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Brief report

Telerehabilitation to treat stress urinary incontinence. Pilot study☆

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ABSTRACT

Background and objective: We aimed to test a new telerehabilitation device for stress urinary incontinence (SUI) in order to make an initial assessment of its effectiveness.
Patients and method: Randomized, controlled pilot study. Intervention: experimental group (10 patients): pelvic floor muscle training, device training and home treatment with it; control group (9 patients): conventional rehabilitation treatment. Outcome measures (baseline and 3 months) overall and specific quality of life: International Consultation Incontinence Questionnaire and King's Health Questionnaire, bladder diary, perineometry, satisfaction with the program and degree of compliance.
Results: Baseline characteristics were similar in both groups. There was no statistically significant difference for any outcome measures between groups at the end of the follow-up. The change in perineometry values at baseline and after the intervention was significant in the experimental group (23.06–32.00, $p = .011$). No group in this study had any serious adverse effects.
Conclusions: The tested device is safe and well accepted. Although there is some evidence of its efficacy in the rehabilitation treatment of SUI, larger trials are needed to appropriately evaluate the potential advantages.

Tratamiento de la incontinencia urinaria de esfuerzo mediante telerrehabilitación. Estudio piloto

Palabras clave:
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Perineometría

RESUMEN

Fundamento y objetivo: Testar un nuevo dispositivo de telerrehabilitación para la incontinencia urinaria de esfuerzo (IUE) y hacer una valoración inicial de su eficacia.
Pacientes y método: Estudio piloto controlado y aleatorizado en pacientes con IUE. En el grupo experimental ($n = 10$) la intervención consistió en entrenamiento de la musculatura del suelo pé lvico, adiestramiento y tratamiento domiciliario con el dispositivo. En el grupo control ($n = 9$) se realizó tratamiento rehabilitador convencional. Las medidas de resultados (iniciales y a los 3 meses) fueron la calidad de vida específica y gené rica determinada mediante: International Consultation Incontinence Questionnaire y King's Health Questionnaire, diario miccional, perineometría, satisfacción con el programa y grado de cumplimiento.
Resultados: Ambos grupos presentaban características basales similares. No hubo diferencias estadísticamente significativas en ninguna medida de resultados entre ambos grupos al final del período de seguimiento. Los valores iniciales y finales de la perineometría del grupo experimental mostraron

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diferencias con significación estadística (23,06 frente a 32, p = 0,011). No se presentaron efectos adversos graves en ningún grupo.
Conclusiones: El dispositivo testado es seguro y bien aceptado. Aunque hay indicios de su eficacia en el tratamiento rehabilitador de la IUE, son necesarios estudios má s amplios para valorar adecuadamente sus ventajas.

Introduction

Urinary incontinence (UI) is defined by the International Continence Society as "any involuntary leakage of urine".[1] Its predominance in Spain is estimated to be above 50% among people over the age of 65[2] and it poses a health issue that greatly impacts on the patient's quality of life.[3] In stress urinary incontinence (SUI), the loss of urine takes place when there is an increase of intra-abdominal pressure. This is due to the weakening of the musculotendinous structures in the pelvic floor. The treatment of choice is conservative and consists of making lifestyle changes, pharmacological treatment and rehabilitation techniques. The latter include pelvic floor muscle training (PFMT) with or without the help of biofeedback (BF), and electrical muscle stimulation. Although evidence exists as to the effectiveness of rehabilitation, the best treatment plan and the appropriate approaches to improve adhesion to it have yet to be determined.[4]

Telerehabilitation (TRH) is based on providing distance rehabilitation services using telecommunication technology. It is proposed as a means of enhancing the accessibility, monitoring and continuity of care, and potentially saving time and money.[5] The medical literature on TRH of UI is scant and the only study found concludes that its effectiveness is similar to that of an in-person treatment.[6]

The purpose of the present study was to compare the effectiveness of treatment with a TRH device with conventional rehabilitation treatment for SUI, and to assess the applicability, reception and adverse effects of the device.

Patients and methods

Type of study

Randomised controlled pilot study

The project was approved by the provincial Biomedical Research Ethics Committee and all participants signed the informed consent document.

The participants were chosen from 38 patients included in the March 2012 waiting list for physiotherapy for SUI in the Department of Rehabilitation of the Hospital Universitario Virgen de las Nieves, Granada, Spain. We contacted all participants by telephone and invited them to an informative meeting. A total of 25 attended the meeting.

Inclusion criteria: Women with SUI, with minimal skills in the use of new technologies.

Exclusion criteria: Neurogenic, oncologic, urge and mixed incontinence; uterine, >II degree bladder and/or rectal prolapse; prior incontinence surgery; specific pharmacological treatment in the previous 6 months; ongoing genitourinary infection; pacemaker users.

The 19 patients who fulfilled the inclusion criteria were randomised using a sealed envelope system by staff unconnected with the trial. Ten were assigned to the intervention group and nine to the control group.

Intervention

The intervention was undertaken by an expert physiotherapist.

Intervention group

1. PFMT: five 30 min sessions over 2 weeks.
2. Training to use the TRH device (3 × 30 min sessions). The device consists of a vaginal probe that wirelessly transmits (Bluetooth) pressure fluctuations. The computer application allows the patient to visualise the correct or incorrect execution of the exercise. The physician can see the parameters asynchronously.
3. Home treatment with the TRH device using a specialised programme. Monthly follow-up by healthcare professionals.

Control group

1. PFMT was the same as with the intervention group.
2. BF: ten sessions (Myomed 932 team, Enraf-Nonius, Germany).
3. Home treatment: a written personalised programme that specifies that the exercises should be performed daily.
4. Follow-up was at 3 months for both groups.

Study variables

Biometric and clinical data: age, level of education, evolution time and trigger factors.

Main result measurements

- *Specific quality of life*: using the International Consultation on Incontinence Questionnaire[7] short form.
- *Generic quality of life*: using the Spanish version of the *King's Health Questionnaire*.[8]

  Both questionnaires were completed at the beginning of the treatment and after 3 months.
- *Bladder diary*: completed during the first 3 days and the last 3 days of the study period. Among other parameters, patients recorded the incidence and severity of episodes of leakage and the activity they were involved in at the time. A reduction of one episode per day was considered clinically significant.

Secondary result measurements

1. *Perineometry:* performed with a Peritron device, a manometer that measures contractions through a vaginal probe. This was conducted by two expert physicians during the initial and final consultation. Both physicians were blinded to the study at the time of the final consultation.
2. *Level of satisfaction with the treatment programme*: measured after 3 months with the visual analogue scale.
3. *Degree of treatment compliance*:
   - Intervention group: through the TRH device record.
   - Control group: through a calendar.
4. *Adverse effects*: advantages and disadvantages of using the TRH device.