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ORIGINAL RESEARCH

Effects of Transcranial Direct Current Stimulation and Pelvic Floor Muscle Training in Women: protocol for a controlled, randomized, double-blind clinical trial

Efeitos da estimulação transcraniana por corrente contínua e treinamento muscular do assoalho pélvico em mulheres: protocolo para um ensaio clínico controlado, randomizado e duplo-cego

Efectos de la estimulación transcraneal por corriente directa y del entrenamiento muscular del suelo pélvico en mujeres: protocolo de un ensayo clínico controlado, aleatorizado y doble ciego

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ABSTRACT | Pelvic floor muscle weakness can lead to urinary incontinence, pelvic organ prolapse, and sexual dysfunction. Although it can be minimized by pelvic floor muscle training (PFMT), its effects are not lasting. Therefore, using combination therapy seems promising. This study aims to evaluate the effect of transcranial direct current stimulation (tDCS) combined with PFMT on intravaginal pressure, pelvic floor muscle strength (PFMS), sexual function (SF), and quality of life (QoL) in healthy women. A total of 32 women, aged from 18 to 45 years, will undergo PFMT (with perineal contractions and relaxation) with the aid of pressure biofeedback associated with active tDCS or sham tDCS. Sessions will last 20 minutes, three times per week, for four weeks, totaling 12 sessions. During the protocol, participants will be instructed to also perform the home-based PFMT daily. The tDCS anodal electrode will be positioned over the supplementary motor area of the dominant cortical hemisphere, whereas the cathodal will be over the contralateral supraorbital region, with a 2mA intensity for 20 minutes. Intravaginal pressure (pressure gauge), PFM strength (measured by digital palpation and the PERFECT scheme), FSFI (Female Sexual Function Index), and QoL (SF-36 questionnaire) will be evaluated before and after the 12 sessions and after a 30-day follow-up.

Keywords | Pelvic Floor; Transcranial Direct Current Stimulation (tDCS); Intravaginal Pressure; Sexual Function; Quality of Life.

RESUMO | A fraqueza muscular do assoalho pélvico pode gerar incontinência urinária, prolapso de órgãos pélvicos e disfunção sexual, e pode ser minimizada pelo treinamento muscular do assoalho pélvico (TMAP). No entanto, este efeito não é duradouro. Assim, terapia combinada parece ser promissora para a melhora deste quadro. Dessa forma, objetiva-se avaliar o efeito da estimulação transcraniana por corrente contínua (ETCC), combinada ao TMAP, sobre a pressão intravaginal, força muscular do assoalho pélvico (FMAP), função sexual (FS) e qualidade de vida (QV) em mulheres saudáveis. Serão 32 mulheres, entre 18 e 45 anos, que realizaram TMAP (contrações e relaxamento do

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períneo) e Biofeedback associados a ETCC ativa ou ETCC sham por 20 minutos, três vezes por semana, por 4 semanas, totalizando 12 sessões. Durante o protocolo, as participantes também realizarão diariamente, em domicílio, o TMAP. O eletrodo anodal da ETCC será posicionado sobre a área motora suplementar do hemisfério cortical dominante, e o catodal sobre a região supraorbital contralateral, com intensidade de 2mA, por 20 minutos. A pressão intravaginal (manômetro de pressão), FMAP (palpação digital, esquema Perfect), FS (Índice de Função Sexual Feminina) e QV (questionário SF-36) foram avaliadas antes e depois das 12 sessões, bem como após acompanhamento de 30 dias.

Descritores | Assoalho Pélvico; Estimulação Transcraniana Por Corrente Contínua (ETCC); Pressão Intravaginal; Função Sexual; Qualidade de Vida.

RESUMEN | La debilidad de la musculatura del suelo pélvico puede provocar incontinencia urinaria, prolapso de órganos pélvicos y disfunción sexual, y puede minimizarse mediante el entrenamiento de la musculatura del suelo pélvico (EMSP). Sin embargo, este efecto no es duradero. En este contexto, una terapia combinada puede ser prometedora para mejorar la situación. Este estudio tiene por objetivo evaluar el efecto de la estimulación transcraneal por corriente directa (ETCC) combinada con EMSP sobre la presión intravaginal, la fuerza muscular del suelo pélvico (FMSP), la función sexual (FS) y la calidad de vida (CV) en mujeres sanas. Participarán 32 mujeres, de entre 18 y 45 años, que se someterán a EMSP (contracciones y relajación del perineo) y a Biofeedback asociado a ETCC activa o ETCC sham durante 20 minutos, tres veces por semana, durante 4 semanas, con un total de 12 sesiones. Durante el protocolo, las participantes también se someterán diariamente a EMSP en casa. El electrodo anodal de la ETCC se colocará sobre el área motora suplementaria del hemisferio cortical dominante, y el electrodo catodal sobre la región supraorbital contralateral, a una intensidad de 2 mA, durante 20 minutos. Se evaluarán la presión intravaginal (manómetro), la FMSP (palpación digital, esquema Perfect), la FS (Índice de Función Sexual Femenina) y la CV (cuestionario SF-36) antes y después de las 12 sesiones, así como tras un seguimiento de 30 días.

Palabras clave | Suelo pélvico; Estimulación Transcraneal por Corriente Directa (ETCC); Presión Intravaginal; Función Sexual; Calidad de Vida..

INTRODUCTION

The strength of the pelvic floor muscles (PFM) in women may be altered after pregnancy and childbirth, during menopause, or due to obesity[1], which can trigger urinary and fecal incontinence, organ prolapse, and sexual dysfunction[2]. Moreover, it affects physical and psychological aspects, with consequent decrease in personal hygiene and quality of life, culminating in depression, low self-esteem, discomfort, feelings of helplessness, and mood changes[3].

To minimize these issues and even enhance it, pelvic floor muscle training (PFMT), in a preventive manner, has been shown to have positive effects for improving sexual function, arousal, vaginal lubrication, and orgasm[5,6], also preventing urinary incontinence after pregnancy[4]. PFMT was introduced by Kegel[7] and continues to be the first line of conservative treatment for urinary incontinence[8]. However, the poor adherence to training demonstrates that these exercises can be somewhat disappointing[9]. For this reason, seeking alternatives to enhance the effects of training seems to be beneficial. Transcranial direct current stimulation (tDCS) can be a tool for this purpose.

The tDCS is considered a neuromodulatory intervention since it modifies the excitability and spontaneous neuronal activity of exposed tissue via depolarization or hyperpolarization of the resting membrane potential[10,11]. Recent studies have shown the combination of tDCS with other therapies potentiates and prolongs their effects[12]. In the last two decades, tDCS has become a relevant tool in the cortical mechanisms of neural plasticity and motor learning, providing lasting changes in cortical excitability[13]. Shafi et al.[14] reported that cortical stimulation for long periods provides long-lasting effects on brain function by increasing the intrinsic plasticity of the motor-sensory system, which may increase the efficacy of other therapies. Kim et al.[15] suggest that the administration of tDCS combined with physical therapy may be more beneficial than functional training alone, since combined therapy provides a specific input to the motor cortex, facilitating both neural activation and synaptic plasticity to promote functional recovery.

Therefore, the hypothesis of this study is that the PFMT combined with tDCS applied to the supplementary motor area may potentiate the effects of training and maintain the results for longer. Some studies[16,17], involving healthy men and women who performed rhythmic PFM contractions, have shown that the supplementary motor region is a specific area of the cerebral cortex for the activation of these muscles.

Therefore, this study aims to evaluate the effect of tDCS combined with PFMT on intravaginal pressure, sexual function, and quality of life in healthy women.

METHODOLOGY

Study design

This is a protocol of a randomized, sham-controlled, double-blind longitudinal clinical trial, which will include 32 women recruited by disseminating flyers at the Nove de Julho University (UNINOVE). The analyses will be conducted at the UNINOVE's Laboratory of Neuromodulation, Functionality, and Analysis of the Human Movement (LANFAM).

Participants

Inclusion criteria will comprise nulliparous women, sexually active, aged from 18 to 45 years, and without complaints of incontinence, urinary infection, and/or cognitive impairment, as evaluated by the mini-mental status examination (MMSE)[18].

Exclusion criteria will be women with contraindications to tDCS; pelvic organ prolapse greater than Stage I following the pelvic organ prolapse quantification system (POP-Q)[19]; pregnant women; those diagnosed with cancer or undergoing palliative care therapy in the pelvic region; undergoing treatment for a urinary tract infection; or another condition in the pelvic region. Participants must sign an informed consent form and their data will be kept confidential.

Randomization

A researcher not involved in the study will randomize participants to two intervention protocols: the experimental group (active tDCS combined with PFMT) and the control group (sham tDCS combined with PFMT) (Figure 1). This process will use www.randomizer.org website (using random block assignment).

	Inscription	Allocation	Post-allocation 1-4 weeks 3 times per week, totalling 12 sessions					Follow-up 30 days
TIME POINT	*-t1*	0	*t1*	*t2*	*t3*	*t4*	*t5*	*t6*
INSCRIPTION:								
Eligibility	X							
Informed consent	X							
Allocation		X						
INTERVENTION:								
[Active tDCS + PFMT + Biofeedback]			●	—	—	●		
[Sham tDCS + PFMT + Biofeedback]			●	—	—	●		
ASSESSMENTS:								
Intravaginal pressure, digital palpation, PERFECT scheme, sexual function, and quality of life		X					X	X

Figure 1. Timeline of development, interventions, and evaluations (SPIRIT Model). tDCS – Transcranial Direct Current Stimulation. PFMT – Pelvic Floor Muscle Training.

Interventions

Pelvic Floor Muscle Training (PFMT)

Before the training sessions, individual instructions will be given on the anatomy and function of the pelvic floor, as well as how to contract the muscle. All instructions will be given individually, only once, seven days before the intervention, for 60 minutes, as described in a similar study[20]. Participants will be accommodated in the supine position for the PFMT, on a stretcher, with the knees slightly bent and hip abduction, with the lower limbs uncovered, as this position offers a better assessment of isolated muscle contraction[21].

The PFMT will be conducted with the aid of pressure biofeedback, designed for training pelvic floor muscles (Perina Urogynecologic Biofeedback, Quark, Brazil).

After zeroing the pressure level on the scale and putting on the procedure gloves, the intracavitary probe, covered by a disposable condom with a lubricating gel, will be introduced into the vaginal canal by the participant herself, so that the rubber disc rests on the perineum. The researcher will then slowly inflate it until the participant feels the contact of the probe with the vaginal wall.

After adjusting the probe and visualizing the biofeedback output signal, the participant will contract the muscles of the perineum, sustaining the contraction for four to six seconds, followed by 10 seconds of relaxation—with the commands contract and relax. This procedure will be repeated for 20 minutes. The training will involve three sessions per week for four weeks, totaling 12 sessions.

All participants will be instructed to avoid activation or contraction of the abdomen, gluteus, and hip adductor muscles during PFM contraction. At the end of treatment, the probe will be deflated slightly and cautiously withdrawn from the vaginal canal.

Home-based PFMT: both groups will be encouraged to perform three sets of 10 repetitions daily for four weeks, at home, for the duration of the in-clinic training protocol with the researcher. The home-based PFMT protocol will be customized and based on the secondary PERFECT assessment. All exercises will be conducted in the sitting or supine position. Participants will be instructed to contract and keep the PFM contracted for one to 10 seconds (time corresponds to the record obtained during the initial assessment), followed by rapid contractions (calculated in the same way).

A set will consist of 10 repetitions of this action (endurance followed by double rest and rapid contractions). For example, if the PERFECT scheme is 6/3 (endurance/fast), participants will hold contractions for six seconds, with twice as much rest time between each one, followed by three rapid contractions. The participants' PFM will be evaluated weekly for adjustments and training progression[22].

At the end of the four-week protocol, the participants will be instructed to interrupt the home exercises, to verify if the results will be maintained after 30 days without training.

Active Transcranial Direct Current Stimulation (tDCS)

The neuroConn DC-Stimulator Plus device will be used for the stimulation procedures. The tDCS anodal electrode (5×5cm) will be positioned over the supplementary motor area (SMA), while the cathodal (5×7cm) will be placed over the contralateral supraorbital region (Fp2) (Figure 2). Both wrapped in a sponge soaked in saline solution. The 2mA current will be administered for 20 minutes in each session, during which the participant will perform the PFMT with biofeedback.

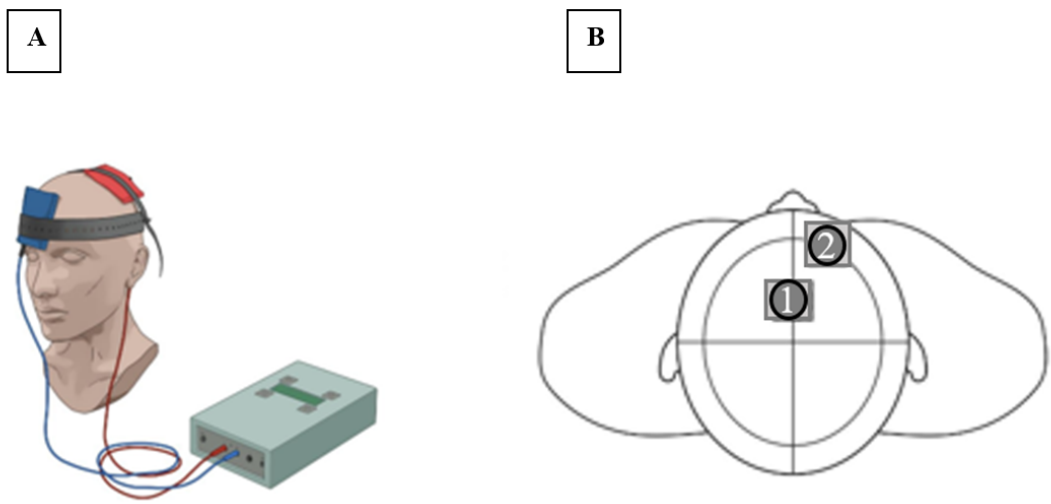

Figure 2: (A) Transcranial direct current stimulation device; (B) positioning of the anode electrode, over supplementary motor area (1) positioning of the cathode, over supraorbital area contralateral to the anode (2). Source: elaborated by the authors.

Sham tDCS

Sham tDCS will be performed with the same device and assembly as the active stimulation group, but with the device being activated for 60 seconds and turned off. When the device is powered on, the current intensity will gradually increase during the first 30 seconds (ramp-up), then gradually decrease during the last

30 seconds (ramp-down). Thus, participants will have a tingling or itching sensation due to the initial electrical stimulation, but they will not receive the continuous current. This procedure will contribute to the "blinding" effect during collection, which can ensure a control effect[3].

Blinding

The NeuroConn DC-Stimulator Plus device presents active and sham stimulation modes. A researcher not involved in the protocol will program the equipment with the codes. The type of stimulation (active or sham) will not be externally noticeable. Therefore, neither the researcher nor the participant will know which treatment is being received (double-blind study).

Outcomes

All assessments will be conducted at the beginning of the study (pre-intervention), after the 12th intervention session (post-intervention), and 30 days after the end of the intervention sessions (follow-up). All participants will be instructed to avoid activation or contraction of the abdomen, gluteus, and hip adductor muscles during assessments[24].

Primary outcome – Intravaginal pressure

The maximum voluntary contraction pressure will be evaluated using a Peritron™ pressure gauge (Laborie Medical – Canada), a reliable and validated method—with 0.98 intraclass correlation[24].

A conical vaginal catheter will be used, with a 26nm diameter and 108nm length, with 33nm active surface measurement. The vaginal catheter, covered with a sterile condom, is connected to a portable microprocessor with a latex tube, which allows the transmission of pressure in centimeters of water (cmH_2O) when compressed by external pressure.

The catheter will be inserted into the vaginal canal until the entire length of the compressible part of the device is above the participant's hymenal ring. Baseline pressure will be recorded, and after the catheter is inflated to $100cmH_2O$, the device will be reset. PFM voluntary contraction will be requested up to their maximum strength, sustaining it for 4 to 6 seconds in a sequence of three consecutive contractions, with an 8-second interval between each, considering the average of the three contractions[21]. At the end, the probe will be deflated slightly and cautiously withdrawn from the vaginal canal.

Secondary outcome – Digital palpation

The contraction strength of the PFM will be measured using the bi-digital examination. The examiner's fingers will be positioned in a hook-like manner approximately four to six centimeters from the vaginal introitus, using a disposable plastic gynecological glove coated with lubricating gel. The modified Oxford scale will be used to quantify muscle function[25], which measures muscle contraction against resistance from 0 (no contraction) to 5 (strong contraction). The reliability of this method, using the intraclass correlation coefficient, is 0.95[26]. The participant will be instructed to perform the maximum PFM contraction once.

PERFECT Scheme

The PERFECT scheme will be used to quantify the intensity, number of fast and slow contractions, and sustained contraction time[22]. Participants will be instructed by verbal commands to contract as hard as possible. The examiner will assess their degree of pressure by a single contraction[24].

This functional assessment comprises the following:

P = power (muscle strength): intensity of voluntary PFM contraction, scored from 0 to 5 by the Oxford scale.

E = resistance (sustained contraction): time (in seconds) at which a voluntary contraction is sustained, as a result of slow-twitch muscle fiber activity (ideally more than 10 seconds).

R = repetition of sustained contractions: number of sustained contractions (5 seconds each) that the participant can perform without compromising intensity, with a rest interval of four seconds between each one.

F = fast (number of fast contractions): number of 1-second contractions (up to 10) performed after a 2-minute rest period (a measure of fast-twitch muscle fiber contractility).

E = each, C = contraction, T = timed: monitors the participant's progress by timing each contraction with a timer. For example, a woman who is initially able to perform three 5-second contractions may progress to 10 contractions in the same treatment period (a practical method of demonstrating progress).

Coordination: It is necessary to monitor the participant's ability to relax quickly and completely. Slow or partial relaxation means poor coordination, whereas fast and complete means the opposite.

Sexual function

Sexual function will be assessed using the Female Sexual Function Index (FSFI)[27], a brief self-administered

questionnaire that will assess participants' sexual response across six domains, such as sexual desire, lubrication, orgasm, satisfaction, and pain. To this end, the scale comprises 19 questions that assess sexual function in the four weeks prior to application. For each question, there is a response pattern with options ranging from 0 to 5 in increasing order based on the presence of the respective function; in questions related to pain, the scoring is reversed. Women considered to be at risk for sexual dysfunction have a total FSFI score of 26 or less[27].

Quality of life

Quality of life will be assessed using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). The final score ranges from 0 (worst general health status) to 100 (best general health status)[28].

Adverse Effects of Stimulation

Possible adverse effects from tDCS are determined using the adverse effects questionnaire associated with tDCS[29] after each session.

DATA ANALYSIS

Descriptive data, sample characteristics, medication use, and physical activity will be represented using either mean and standard deviation or median and interquartile range; their normality will be assessed using the Shapiro-Wilk test. To compare the effects of PFMT associated with active and sham tDCS, in the pre- and post-intervention and follow-up periods in the PERFECT scheme and in the FSFI and SF-36 questionnaires, generalized estimating equation data analysis will be used, followed by a post-hoc analysis of paired comparisons, using Bonferroni correction for multiple comparisons. A $p<0.05$ will be considered significant.

The Statistical Package for Social Sciences (SPSS), version 22.0 will be used to obtain the results.

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