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PELVIC FLOOR TELEREHABILITATION: A NEW DEVICE DESCRIPTION AND THE EVALUATION OF IT EFFECTIVENESS.

Hypothesis / aims of study

Describe the use of a new telerehabilitation device for pelvic floor muscle training and evaluate its effectiveness.

Study design, materials and methods

Study design:

Prospective study in women with stress urinary incontinence (SUI) treated at the Rehabilitation Service between March and July 2012.

Materials:

A new device based on a network platform, and a patient kit:

The patient's kit consists of:

- a pressure sensor (vaginal probe), which transform the muscles pressure to air pressure
- a Bluetooth device, which is reponsible for digital biosignals acquisition (air pressure) and transmission of the digitalized signals to the mobile terminal.
- a mobile application, which receives from the network platform the exercises the patient have to do, helps the patient in the exercises execution providing biofeedback, and once the rehabilitation session has been performed, send the signals to the platform.



The *network platform* it is a platform on the web, accessible from the Internet safely, and it is responsible for signal reception and management of rehabilitation sessions.

The system allows to establish a timetable for an specific rehabilitation program in accordance with a personal calendar.

How does it work?

The patient receives the training to be done daily. Once the exercise is done, the mobile application send the pressure signals to the platform, and the signals are stored.

The professional can review each session, evaluate the results, and also define new types of exercises and sessions depending on the most convenient treatment

Methods:

A sample of 10 female patients with SUI, who know how to use Smartphone and/or PC.

All patients signed informed consent.

Exclusion criteria: secondary, mixed and urgency incontinence. Higher grades II prolapses. Previous surgery. 6 months prior drug treatment. Active infections.

Intervention: education talks, pelvic floor muscle training with phsysiotherapist supervision and home treatment with the described device.

Outcome measures: (Initial & 3 months): general and specific quality of life scales (International Consultation Incontinence Questionnaire and KING'S). Voiding diary. Perineometry. Program's satisfaction (visual analogue scale). Adverse events.

Statistical Analysis: SPSS v.20

<u>Results</u>

One patient left the study early because of family issues. Therefore, the final number of the sample was 9.

| Adverse events | 6 (66.7%) |
|--------------------------------------|-------------|
| Program's satisfaction at the end of | 7.83+/-1.84 |
| treatment (median +/-sd) | |

Comparison of initial vs final results

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|------------------|--------------------|-------|
| ICIQ (Me[Q1-Q3]) | | 0.205 |
| Initial | 9.5[6.75-12.75] | |
| Final | 8[5-10.5] | |
| KING (Me[Q1-Q3]) | | 0.678 |
| Initial | 32.03[18.36-41.40] | |
| Final | 32.8[16.4-37.49] | |

| Average no. of escapes (Me[Q1-Q3]) | | 0.068 |
|------------------------------------|------------------|-------|
| Initial | 0.83[0.41-1.25] | |
| Final | 0[0-0] | |
| Perineometry (Me[Q1-Q3]) | | 0.011 |
| Initial | 23.06[8.2-37.86] | |
| Final | 32[21.5-61.5] | |
| Perineometry (median +/-sd) | | 0.011 |
| Initial | 24.02+/-16.42 | |
| Final | 39.44+/-21.43 | |

Interpretation of results

Statistically significant difference was observed between the initial and final values of perineometry 23.07 to 32 (p=0.011). As well as clinical significant improvement was observed in the number of leakage. The remaning variables are shown no significant differences before and after treatment.

Although the number of adverse events was high, this didn't have great clinical relevance since they were just discomfort and stinging at the beginning of the treatment and these adverse effects dissapeared after the first week of treatment.

Concluding message

Telerehabilitation is shown as an effective alternative in the rehabilitation treatment of SUI. Larger studies are needed to adequately assess all the benefits of this treatment modality.

Besides that, using a telerehabilitation platform allow us to know in detail the adequate execution of the exercises at home as well as the fulfillment of the guideline established.

References

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Disclosures

Funding: Telefonica I+D has provided the devices to be used. **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Comité de Ética de la Investigación de Centro de Granada (CEI-GRANADA) **Helsinki:** Yes **Informed Consent:** Yes