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Original Article

Effects of behavioural therapy versus interferential current on bladder dysfunction in multiple sclerosis patients; a randomised clinical study



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المخلص

أهداف البحث: لمقارنة تأثير العلاج السلوكي (التغذية الراجعة) والتيار التداخلي على اختلال وظائف المثانة لدى مرضى التصلب المتعدد.

طرق البحث: تم تقسيم خمسين مريضاً يعانون من مرض التصلب المتعدد التدريجي الثانوي (الذين يعانون من اختلال وظائف المثانة) بالتساوي إلى مجموعتين بشكل عشوائي. تلقت المجموعة "أ" العلاج السلوكي (تدريب التغذية الراجعة)، بينما تلقت المجموعة "ب" تدريب تيار تداخلي. تم تقييم كلا المجموعتين من خلال ديناميكا البول لضغط عضلة المثانة ومعدل التدفق الأقصى قبل وبعد ثمانية أسابيع من العلاج السلوكي والتدريب التداخلي.

النتائج: كلا المجموعتين أظهرت زيادة ذات دلالة احصائية في ضغط عضلة المثانة ومعدل التدفق الأقصى بعد ثمانية أسابيع من التدريب. بينما أظهرت المجموعة فقط زيادة أكبر بالملاحظة.

الاستنتاجات: أظهر كل من العلاج السلوكي والتدريب بالتيار التداخلي فاعلية في علاج ضعف المثانة لدى المرضى الذين يعانون من مرض التصلب المتعدد التدريجي الثانوي، مع تأثيرات إيجابية أكثر وضوحاً في مرضى مجموعة العلاج السلوكي.

الكلمات المفتاحية: اختلال وظائف المثانة؛ العلاج السلوكي؛ التيار التداخلي؛ التصلب المتعدد؛ ديناميكا البول

Abstract

Objectives: This study examines the effect of behavioural therapy (biofeedback) and interferential current on bladder dysfunction in multiple sclerosis patients.

Methods: Fifty patients with secondary progressive type multiple sclerosis (SPMS) suffering from bladder dysfunction were divided equally into two groups randomly. Group A (GA) received behavioural therapy (biofeedback training), while Group B (GB) received interferential current training. Both groups were assessed by urodynamics for detrusor pressure and maximum flow rate before and after eight weeks of behavioural therapy and interferential training.

Results: Both groups, GA and GB, showed significant increase in the detrusor pressure and maximum flow rate after eight weeks of training. There was no significant difference between both methods. However, GA showed more improvement by close observation.

Conclusions: Both behavioural therapy and interferential current training effectively managed bladder dysfunction in patients with SPMS, with more evident effects in behavioural therapy patients by close observation.

Keywords: Behavioural therapy; Bladder dysfunction; Interferential current; Multiple sclerosis; Urodynamics

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Introduction

Multiple sclerosis (MS) is a progressive central nervous system (CNS) degenerative disorder presented with a variety of clinical courses.¹ Today, approximately 2.5 million persons in the world deal with MS, leading to a wide range of functional limitations.^{2,3} Patients with MS have periods of increasing symptoms called the relapsing stage and periods of decreasing or full recovery of symptoms called the remission stage. The most common type of MS is the secondary progressive type (SPMS), and it is characterised by progressive relapse attacks.¹ Bladder dysfunction, fatigue, spasticity, pain, and depression are the most common manifestations for demyelinating diseases such as MS.⁴ Patients with MS who have spinal cord demyelination are especially more prone to have bladder problems.⁵ The inability to contract or relax bladder muscles during micturition, or a combination of both, are the common types of bladder dysfunctions in patients with MS.⁶ Bladder dysfunction is considered as one of the problems that could increase the severity of the other symptoms for those patients, especially for SPMS types who have no time between attacks to recover.⁶

Approximately 90% of patients with MS may complain of bladder dysfunctions throughout the course of the disease, and this is especially true for those with SPMS.⁷ This is caused by neurological changes that affect the function of the detrusor-sphincter, leading to overactivity of detrusor, detrusor lowered control, and/or dyssynergia of detrusor-sphincter.⁸ The bladder dysfunction earnestly affects the quality of life, and its severity varies between the subtypes of MS.^{9,10}

Many treatment options, such as surgery and Anticholinergics, are available for bladder dysfunction. However, surgical interferences are rarely indicated and pharmacological methods may be associated with unwanted side effects.

Finding a non-invasive or non-pharmacological method to improve bladder dysfunction in patients with MS, especially the SPMS type, is the target of most researches because patients will depend on this tool for a long time, as the disease is progressive in nature. Many trials have studied the effect of Biofeedback or interferential current on bladder dysfunctions,^{11–13} but none of these studies, as far as we know, compare the effect between Biofeedback training and interferential current on bladder dysfunctions for patients with SPMS.

Electromyography (EMG) biofeedback is a physical therapy intervention that uses auditory and visual feedback to control the contraction or relaxation of muscles. Repeated biofeedback training can induce motor learning of muscles. Biofeedback enhances the function of pelvic floor muscles by enhancing the force generation, correct timing, and

coordination of the pelvic floor muscles. Electromyography Biofeedback is considered as a behavioural therapy training modality.¹⁴

Interferential therapy (IF) is also a widely used neuromuscular stimulation current. It is used in patients with bladder dysfunctions with good safety and effectiveness, if treatment with anticholinergics have failed. Interferential therapy includes an interference of two medium frequency currents that produce a low-frequency effect equal to the difference between the two currents. This current produces neuromuscular electrical stimulation for the bladder muscles.^{15,16,17}

Electromyography biofeedback and interferential therapy are commonly used to manage bladder dysfunctions in many neurological cases. To the best of our knowledge, no published study has demonstrated the effect of electromyography biofeedback and interferential therapy in managing bladder dysfunction in patients with SPMS.

Finding an effective, non-invasive tool for managing bladder dysfunction in patients with SPMS is substantially important, as there is a relationship between bladder dysfunction and quality of life or disability for patients with SPMS. The current study addresses a comparison between IF and biofeedback in treating bladder dysfunction in patients with SPMS.

The present study used the objective (Urodynamic test) assessment to test a null hypothesis that assumes that there is no difference in outcomes of using biofeedback versus interferential (IF) to treat patients with bladder dysfunction associated with Multiple Sclerosis.

Materials and Methods

This was a randomised clinical trial with a pre-post test design to measure and compare the effect of biofeedback training (behavioural therapy) versus IF current on bladder dysfunction in patients with secondary progressive MS (SPMS). Clinical trial registration number: NCT04635709.

Patients' selection

Fifty male patients diagnosed with SPMS for about one to two years and suffering from bladder dysfunction were enlisted for this study. All the patients were referred by a neurologist and diagnosed with spinal plaque types according to MRI. Male patients were selected for practical reasons, that is, to avoid the interruption of training by menstruation and female bladder dysfunctions as a complication of labour. The patients were between 25 and 35 years of age. All the selected patients had normal mental examinations according to the mini mental scale. Also, all the selected patients were medically stable and with moderate disability according to Expanded Disability Status Scale (EDSS). All the patients were asked to continue on their medication besides the research programme.

The patients were divided randomly by excel sheet into two equal groups; group A (GA) and group B (GB). The randomisation was done by firstly putting the names of all the selected patients in a column, then making the rand

formula for each patient in a second column. The third column was made to put randomly group A (GA) or group B (GB) beside each patient name. Finally, we sorted the numbers of rand formula column from smallest to largest, thus randomly rearranging patients into specific groups.

Patients in GA received behavioural therapy, while patients in GB received IF current. Study aim and procedures were demonstrated for all the patients and an informed consent was obtained from all the participants.

Patients with any other neurological deficits, orthopaedics abnormalities, auditory dysfunction, history of bladder dysfunctions before the diagnosis of MS or suffering any relapse during the treatment period, were excluded from this study.

The training protocol was conducted three times per week for eight weeks. Each training session lasted for about 20 min. Each patient completed the training programme during the remission period only.

Methodology

Instrumentation for evaluation

A urodynamic investigation system (Dantic urodynamic 5000/5500) was used to perform the urodynamic investigation (detrusor pressure and maximum flow rate). All patients underwent multichannel cytometry assessment before and after the treatment programme.¹⁸

The urodynamic studies are the gold standard for objectively diagnosing bladder dysfunctions, and permits an accurate assessment of bladder dysfunction and the risk factors for urinary tract deterioration in patients with MS. Urodynamics are important for the selection of the most effective treatment methods.¹⁹

Instrumentations for treatment

A Myo 200 EMG biofeedback device was used to measure the myoelectric activity of pelvic-floor muscles. EMG biofeedback training was carried out to enhance the patient's muscle activity and improve the maximum muscle contraction. Myo 200 EMG biofeedback device consists of three surface electrodes; two active electrodes and one earth electrode.

An interferential therapy machine (Duo 200, Gymna, Belgium) was used for interferential stimulation of the pelvic floor muscles. The advantage of IF current is its ability to reach deep tissues with less discomfort, because its kilohertz frequency decreases skin impedance. The basic principle of interferential therapy is to utilise the strong physiological effects of low frequency electrical stimulation of muscle and nerve tissues, without the associated painful and somewhat unpleasant side effects of such stimulation. A 20 Hz was used for motor nerve stimulation or combining muscle stimulation with increased blood flow.^{20,21}

Procedures

Urodynamic test assessment procedures were done before and after the treatment for all patients of both groups. All the participants were requested to empty the bladder as completely as possible, immediately before applying the test.

They were then asked to assume the crock lying position, and a sterile sheet was placed under the external genitalia. A single lumen catheter had been applied using an antiseptic technique, and the Y-piece mounted on the catheter. One piece was connected with the manometer connecting the tube to the infusion pump. A rectal balloon was used as well; it was inserted into the rectum to record the intra-abdominal pressure. Before recording, the system was first emptied of air and infused with 37 °C warm sterile normal saline (at a medium rate of 50 ml/min). The patients were asked to void, and the detrusor pressure was calculated electronically (the vesical pressure (Pves) minus the abdominal pressure (Pabd)). The maximum flow rate of patients' urination was also measured.¹⁸

Training procedures started with a discussion about the structure of the urinary system and pelvic floor muscle, and what happens during normal and abnormal continence. How to train pelvic floor muscle (PFME) for bladder rehabilitation were also demonstrated for the patients. Patients were also asked to make an interrupted micturition at home, to localise the action of pelvic floor muscles so the exercise during the session could be easy, correct, and efficient.

At the beginning of the behavioural therapy session, the patients were asked to micturate before the session, and to wear comfortable clothing. All the exercises were done from the crock lying position with the head elevated by a pillow. Alcohol was used to clean the skin before placing the electrodes to reduce skin impedance. The earth electrode was connected to the knee after being soaked in 1% saline solution. Positive electrode was on the perineum region, and the negative electrode was placed at the bulky area of the pelvic floor muscles, about three centimetres from the positive electrode site. The patient's personal data were fed to the computer of the EMG biofeedback device with I.D. (identification) to obtain the patient's data. Afterwards, results were stored in the same file for each patient.^{22–24}

The exercises started by first inhaling and exhaling deeply to release the tension from the body, to focus on the contraction of the pelvic floor muscles. The contraction of these muscles was done correctly by asking the patients to pull the muscles inward as if they were trying to stop micturition. The patients were instructed to breathe normally and to relax the buttocks and stomach muscles during the contractions of the PFM. The patients were instructed to make forceful perineal contractions, and the EMG activities during the maximal contraction were recorded. An auditory feedback was produced by the device for the patients' encouragement. The physical therapist encouraged patients to exert their maximum effort to elevate the auditory feedback signals. Recruitment to maximal contraction was maintained for 5 s, followed by a gradual relaxation with 15–30 s rest interval.^{22–24} The exercise was repeated for twenty minutes three days per week for eight weeks.

Interferential current with low frequency current was applied, using four electrodes placed on the lower abdomen and gluteal area to cross the currents through the bladder and pelvic floor muscles for 20 min. During the stimulation, all the patients were asked to contract the bladder muscle to enhance the perception of bladder control.^{14,25}

Statistical procedures

Sample size

Calculations to determine the sample size were performed for detrusor pressure as a primary outcome measure using G power 3.1 software. The calculations were based on an effect size of 0.62 (based on a pilot study made by the researchers on ten patients (five for each group), an alpha level of 0.05, a desired power of 80%, and a numerator degree of freedom of 1 and 2 experimental groups. The estimated desired total sample size in the study was 50 patients. To achieve the expected dropout before the study's completion, a total of 68 patients were included in the study (Figure 1).

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 20 (SPSS Inc., Chicago, IL). The normality of distributions and the homogeneity of variances were evaluated by Shapiro–Wilk and Levene tests. Participants' characteristics were compared between both groups using a t-test. Data was considered statistically significant when $P < 0.05$. A mixed design ANOVA (group \times time) was used to determine if there were any differences between or within groups and the interaction of treatment group by time.^{24,26}

Results

Demographic data

Sixty-eight MS patients were screened for eligibility. Eight did not match the specified inclusion criteria of the study, one refused to complete the study, and nine did not complete the study due to a relapse in their multiple sclerosis. The remaining fifty patients completed the study (Figure 1 study flow chart). The mean values in age for GA and GB were 25.8 ± 5.7 and 27.4 ± 4.9 , respectively. The mean values in the duration of the disease for GA and GB were 17.8 ± 5.7 and 18.1 ± 5.7 , respectively. The mean values in BMI for GA and GB were 28.2 ± 2.1 and 27.3 ± 2.2 , respectively. No significant differences were found between groups in age, duration of the disease, or BMI ($P = 0.564$), ($P = 0.764$), and ($P = 0.29$), respectively.

Detrusor pressure

In regards to detrusor pressure, there was significant interaction between type of intervention (behavioural therapy or interferential current) and time, $F(1, 28) = 7.562$,

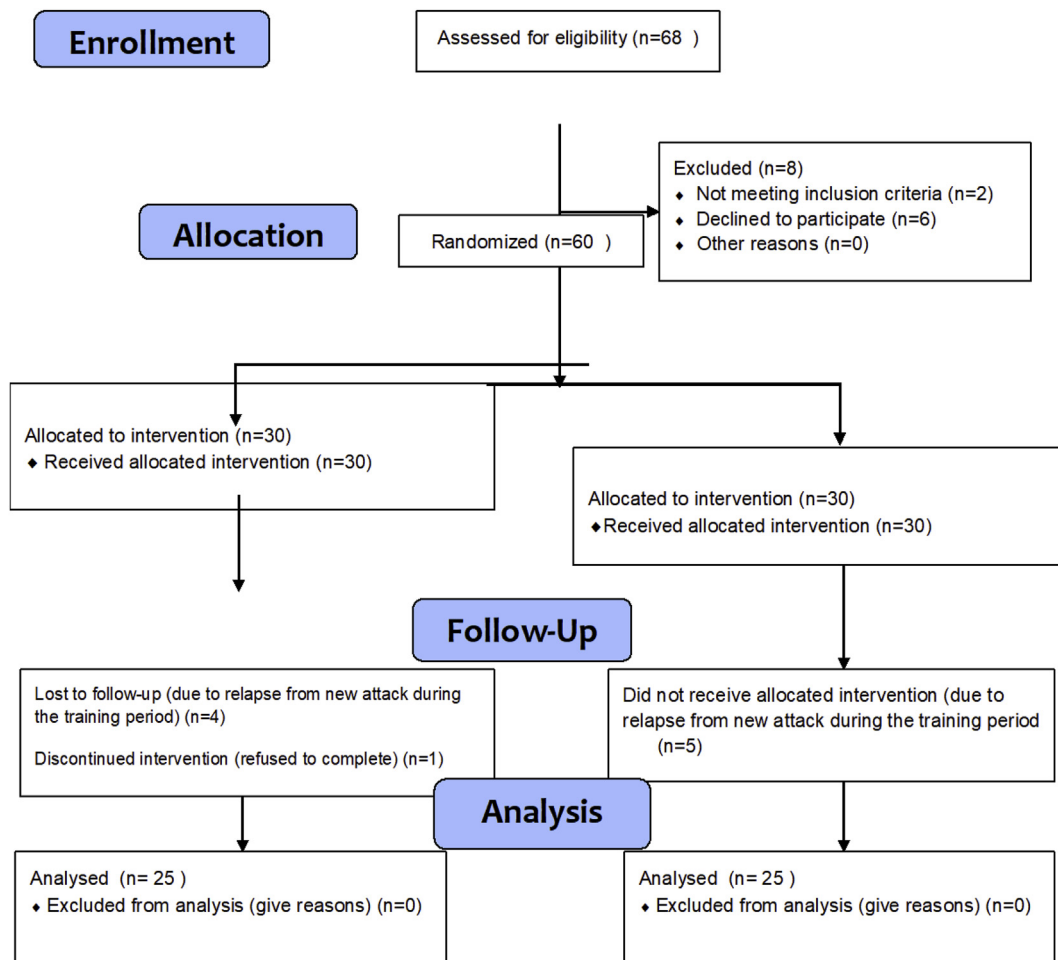


Figure 1: Diagram showing the flow of the study.

$p = 0.010$ partial eta squared (η^2) = 0.213. There was a significant main effect for time, $F(1, 28) = 84.983$, $p = 0.000$, $\eta^2 = 0.752$, with both groups' subjects showing increased mean values of detrusor pressure across the two time points (Table 1). The main effect comparing the two groups of subjects was not significant, $F(1, 28) = 0.713$, $p = 0.406$, $\eta^2 = 0.025$, suggesting no significant difference in mean values of detrusor pressure between GA and GB.

Maximum flow rate

In regards to maximum flow rate, there was significant interaction between type of intervention (behavioural therapy or interferential current training) and time, $F(1, 28) = 6.208$, $p = 0.019$, $\eta^2 = 0.181$. There was a significant main effect for time, $F(1, 28) = 157.995$, $p = 0.000$, $\eta^2 = 0.849$, with both groups' subjects showing increased mean values of maximum flow rate across the two times (Table 1). The main effect comparing the two groups of subjects was not significant, $F(1, 28) = 2.144$, $p = 0.154$, $\eta^2 = 0.071$, suggesting non-significant difference in mean values of Maximum flow rate between GA and GB. However, close observation of post treatment means values shows that although subjects in both groups improved in their maximum flow rate after treatment, there was more improvement in the GA than GB.

Table 1: The mean values of detrusor pressure and maximum flow rate in both groups.

| Detrusor pressure | Group A (n = 15) (Mean \pm SD) | Group B (n = 15) (Mean \pm SD) |
|--------------------------|-------------------------------------|-------------------------------------|
| Pre treatment | 23.33 \pm 14.45 | 25.26 \pm 11.30 |
| Post treatment | 44.300 \pm 8.71 | 36.86 \pm 7.89 |
| Maximum flow rate | | |
| Pre treatment | 5.46 \pm 6.62 | 5.13 \pm 5.80 |
| Post treatment | 23.40 \pm 9.66 | 17.13 \pm 4.89 |

Discussion

The results of the current study revealed improvements in bladder dysfunction (detrusor pressure and maximum flow rate) in group A (GA) that received behavioural therapy, and in group B that received interferential (IF) current after eight weeks of rehabilitation, for patients with multiple sclerosis secondary progressive type (SPMS). No significant difference was found between the levels of observed improvement in each group. However, a higher level of bladder dysfunction was observed in the behavioural therapy group, particularly in the maximum flow rate measurement category.

Bladder dysfunction among multiple sclerosis (MS) patients results from the blocking or delaying of nerve signals to the bladder and urinary sphincter. These blockages and delays happen as a result of demyelination in the brain and/or spinal cord. The detrusor muscle and the sphincter muscle are the main muscles involved in voiding the bladder. The detrusor muscle in the bladder wall involuntarily contracts as a result of MS demyelination, decreasing the volume of

urine. This leads to a subsequent decrease of detrusor pressure in urodynamic tests, and symptoms of frequent urination, an urgent need to urinate, and urine leakage are often observed. These symptoms often interfere with the sleep of the MS patient, resulting in increased fatigue and, in turn, increased disability. The sphincter muscle of the bladder controls the spout of urine. The patient is often unable to empty the bladder, despite the lingering sensation of fullness. This occurs when the nerve impulse that causes the sphincter muscle to open is interrupted; the sphincter muscle closes before all the urine is emptied from the bladder, leading to a decrease in maximum flow rate in urodynamic tests.²⁷⁻³⁰

Voiding pressure-flow analysis via urodynamic testing remains the best method for diagnosing and improving bladder dysfunction. The relationship between pressure and flow of urine is more defined in men than in women.³¹ This explains, in addition to the reasons mentioned in the methodology, why the current study focused on male patients. A decrease in a patient's maximum flow rate and detrusor pressure are the key indicators of bladder dysfunction. An increase in the measurements of these indicators is correlated with improvement of bladder functions contractility, and also reflects a significant effect of the treatment. The urodynamic study/test has two phases; the filling and storage phase and the voiding phase. The voiding phase of a urodynamic test is the main method for diagnosing bladder obstruction. Detrusor pressure and urinary flow rate can be deliberated to measure the outlet resistance.³¹ For this reason, the current study adopted both of the aforementioned measurements to assess both groups.

The IF current may likely have contributed to the improvement in Group B, as it can be used to augment existing bladder contractions. The stimulation frequency of the IF current can potentially activate both the smooth and skeletal muscles involved in urinary tract function. Thus, the IF current can affect how the urinary muscles tense and release. It can potentially improve neural muscular control. It can enhance the coordination between sphincter contraction and relaxation by enhancing the activity of intact musculature of pelvic floor muscle. This finding aligns with Kajbafzadeh et al., who found positive effects of the IF current in managing non-neuropathic underactive bladders. The IF current could potentially be helpful for SPMS cases due to its ability to delay the deterioration of bladder dysfunction in MS patients as MS attacks progress. This is because the IF current could augment the contraction of the intact neural muscle in the bladder.

IF stimulation teaches patients to enhance the control of their bladder muscles as they experience the sense of vibration that IF stimulation causes. The improvement gained through this method may also augment the contraction of the intact neural muscle. This allows the patients to train their cortical perception to control bladder contraction, leading to more firing and contraction of the intact neural muscle. This concept aligns with Daia et al.,¹⁴ who studied the effect of IF on bladder dysfunction management in patients with spinal cord injuries.

Daia et al.¹⁴ carried out a study using interferential current on 332 patients diagnosed with bladder dysfunction immediately after spinal cord injury. Patients were asked to

contract their bladder muscles to improve the perception of controlling the bladder, and this controlled the intensities that triggered the vibration sensation. The mental association within the IF therapy helped patients to regain micturition control.¹⁴ It may also explain Group B's bladder dysfunction improvement in the current study; mental perception augmented more firing of intact myelinated muscles in patients with SPMS.

Biofeedback allows the translation of both normal and abnormal physiological unconscious processes into visual or auditory conscious signals; this may explain Group A's improvement in the current study. Biofeedback is synonymous with behavioural therapy. Little information is known regarding the perineal region by the patients; this assists the development of poor control in its functions. Biofeedback assists in realising these functions, creating a "communication cycle" between patient and computer.³² Neuromodulation modalities include training the pelvic floor muscles through biofeedback. Surface electrodes are used to record the actions of the correct muscles by placing the electrodes on the motor point of these muscles. This translates the electrical activity of the muscles into auditory or visual feedback, and it increases or decreases the action of the recorded muscles. This aligns with Ibrahim et al.,³³ who utilised biofeedback to evaluate the efficacy of pelvic floor muscle training (PFMT) in women with pelvic floor dysfunction (PFD). The researchers concluded that the combination of biofeedback and PFMT is an efficient treatment compared to PFMT alone, and this was a result of motivation with the visual and auditory feedback.³³ Motivation through visual or auditory feedback could enhance the learning process and augment the awareness of muscle contraction. This leads to increased contraction of the bladder's intact neural muscles, resulting in bladder dysfunction improvement. This explains why a higher level of bladder dysfunction improvement was observed for the behavioural therapy group in the current study, despite the fact that improvement was observed in both groups.

In the current study, the authors focused on demonstrating pelvic floor exercises to each patient before the treatment session. This was done to correctly isolate PFM and maximise the benefit of biofeedback training as a behavioural therapy of awareness and motivation. To attain the best training effects, the patient should perform maximum pelvic floor muscle contraction. Many studies have approved mixed abdominal muscle contraction along with bladder muscle contraction during trials to contract the bladder. Biofeedback can improve the sensibility, and isolate the action of correct PFM contraction. As in the case of the current, it can also increase encouragement to repeat the correct action through auditory feedback. Optic neuritis is common in cases of MS, and it often affects the vision of MS patients; this makes auditory feedback a better option than visual feedback.^{34,35} In the current study, the increased improvement in Group A as compared to Group B may be attributed to the auditory type of feedback and learning by biofeedback.

The number of cases in the study was limited, due to the refusal of female patients to participate in this study because of its clinical procedure. Additionally, the study excluded cases of patients that experienced new attacks during the treatment programme. These factors resulted in a limited number of patient cases that were ultimately included in this study.

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Conflict of interest

The authors have no conflicts of interest to declare.

Ethical approval

The study was approved by the Ethics Committee of the College of Medical Rehabilitation Sciences, Taibah University (Approval No. CMR-PT-2019-01) and approval date is (01-2019).

Authors' contributions

AMA established and designed this study, conducted research work, collected data, and shared in data interpretation and manuscript writing. OAK and HAE shared in designing the study, and data collection and organization. EHR and WMR analysed and interpreted data, and wrote the initial and final drafts of manuscript. AMA, OAK, HAE, and WMR shared in conception of the research, data analysis and interpretation, writing the manuscript and provided logistic support. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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