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The Effect of Pelvic Floor Training with a Non-Invasive Biofeedback Training Device and APP

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Introduction

As a symptom of pelvic floor dysfunction, urinary incontinence is commonly found in adult women and men. Results of a Germany –wide study shows that 13 % individuals across all age groups are effected by urinary incontinence. Women are more frequently effected (15% vs. 10 %) [1]. The prevalence increases with age. In the group of 18 – 40 – years olds about 6 % of participants reported being incontinent. A total of 23 % of individuals over the age of 60 years suffered from an urinary incontinence [1–3]. Therefore, the desease has a significant socioeconomic impact. Pelvic floor training is an effective form of therapy for urinary incontinence. A training supported by biofeedback has been shown to significantly reduce incontinence episodes and is included in the current S2e guideline as recommendation C LOE [1-3].

Aim

It is the aim of the ongoing study to evaluate the efficacy of the pelvic floor training by means of biofeedback methods using the ACTICORE1 on the improvement of urinary incontinence and associated symptoms and quality of life quality of life.

Method

A multicenter randomized controlled Clinical pilot study was performed to evaluate the efficacy of the pelvic floor training by means of biofeedback methods using the ACTICORE1 on the improvement of urinary incontinence. The study was conducted between October 2021 and January 2022. Patients enrollment took place at the German Pelvic Floor Center at the St. Hedwig Hospital Berlin (Germany) and at the University Hospital Brandenburg an der Havel (Germany). The intervention group was instructed to use Acticore 1 for 6 min daily . The control group expected Acticore 1 after 12 weeks and was instructed not to do any other training. Inclusion criteria: over 18 years men and women and an ICIQ Score ≥ 5. Exclusion criteria: refusing to participate, vulvodynia, pelvic pain, paraplegic due spine trauma, acute wound, ICIQ>4 and ASA<3, Physiotherapy. Primary endpoint: ICIQ score after 12 weeks Secondary endpoint: ICIQ Score and QoL using the EG-5D-3L questionnaire 4, 8, 12 weeks after patients enrollment. Acticore1 APP is a digital hometraining program for strengthening the pelvic floor muscles. The patient is sitting on a sensor, that does not need to be inserted (Figure 1).

Figure 1: Acticore1 device (CE certified approved device) with smartphone APP

Statistics

For nominally scaled variables, absolute and relative frequencies were calculated per each group. All biometric variables were tested using a Q-Q-Plot. The calculation of non – normally distributed dependent variables the Wilcoxon Test (two-tailed) between 2 time points and the Mann-Whitney U-Test for independent variables for group comparism of 2 groups were used. Since conservatively it is not assumed that the values of the ICIQ are normally distributed, a nonparametric test Procedure (Wilcoxon rank) was performed.Missing values were not replaced. Statistical significance with null hypothesis was accepted with a significance level of $p \leq 0,05$. Due to Corona an amandment was made to reduce the sample size from 60 to 40.

Results

A total of 40 individuals was recruited for the present study. In 30 cases patients suffered from a stress incontinence. The average initial ICIQ score was 11.5.

Table 1: Summarized EQ-5D-3Ldata

	Initial Data on EQ-5D-3L			Data on EQ-5D-3L after 12 weeks		
Characteristics	ACTICORE N=10[1]	Control N=14[1]	p-Value[2]	ACTICORE N=10[1]	Control N=14[1]	p-Value[2]
mobility			>0,9			0,14
0	0,0 (0,0%)	0,0		2,0 (20%)	0,0 (0,0%)	
1	8,0 (80%)	12,0		6,0 (60%)	13,0 (92,9%)	
2	2,0 (20%)	2,0		2,0 (20%)	1,7 (7,1%)	
Self care			>0,9			0,2
0	0,0 (0%)	0,0		2,0 (20%)	0,0 (0,0%)	
1	10,0 (10%)	14,0		8,0 (80%)	13,0 (92,9%)	
2	0,0 (0%)	0,0		0,0 (0%)	1,0 (7,1%)	
Usual acticity			0,3			0,3
0	0,0 (0%)	0,0		2,0 (20%)	0,0 (0,0%)	
1	9,0 (90%)	9,0		6,0 (60%)	10,0 (71,4%)	
2	1,0 (10%)	5,0		2,0 (20%)	4,0 (28,6%	
Pain discomfort			0,4			0,092
0	0,0 (0%)	0,0		2,0 (22,2%)	0,0 (0,0%)	
1	7,0 (70%)	7,0		5,0 (55,6%)	6,0 (42,9%)	
2	3,0 (30%)	7,0		2,0 (22%)	8,0 (57,1%)	
NA			0,2	1	0	
Anxiety/Depression						0,075
0	0,0 (0%)	0,0		2,0 (20%)	0,0 (0,0%)	
1	7,0 (70%)	6,0		6,0 (60%)	6,0 (42,9%)	
2	3,0 (30%)	8,0		2,0 (22,2%)	8,0 (57,1%)	
Health Status	77,5 (9,5)	78,6 (8,6)	0,8	76,5 (11,3)	72,1 (11,9)	0,4
NA				0	1	

[1]*n (%); Continuus measurements are presented as mean (SD);* [2]*Fishers exact test; Wilcoxon-Mann-Whitney-Test, NA: not applied*

Regarding quality of life using the EG 5D-3L, no significances were found between both groups and intraindividually. Study participants in the ACTICORE group showed a statistically significant intraindividual improvement in SUI symptoms.

Table 2: Basic data

Basic data	Acticore group N=21	Control group N= 19	p-value
Age	52 [39-53,5]	43 [37-53,5]	0,5
Sex Female Male	18 (85,7%) 3 (14,3%)	17 (89,5%) (10,5%)	>0,9
Cause of UI SUI Urge Mixed	15 (71,4%) 3 (14,3) 3 (14,3)	15 (78,9%) 2 (10,5) (10,5)	>0,05
Using pads	14 (66,7%)	8 (42,1%)	0,12
Negative impact of UI on sexuality	20 (5,0-80,0)	17,5 (0-57,5)	0,4

UI=Urge incontinence, SUI= stress urinary incontinence

Table 3: ICIQ results

	Acticore group, n=21	Control group n=19	p-value *
Initial ICIQ	12.0 (9.0-13.0)	11.0 (8.0-13.5)	0,5
ICIQ after 4 weeks	10.0 (7.0-12.5) 6 missing	11.0 (0.0-14.5) 8 missing	0,2
ICIQ after 8 weeks	8.0 (6.5-12.5) 10 missing	11.5 (10.0-14.2) 7 missing	0,033
ICIQ after 12 weeks	7.5 (6.2-10.2) 11 missing	10.5 (8.2-13.8) 5 missing	0,2

** Fishers exact test*

ICIQ score from 12 to 7.5). An improvement of 4.5 ICIQ-Score points was considered as a clinically important difference according to Nyström et al. Table 3 summarizes information on ICIQ data. ACTICORE1 has already been evaluated with pilot trial on fecal incontinence.

Discussion

The results show that pelvic floor training with ACTICORE1 provides adequate pelvic floor training. Following the evaluation of ACTICORE1 in fecal incontinence, the present study aimed to investigate the benefit of pelvic floor muscle training with this device in urinary incontinence. Both groups statistical significant differed only after 8 weeks and not after 12 weeks (primary endpoint). That can be explained by the high rate of lost to follow-up in the ACTICORE group (52%). The intraindividual improvement of patients in the ACTICORE group was statistically significant and may reflect the positive effect of biofeedback training demonstrated in the literatures. ACTICORE1 has the advantage, that the sensor does not have to be inserted in comparison to other devices. The gaming aspect may increase the adherence of patients and can also be considered a benefit.

Conclusion

Biofeedback training with ACTICORE1significantly reduces symptoms of urinary incontinence after 12 weeks. It is a non-invasive way to motivate patients to complete their home exercise programme in a controlled way with adapted increases.

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