

INFORMATION AND COMMUNICATION TECHNOLOGIES (ICT) SELF-MANAGEMENT SYSTEM FOR PELVIC FLOOR MUSCLE TRAINING: A PILOT STUDY IN WOMEN WITH STRESS URINARY INCONTINENCE.

Introduction

Information and Communication Technologies (ICT) applied to healthcare systems can increase the accessibility to treatments, empower patients and healthcare workers and invest in research towards the personalised medicine of the future. E-Health tools for urinary incontinence (UI), scientifically evaluated, could provide an effective and widely accepted treatment.

The main objective of this pilot study is to perform a thorough test of the functionality of the ICT self-management system in order to analyse its technical readiness, for clinical use and research purposes. The video will show all the components of the ICT-system and how it works.

Design

21 women, between 18 to 75 years old, with mild or moderate stress urinary incontinence (SUI) according to their answers to the UDI-6 and ICIQ-UI-SF questionnaires, were recruited in two University Hospitals in two European countries. All patients received information about all treatments options for SUI and accepted to be treated with conservative treatment. Informed consent was obtained and all patients agreed to participate in this study using the ICT self-management system for pelvic floor muscle training (PFMT) at home for a period of three months. This system integrates three components: 1) Portable vaginal biofeedback device and abdominal belt with surface electromyography (EMG)-sensors to collect data on patient's pelvic floor and abdominal muscle activity during PFMT; 2) Smartphone with application and serious games, designed specially to facilitate and support conservative treatment for SUI (PFMT and behavioural modification); 3) A web portal that helps therapist to remotely supervise the treatment sessions and to monitor progress. Moreover, the web portal permits communication between patient and therapist.

All patients performed a training program designed by a therapist. During the period of treatment, patients were requested to report both clinical and technical issues, related to the ICT self-management system, via the web portal, application or telephone to the therapist. Notified issues were stored in a database for further analysis. After patients finished the treatment, they filled out specific questionnaires to evaluate functionality and usability of the system based on their experience.

Results

21 women were included, age ranging from 32 to 67 years (median 45) with a median BMI of 23 kg/m², a median parity of 2 and a median ICIQ-UI-SF of 11 (IQR 9-12). None of the patients reported problems regarding the use of the ICT self-management system. There were six dropouts, three for technical issues and three for personal reasons (non-medical). The 15 patients who performed the treatment for a period of three months had an adherence to the training program of 70,4% (range 41,8-86,2%). During this evaluation of the systems' functionality, we observed different minor technical issues mainly related to software calculations and fatigue of the materials used in the prototype. All issues were resolved, which consequently improved the system. Only minor clinical events occurred (vaginitis, urinary infection). However, despite the technical issues, most patients (80%) were pleased or very pleased with the ICT self-management system.

Conclusion

Overall, the ICT-self-management system performed well in usability testing and guarantees good adherence to PFMT. In addition, it help therapists to monitor their patients and communicate with them. Different minor technical issues were detected. All issues were resolved and their detection resulted in improved functionality of the ICT self-management system. Clinical issues related to treatment were minimal and similar to other treatment modalities that use vaginal devices. Technical teams are implementing all improvements in order to develop the definitive ICT self-management system, which will be evaluated in a randomized clinical trial.

Disclosures

Funding: This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 643535 (WOMEN-UP project). **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Comité Ético de Investigación Clínica del Hospital Clínic de Barcelona (CEIm). **Helsinki:** Yes **Informed Consent:** Yes