – validation study?

4: 3 with available data (abstract/full text publication)

Survey – Results

Development of content – testing?

- No testing (4)
- Personal / inhouse (5)
- Patients (5, one planned)

Survey – Results

Availability

Apple: Download on the App Store
Android: Download on Google play

Downloads

- >100
- 70
- >500
- 5,000
- >30,000
- >180,000

- Thousands
- 10,000
- No information / trade secret (3)
Survey – Summary / conclusions

Many apps available
Low response rate

Only few Apps with formal development phase, testing and piloting

Patients and PT involved in development of Apps

For only 3 studies, background information is available from the literature

Evolution of eHealth research

300 Registered mHealth trials at clinicaltrials.gov (2015)
Versus 165,000 Medical Apps in 2015

Conclusion: No evidence of effectiveness for majority of medical apps

Patient Adoption of mHealth. Report by the IMS Institute for Healthcare Informatics. August 2015

Reasons to perform research

Reasons to perform research/ evaluate eHealth technology

Improve quality, utility and effectiveness of eHealth intervention AND healthcare
Evaluate safety prevent harm
Conserving resources
Ineffective intervention: improve or stop?
Promote confidence of end users
Higher confidence in quality → better uptake
Engage stakeholders
Improvement of quality & implementation

How to perform Research

Evaluating eHealth, different questions

What do people feel about the application?
How many people like it?
What do people like about it?
Performance (compared to)?
Cost-effectiveness?
Effect on outcome?
How to improve?

The case for randomized controlled trials to assess the impact of clinical information systems.
Liu JL, Wyat CJ. J Am Med Inform Assoc 2013
How to perform research

Evaluating eHealth, different questions
different methods

- Experimental designs/ Quasi-experimental designs
- Quantitative evaluation/ Qualitative evaluation

Where to start?
1. Research questions
2. Match study methods

Mixed methods evaluation is recommended

Our mixed methods evaluation →

URinControl- Study in progress

App for incontinence
versus
Usual Care (Dutch guidelines)

Developed by:
Department of General Practice, University Medical Center Groningen.
Janny Dekker, Marco Blanker, Anne Loohuis, Marjolein Berger

Institutes: University of Groningen, ZonMw (government funding), J.P. Boer foundation
Others involved: patients, healthcare professionals (e.g. Marijke Sleker), researchers, policy makers

Award winning research proposal (Prof. Huygenprijs)

URinControl- an example

App for incontinence
versus
Usual Care (Dutch guidelines)

Content:
- All types of incontinence (urgency/stress/mixed)
- Information, monitoring and treatment (PFMT and bladder training)
- Animations, Reminders, Graphs, Pee-button, Games for distraction

Goals
1. Can App replace or complement usual care?
2. Prepare succesfull implementation
3. Optimize tool

Mixed methods study design

URinControl- an example

App for incontinence
versus
Usual Care (Dutch guidelines)
From question (Q) to methods (M) (1):

Q: Can App replace standard care?
M: Pragmatic Randomized Controlled Trial
   Goal: Create an evidence based tool that can be implemented in professional guidelines.

Q: How do patients make use of the app?
M: Logdata (attrition/ adherence)
   Goal: to evaluate usage and improve tool

From question (Q) to methods (M) (2):

Q: What are experiences of patients using the app?
M: Qualitative research (interviews/focus group sessions)
   Goal: to understand usage and improve tool

Q: Can usage or patient experiences predict treatment success?
M: Combination of data from RCT, logdata and qualitative research
   Goal: to evaluate success within subgroups and improve tool

Q: What are preferences and experiences of caregivers?
M: Qualitative/ Semi-quantitative; survey/interviews/focus group sessions
   Goal: to involve stakeholders and prepare implementation

URinControl- an example

App for incontinence versus Usual Care (Dutch guidelines)

Status of research
Design article (with more details) will be submitted in 2016

Expected end of inclusion period trial: November 2017
Follow-up moments after 4 months and 12 months
Qualitative projects will be conducted in 2016/2017

Take home messages

- Many Apps, little evidence
- mHealth research: Different questions/Different methods
  - Depends on goal App
  - Multimethod is recommended
- mHealth offers new possibilities for data collection

Take home messages

Questions Discussion Experiences from the audience?
W8
From research to implementation of eHealth

Eva Samuelsson
General Practitioner, Associate professor
Department of Public Health and clinical medicine, Umeå university, Sweden

Disposition

- eHealth and mHealth
- In the population, in primary care and in specialist care
- Examples of collecting data in mHealth studies
  - The iDry® app
  - The Tät® app
    - RCT
    - Implementation study
- Take home messages

FROM INNOVATION TO IMPLEMENTATION
eHealth in the WHO European Region

- Based on 2015 WHO global survey of eHealth
- It is a challenge for every country to deliver high quality, effective and safe care at an affordable cost
- The use of eHealth in different countries

165 000 Health apps
- Quality, safety and reliability?
  - Usability, functionality and meaningfulness?
- The role of National health authorities
  - Evaluate
  - Regulate

Women with urinary incontinence - help seeking and the role of mHealth

The role of mHealth
- Information
- Self-management
- Communication
- Motivation
- Assessment
- Treatment

All women with UI
Primary Care
Specialist Care

App Study iDry®

- Released nov 2012 as free download
- Document UI symptoms and improvement
- User data collected automatically -sent anonymously to the development team’s servers
**iDry®-user data**

**Users**
1231 downloads in 19 months
878 entered data
- 50% used in one day
- 46% used it less than one month
- 3% used it more than one month
Mean age 50.8, Male 73%

**Results**
Short-term users reduced pad use
Bladder training positively correlated with a reduction in pad use and leakage amount

---

**The eContinence project**

**Overall aim**
to develop, evaluate, and implement treatment programmes for urinary incontinence via Internet, smartphone, and PC tablet applications

---

**The app Tät®**

- Information
- Lifestyle
- Exercises
- Graphic support
- Reminders

---

**Results from RCT Tät® app**

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Treatment group</th>
<th>Baseline n=123</th>
<th>Follow-up n=121</th>
<th>Between group p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICIQ-UI SF</td>
<td>App group</td>
<td>11.1 (3.0)</td>
<td>7.6 (3.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Control group</td>
<td>11.0 (2.6)</td>
<td>10.2 (3.2)</td>
<td></td>
</tr>
</tbody>
</table>

*one way ANCOVA

---

**The app; treatment of SUI**

We demonstrated the **efficacy** for symptom severity in a randomised controlled study (RCT)*.

The app was released in Swedish for free in May 2015 with a questionnaire incorporated.

We conduct an implementation study; comparison of data from the users six months after release of the app with data from the RCT.

---

**Implementation of app (first six months)**

2006 initial questionnaires
273 (14%) followup after three months

Users in an unselected population were younger than in the RCT
Two-thirds of the users reported some urinary incontinence. The incontinence was overall less severe than in the RCT mean ICQ UI-SF 8.7(SD 3.9)

---


Price award to Ina Asklund; ICS congress 2015; Best abstract (conservative treatment)
Efficacy-effectiveness

App group (RCT) (n=61)
decrease in ICIQ UI-SF of -3.2 (95%CI -4.3 — 2.1)

Implementation group (n=216)
decrease in ICIQ UI-SF of -2.63 (95%CI -1.9 — 3.4)

Conclusion of the implementation study;
The app was effective even in an unselected population of Swedish women.

Take home messages

mHealth provides new possibilities to collect data:
Different methods
- Automatically from app use
- Questionnaires* when downloaded
- Web questionnaires
- Other possibilities
- Possibility to study the use and effect after implementation
- User security and validity of data

Treatment of SUI with the support of an app was effective even in an unselected Swedish population

Questions?

• Your experiences of mHealth?
• Cultural differences?
• Does the health care system in your country facilitate and regulate the use of mHealth?
Ina Asklund

Affiliations to disclose*: 

none

Funding for speaker to attend:

☐ Self-funded
☒ Institution (non-industry) funded
☐ Sponsored by:

How do women describe their experiences of internet and app treatment?

Ina Asklund

General practitioner

Department of Public Health and Clinical Medicine

Umeå University, Sweden

Why qualitative studies?

• Important to understand why and how a new treatment works.

• Can lead to improvements of the app and the internet programme.

• Can help in the development of future treatment programmes for other conditions.

Internet-based treatment of SUI

250 women randomized to treatment via internet or via a brochure

Follow-up after 3 months with questionnaires about symptom severity (ICIQ-UI SF) and quality of life (ICIQ-LUTSqol)

Results showed both groups had significant improvements

21 women were interviewed about their experiences of treatment

Results from the interviews-internet

Hidden but present – life with incontinence
At a distance but close – the relationship to the care provider
By myself but not alone – the sense of empowerment

Acknowledged but not exposed

Conclusion: Women with incontinence might feel alone and exposed. Participating in a treatment made them feel acknowledged, supported and more in control.

Mobile app treatment of SUI

123 women randomized to treatment with a mobile app or to a control group

Follow-up after 3 months showed that women using the app had significant improvements compared to the control group.

15 women in the app group were interviewed about their experiences.

Sjöström M et al. Internet-based treatment of stress urinary incontinence: a randomised controlled study with focus on pelvic floor muscle training. BJU Int. 2013 Aug


*All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned in your presentation.
Results from the interviews-app

The app was an effective and easy treatment

New technique changed women's attitudes

Women felt confident and capable of self-treatment

"Yes, I think that's mainly it, it's easily accessible, it's right there and it's a constant reminder."

Conclusion: Women experienced the app as an easily accessible, effective and modern treatment option that supported and motivated them to self-manage their incontinence.

Conclusions

Treatment programs for SUI delivered via a mobile app or the internet are effective and appreciated.

Women experience these treatment programs as easily accessible first-line options that can support and motivate them in their self-management of SUI.

Possibilities

- Easily accessible and lower the barrier for health seeking
- Smartphones and apps are part of everyday life
- Reminders may increase motivation and adherence
- New technique changes attitudes

Difficulties

- How to keep the motivation up?
- How to support and confirm progress?
- How to give advice if the treatment doesn’t work?

Quiz to the audience

Ways to keep the motivation up?

What would motivate you to perform PFMT regularly?

1. Individualized feedback about my training in my smartphone.
2. A training programme designed as a game.
3. Sharing my exercise statistics with my friends and compete with them.
4. Having regular appointments with a health-care professional.

Thank you!