EVALUATION OF THE CONNECTED BIOFEEDBACK KEGEL TRAINER EMY IN THE MANAGEMENT OF STRESS URINARY INCONTINENCE

INTRODUCTION AND AIM OF THE STUDY

Urinary incontinence is a common health problem leading to significant decrease in quality of life. 1 out of 5 women are suffering from urinary leaks (1). Pelvic floor muscle training is one of the first steps in the management of stress urinary incontinence (2). Biofeedback technology has been previously shown to be efficient in improving incontinence symptoms and to be superior compared to other techniques (3). Pelvic floor training with biofeedback devices enables women to gain awareness of their pelvic floor muscles and to train them actively. In addition, the use of a mobile application was reported to strongly stimulates user's engagement to the treatment (4). The innovative Kegel trainer Emy combines a medical biofeedback device with a smart mobile application. It allows women to strengthen the pelvic floor at home. Exercises are based on the recognised PERFECT scheme (5) to enable personalised training according to therapeutic guidelines. The aim of this study was to evaluate the efficiency of pelvic floor exercises with the Emy Kegel trainer in patients suffering from stress urinary incontinence.

INTERPRETATION OF RESULTS

The quality of life improved significantly for

98% of women

93% of women reported a strong impact on their quality of life after the 1st month of training. This rate increased over the study period of 3 months to 98% (Figure 1).



Figure 1. Rate of women that reported an increase in their quality of life

Frequency and severity of incontinence symptoms decreased for

Symptoms of urinary incontinence significantly decreased with the pelvic floor training over time. Most women report less urinary leaks from the 1st month of training. Overall, a mean decrease of 60% in urinary scores was observed at the end of the study periode (Figure 5, page 2).

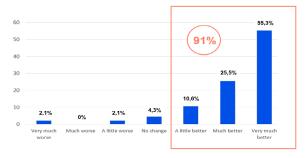


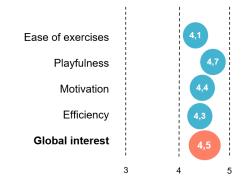
Figure 2. Patient's global impression of improvement by the treatment

of patients experienced an improvement of their incontinence from the pelvic floor training with Emy

Patients evaluated their global impression of improvement obtained by the treatment. After the 3 months study period, 55% described their final condition as "very much better", 26% as "much better" and 11% as "a little better" (Figure 2).

96% were satisfied by the exercises with the Emy Kegel trainer

Women expressed their satisfaction of use in questions about the device, its mobile application and its usage. The global interest of pelvic floor training with Emy was rated at 4.5 of 5. Next to the efficiency, patients appreciated especially the playful and motivating approach (Figure 3).



 $0 = the \, \underline{worst} \, and \, 5 = the \, best$ Figure 3. Satisfaction of use of the Emy Kegel trainer

CONCLUSION

This study suggests that pelvic floor training using Emy Kegel trainer is beneficial in terms of improvement of quality of life and decrease of symptoms in urinary incontinence. The novelty and advantage of this innovation lies in the possibility to perform efficient perineal rehabilitation at home. Women positively outlined the ease of use and the playful approach that strongly increase motivation. The possibility to adapt individual training sessions and to follow personal progress over time highly boost compliance.

STUDY DESIGN

This prospective, single-center and non-comparative study was conducted between the 19/09/2019 and 15/09/2020 at the Hôpitaux Universitaires de Strasbourg, France. Original publication currently under revision.

Materials and methods: Fifty-five women suffering from stress urinary incontinence received the Kegel trainer Emy and were asked to use it at least five times ten minutes a week for a duration of three months. At each monthly visit, patients were asked to fill 2 questionnaires evaluating (I) quality of life and (II) frequency and severity of incontinence symptoms. At the final visit, patients evaluated their condition compared with how it was before the study and their satisfaction of use provided by the Kegel trainer Emy. In total, 52 of 55 patients completed the study. The median age of patients is 41 years.

RESULTS AND GRAPHICAL PRESENTATION

Improvement of qualify of life

Quality of life was evaluated by the internationally validated Contilife questionnaire by impact of incontinence symptoms on daily physical activities, general and self-image well-being, sexuality In average, women report an increase in quality of life of 39% over 3 months with the biggest improvements on physical activities (+65% after 2 months) and general well-being (+34% after two months). 93% of women reported the strongest evolution within the first month of training with Emy (Figure 4). At the beginning of the study, the mean Contilife score was 6.6 ± 1.5 points. A significative increase of the mean Contilife score was found over time (p<0.001) with an average increase of 0.8 +/- 0.1 points at each month and a score of 9.2 \pm 1.0 at the final visit (Figure 4).

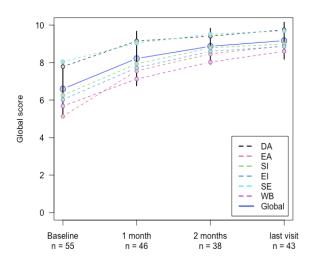


Figure 4. Evolution of the Contilife score over time. The higher the score, the better the quality of life, 10 being the best outcome. (DA: Daily activities, EA: Effort activities, SI: Self-image, EI: Emotional impact, SE: Sexuality, GW: General Well-being, Global: Global score).

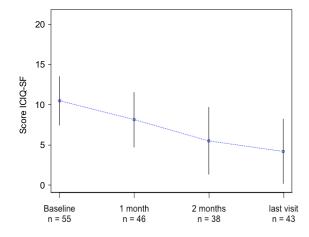


Figure 5. Evolution of the ICIQ-SF score (International Consultation on Incontinence Questionnaire – Short Form): The overall score is from 0 to 21 points, with 0 corresponding to mild urinary symptoms and 21 to very severe symptoms. The global score results from addition of the individual sub-scores. A minimal clinically important difference for the ICIQ-SF is an improvement of 2 points.

Frequency and severity of incontinence symptoms decreased from the 1st month

Severity of urinary incontinence symptoms was assessed with the internationally validated ICIQ-SF questionnaire (7), which individually evaluates the (I) frequency of urinary leaks, (II) amount of leakage and (III) overall impact of urinary leaks on the daily life of women. At the inclusion visit, the average score of the ICIQ-SF was 10.5 +/- 3.0. A significant difference in the ICIQ-SF score over time was found (p<0.001) with an average decrease of 2.2 +/- 0.3 points at each time. At the final visit of 3 months, an average score of 4.2 +/- 4.0 was observed. In total, the urinary symptoms decreased by 60% after three months training (Figure 5).

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