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Original Article

Prospective evaluation of the connected biofeedback EMY Kegel trainer in the management of stress urinary incontinence



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ABSTRACT

Introduction: The aim of this study was to evaluate changes in the quality of life with the connected biofeedback EMY Kegel trainer in patients suffering from stress urinary incontinence.

Material and methods: This was a prospective, single-center, non-comparative study, which took place between September 2019 and October 2020, in the University Hospitals of Strasbourg. Eligible patients were instructed to use the EMY probe for a minimum of 10 min per day for five days per week. To assess quality of life and urinary symptoms, the Contilife and ICIQ-SF scores were completed each month until the final visit (M3). The PGI-I was also completed at 3 months to assess the benefit of the EMY Kegel Trainer.

Results: A total of 55 patients were included. At the inclusion visit (M0), the mean Contilife and ICIQ-SF scores were respectively at 6.6 ± 1.5 and 10.5 ± 3.0 points. At the final visit (M3), the mean Contilife score increased to 9.2 ± 1.0 , indicating an improvement in quality of life. The mean ICIQ-SF score decreased to 4.2 ± 4.0 , indicating an improvement in urinary symptoms. The PGI-I questionnaire identified a positive assessment of the EMY Kegel trainer. On the 55 patients included, 35 (64%) reported completing at least 36 sessions during the study, i.e. an average of 3 sessions per week.

Conclusions: This study suggests that perineal rehabilitation by biofeedback using the EMY Kegel trainer might be beneficial.

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Introduction

Urinary incontinence is a common condition leading to a significant decrease in quality of life. All expert panels agree that pelvic floor muscle training with hygiene and dietary rules are the first step in the management of stress urinary incontinence [1–3]. Functional electrostimulation seems less effective than voluntary contraction exercises, and is not currently recommended [2]. A Cochrane review published in 2011 investigated the role of biofeedback [4]. It included 24 trials comparing pelvic floor muscle training and pelvic floor muscle training with biofeedback. The rate of improvement of urinary incontinence symptoms was greater in patients undergoing biofeedback therapy. The authors point out, however, that this outcome could be skewed by a confounding factor such as amount of contact time with

health professionals. Given these circumstances, current guidelines do not currently recommend biofeedback as a first-line treatment.

Recently, the French society Fizimed developed a medical device to improve the management of women suffering from stress urinary incontinence: the EMY Kegel trainer. This device is a biofeedback vaginal probe that connects to the patient's smartphone. The product was developed following strict safety and performance criteria for medical devices and has received CE conformity marking.

The aim of our study was to evaluate changes in the quality of life with the connected EMY Kegel trainer in patients suffering from stress urinary incontinence. Secondary objectives were to assess patient compliance with pelvic floor muscle training the EMY Kegel trainer, to observe changes in urinary scores over the duration of the trial, and to evaluate the benefit of using the EMY connected perineal probe for stress urinary incontinence. Patient feedback and impressions will be used to improve this device prior to setting up a comparative study.

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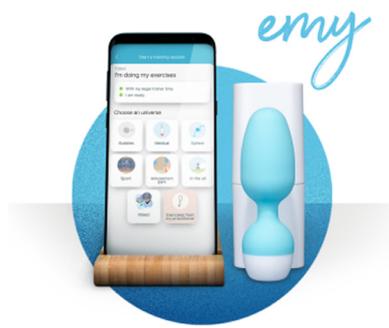


Fig. 1. Picture of EMY Kegel Trainer.

Material and methods

Study participants and design

This was a prospective, single-center, non-comparative study. It took place between September 2019 and October 2020, in the University Hospitals of Strasbourg, France. In order to be eligible for the study, patients had to 1) report at least one episode of urine leakage per week in the last 3 months; 2) be 18 years of age or older with no upper age limit; 3) have given birth at least 6 months beforehand; 4) be able to perform an effective voluntary contraction and avoid abdominal synergy and apnea during the contraction (attested by the partner health professional referring the patient to the study); 5) have responded favorably to perineal re-education for stress urinary incontinence or mixed stress incontinence in at least two sessions (attested by the partner health professional referring the patient to the clinical trial); 6) have signed an informed consent form; 7) be using effective contraception throughout the study (declarative); 8) have a functioning smartphone with at least Android 5 and iOS 8; and 9) be able to read and write in French.

Non-inclusion criteria were patients who 1) were undergoing other forms of perineal rehabilitation during the study period; 2) had a neurological disease, congenital malformation, urinary incontinence or prolapse treated surgically or medically, perineal hypoesthesia or local conditions prohibiting the use of an intravaginal probe; 3) presented urge incontinence or mixed urinary incontinence with predominance of urgency; 4) presented a contraindication to the use of the medical device; 5) with genitourinary cancer (within the previous five years); 6) had extra-urethral "incontinence" (fistula, ectopic ureter); 7) had severe urinary retention; 8) were fitted with a sacral neuromodulation box; 9) were in a period of exclusion (determined by a previous or current study); 10) could not give fully informed consent (subject in an emergency situation, difficulties in understanding the subject, etc.); 11) were under legal protection, guardianship or trusteeship; 12) were pregnant (positive urine test) or 13) breastfeeding.

This study was approved by the institutional review board and by the Patient Protection Committee in February 2019 (CPP Ouest 1 No. 2019-A00059–48).

Medical device: the EMY Kegel trainer

The EMY Kegel trainer is a biofeedback device measuring 105 mm x 32 mm and weighing less than 55 g (Fig. 1). Its design was developed to fit the natural anatomy of women and based on the perineal rehabilitation probes used in perineal rehabilitation. It is entirely manufactured, assembled and stocked in France. EMY is composed of 1) an internal (intra-vaginal) part equipped with sensors based on an innovative and patented technology measuring perineal contractions (biofeedback technology); 2) an external part which sends recorded data to the smartphone via a Bluetooth antenna. The sensors are based on an innovative and patented technology, and allow a

sensitive and reproducible measurement of perineal muscle contractions. The device is a class 1 medical device, and the entire product was designed and produced to medical standards. All its constituent materials are medical-grade and biocompatible, in line with the CE Medical standard. The Bluetooth emitter used is Bluetooth Low Energy, which is of very low intensity (emits around 1000 times fewer waves than a smartphone) and meets the ISO 60 601 standard.

The EMY Kegel trainer comes with a case for storage, transport and recharging. The user can connect this box using a USB cable and recharge the probe by induction. The probe does not have a recharging port so that it can be thoroughly cleaned, thus avoiding the risk of bacterial contamination.

A smartphone application comes with the EMY Kegel trainer. It contains several sections. The first is a "play" sequence where the patient practices rehabilitation exercises which are piloted by the EMY Kegel trainer. All exercises are based on clinical protocols. The second allows follow-up of the patient's objectives, which she can define in terms of session duration and number of sessions per week. She can then simply see where she stands in relation to the objectives initially set. Other sections include a reminder function, instructions for use and FAQs, and an encyclopedia where the patient can learn more about the perineum, rehabilitation, and incontinence. Exercises are adapted to each patient and based on recognized therapeutic protocols. These protocols are derived from the PERFECT Scheme: Power, Endurance, Repetitions, Fast contractions, Every Contraction Timed [5]. The application's built-in program can analyze the results obtained and automatically set the difficulty level of the next workout.

Outcome definition

The main outcome is the Contilife questionnaire to evaluate changes in the quality of life. Contilife is a quality-of-life questionnaire that includes 28 questions exploring which daily activities are disrupted by urinary incontinence symptoms, types of stress causing urinary incontinence, as well as emotional impact, self-image and sexuality [6]. The higher the score, the better the quality of life. While this questionnaire has the disadvantage of being long, it has the major advantage over other more restricted questionnaires of exploring a wider field.

Secondary evaluation criteria are the logbook for assessing compliance, the ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form) for changes in urinary symptoms, as well as the PGI-I (Patient Global Impression and Improvement) for assessing benefits accrued from using the probe. The logbook records the frequency of the exercises performed, their duration and any additional comments. The ICIQ-SF is a validated and standardized questionnaire for assessing the severity of urinary incontinence symptoms [7]. The overall score is from 0 to 21 points, with 0 corresponding to mild urinary symptoms and 21 to very severe symptoms. A minimal clinically important difference for the ICIQ-SF is an improvement of 2 points. The PGI-I questionnaire was originally modelled after psycho-pharmacological scales first described in 1976 (Clinical Global Impression) [8], and has been validated for stress urinary incontinence [9].

Practical conduct of the study

During a routine consultation at the University Hospitals of Strasbourg (in the urology and gynecology departments) or in a partner practice (doctors, physical therapists, midwives), eligible patients were informed about the study and given the opportunity to participate. When patients showed interest in the study, they were given a written briefing document.

After a minimum period of 7 days' reflection, patients were invited to attend an inclusion visit (M0) and sign the informed

consent. A pregnancy test (urinary) was performed for each eligible patient. If the test was positive, the patient could not be included. During this inclusion visit, the following data were collected by the investigator: age, weight, height, socio-professional profile, number of births, type of delivery, menopausal or not, and hormonal treatments. The Contilife, ICIQ-SF and PGI-I questionnaires were presented by the investigator. Only the first two were completed by participating patients at this time. The investigator also handed over the first logbook. An introduction to the EMY biofeedback probe was provided by a Fizedem representative. If needed, the representative also helped the patients to download the application on their smartphone. Patients could perform an on-site trial if desired.

Patients included in the study were instructed to use the EMY probe for a minimum of 10 min per day for five days per week. Exercises had to be performed in a semi-seated position, with the back, head and shoulders resting on a cushion. The EMY application offers numerous exercises which can be classified into four categories: 1) Strength, requiring a powerful contraction to increase the strength of the perineum; 2) Endurance, requiring a long contraction to increase the duration of perineal contraction; 3) Repetition, requiring repeated contractions to simulate perineal contractions when walking or running; and 4) Fast, requiring rapid contractions to simulate the activity of the pelvic floor during reflex contractions (coughing, sneezing). In each category, patients could opt for analytical exercises with simple graphics (sphere, scales, etc.) or exercises with a more playful universe (rocket, birds, hot-air balloon, etc.).

Two follow-up visits at 1 month (M1) and 2 months (M2) were conducted, the first at the University Hospitals of Strasbourg and the second by telephone. These visits served to assess difficulties encountered and patient compliance. During the M1 follow-up visit, physical therapists ensured that abdominal synergy and apnea were absent during the contraction. The first logbook was retrieved at this visit. Both the Contilife and ICIQ-SF questionnaires were completed at each follow-up visit.

At the end-of-protocol visit at 3 months (M3), PGI-I was completed in addition to the Contilife and ICIQ-SF scores. The last two logbooks were retrieved at this visit.

Statistical analysis

A descriptive analysis of all the variables was performed. Qualitative data were reported as frequency (percentage) and quantitative data were described using mean and standard deviation or median and inter-quartile range. Linear mixed model with subjects used as random effect were used to estimate change over time. All statistical analyses were performed using software R version 4.0.3.

As the study had only one treatment arm, it was not necessary to calculate a sample size. The number of patients participating in the study was set at 55. With this sample size, and assuming a standard deviation of 1.5 points on the Contilife score, the width of 95% confidence interval of the mean score would then be less than 1 points (0.8).

Results

Patient characteristics

A total of 55 patients were included in our study. Initial characteristics of these patients can be found in Table 1.

Quality of life

At the beginning of the study, the mean Contilife score was 6.6 ± 1.5 points (mean ± SD). At 1 month and 2 months it was 8.2 ± 1.5 and 8.9 ± 1.0 respectively. At the final visit, the mean score had increased to 9.2 ± 1.0. Overall changes in the Contilife score can

Table 1
Characteristics of the patients included.

	Total
Total number	55
Age, years	41.0 [34.5, 46.5]
Weight, kg	66.0 [59.0, 75.5]
Height, cm	165.0 [163.0, 170.0]
BMI, kg/m2	23.9 [20.7, 26.3]
Socio-professional profile	
Farmer	0
Craftsman, shopkeeper and company director	2 (3.7%)
Executive and senior intellectual profession	23 (42.6%)
Intermediate profession	0
Employee	25 (46.3%)
Worker	0
Retired	1 (1.9%)
No professional activity	3 (5.6%)
Gestivity	2.0 [2.0, 3.0]
Parity	2.0 [1.0, 2.0]
Years since last birth	6.4 [3.0, 13.3]
Menopause	
With hormonal treatment	1 (2%)
Without hormonal treatment	6 (11%)

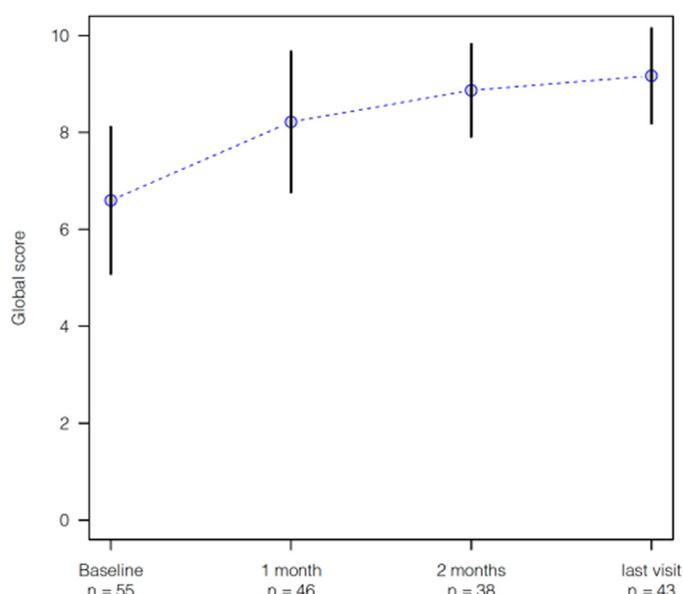


Fig. 2. Overall changes in the mean Contilife score (the higher the score the better the quality of life).

be visualized in Fig. 2, and for each sub-setion in Fig. 3. Changes in the score over time were significant ($p < 0.001$ - mixed model) with a mean increase of 0.8 ± 0.1 points on each measurement.

Urinary symptoms

At the inclusion visit, the mean ICIQ-SF score was 10.5 ± 3.0 (mean ± SD). At 1 month and 2 months it was 8.2 ± 3.4 and 5.5 ± 4.2 respectively. At the final visit (three months), a mean score of 4.2 ± 4.0 was observed. Fig. 4 shows changes in this score over time. Again, changes in the ICIQ-SF score over time were significantly different ($p < 0.001$ - mixed model), with a mean decrease of 2.2 ± 0.3 points on each measurement.

Utility

Of the 55 patients included, 26 (55%) described their post-operative condition as “very much better”, 12 (26%) as “much better” and 5

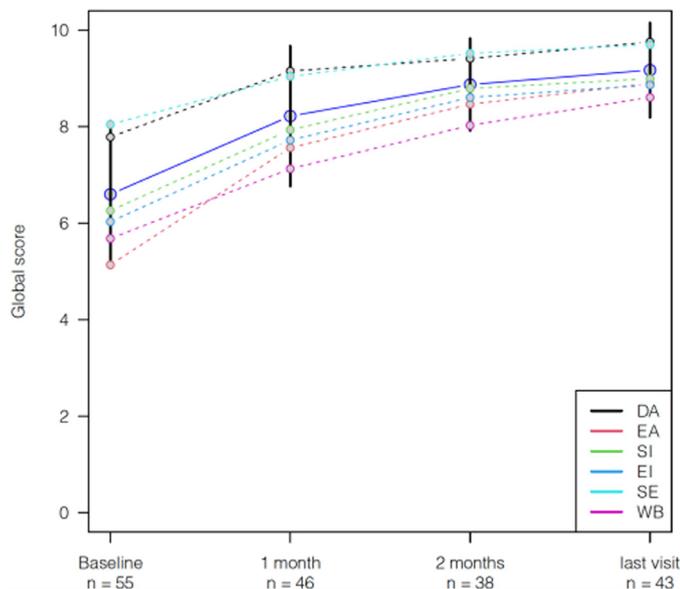


Fig. 3. Changes in the Contilife score in each sub-section (DA: Daily activities, EA: Effort activities, SI: Self-image, EI: Emotional consequences, SE: Sexuality, WB: General Well-being).

(11%) as “a little better”. A total of 43 (91%) patients thus experienced a benefit from using the EMY Kegel trainer. Two patients (4%) found no improvement after using the EMY Kegel trainer, and two (4%) described it as “a little worse” and as “very much worse”. A total of 4 (9%) patients thus experienced no benefit from using the EMY Kegel trainer. Eight patients did not complete the PGI-I questionnaire, i.e. 15% of data were lost to follow-up. Overall, the utility of the probe was positively rated at 4.5 ± 0.8 out of 5. Thirteen patients (26%) reported experiencing a side-effect or adverse event (mainly discomfort, dryness or irritation). No major side-effect or adverse event was reported.

Compliance

On the 55 patients included, 35 (64%) reported completing at least 36 sessions during the study, i.e. an average of 3 sessions per week. The median number of sessions performed per week by the patients in this study was 3.8 [1.7 – 4.4] (median [IQR]).

Discussion

Summary of main results

In this prospective study, we evaluated the value of biofeedback therapy using the EMY Kegel trainer in patients with stress urinary incontinence. A significant improvement in quality of life over time was observed, as well as an improvement in urinary symptoms. Patients included in this study confirmed the utility of the EMY Kegel trainer, both in terms of treatment outcome and compliance. The advantage and novelty of this perineal rehabilitation device is that remedial exercises can be carried out at home. This makes it possible to adapt the number of sessions per week according to the time available, thus boosting compliance.

Results in the context of published literature

Biofeedback has been used for many years to assist patients and clinicians in rehabilitation in many different areas of medicine [10]. Previous studies have sought to evaluate the impact of biofeedback in perineal rehabilitation [11–13], but their results have been

inconstant. The goal of this technique is to provide patients with real-time biological information that would otherwise be unknown. Providing patients and clinicians with biofeedback during rehabilitation may potentially improve the accuracy of functional tasks, increase compliance with treatment, and reduce the need for ongoing contact with healthcare professionals to monitor its implementation. It is important to emphasize, however, that biofeedback is not a stand-alone therapy, but a complementary technique for pelvic floor muscle training in all cases. Several studies have recently investigated the value of a home rehabilitation probe, with biofeedback or electro-stimulation [14–17]. Due to the highly variable primary endpoint in these studies, a comparison of the results between the different devices is currently not feasible. However, the study of the benefit of home rehabilitation remains interesting. Legendre et al. conducted a prospective longitudinal study of ten patients with de novo urinary incontinence evaluating a home electro-stimulation named Keat pro system [14]. They concluded that self-rehabilitation in addition to conventional pelvic floor muscle training objectively improves the perineal muscle building achieved after conventional rehabilitation. Their primary endpoint was the biometric of the levator ani and was assessed by three-dimensional perineal ultrasound. Another study on the evaluation of a biofeedback rehabilitation probe named Elvie was partially published in 2007 [17]. From a self-reported questionnaire sent electronically to patients in the United States and the United Kingdom, an increase in compliance was observed suggesting a potential benefit of self-rehabilitation. Home rehabilitation thus seems promising. It is important to note, however, that this technique mainly aimed at young women able to use a smartphone and presenting moderate but still disabling incontinence. Our study included a young population with a median age of 41.0 [34.5, 46.5] years and a mean baseline ICIQ-SF score of 10.5 ± 3.0 . The same characteristics were found in the previously mentioned studies, confirming the target population of these self-rehabilitation probes.

Strengths and weaknesses

The main strength of this study is its strict methodology with prospective recruitment. The inclusion of a multidisciplinary team (gynecologist, urologist and physiotherapist) for the elaboration of this study is also one of its qualities. The main shortcomings of this study are the absence of a comparative group and the small sample size. It was however planned as a preliminary study in order to evaluate the possibility of carrying out a controlled prospective intervention study at a later date.

Implications for practice and future research

This study seems to open new therapeutic perspectives for stress urinary incontinence in women and provides additional data on a still controversial technique. Given the potential impact of this technique on the quality of life of many women suffering from urinary incontinence, further research in this area is to be encouraged, particularly on its effectiveness and the medico-economic aspect. The Emy Kegel trainer currently costs 199 euros and is not yet covered by French social security. It can however be partially or totally covered by the patient's private health insurance. Moreover, after the initial therapeutic education and acquisition of autonomy by the patient, its use may allow to avoid appointments related to the rehabilitation. In the medium term, it could reduce the cost of managing stress urinary incontinence.

Conclusion

In conclusion, this study suggests that perineal rehabilitation by biofeedback using the EMY Kegel trainer might be beneficial. A

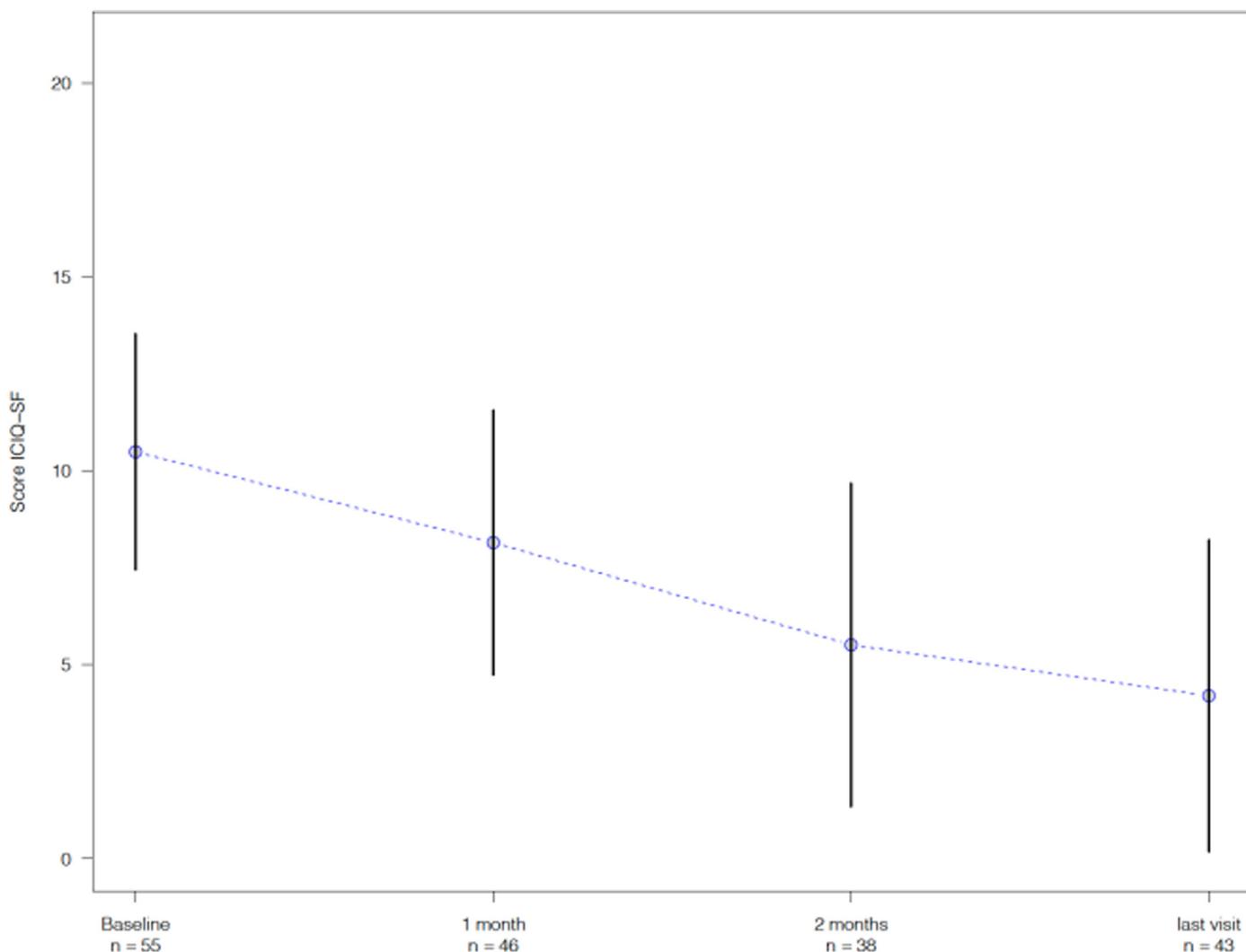


Fig. 4. Changes in the ICIQ-SF score (the lower the score the better the urinary symptoms).

comparative study with pelvic floor muscle training should be conducted in the future to confirm the benefit suggested by this study.

Declarations of interest

none

Author's contribution

F JOCHUM : Data collection, Data analysis, Manuscript writing
 O GARBIN : Project development, Data collection
 J GODET : Data analysis
 M RAGUENEAU : Data collection
 C MEYER : Data collection
 S BILLECOCQ : Protocol writing
 L LECOINTRE : Project development, Manuscript editing
 C AKLADIOS : Project development, Manuscript editing
 A HOST : Project development, Data collection, Manuscript editing

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