Original article

Feasibility of transcranial direct current stimulation (tDCS) combined with pelvic floor muscle training (PFMT) in female urinary incontinence: randomized controlled trial

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ABSTRACT | INTRODUCTION: Pelvic floor muscle training (PFMT) is widely regarded as the most conservative and effective non-pharmacological treatment option for women suffering from urinary incontinence (UI). Transcranial direct current stimulation (tDCS) is a non-invasive, non-pharmacological neuromodulation technique that has demonstrated promising results in a variety of medical conditions. However, there has been little research into the feasibility of tDCS as an adjunct therapy to PFMT in improving symptoms in women with UI. **OBJECTIVE:** To explore the feasibility (recruitment and retention) of tDCS as an adjunct therapy to PFMT to relieve symptoms of female UI. **METHODS AND MATERIALS:** Eleven female patients were randomly assigned to receive 12 non-consecutive sessions of PFMT combined with 20 minutes (2mA) of anodal (Cz) or sham tDCS for 4 weeks. Feasibility (primary outcome) was assessed through recruitment and retention rates. Secondary outcomes included four domains: (1) urinary leakage, (2) severity of incontinence, (3) impact on quality of life, and (4) symptoms and adverse events. **RESULTS:** Eleven patients were evaluated, and nine women completed the treatment protocol. The recruitment rate was 100%, and retention was 81.8%. Clinical results showed that anodal tDCS is viable as adjunctive therapy to PFMT protocol and may result in minimal clinically important differences (MCID) in UI symptoms. **CONCLUSION:** The high rate of recruitment and retention indicates that tDCS in combination with PFMT is a feasible adjunct therapy for female UI treatment. This research supports the recommendation for a full RCT, with prioritization of outcomes required for hypothesis testing.

Clinical Trial Registry: NCT04084340.

KEYWORDS: Urinary Incontinence. Exercise Therapy. Electrical Stimulation Therapy. Feasibility Studies.

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1. Introduction

The International Continence Society (ICS) defines urinary incontinence (UI) as any involuntary loss of urine. UI types include stress, urgent, or mixed. The term "stress UI" refers to any level of effort that causes urinary loss due to an increase in intra-abdominal pressure and failure of the detrusor muscle to contract. Urgent UI is associated with a sudden and intense urge to urinate. In this type of involuntary urinary loss, the detrusor muscle contracts when it should not, increasing bladder pressure.[1] The mixed UI has characteristics of both types. UI is a public health problem due to its negative impact on the physical[2], psychosocial[3] and economic[4] aspects of life. It is a considerable risk factor for sexual dysfunction in both women and men.[5] Although its precise prevalence is not yet known, female UI may affect 17.1% of nonpregnant women[6] and this percentage increases with several factors, including age, overweight, and number of pregnancies.[7]

Pelvic floor muscle training (PFMT) has been advocated as the main non-pharmacological approach for UI, owing to the highest positive evidence, low side effects, and reduced costs.[8] Popularized by Arnold Kegel[9], this strategy relies on consistent and voluntary contractions of the pelvic floor musculature, according to a protocol that describes the frequency, intensity, and progression of the exercises and the duration of the training period. Despite the strong positive evidence, there are still barriers preventing adherence to PFMT protocols, mainly due to the long period of training to achieve clinical benefits. In this case, some patients are more likely to undergo unnecessary surgical procedures.[10] Another factor that challenges the correct execution of pelvic floor exercises, which is frequently observed in clinical practice, is that many women have difficulties contracting the pelvic floor musculature.[11] Adjuvant therapies that could potentially improve UI outcomes following PFMT are extremely valuable in this context. A previous meta-analysis, however, found insufficient evidence to combine other active treatments with PFMT.[12] This evidence challenges combination therapies based only on a biomechanical approach.

Brain imaging techniques, such as functional magnetic resonance imaging (fMRI) are widely used to help decode the brain-bladder interaction and pelvic floor function/dysfunction, and have helped to identify brain correlates of many diseases, including UI.[13] In this scenario, new treatment options have emerged, targeting brain mechanisms related to urinary loss. In healthy subjects, voiding tasks showed a cluster of activation in the pons, cerebellum, insula, thalamus, inferior frontal gyrus, and anterior cingulate cortex.[14] In contrast, the pattern of brain activation seems to be different in women with UI. When compared with healthy women, the sites of the primary motor and somatosensory cortical representation of the lower urogenital tract and the anterior cingulate cortex and supplementary motor area (SMA) seem to be more active.[15] These altered brain activity may be related to the mechanisms of some urogynecologic dysfunctions. For instance, in patients with bladder hyperactivity, an exaggerated response to the SMA may evoke urgency. In women with urgent UI, the prefrontal cortex (PFC) activity, which has an inhibitory function over the bladder, has a diminished activity compared to that in healthy women.[15] About clinical outcomes, a recent review found that cortical inhibition can be modulated to improve urinary continence and decrease neurogenic bladder hyperactivity in patients with Parkinson's disease and multiple sclerosis.[16]

In this context, therapeutic strategies targeting brain structures involved in UI and pelvic floor dysfunction may be an efficient adjunct therapy to boost the clinical efficacy of exercise therapy.[17] Transcranial direct current stimulation (tDCS) is a non-invasive, non-pharmacological, and well-accepted strategy to influence brain activity through manipulation of neuronal excitability[18] beyond the stimulation period.[19] Although the exact mechanisms of action remain unclear, it is known that tDCS has synaptic and non-synaptic effects. The parametrization of tDCS is crucial for its effects, where the anodal pole generally increases cortical excitability, and the cathodal pole induces opposite effects.[18] When applied over specific brain areas, the facilitatory effects of tDCS may increase the excitability of the corticospinal pathway, qualitatively and quantitatively favoring motor unit recruitment strategies[20], and improving muscle strength.[21] Currently, many studies demonstrate the potential of tDCS in improving the clinical outcomes of different health conditions.[22] However, the most promising application of tDCS would be to expand the clinical efficacy of existing treatments.[23-25]

In this case, there remains much research to be carried out, especially on healthy women with UI. The promising benefits of adding tDCS prior to exercise therapies remain uncertain on the clinical outcomes. If brain stimulation combined with PFMT yields better outcomes than PFMT alone, this combination could expand the possibilities of non-pharmacological and noninvasive treatments for UI, especially in women refractory to current approaches. This clinical trial protocol aims to investigate whether adding brain targeting strategies (tDCS) can improve the clinical efficacy of PFMT treatment in women with UI.

1.1 Objective

The primary objective of this study was to explore the feasibility (recruitment and retention) of transcranial direct current stimulation (tDCS) as an adjunct therapy to pelvic floor muscle training (PFMT) to relieve symptoms of female urinary incontinence (UI).

The secondary objectives were as follows:

1) To investigate the difference in urinary leakage between anodal tDCS + PFMT and PFMT alone after 12 sessions of treatment.

2) To investigate the difference in incontinence severity between anodal tDCS + PFMT and PFMT alone after 12 sessions of treatment.

3) To investigate the difference in the impact of the quality of life between anodal tDCS + PFMT and PFMT alone after 12 sessions of treatment.

4) To investigate the difference in emotional impact between anodal tDCS + PFMT and PFMT alone after 12 sessions of treatment.

5) To investigate the difference in the PFM strength between anodal tDCS + PFMT and PFMT alone after 12 sessions of treatment.

6) To investigate the difference in the perception of the overall effect between anodal tDCS + PFMT and PFMT alone after 12 sessions of treatment.

1.2. Hypothesis

We hypothesized that tDCS is a feasible and acceptable adjunct therapy to PFMT to reduce UI symptoms, improve quality of life, pelvic floor muscle strength, and global perception of recovery.

2. Materials and Methods

This two-arm parallel feasibility study was performed to determine the efficacy of anodal tDCS combined with PFMT in female patients with UI.

2.1. Approval and Registration

This project was approved by the Research Ethics Committee of the Universidade Federal do Delta do Parnaíba (protocol 3.408.788/19) and registered at Clinicaltrials.gov as NCT04084340.

2.2. Procedures

Female patients referred by their physicians or seeking treatment with complaints of urinary leakage were fully informed about the present study. An experienced physical therapist explained the study's objectives, treatment details, and risks. All participants agreed with the conditions, signed the consent form and met the eligibility criteria to participate.

2.3. Participants and Eligibility

Eleven female participants were recruited for this study who sought treatment at the physical therapy school clinic through medical referral and spontaneously complaining of urinary incontinence for more than three months. Participants who met the following criteria were eligible: (1) age between 18 and 65 years, (2) seeking treatment for UI, and (3) complaints of urinary loss.

Excluding criteria were: (1) Grade III or IV vaginal dystopias (assessed by the Pelvic Organ Prolapse Quantification System [POP–Q][26]; (2) intrapelvic tumors; (3) symptoms of urinary loss related to a neurological

disease (stroke, Parkinson's disease, multiple sclerosis, medullary lesions); (4) a cardiac pacemaker or other implanted devices; (5) current pregnancy; (6) urinary tract infections; and (7) previous treatment with tDCS.

2.4. Randomization and Allocation Concealment

A randomization-generating program divided patients into one of the following two groups: (1) real tDCS (tDCS-r) + PFMT, and (2) sham tDCS (tDCS-s) + PFMT. An external collaborator was responsible for the randomization and allocation concealment procedures. Treatment allocation was revealed for both the evaluator and patients only at the end of the study.

2.5. Initial Evaluation

Initially, participants were evaluated through a non-structured interview to collect personal information, clinical history, and anthropometric characteristics. Subsequently, a specific clinical assessment was carried out according to the recommendations of the European Association of Urology for diagnosis and treatment.[27] The main outcomes included fall within four domains: (1) urinary leakage, (2) incontinence severity, (3) quality of life impact, and (4) symptoms and adverse events.

2.6. Primary Variable

2.6.1. Feasibility

Participant recruitment rate and retention were calculated to express feasibility measures. The recruitment rate can be calculated by dividing the number of patients scheduled for a baseline assessment by the number of participants who signed up as "interested" in the study.[28] After four weeks of treatment, retention was calculated by dividing the number of post-treatment participants by the number of pre-treatment participants. While recruitment rates can be compared to other studies, 80-100% of retention is considered a strong trial.[29] We implemented the following strategies to ensure an appropriate recruitment and retention rate: (1) physical therapy standard treatment for all participants; (2) full explanation of the study protocol before beginning; (3) flexible treatment schedule; (4) personalized treatment; (5) parking for cars and motorcycles; and (6) telephone and email support in case of doubts or questions. We also seek to identify barriers to participation and issues with assessment procedures.

2.7. Secondary Variables

2.7.1. Urinary leakage

Urinary leakage was measured using a pad test. Pad testing yields an objective measurement of fluid loss over a certain period. The outcome of the 1-h pad test was recorded as the weight gain measured on a verified spring balance. Pad test assessment: Change in 1-hour exercise (stress) was classified as mild, moderate, or severe urinary leaking.[30]

2.7.2. Incontinence severity

Incontinence severity was assessed using the Brazilian version of the Incontinence Severity Index (ISI), which quantifies the frequency and number of urinary leaking episodes. The ISI comprises two questions about the quantity and frequency of urinary losses. The scores range from 0 to 12: 0 continent, 1 or 2, mild incontinence; 3 or 6, moderate incontinence; 8 or 9, severe incontinence; 12, very severe incontinence.[31]

2.7.3. Quality of life impact

The quality of life impact of urinary incontinence was assessed by the Brazilian Version of International Consultation on Incontinence Questionnaire - Urinary Incontinence (ICIQ-UI short form). The ICIQ-UI short form provides a score ranging from 0 to 21. A higher score indicates a greater symptom severity.[32]

2.7.4. Quality of life of women with UI (severity symptoms)

Quality of life was analyzed using the Brazilian version of the King's Health Questionnaire (KHQ). This questionnaire is a patient self-administered self-report and has three parts consisting of 21 items. The scores from eight subscales (domains) range from 0 (best) to 100 (worst). Decreases in KHQ domain scores indicate an improvement in the quality of life.[33]

2.7.5. Emotional impact

The emotional impact of UI on the quality of life was analyzed using the Brazilian version of the Incontinence Quality of Life Questionnaire (IQOL), which evaluates the social, physical, and mental aspects of women with UI. The IQOL is a self-report questionnaire with 22 questions and three subscales (domains). The scores range from 0 (worst) to 100 (best).[34]

2.7.6. Pelvic floor muscle strength: Subjective test

Pelvic floor strength was analyzed by bidigital vaginal palpation of the vaginal introitus, through the new PERFECT scheme using the modified scale de Oxford.[35]

2.7.7. Pelvic floor muscle strength – Quantitative test

Pelvic floor strength was analyzed by a clinical perineometer (Perina Clínico Biofeedback, *Quark*®, Brazil) in cm H_2O with a 9- and 1.1-cm probe size and diameter, respectively. It records the contraction pressure by means of visual signals on a numerical scale, by means of an anal or vaginal probe, it is possible to visualize the intensity of the contraction by means of a luminous linear LED scale.[36,37]

2.7.8. Urinary leaking

A diary was delivered to the participant to note the urinary frequency daytime, night, amount of loss, and exchange of absorbents if used, across 24h.[38,39]

2.7.9. Perception of the Global Effect

The global perceived effect scale was used to assess the perception of recovery following therapy. The 11-point scale goes from -5 to +5, with 0 indicating no change, +5 indicating full recovery, and -5 indicating severe illness.[40]

2.8. Other Outcomes

2.8.1. Depressive and Anxiety Symptoms

Depression and anxiety symptoms were assessed using the Beck Depression Inventory (BDI) and the Visual Analog Scale (VAS), respectively, to avoid misinterpretation of treatment success due to the influence of psychosocial changes. The BDI consists of 21 items with values ranging from 0 to 3, with higher scores indicating more depressed symptoms.[41] The VAS is a 100mm horizontal line with no and severe anxiety anchors on the left and right sides.[42]

2.8.2. Patient Satisfaction

The MedRisk questionnaire, which measures patient satisfaction with physical therapy care, was used to assess patients' satisfaction with treatment. This questionnaire contains 20 items, 10 of which are related to the therapist-patient interaction, eight of which are not, and two of which are considered overall items. The patient satisfaction score ranges from 1 ("strongly disagree") to 5 ("strongly agree") or by selecting the option "not applicable," where high scores indicate high satisfaction.[43]

2.9. Treatments

The period of the treatment protocol was four weeks, with three weekly sessions, totaling 12 sessions. All treatments were carried out individually on non-consecutive days.

2.10. Calibration of the Participants' Expectations

A possible sensation from brain stimulation was explained during the pre-treatment phase. It has been reported that the electrical stimulation unit may cause slight tingling, itching, a burning sensation, or even no noticeable sensation at all or just at the beginning of the application.

2.11. tDCS

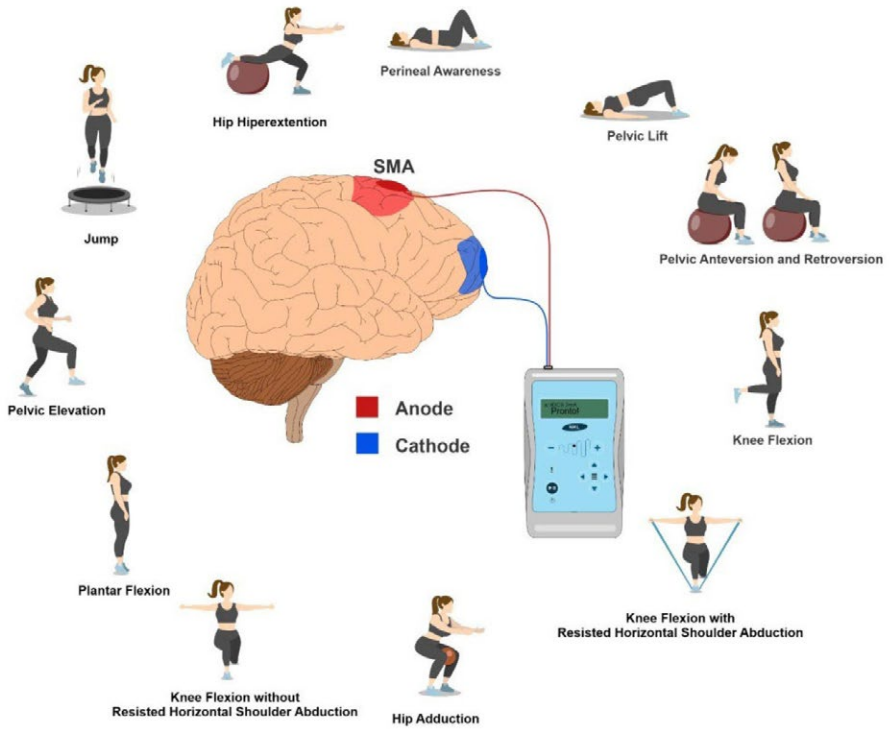
A constant direct current stimulator (Microestim, NKL®, Brazil) was used for transcranial electrical stimulation. The tDCS parameterization included two electrodes (35 cm^2; 5 × 7 cm) (NKL®, Brazil) covered with a sponge moistened with saline solution (1% saline) and fixed to the head with elastic bands. The mounting of the electrode targeting the supplementary motor cortex followed the recommendations of the International 10-20 system.[44] The anode electrode (positively charged) was placed 1.8 cm before the location of Cz, and the cathode electrode (negatively charged) was

placed centrally on the forehead directly above the eyebrows.[45] The current intensity for real tDCS was fixed at 2 Ma, with a density of 0.057 Ma / cm² and application time of 20 min. For the sham application, the tDCS device has been programmed to maintain the same appearance as the real tDCS. However, the electric current was applied for 30s.[25]

2.12. Pelvic floor training

Immediately after the application of tDCS, the PFMT was started according to the patient's tolerance, which included stretching and strengthening exercises[8,9] (Figure 1). The supplementary (Table 5 – Supplement 1) file contains a detailed description of the exercise protocol and progression.

Figure 1. tDCS and PFMT protocol



Source: the authors (2024).

2.13. Statistical Analysis

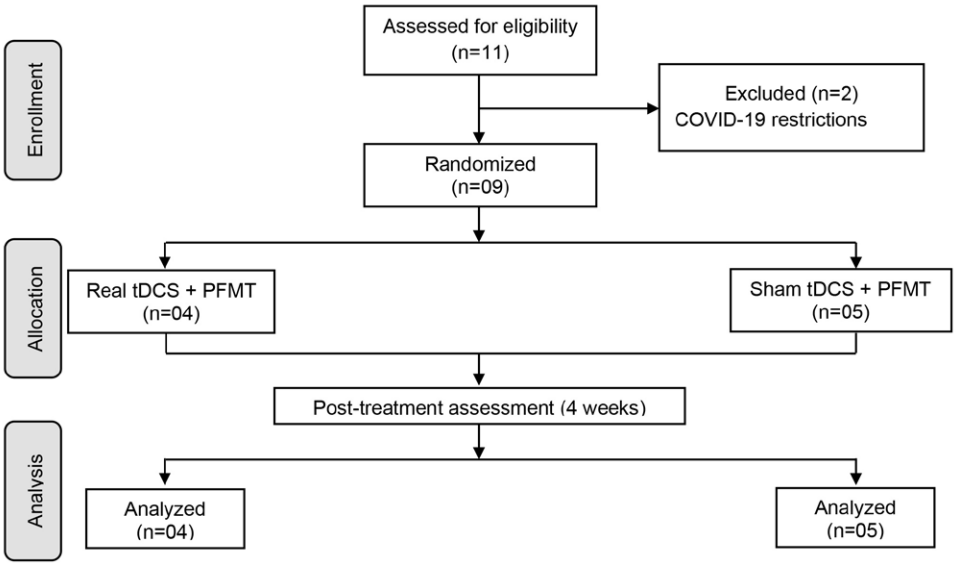
Given the sample size in each group, the analyses were presented descriptively, considering minimally important clinical changes (MCMI) in each outcome. Analyses were conducted using IBM SPSS v.20 software for Windows.

3. Results

Eleven patients were evaluated, and nine women completed the treatment protocol. The recruitment rate was 100%, and retention was 81.8%. Five and four patients were allocated to the anodal + PFMT and sham + PFMT groups, respectively, without any dropouts after enrollment. Figure 2 depicts the participants' progression through the study. The baseline general and urogynecological characteristics are presented in Tables 1 and 2, respectively. No adverse effects or side effects were reported during or after the intervention protocols were implemented. The pre- and post-

treatment clinical characteristics for the outcomes of muscle capacity of the pelvic floor, quality of life, and impact of UI are described in Tables 3 and 4, respectively.

Figure 2. Flow chart illustrating the study process. tDCS and PFMT indicate transcranial direct current stimulation and pelvic floor muscle training, respectively



Source: the authors (2024).

Table 1. Participants characteristics (to be continued)

	M	SD
Age (years)	39.1	12.0
Weight (Kg)	66.8	10.8
Height (m)	1.6	0.1
BMI (Kg/m^2)	27.4	5.2
Race n (%)		
White	4 (44.4)	----
Mixed (Pardo)	5 (55.6)	----
Black	----	----
Education n (%)		
Elementary school	4 (44.4)	----
High school	----	----
Higher education	5 (55.6)	----
Marital status n (%)		
Married	6 (66.7)	----
Single	3 (33.3)	----
Employment status n (%)		
Employed	6 (66.7)	
Unemployed	1 (11.1)	
Student	2 (22.2)	

Table 1. Participants characteristics (conclusion)

	M	SD
Sedentarism n (%)		
Yes	4 (44.4)	
No	5 (55.6)	

BMI: Body mass index. Continuous variables are expressed in terms of mean (M) and standard deviation (SD).
Source: the authors (2024).

Table 2. Participants' urogynecological characteristics

	M	SD
Menarche (years)	12.3	1.1
1st Sexual intercourse (years)	16.8	7.3
Sexually active n(years)	6 (10.6)	14.1
Sexually inactive n(years)	3 (2.7)	5.9
Gestation	1.3	1.1
Births	1.1	1.2
Cesarean	----	----
Natural	1.1	1.2
Abortion	0.2	0.7
Menstrual cycle n (%)		
Regular	7 (77.8)	----
Irregular	2 (22.2)	----
Pain intercourse n (%)		
Yes	----	----
No	9 (100)	----
Cauterization n (%)		
Yes	3 (33.3)	----
No	6 (66.7)	----
Surgery n(%)		
Yes	5 (55.6)	----
No	4 (44.4)	----
Episiotomy n(%)		
Yes	5 (55.6)	----
No	4 (44.4)	----
Laceration n(%)		
Yes	4 (44.4)	----
No	5 (55.6)	----
Insufficient	3 (6)	----

Continuous variables are expressed in terms of mean (M) and standard deviation (SD).
Source: the authors (2024).

Table 3. Pre- and post-treatment pelvic floor assessments

	sham tDCS (n=5)		real tDCS (n=4)	
	Pre	Post	Pre	Post
***Performance* n (%)**				
No contraction	----	----	----	----
Weak	1 (20)	1 (20)	1 (25)	----
Moderate	3 (60)	2 (40)	2 (50)	1 (25)
Good	1 (20)	1 (20)	1 (25)	3 (75)
Strong	----	1 (20)	----	----
***Endurance* n(%)**				
< 5s	2 (40)	----	3 (75)	1 (25)
< 10s	3 (60)	5 (100)	1 (25)	3 (75)
> 10s	----	----	----	----
Repetitions	4.0 (1.0)	6.2 (3.1)	3.5 (0.6)	4.0 (0.0)
Fast	5.4 (1.5)	7.4 (0.9)	5.8 (0.5)	8.0 (0.8)
Elevation n(%)				
Yes	4 (80)	4 (80)	3 (75)	4 (100)
No	1 (20)	1 (20)	1 (25)	----
***Co-contraction* n(%)**				
Yes	2 (40)	2 (40)	4 (100)	2 (50)
No	3 (60)	3 (60)	----	2 (50)
***Timing* n(%)**				
Present	1 (20)	1 (20)	1 (25)	1 (25)
Absent	4 (80)	4 (80)	3 (75)	3 (75)
Perineometry (cm/H_2O)				
Mean	6.9 (2.9)	10.3 (6.0)	5.8 (4.2)	18.5 (14.7)
Peak	7.5 (3.0)	11.4 (6.9)	7.0 (5.2)	20.0 (16.3)
***Pad test* (g)**	13.3 (8.2)	0	16.4 (12.9)	0
PFAn(%)				
Contraction perception	4 (100)	4 (100)	4 (100)	4 (100)
UI	5 (100)	4 (80)	4 (100)	3 (75)
Stress UI	4 (80)	4 (80)	3 (75)	2 (50)
Fecal incontinence	1 (20)	----	----	----
Overactive bladder	2 (40)	----	2 (50)	----
Urge UI	4 (80)	1 (20)	2 (50)	1 (25)
Urinary infection	1 (20)	----	----	----
Constipation	2 (40)	2 (40)	----	----

PFA: Pelvic floor assessment. tDCS: Transcranial direct current stimulation. UI: Urinary incontinence. Continuous variables are expressed in terms of mean (M) and standard deviation (SD).
Source: the authors (2024).

Table 4. Mean (SD) of clinical UI outcomes before and after treatment

	sham tDCS (n=5)		real tDCS (n=4)	
	Pre	Post	Pre	Post
ICIQ_SF	11.6 (2.8)	5.4 (3.0)	11.0 (4.2)	7.8 (7.5)
I-QOL				
Avoidance and limiting behavior	64.0 (11.4)	73.5 (4.5)	55.6 (13.4)	68.8 (8.5)
Psychosocial impact	64.0 (16.6)	77.3 (4.8)	68.9 (16.6)	76.7 (6.7)
Social embarrassment	35.2 (23.0)	63.2 (11.8)	44.0 (19.9)	67 (10.5)
Total	85.1 (17.3)	105.5 (5.2)	81.5 (22.9)	101.8 (12.2)
UI severity	6.8 (5.6)	2.2 (1.3)	5.5 (2.6)	4.8 (3.0)
Global perception	-1.8 (1.8)	3.4 (0.5)	-2.0 (2.9)	2.8 (1.3)
Depression	15.4 (9.8)	6.8 (6.5)	5.8 (4.8)	3.3 (3.9)
Anxiety	46.4 (34.1)	34.4 (35.1)	14.8 (7.3)	4.5 (6.5)
KHQ				
General health	40.0 (13.7)	25.0 (0.0)	18.8 (12.5)	25.0 (20.4)
UI impact	53.2 (30.0)	20.0 (29.9)	66.8 (27.4)	16.5 (19.1)
Limitations of daily activities	33.3 (23.6)	10.0 (14.5)	25.0 (21.5)	0.0 (0.0)
Physical limitations	30.0 (29.9)	3.4 (7.6)	25.0 (9.2)	8.5 (9.8)
Social limitations	15.4 (12.5)	8.8 (4.9)	2.8 (5.5)	2.8 (5.5)
Personal relationships	19.8 (18.1)	19.8 (18.1)	25.0 (32.0)	29.3 (28.5)
Emotions	51.2 (34.1)	6.6 (14.8)	13.8 (10.5)	5.5 (6.4)
Sleep and dispositions	10.0 (14.8)	0.0 (0.0)	12.5 (25.0)	4.3 (8.5)
Gravity	37.2 (14.7)	16.0 (7.7)	35.0 (22.2)	15.5 (22.2)

tDCS: Transcranial direct current stimulation. ICIQ-SF: International Consultation on Incontinence Questionnaire - Short Form (0-21). A higher score indicates a greater symptom severity. I-QOL: The Incontinence Quality of Life Questionnaire (0-100). A higher score indicates better outcome. UI Severity: Incontinence Severity Index (0-12). The higher the score, the more severe the urinary incontinence. Global perception: Perception of Global Effect (-5 to +5). A higher score indicates better outcome. Depression: Beck Depression Inventory (0-63). A higher score indicates worst depression symptom. Anxiety: Visual Analog Scale (0-100). A higher score indicates worst anxiety symptom. KHQ: King's Health Questionnaire (0-100). Decreases in KHQ domain scores indicate an improvement in the quality of life.
Source: the authors (2024).

3.1. Primary outcomes

3.1.1. Feasibility

The recruitment and retention rates were 100% (11/11) and 81.8% (9/11), respectively. Due to the social isolation caused by the COVID-19 pandemic, two patients did not complete the entire protocol. The following were the main barriers reported by participants: (1) long time for baseline assessment, requiring a longer leave of absence from work than anticipated, or requiring a longer leave of absence to return to domestic or life activities; and (2) difficulty recording urinary frequency during the day, night, and amount of loss over 24 hours using the diary provided at the baseline assessment time. Even though our research group was composed of experienced physical therapists and used all clinical measures recommended by most guidelines, our researchers in charge of assessment found the collection of baseline data to be time-consuming.

3.2. Secondary outcomes

3.2.1. Urinary loss

The amount of urinary loss, measured by the Pad Test, was completely reduced after both PFMT (13,3 g to 0) and tDCS+PFMT (16,4g to 0) protocols (Table 3).

3.2.2. Severity of incontinence

The ISI (0/better to 12/worse) showed a reduction of 67% after PFMT and 12% after tDCS+PFMT. There was only minimal clinical improvement (a reduction of one point) in the PFMT group (Table 4).

3.2.3. UI impact

The ICIQ-SF (0/better to 21/worse) demonstrated clinically important improvement in both groups. There was a 53.4% (-6.2 points) reduction in the impact of UI on quality of life after PFMT and a 29.1% (-3.2 points) reduction after tDCS+PFMT (Table 4).

3.2.4. Emotional impact

The IQOL (0/worse to 100/better) showed improvement in three domains: social behavior (14.8% PFMT and 23.7% tDCS+PFMT); psychosocial impact (20.8% and 11.3%); and embarrassment and social embarrassment (79.5% and 52.3%). The IQOL total score improved by 24.0% for the PFMT group and 24.9% for the tDCS+PFMT group (Table 4).

3.2.5. Quality of life

The KHQ (0/better to 100 points/worse) showed improvement (points reduction) in eight domains: general perception of health (-15.0 PFMT); urinary incontinence impact (-33.2 PFMT and -50.3 tDCS+PFMT); limitation of daily activities (-23.3 PFMT and -25.0 tDCS+PFMT); physical limitations (-26.6 PFMT and -16.5 tDCS+PFMT); social limitations (-6.6 PFMT); emotions (-44.6 PFMT and -8.3 tDCS+PFMT); sleep and dispositions (-10.0 PFMT and -8.2 tDCS+PFMT) and gravity (-21.2 PFMT and -19.5 tDCS+PFMT). Except for the domain of personal relationships, it demonstrated a clinically important improvement (-5 points) in all domains in at least one group (Table 4).

3.2.6. Perception of the global effect

The GPS (-5/worse to +5/better) showed an increase in the perception of recovery in both groups, with an increase of 5.2 (-1.8 pre and 3.4 post) and 4.8 points (-2.0 pre and 2.8 post) for the PFMT and tDCS+PFMT groups, respectively (Table 4).

3.2.7. Voiding Diary

The voiding diary showed important flaws and inconsistencies in the records, making its interpretation difficult.

3.3. Confusion factor

3.3.1. Depressive symptoms

The BDI (0/best to 63/worse) showed a 55.8 and 43.1% reduction for the PFMT and tDCS+PFMT groups, respectively (Table 4).

3.3.2. Anxiety

The anxiety scale (0/best to 100/worst) showed a 25.9 and 69.6% reduction for PFMT and tDCS+PFMT groups, respectively (Table 4).

3.4. Patients' satisfaction

In general, patients from both groups reported high satisfaction with assistance and they would return to the clinic for future services or treatments (Table 6 - Supplement 2).

4. Discussion

According to our review, this is the first randomized clinical trial with patient and clinical assessor blinding to evaluate the feasibility of incorporating a noninvasive brain stimulation technique into a pelvic floor muscle training program for women with urinary incontinence. Recruitment rates were 84.6%, indicating that most patients interested in physical therapy treatments combined with neuromodulation techniques attended to carry out the initial assessment. Although pelvic floor muscle training (PFMT) is considered a non-pharmacological gold standard treatment for female urinary incontinence (UI), some women do not achieve complete symptom relief.[8] This condition may prompt patients to seek and enroll in new treatment options, even if they are unfamiliar with tDCS treatment, as our participants were. Another reason for our high recruitment rate could be the expectation of symptom improvement

from tDCS therapy. Along with the recruitment rate, patient expectations of symptom improvement could explain the higher retention rate (81.8%).

There are literally hundreds of variables associated with exercise adherence[46,47], which is estimated to be 64% in the short term and 26% in the long term.[46,48] Because our participants were aware that tDCS has neuromodulatory effects on the corticospinal system and neuromuscular function, they may have been motivated to complete the treatment protocol by the prospect of cure in a short time interval and long-term maintenance. Moreover, our protocol offered the first-line treatment for UI, as all patients received exercise therapy, regardless of their tDCS allocation. This study design attempted to ensure that all participants had the same opportunity to receive the best conservative treatment available. The addition of tDCS to PFMT could improve or accelerate the exercise benefits. However, we cannot rule out the fact that our protocol was carried out in a public health service, which may have influenced patient adherence. We proposed a very purposeful approach with some features more commonly seen in private settings: (1) one-on-one service; (2) private parking, including for companions; (3) flexible hours; (4) quick rescheduling of absences; (5) telephone reminders; and (6) direct contact for questions and queries.

There are few studies investigating recruitment and retention rates using neuromodulatory techniques such as tDCS. O'Neill and colleagues (2018) demonstrated the feasibility of patient self-administration of tDCS stimulation at home in a pilot randomized controlled trial. They found a recruitment and retention rate of 100 and 87.5%, respectively.[49] According to the authors, the reasons for losses and exclusions from the analysis were pain exacerbation (sham group); failure to complete or return pain diaries; and difficulties in fitting treatment sessions into a daily schedule. We also have difficulties fulfilling the urinary diary. The main reason given was the time commitment required to carry out and follow up throughout the day. In future studies, researchers may want to exclude the voiding diary or develop alternative methods of administering these instruments, such as through telephone interviews. We also recommend prioritizing outcomes, which is required for hypothesis testing, because assessments took a long time, according to both patients and assessors.

Treatment adherence is critical in muscle strength training because results are highly dependent on regular training. We observed easy tolerance of patients to treatment in all groups, and none of the participants gave up. Studies using biofeedback and training with vaginal cones reported low adherence due to poor device tolerance. For example, several studies report treatment dropout rates of 27%, which increased to 42% after 6 months.[50] These higher dropout rates could be attributed to adverse events such as those previously described, such as the inability to use cones, pain, vaginitis, and bleeding.[51] All of our patients tolerated the use of tDCS well and performed the PFMT exercises well because they thought they were simple. At the end of treatment, patients reported higher satisfaction with care, and they would return to the clinic for future services or treatments. It is possible that these factors (tolerance, execution, and satisfaction) contribute significantly to patients' increased commitment to treatment, resulting in greater time savings and lower associated costs.

The secondary outcomes showed improvement in both PFMT alone (sham tDCS) and PFMT combined with tDCS. Urinary loss, the severity of UI and the impact of UI on quality of life assessed by the pad test, incontinence severity index (ISI) and the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), respectively, reached a minimal clinically important difference.[52-54]

Adding tDCS to pelvic floor muscle training can enhance the benefits of exercise therapies by improving motor signals from the brain to lower motor neurons (corticospinal tract). Some evidence suggests that tDCS improves neural factors such as motor unit synchronization.[20,55] In this context, improving motor unit recruitment strategies induced by tDCS may optimize pelvic floor muscle exercise. As a result, pelvic floor muscle activation can be improved, particularly during exercise therapies for women suffering from urinary incontinence. In addition to improving motor drive and muscle performance, tDCS technique is considered safe and well-tolerated. Adverse events such as tingling, itching, or burning sensation, headache is frequently observed, but with mild magnitude and generally disappear after the end of stimulation.[56] Taken together, these results suggest that transcranial direct current stimulation can be

used as an adjuvant therapy to pelvic floor muscle training treatments. There have been few studies on the efficacy of tDCS on female bladder problems. In a randomized double-blind controlled trial, 30 women with multiple sclerosis, urinary incontinence, and pelvic floor muscle (PFM) dysfunctions were divided into two groups: anodal tDCS applied to the primary motor cortex (M1) combined with PFMT and sham tDCS + PFMT. For eight weeks, tDCS (20 min, 1.5 mA, electrodes 5 x 7 cm) was used concurrently with PFMT three times per week. When the experimental group was compared to the control group, a significant improvement in PFM function occurred in the fourth week of intervention and lasted for one month. Both groups reported significant improvements in PFM function at 8 weeks compared to baseline. Although the UI was reduced in both groups after 8 weeks, the benefits were only maintained in the active tDCS group until the 1-month follow-up.[57]

The main limitation of this study is the small sample size, which prevented inferential statistical analyses about the efficacy of tDCS combined with PFMT from being performed. Given the impact of the UI on quality of life (ICIQ-SF) and the results for post-treatment tDCS+PFMT (M = 7.8 ± 7.5) and sham tDCS+PFMT (M = 5.4 ± 3.0), with an effect size of 0.23, α = 0.05, and a power of 80%, a total of 96 subjects would be required for full randomized clinical trials.

5. Conclusion

The feasibility results show that tDCS as an adjunct therapy to PFMT treatment of female urinary incontinence has a high recruitment and retention rate, as well as promising preliminary results. These findings support the recommendation for a full RCT, with outcome prioritization required for hypothesis testing.

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Authors' contributions

Brandão AMC, Dias SFL, Monteiro MGCT and Hazime FA were responsible for the study design and data collection. Brandão AMC, Dias SFL, Monteiro MGCT, Nunes JMO, Lopes TS, Baptista AF, Sá KN and Hazime FA were responsible for data analysis and interpretation, as well as manuscript drafting and critical review.

Conflicts of interest

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

References

1. Haylen BT, Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Neurourol Urodyn. 2010;29(1):4-20. http://dx.doi.org/10.1002/nau.20798

2. Aoki Y, Brown HW, Brubaker L, Cornu JN, Daly JO, Cartwright R. Urinary incontinence in women. Nat Rev Dis Primers. 2017;3:17097. http://dx.doi.org/10.1038/nrdp.2017.97

3. Sinclair AJ, Ramsay IN. The psychosocial impact of urinary incontinence in women. Obstet Gynaecol. 2011;13(3):143-8. http://doi.wiley.com/10.1576/toag.13.3.143.27665

4. Rubilotta E, Balzarro M, D'Amico A, Cerruto MA, Bassi S, Bovo C, et al. Pure stress urinary incontinence: analysis of prevalence, estimation of costs, and financial impact. BMC Urol. 2019;19(1):44. http://dx.doi.org/10.1186/s12894-019-0468-2

5. Sarikaya S, Yildiz FG, Senocak C, Bozkurt OF, Karatas OF. Urinary incontinence as a cause of depression and sexual dysfunction: Questionnaire-based study. Rev Int Androl. 2020;18(2):50-4. http://dx.doi.org/10.1016/j.androl.2018.08.003

6. Wu JM, Vaughan CP, Goode PS, Redden DT, Burgio KL, Richter HE, et al. Prevalence and Trends of Symptomatic Pelvic Floor Disorders in U.S. Women. Obstet Gynecol. 2014;123(1):141-8. https://doi.org/10.1097/aog.0000000000000057

7. Xue K, Palmer MH, Zhou F. Prevalence and associated factors of urinary incontinence in women living in China: a literature review. BMC Urol. 2020;20(1):159. http://dx.doi.org/10.1186/s12894-020-00735-x

8. Dumoulin C, Cacciari LP, Hay-Smith EJC. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev. 2018;10(10):CD005654. http://dx.doi.org/10.1002/14651858.CD005654.pub4

9. Kegel AH. Progressive resistance exercise in the functional restoration of the perineal muscles. Am J Obstet Gynecol. 1948;56(2):238-48. http://dx.doi.org/10.1016/0002-9378(48)90266-x

10. Dumoulin C, Hay-Smith J, Frawley H, McClurg D, Alewijnse D, Bo K, et al. 2014 consensus statement on improving pelvic floor muscle training adherence: International Continence Society 2011 State-of-the-Science Seminar. Neurourol Urodyn. 2015;34(7):600-5. http://dx.doi.org/10.1002/nau.22796

11. O'Neill AT, Hockey J, O'Brien P, Williams A, Morris TP, Khan T, et al. Knowledge of pelvic floor problems: a study of third trimester, primiparous women. Int Urogynecol J. 2017;28(1):125-9. http://dx.doi.org/10.1007/s00192-016-3087-4

12. Ayeleke RO, Hay-Smith EJC, Omar MI. Pelvic floor muscle training added to another active treatment versus the same active treatment alone for urinary incontinence in women. Cochrane Database Syst Rev. 2015;2015(11):CD010551. http://dx.doi.org/10.1002/14651858.CD010551.pub3

13. Tadic SD, Griffiths D, Schaefer W, Cheng CI, Resnick NM. Brain activity measured by functional magnetic resonance imaging is related to patient reported urgency urinary incontinence severity. J Urol. 2010;183(1):221-8. http://dx.doi.org/10.1016/j.juro.2009.08.155

14. Harvie C, Weissbart SJ, Kadam-Halani P, Rao H, Arya LA. Brain activation during the voiding phase of micturition in healthy adults: A meta-analysis of neuroimaging studies. Clin Anat. 2019;32(1):13-9. https://doi.org/10.1002/ca.23244

15. Kitta T, Mitsui T, Kanno Y, Chiba H, Moriya K, Shinohara N. Brain-bladder control network: the unsolved 21st century urological mystery. Int J Urol. 2015;22(4):342-8. https://doi.org/10.1111/iju.12721

16. Vacher P, Charlanes A, Chesnel C, Pagès A, Malot C, Le Breton F, et al. Intérêt de la stimulation transcrânienne dans les troubles pelvi-périnéaux. Progrès en Urologie. 2019;29(7):349-59. https://doi.org/10.1016/j.purol.2019.03.001

17. Griffiths D, Clarkson B, Tadic SD, Resnick NM. Brain Mechanisms Underlying Urge Incontinence and its Response to Pelvic Floor Muscle Training. J Urol. 2015;194(3):708-15. http://dx.doi.org/10.1016/j.juro.2015.03.102

18. Nitsche MA, Paulus W. Excitability changes induced in the human motor cortex by weak transcranial direct current stimulation. J Physiol. 2000;527 Pt 3(Pt 3):633-9. http://dx.doi.org/10.1111/j.1469-7793.2000.t01-1-00633.x

19. Nitsche MA, Paulus W. Sustained excitability elevations induced by transcranial DC motor cortex stimulation in humans. Neurology. 2001;57(10):1899-901. http://dx.doi.org/10.1212/wnl.57.10.1899

20. Krishnan C, Ranganathan R, Kantak SS, Dhaher YY, Rymer WZ. Anodal transcranial direct current stimulation alters elbow flexor muscle recruitment strategies. Brain Stimul. 2014;7(3):443-50. http://dx.doi.org/10.1016/j.brs.2014.01.057

21. Machado S, Jansen P, Almeida V, Veldema J. Is tDCS an Adjunct Ergogenic Resource for Improving Muscular Strength and Endurance Performance? A Systematic Review. Front Psychol. 2019;10:1127. http://dx.doi.org/10.3389/fpsyg.2019.01127

22. O'Connell NE, Marston L, Spencer S, DeSouza LH, Wand BM. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev. 2018;3:CD008208. https://doi.org/10.1002/14651858.CD008208.pub4

23. Schabrun SM, Jones E, Cancino ELE, Hodges PW. Targeting chronic recurrent low back pain from the top-down and the bottom-up: a combined transcranial direct current stimulation and peripheral electrical stimulation intervention. Brain Stimul. 2014;7(3):451-9. http://dx.doi.org/10.1016/j.brs.2014.01.058

24. Mendonca ME, Simis M, Grecco LC, Battistella LR, Baptista AF, Fregni F. Transcranial Direct Current Stimulation Combined with Aerobic Exercise to Optimize Analgesic Responses in Fibromyalgia: A Randomized Placebo-Controlled Clinical Trial. Front Hum Neurosci. 2016;10:68. https://doi.org/10.3389/fnhum.2016.00068

25. Hazime FA, Baptista AF, Freitas DG, Monteiro RL, Maretto RL, Hasue RH, et al. Treating low back pain with combined cerebral and peripheral electrical stimulation: A randomized, double-blind, factorial clinical trial. Eur J Pain. 2017;21(7):1132-43. http://dx.doi.org/10.1002/ejp.1037

26. Persu C, Chapple CR, Cauni V, Gutue S, Geavlete P. Pelvic Organ Prolapse Quantification System (POP-Q) - a new era in pelvic prolapse staging. J Med Life. 2011;4(1):75-81. Cited: PMID: 21505577.

27. Burkhard FC, Bosch JLHR, Cruz F, Lemack GE, Nambiar AK, Thiruchelvam N, et al. EAU guidelines on Urinary incontinence in adults [Internet]. Netherlands: European Association of Urology; 2020. Available from: https://uroweb.org/eau-guidelines/discontinued-topics/urinary-incontinence

28. Husband CJ, Wharf-Higgins J, Rhodes RE. A feasibility randomized trial of an identity-based physical activity intervention among university students. Health Psychol Behav Med. 2019;7(1):128-46. http://dx.doi.org/10.1080/21642850.2019.1600407

29. Jackson N, Waters E, Guidelines for Systematic Reviews in Health Promotion and Public Health Taskforce. Criteria for the systematic review of health promotion and public health interventions. Health Promot Int. 2005;20(4):367-74. http://dx.doi.org/10.1093/heapro/dai022

30. O'Sullivan R, Karantanis E, Stevermuer TL, Allen W, Moore KH. Definition of mild, moderate and severe incontinence on the 24-hour pad test. BJOG. 2004;111(8):859-62. https://doi.org/10.1111/j.1471-0528.2004.00211.x

31. Pereira VS, Santos JYC, Correia GN, Driusso P. Translation and validation into Portuguese of a questionnaire to evaluate the severity of urinary incontinence. Rev Bras Ginecol Obstet. 2011;33(4):182-7. https://doi.org/10.1590/S0100-72032011000400006

32. Tamanini JTN, Dambros M, D'Ancona CAL, Palma PCR, Netto Jr NR. Validation of the "International Consultation on Incontinence Questionnaire - Short Form" (ICIQ-SF) for Portuguese. Rev Saúde Pública. 2004;38(3). http://dx.doi.org/10.1590/s0034-89102004000300015

33. Tamanini JTN, D'Ancona CAL, Botega NJ, Netto Jr NR. Validation of the Portuguese version of the King's Health Questionnaire for urinary incontinent women. Rev Saúde Pública. 2003;37(2):203-11. https://doi.org/10.1590/S0034-89102003000200007

34. Souza CCC, Rodrigues AM, Ferreira CE, Fonseca ESM, Bella ZIKJ, Girão MJBC, et al. Portuguese validation of the Urinary Incontinence-Specific Quality-of-Life Instrument: I-QOL. Int Urogynecol J. 2009;20(10):1183-9. http://dx.doi.org/10.1007/s00192-009-0916-8

35. Laycock J, Jerwood D. Pelvic Floor Muscle Assessment: The PERFECT Scheme. Physiotherapy. 2001;87(12):631-42. https://doi.org/10.1016/S0031-9406(05)61108-X

36. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bø K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. Neurourol Urodyn. 2006;25(3):236-42. http://dx.doi.org/10.1002/nau.20201

37. Roza T, Mascarenhas T, Araujo M, Trindade V, Jorge RN. Oxford Grading Scale vs manometer for assessment of pelvic floor strength in nulliparous sports students. Physiotherapy. 2013;99(3):207-11. http://dx.doi.org/10.1016/j.physio.2012.05.014

38. Brown JS, McNaughton KS, Wyman JF, Burgio KL, Harkaway R, Bergner D, et al. Measurement characteristics of a voiding diary for use by men and women with overactive bladder. Urology. 2003;61(4):802-9. http://dx.doi.org/10.1016/s0090-4295(02)02505-0

39. Bright E, Drake MJ, Abrams P. Urinary diaries: evidence for the development and validation of diary content, format, and duration. Neurourol Urodyn. 2011;30(3):348-52. http://dx.doi.org/10.1002/nau.20994

40. Costa LOP, Maher CG, Latimer J, Ferreira PH, Ferreira ML, Pozzi GC, et al. Clinimetric testing of three self-report outcome measures for low back pain patients in Brazil: which one is the best?. Spine. 2008;33(22):2459-63. http://dx.doi.org/10.1097/BRS.0b013e3181849dbe

41. Gorenstein C, Andrade L. Validation of a Portuguese version of the Beck Depression Inventory and State-Trait Anxiety Inventory in Brazilian subjects. Braz J Med Biol Res. 1996;29(4):453-7. Cited: PMID: 8736107.

42. Williams VSL, Morlock RJ, Feltner D. Psychometric evaluation of a visual analog scale for the assessment of anxiety. Health Qual Life Outcomes. 2010;8:57. http://dx.doi.org/10.1186/1477-7525-8-57

43. Beattie P, Turner C, Dowda M, Michener L, Nelson R. The MedRisk Instrument for Measuring Patient Satisfaction With Physical Therapy Care: a psychometric analysis. J Orthop Sports Phys Ther. 2005;35(1):24-32. http://dx.doi.org/10.2519/jospt.2005.35.1.24

44. Herwig U, Satrapi P, Schönfeldt-Lecuona C. Using the international 10-20 EEG system for positioning of transcranial magnetic stimulation. Brain Topogr. 2003;16(2):95-9. http://dx.doi.org/10.1023/b:brat.0000006333.93597.9d

45. Carlsen AN, Eagles JS, MacKinnon CD. Transcranial direct current stimulation over the supplementary motor area modulates the preparatory activation level in the human motor system. Behav Brain Res. 2015;279:68-75. http://dx.doi.org/10.1016/j.bbr.2014.11.009

46. Sluijs EM, Knibbe JJ. Patient compliance with exercise: Different theoretical approaches to short-term and long-term compliance. Patient Educ Couns. 1991;17(3):191-204. https://doi.org/10.1016/0738-3991(91)90060-I

47. Howard DB, Gosling CM. A short questionnaire to identify patient characteristics indicating improved compliance to exercise rehabilitation programs: A pilot investigation. Int J Osteopath Med. 2008;11(1):7-15. https://doi.org/10.1016/j.ijosm.2007.12.002

48. Borello-France D, Burgio KL, Goode PS, Markland AD, Kenton K, Balasubramanyam A, et al. Adherence to behavioral interventions for urge incontinence when combined with drug therapy: adherence rates, barriers, and predictors. Phys Ther. 2010;90(10):1493-505. http://dx.doi.org/10.2522/ptj.20080387

49. O'Neill F, Sacco P, Bowden E, Asher R, Burnside G, Cox T, et al. Patient-delivered tDCS on chronic neuropathic pain in prior responders to TMS (a randomized controlled pilot study). J Pain Res. 2018;11:3117-28. http://dx.doi.org/10.2147/JPR.S186079

50. Oláh KS, Bridges N, Denning J, Farrar DJ. The conservative management of patients with symptoms of stress incontinence: a randomized, prospective study comparing weighted vaginal cones and interferential therapy. Am J Obstet Gynecol. 1990;162(1):87-92. http://dx.doi.org/10.1016/0002-9378(90)90827-t

51. Bø K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. BMJ. 1999;318(7182):487-93. http://dx.doi.org/10.1136/bmj.318.7182.487

52. Barber MD, Spino C, Janz NK, Brubaker L, Nygaard I, Nager CW, et al. The minimum important differences for the urinary scales of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. Am J Obstet Gynecol. 2009;200(5):580.e1-7. http://dx.doi.org/10.1016/j.ajog.2009.02.007

53. Lim R, Liong ML, Lim KK, Leong WS, Yuen KH. The Minimum Clinically Important Difference of the International Consultation on Incontinence Questionnaires (ICIQ-UI SF and ICIQ-LUTSqol). Urology. 2019;133:91-5. http://dx.doi.org/10.1016/j.urology.2019.08.004

54. Abdel-fattah M, Barrington JW, Youssef M. The standard 1-hour pad test: does it have any value in clinical practice?. Eur Urol. 2004;46(3):377-80. http://dx.doi.org/10.1016/j.eururo.2004.04.018

55. Dutta A, Krishnan C, Kantak SS, Ranganathan R, Nitsche MA. Recurrence quantification analysis of surface electromyogram supports alterations in motor unit recruitment strategies by anodal transcranial direct current stimulation. Restor Neurol Neurosci. 2015;33(5):663-9. http://dx.doi.org/10.3233/RNN-140469

56. Matsumoto H, Ugawa Y. Adverse events of tDCS and tACS: A review. Clin Neurophysiol Pract. 2017;2:19-25. http://dx.doi.org/10.1016/j.cnp.2016.12.003

57. Ramezani M, Ehsani F, Delkhosh CT, Masoudian N, Jaberzadeh S. Concurrent multi-session anodal trans-cranial direct current stimulation enhances pelvic floor muscle training effectiveness for female patients with multiple sclerosis suffering from urinary incontinence and pelvic floor dysfunction: a randomized clinical trial study. Int Urogynecol J. 2023;34:1771-9. http://dx.doi.org/10.1007/s00192-022-05429-6

Supplementary files

Supplement 1. Table 5. Exercise therapy protocol for type I and type II muscle fibers

Exercise	Position	Sets/Duration*
First week		
1. Perineal awareness	Pelvic floor muscles contraction ("contract in and relaxing out") in dorsal decubitus with bipedal support (bridge).	3 sets of 10 repetitions
2. Pelvic lift	Pelvic floor muscle contraction (phasic fibers) in dorsal decubitus with bipedal support and pelvis elevation (bridge)	3 sets of 10 repetitions
3. Pelvic anteversion and retroversion	Sitting on a Swiss ball (hip flexion), performing pelvic retroversion with contraction of the pelvic floor muscles (fast fibers). Relaxing during anteversion	3 sets of 10 repetitions
4. Pelvic anteversion and retroversion	Sitting on a Swiss ball (hip flexion), performing pelvic retroversion with (holding 5s) contraction of pelvic floor muscles (tonic fibers). Relaxing during anteversion	3 sets of 8 repetitions
Second week		
1. Knee flexion	Knee flexion (up to 30°) in the orthostatic position associated with contraction of the pelvic floor muscles	3 sets of 10 repetitions
2. Knee flexion + horizontal shoulder abduction	Knee flexion (up to 30°) in the orthostatic position associated with horizontal shoulder resistance (elastic bands) abduction (90°) and pelvic floor muscle contraction (fast fibers)	3 sets of 10 repetitions
3. Hip adduction	Bass squeeze in the orthostatic position (knee flexion up to 30°) associated with pelvic floor muscle contraction (fast fibers)	3 sets of 10 repetitions
4. Knee flexion	Knee flexion (up to 30°) in the orthostatic position associated with (holding 5s) contraction of the pelvic floor muscles	3 sets of 8 repetitions
Third week		
1. Knee flexion + shoulder abduction	Knee flexion (up to 30°) in the orthostatic position associated with 90° shoulder abduction and contraction of the pelvic floor muscles	3 sets of 10 repetitions
2. Plantar flexion	Plantar flexion in the orthostatic position associated with contraction of the pelvic floor muscles (fast fibers)	3 sets of 10 repetitions
3. Pelvic elevation	Walking up and down the stairs with pelvic floor muscle contraction (fast fibers)	3 sets of 10 repetitions
4. Knee flexion + shoulder abduction	Knee flexion (up to 30°) in the orthostatic position associated with 90° shoulder abduction and (holding 5s) contraction of the pelvic floor muscles	3 sets of 8 repetitions
Fourth week		
1. Pelvic elevation	Walking up and down the stairs with pelvic floor muscle contraction (fast fibers)	3 sets of 10 repetitions
2. Jump	Jumping on a trampoline associated with pelvic floor muscle contraction (fast fibers)	3 sets of 10 repetitions
3. Hip hyperextension	Hip hyperextension in the orthostatic position (contralateral knee flexed) associated with pelvic floor muscle contraction (fast fibers)	3 sets of 10 repetitions
4. Hip hyperextension	Hip hyperextension in the orthostatic position (contralateral knee flexed) associated with (holding 5s) pelvic floor muscle contraction	3 sets of 8 repetitions

*Minimum of 30s of rest between series.
Source: the authors (2024).

Supplement 2. Table 6. Patients' satisfaction with physical therapy care (MedRisk)

Factors/Questions	Sham tDCS+PFMT (n=5)	tDCS+PFMT (n=4)
Interpersonal		
The office receptionist was courteous	4.8 ± 0.4	4.5 ± 0.5
The registration process was appropriate	4.8 ± 0.4	5.0 ± 0.0
The waiting area was comfortable (lighting, temperature, furnishings)	4.8 ± 0.4	4.8 ± 0.4
My therapist treated me respectfully	5.0 ± 0.0	4.8 ± 0.4
The office staff was respectful	4.8 ± 0.4	3.0 ± 2.0
The office and its facilities were clean	4.8 ± 0.4	4.3 ± 0.8
Convenience and Efficiency		
The office hours were convenient for me	4.8 ± 0.4	5.0 ± 0.0
My therapist thoroughly explained the treatment(s) I received	5.0 ± 0.0	4.5 ± 0.5
My therapist answered all my questions	4.8 ± 0.4	4.8 ± 0.4
Patient Education		
My therapist advised me on ways to avoid future problems	4.8 ± 0.4	4.5 ± 0.5
My therapist gave me detailed instructions regarding my home program	5.0 ± 0.0	4.3 ± 0.8
Global		
Overall, I am completely satisfied with the services I received from my therapist	5.0 ± 0.0	4.8 ± 0.4
I would return to this office for future services or care	4.8 ± 0.4	5.0 ± 0.0

PFMT: Pelvic floor muscle training. tDCS: Transcranial direct current stimulation. MedRisk: The score ranges from 1 to 5, where high scores indicate high satisfaction. Data are expressed as mean and standard deviation.
Source: the authors (2024).