Long-term effect of biofeedback training on functional nonretentive fecal incontinence in children: a randomized controlled study

Emad M. Abdelrahman[a], Mohamed A. Abdel Ghafar[b], Ali O. Selim[c], Olfat I. Ali[d], Ahmed E. Sakr[e], Mohamed S. Kharoub[a]

[a]Department of General Surgery, Faculty of Medicine, Benha University, Egypt, [b]Physical Therapy Program, Batterjee Medical College for Science and Technology, Jeddah, Saudi Arabia, [c]Departments of Physical Therapy for Surgery, [d]Basic Science, Faculty of Physical Therapy, Cairo University, Cairo, Egypt, [e]Department of General Surgery, Benha Teaching Hospital, Benha, Egypt

Correspondence to Emad M. Abdelrahman, MD, Fareed Nada Street, Benha 13518, Egypt
Tel: +01226763986;
e-mail: emadsahan301@gmail.com, emad.sarhan@fmed.bu.edu.eg

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Background
Functional nonretentive fecal incontinence (FNRFI) is an extremely embarrassing and psychologically frustrating shameful problem with bad impact on children.
The aim of this study was to evaluate the long-term effect of biofeedback training in the treatment of FNRFI in children and its impact on the quality of life (QoL).
Patients and methods
This prospective randomized controlled study included 100 children with FNRFI, who were randomly assigned into two groups. Group A was treated using Kegel exercises and dietetic regulation, while group B was treated by biofeedback training. Follow-up was planned for 24 months for manometric findings, incontinence score, frequency of incontinence episodes, and the QoL.
Results
There was a statistically significant decrease in incontinence episodes and scores in both groups when compared with the initial record at 3, 12, and 24 months with better outcome in group B. There was statistically significant improvement in QoL domains in group B when compared with group A (P<0.001).
Conclusion
Biofeedback is an effective method for the treatment of FNRFI and its effect is maintained over time with satisfactory improvement of QoL.
Level of evidence: Level I.
Type of study: Treatment study.

Keywords:
biofeedback, fecal incontinence, quality of life

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Introduction

Functional nonretentive fecal incontinence (FNRFI) in children is a worrisome problem. This entity is characterized by fecal incontinence despite no anatomical, metabolic, or inflammatory cause in a child with a developmental age of more than 4 years once at least per month for 2 successive months [1,2].

FNRFI is diagnosed by exclusion of anatomical and neurological causes in addition to colonic transit time where total and segmental transit time must be normal [3]. The underlying mechanism of FNRFI is largely unknown. Approximately 80% of these children FI is results of constipation and is treated with laxatives, the remaining 20% without signs of fecal retention are classified as FNRFI [4,5].

WHO defined quality of life (QoL) as a multidimensional concept reflecting the individual well-being either emotionally, physically, or socially [6].

Fecal incontinence is a frustrating problem with very bad impact on all components of QoL including lifestyle, emotion, behavior, and embarrassment. Children with fecal incontinence usually suffer silently. The improvement of QoL component is the cornerstone in determining the long-term effect of any modality of treatment [7].

Biofeedback is considered by many studies as an effective, simple, noninvasive modality with acceptable short-term improvement of rectal sensation as well as anal pressure with a great controversy about its long-term effect [8,9]. This had motivated the authors to conduct this study to reflect their experience in biofeedback training in the treatment of FNRFI as regards the long-term effect and its role in improving the QoL in comparison with conventional treatment using Kegel exercises protocol and dietetic regulation.

Patients and methods

Study design and patients

This prospective randomized controlled study was conducted at the Colorectal Surgery Unit, General Surgery Department, Benha University Hospital throughout the period from October 2016 till December2021. Ethical approved to conduct this study was obtained from the corresponding universities' ethics and research committees.

Registration of clinical trial at: https://clinicaltrials.gov/ct2/show/NCT04472923

The present study included 108 children with FNRFI, and 100 children completed the follow-up period. Inclusion criteria was the specific entity of FNRFI where children have fecal incontinence with normal bowel habits, stool consistency, and defecation frequency.

Exclusion criteria included children with traumatic sphincter injury and spinal disorders precipitating incontinence. Children with anorectal malformation or those suffering from fecal impaction were also excluded. A written informed consent was obtained from parents of all included children within the study.

Procedures

After complete history taking and physical examination, endoanal ultrasound using BK Medical Flex Focus 400 (Copenhagen, Denmark) was done to enroll out children with anal sphincter injury requiring surgery. Both total and segmental colonic transit time was detected using the radiopaque marker test [5].

All included children were subjected to initial manometric assessment for anal sensation and pressures where first sensation, first urge, intense urge, resting, and squeeze pressure were recorded by high-resolution anorectal manometry (Solar GI HRAM MMS, The Netherlands) with a 24-channel water-perfused catheter with latex balloon.

The severity of the condition was assessed through the Vaizey score [10] ranging from 0 (perfect continence) with a maximum score of 24 indicating total incontinence, as well as the frequency of incontinence episodes per month. The impact on the QoL was also assessed through fecal incontinence quality of life (FIQL) scale [11]. FIQL was modified where two items related to sexuality were removed and the word depressed was replaced with sad. So, the modified questionnaire is composed of 27 questions for four main domains: lifestyle, behavior, depression, and embarrassment [12].

Randomization

Single blinded randomization was done by a specific software (Random Allocation Software 1.0, 2011) into two equal groups.

Group A

In this group, children received conventional treatment in the form of:

Kegel exercises: in crook lying position the child was directed to draw the pelvic muscles inward and upward and maintain this contraction for 6 s followed by 6 s relaxation for 20 times with gradual increase in duration till 10 s contraction and relaxation for 30 times. These exercises were applied twice/week for 3 months [9].

Dietetic regulation including bulk-forming diet, fruits, cereals, and vegetables while avoiding fast and spicy food and drinks. Zinc oxide crème was used to prevent perianal excoriation resulting from soiling.

Group B

Children in this group were treated using biofeedback training in addition to conventional therapy used in group A.

Before starting biofeedback training, both parents and children were fully announced about the procedure. Two types of catheters were used for biofeedback training. A 24-channel water-perfused catheter with a latex balloon for sensory training and a double-lumen rectal PVC balloon clothed catheter (MMS U-72210) for strength training. The biofeedback session lasted for 20–30 min/two sessions/week for 3 months.

Biofeedback was done for all patients in crook lying position and facing the monitor. The protocol for the biofeedback therapy included two components:

(1) Strength training by instructing the child to contract the anal sphincter without balloon inflation with trial to modify this contraction.
(2) The sensory training by successive inflations and deflations of a balloon in stepwise increments of 5 ml of air or saline the patients were required to retrain the rectal sensory threshold, usually with a tatget to discriminate and respond to smaller ballon volumes [8].

Outcomes

The primary outcome was a decrease in the number of incontinence episodes and improvement of the clinical condition assessed by the Vaizey incontinence score and FIQL.

The secondary outcome was in the form of change in manometric findings.

According to the clinical response after 3 months, biofeedback group and control group were classified according to their response into four groups: group A, fully continent; group B, reduction in incontinence episodes of more than 75%; group C, reduction in incontinence episodes of less than 75%; and group D, no improvement or deterioration than before therapy. Group D were excluded from the long-term follow up as it failed to achieve the primary outcome goals. The remaining three groups were subjected to the long-term follow-up after 12 and 24 months from the initiation of the treatment program. Follow-up was done either during a clinical visit or by telephone. Successful treatment was considered if there were less than two incontinence episodes/month.

Statistical analysis

The sample size was calculated depending on the incontinence episodes, which is the primary outcome of this study. A sample size of 32 in each group was considered with a power of 80%, *P* value of 0.05, and an effect size of 0.7 using G*power 3.1 software (Universities, Dusseldorf, Germany).

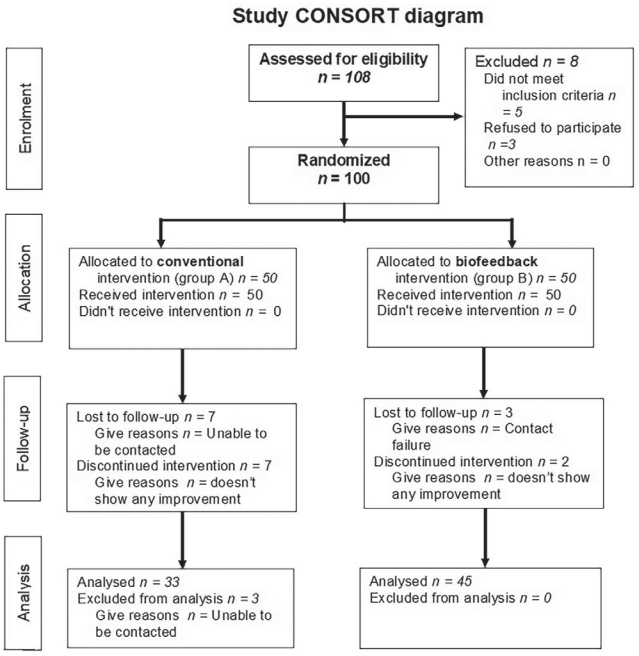
The measured outcomes were explored for normality by checking the data distribution. All measured parameters showed a parametric distribution. Two-way mixed model MANOVA (IBM Corp., Armonk, NY, USA) was utilized to compare between measured variables and across different time periods. For demographic data of participants, independent *t* test was used and for nominal data χ^2 was used. Numerical data were presented as mean and SD while nominal data was presented as number and percentage. The significance level was set at *P* value less than or equal to 0.05. SPSS statistics version 20 was used for statistical analysis.

Results

The current study included 100 eligible children who were randomly divided and assigned to one of the two equal groups (A and B). Figure 1 with a mean age of 9.36 ± 2.87 and 9.9 ± 2.7, respectively. There was no statistically significant difference between the two groups as regards sociodemographic data (Table 1).

The initial assessment of the included children revealed no statically significant difference between the two groups regarding manometric finding, incontinence score, incontinence episodes, and all QoL domains (Tables 2, 3).

Figure 1



Study flowchart.

Table 1 Sociodemographic data of the two groups

Variables	Group A (*N*=50 patients)	Group B (*N*=50 patients)	*P* value
Age			
Mean±SD	9.36±2.87	9.9±2.7	0.337
Sex			
Boys	21/42%	24/48%	0.546
Girls	29/58%	26/52%	

There was statistically significant increase in the squeeze and resting pressure as well as significant improvement of rectal sensation in group B after 3 months when compared with the initial assessment (*P*<0.001) (Table 2).

In group A, only squeeze and resting pressure showed a statistically significant increase after 3 months (*P*<0.001). However, there was no statistically significant improvement in rectal sensation when compared with initial assessment (Table 2).

There was statistically significant decrease in the incontinence score as well as incontinence episodes at 3,12, and 24 months follow-up in both groups when compared with the initial records with statistically significant decrease in group B than group A (*P*<0.001) throughout the whole course follow-up (Table 4).

In group B, there was statistically significant improvement of all QoL domains at 3, 12, and 24 months when compared with the initial records

Table 2 Short-term manometric follow-up within and between the two groups

	Group A (*N*=50 patients)	Group B (*N*=50 patients)	*P* value
Resting pressure			
Before treatment	27.6±6.85	29.58±3.83	0.078
After 3 months	28.2±6.45	39.24±3.74	<0.001*
P value	0.024*	<0.001*	
Squeeze pressure			
Before treatment	96.62±14.38	97.52±17.72	0.781
After 3 months	104.4±13.34	140.32±12.53	<0.001*
P value	0.07	<0.001*	
First sensation			
Before treatment	98.06±29.44	98.6±58.69	0.954
After 3 months	89.54±25.68	54.4±23.4	<0.001*
P value	0.33	<0.001*	
First urge sensation			
Before treatment	152.4±34.91	155±55.55	0.731
After 3 months	147.78±33.92	133.8±36.41	0.043*
P value	0.210	<0.001*	
Intense urge sensation			
Before treatment	198.6±35.16	201.8±37.62	0.661
After 3 months	192.76±34.79	170.4±27.1	<0.001*
P value	0.066	<0.001*	

*Statistically significant.

Table 3 Comparison between the two groups regarding changes in incontinence score, incontinence episode, and quality of life parameters

	Group A (mean±SD)	Group B (mean±SD)	*P* value
Incontinence score			
Before treatment	13.39±3.29	13.85±3.26	0.575
After 3 months	10.42±2.92	3.91±3.05	<0.001*
After 12 months	9.78±2.93	1.91±2.79	<0.001*
After 24 months	9.48±3.05	1.78±2.49	<0.001*
Incontinence episodes			
Before treatment	29.73±7.73	32.84±7.35	0.098
After 3 months	24.15±7.22	8.55±7.08	<0.001*
After 12 months	22.69±7.31	2.94±5.95	<0.001*
After 24 months	21.94±7.25	2.49±5.01	<0.001*
Lifestyle			
Before treatment	1.92±0.45	1.84±0.32	0.435
After 3 months	2.02±0.41	3.26±0.63	<0.001*
After 12 months	2.13±0.44	3.42±0.59	<0.001*
After 24 months	2.19±0.44	3.49±0.51	<0.001*
Emotion (depression)			
Before treatment	2.09±0.54	2.10±0.35	0.914
After 3 months	2.27±0.53	3.42±0.53	<0.001*
After 12 months	2.38±0.49	3.63±0.46	<0.001*
After 24 months	2.46±0.52	3.65±0.47	<0.001*
Behavior			
Before treatment	1.99±0.46	1.92±0.33	0.446
After 3 months	2.11±0.46	3.29±0.61	<0.001*
After 12 months	2.20±0.45	3.46±0.57	<0.001*
After 24 months	2.32±0.50	3.51±0.52	<0.001*
Embarrassment			
Before treatment	2.18±0.50	2.17±0.35	0.888
After 3 months	2.37±0.49	3.49±0.51	<0.001*
After 12 months	2.50±0.46	3.67±0.44	<0.001*
After 24 months	2.57±0.46	3.68±0.41	<0.001*

*Statistically significant.

(P<0.001). In group B, there was statistically significant improvement of all QoL domains when compared with the corresponding time follow-up results for group A.

In group A, there was no spastically significant improvement in QoL domains at 3 months follow-up when compared with the initial results. However, there was significant improvement in some of the domains over time but less than that of group B (Table 4).

Figures 2–4 demonstrate that 75% of the effect of biofeedback was maintained in more than 70% of patients over 2 years follow-up. On the other hand, only 9.1% of patients in group A maintained significant improvement of more than 75%.

Discussion

Over decades, management of FNRFI in children had assumed to be a gray area for many physicians.

Table 4 Mean difference and 95% confidence interval and pairwise comparison values of the incontinence score, incontinence episodes, and quality of life in both groups

	Group A		Group B	
	MD (95% CI)	*P* value	MD (95% CI)	*P* value
Incontinence score				
Pre–post 3 months	2.97 (2.049–3.891)	0.01*	6 (4.5–7.5)	<0.001*
Pre–post 12 months	3.61 (2.463- 4.749)	<0.001*	10.99 (9.8–11.9)	<0.001*
Pre–24 months	3.91 (2.794–5.025)	<0.001*	10.9 (9.83–11.99)	<0.001*
Post 3–post 12 months	0.636 (–0.039–1.312)	0.064	4.89 (3.7–6)	<0.001*
Post 3–24 months	0.939 (0.231–1.648)	0.05	4.9 (3.75–6.1)	<0.001*
Post 12–24 months	0.303 (0.000–0.606)	0.052	0.022 (0.31–0.36)	0.894
Incontinence episodes				
Pre–post3	5.576 (3.225–7.927)	0.01*	24.6 (22.5–26.8)	<0.001*
Pre–post 12 months	7.030 (4.157–9.904)	0.01*	26.6 (24.3–29)	<0.001*
Pre–24 months	7.788 (5.021–10.555)	0.01*	26.9 (24.4–29.4)	<0.001*
Post 3–post 12 months	1.455 (–0.242–3.152)	0.092	1.98 (0.73–3.2)	0.002*
Post 3–24 months	2.212 (0.450–3.974)	0.15	2.2 (0.91–3.54)	0.001*
Post 12–24 months	0.758 (–0.020–1.535)	0.056	0.24 (0.45–0.94)	0.484
Lifestyle				
Pre–post 3 months	–0.105 (–0.246-.037)	0.145	–1.45 (–1.6—1.31)	<0.001*
Pre–post 12 months	–0.214 (–0.367–0.061)	0.07*	–1.56 (–1.7—1.41)	<0.001*
Pre–24 months	–0.282 (–0.420–0.144)	<0.001*	–1.6 (–1.75—1.45)	<0.001*
Post 3–post 12 months	–0.109 (–0.228–0.010)	0.072	–0.11 (–0.22–0.02)	0.055
Post 3–24 months	–0.177 (–0.289–0.066)	0.02*	–0.15 (–0.26—0.04)	0.009*
Post 12–24 months	–0.068 (–0.125-0.011)	0.019*	–0.04 (–0.11–0.03)	0.244
Emotional				
Pre–post 3 months	–0.176 (–0.301–0.050)	0.077	–1.36 (–1.49—1.22)	<0.001*
Pre–post 12 months	–0.291 (–0.425–0.157)	<0.001*	–1.5 (–1.6—1.37)	<0.001*
Pre–24 months	–0.379 (–0.523–0.235)	<0.001*	–1.5 (–1.65—1.35)	<0.001*
Post 3–post 12 months	–0.115 (–0.227–0.003)	0.44	–0.15 (–0.25—0.05)	0.005*
Post 3–24 months	–0.203 (–0.326–0.080)	0.02*	–0.14 (–0.26—0.03)	0.015*
Post 12–24 months	–0.088 (–0.135–0.041)	0.01*	0.01 (–0.05–0.1)	0.812
Behavior				
Pre–post 3 months	–0.118 (–0.256–0.020)	0.092	–1.43 (1.57–1.29)	<0.001*
Pre–post 12 months	–0.215 (–0.369–0.062)	0.007*	–1.54 (1.69–1.39)	<0.001*
Pre–24 months	–0.321 (–0.461–0.181)	<0.001*	–1.57 (1.72–1.42)	<0.001*
Post 3–post 12 months	–0.097 (–0.217–0.024)	0.113	–0.11 (–0.22–0.001)	0.053
Post 3–24 months	–0.203 (–0.316–0.090)	0.001*	–0.14 (–0.25—0.03)	0.011*
Post 12–24 months	–0.106 (–0.165–0.047)	0.001*	–0.04 (–0.1–0.03)	0.30
Embarrassment				
Pre–post 3 months	–0.188 (–0.301–0.075)	0.01*	–1.35 (–1.47—1.22)	<0.001*
Pre–post 12 months	–0.315 (–0.441–0.189)	<0.001*	–1.47 (–1.6—1.33)	<0.001*
Pre–24 months	–0.385 (–0.508–0.262)	<0.001*	–1.5 (–1.6—1.33)	<0.001*
Post 3–post 12 months	–0.127 (–0.233–0.022)	0.19	–0.12 (–0.22—0.02)	0.019*
Post 3–24 months	–0.197 (–0.310–0.084)	0.01*	–0.12 (–0.23—0.02)	0.024*
Post 12–24 months	–0.070 (–0.111–0.029)	0.01*	–0.002 (–0.05–0.5)	0.928

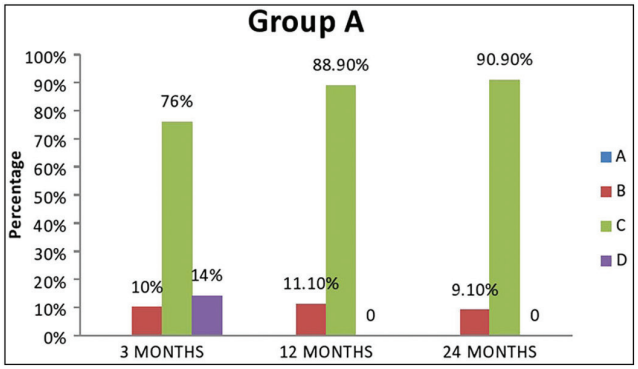
CI, confidence level; MD, mean difference; *P* value: significance level.
*Statistically significant.

Many therapeutic modalities were described among which biofeedback training was a widely accepted one [13].

The main issue in the treatment of FNRFI in children is the unexpected outcome although prolonged time for treatment is usually required [14].

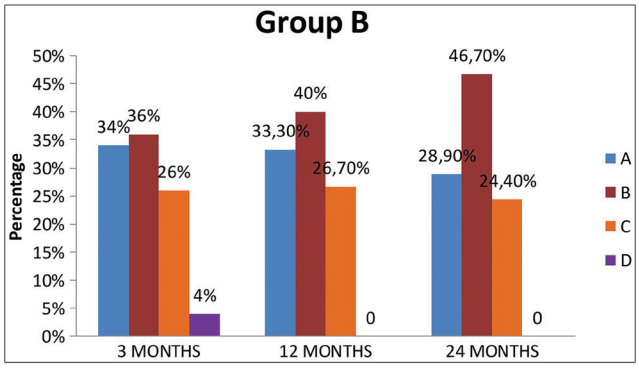
Being effective, easy, and noninvasive, biofeedback training was recommended by many studies to be the first-line treatment of FNRFI [15]. The short-term outcome was favorable as reported by many studies [16–18], which showed improvement of anal pressure, rectal sensation, and incontinence score, and this matched the results of the current study where there was statistically significant increase in the anal pressure including both squeeze and resting pressures as well as improvement of rectal sensation and fecal incontinence score. The improvement of squeeze pressure is assumed to be as result of direct effect of biofeedback training while resting pressure was assumed to be due to improvement in rectal sensation and partially due to direct effect of biofeedback training.

Figure 2



Short-term and long-term results of group A according to clinical outcome.

Figure 3



Short-term and long-term results of group B according to clinical outcome.

The current study showed that the incontinence score and episodes were decreased significantly in the biofeedback group by more than 75% in 70% of cases, and this effect is maintained over a 24-month follow-up and among them 28.9% were fully continent.

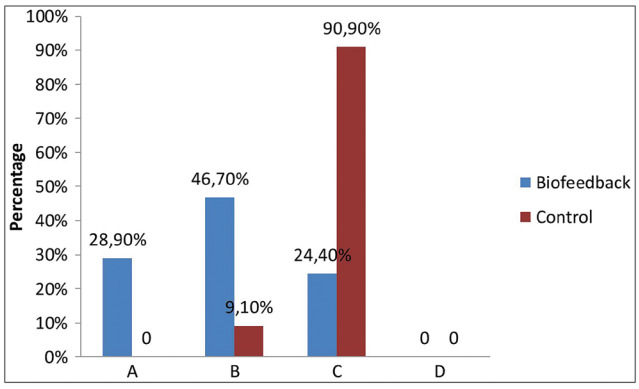
This point is of great controversy where Enck *et al.* [19], Ozturk *et al.* [20], and Pager *et al.* [21] reported almost the same results, while Lacima *et al.* [15] demonstrated more fully continent cases (35%) after 3 years of follow-up.

Guillemot *et al.* [22] and other studies [15,23,24] have demonstrated time decay in the effect of biofeedback. They described that there is great decay in the outcome of biofeedback after 3 years follow-up when compared with the initial promising results after a 6-month follow-up. This may be attributed to several methodological drawbacks in their studies including small sample size and lack of comparison with the control group.

In the current study, there was better outcome in the biofeedback group more than the conventional one, and this was matched with Lacima *et al.* [15], who demonstrated statically significant decrease in the incontinence episodes in patients treated with biofeedback when compared with those treated with pelvic floor exercise and the latter group showed decay of the effect over time.

The great debate and variability in the long-term outcome of biofeedback in controlling incontinence is assumed to be the inclusion criteria, where in the current study there was selection of a specific entity which is FNRFI, while in other studies other types of fecal incontinence were included, making the results unfavorable, especially in studies including patients

Figure 4



Comparison of the clinical outcome in groups A and B by the end of study.

with weak anal sphincter or those with sphincter injuries requiring surgical repair [15]. Another point to be described is the nonuniversal acceptance of the cutoff value of success, where some studies considered that a 50% or more decrease in episode is a success; the other has more strict criteria and in both the assessment was only by using fecal incontinence diaries. On the other hand, the assessment of the results in the current study was essentially objective depending on both the fecal incontinence diaries and the manometric finding, which give this study a great point of strength.

In the current study, there was statically significant improvement in lifestyle, emotion, behavior, and embarrassment domains of QoL in the biofeedback group more than the control group over time, and this can be simply explained by the reflection of decrease in the incontinence score and episodes on QoL domains, and this matched with Gabr *et al*. [25], who concluded in their studies that improvement in the incontinence score and decrease in the incontinence episodes using bowel management program had improved the QoL in children with incontinence.

Leite *et al*. [7] and Meyer and Richter [26] described that even with simple decrease in the frequency of the episodes and getting rid of the protective clothes, there is a major improvement in the QoL resulting in greater social engagement, less insulation, and greater self-esteem.

Conclusion

According to the current results, biofeedback addition to conventional therapy is considered as a feasible, effective, and noninvasive method for the treatment of FNRFI with favorable long-term maintenance of its effect together with a remarkable positive impact on all domains of QoL.

Study limitations: lack of similar studies to compare with.

Recommendations: further studies should be conducted to establish the long-term effects of biofeedback in the treatment of FNRFI in children.

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Authors contribution: Emad M. Abdelrahman: concept and designed the study, analyzed data, and drafted the manuscript. Mohamed A. Abdel Ghafar: study design, supervised cognitive and behavioral assessments. Ali O. Selim: collected the data and helped in data analysis. Olfat I. Ali: statistical analysis. Ahmed E. Sakr: collected the data and drafted the manuscript. Mohamed S. Kharoub: drafting and final revision.

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Conflicts of interest

There are no conflicts of interest.

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