

*Efeitos do treinamento muscular do assoalho pélvico versus Ginástica Abdominal Hipopressiva* (GAH) na incontinência urinária de esforço de mulheres climatéricas: ensaio clínico randomizado

Efectos del entrenamiento muscular del suelo pélvico versus la gimnasia abdominal hipopresiva (GAH) sobre la incontinencia urinaria de esfuerzo en mujeres climatéricas: ensayo clínico aleatorizado

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**ABSTRACT** | Pelvic floor muscle training (PFMT) is recommended as first-line treatment for stress urinary incontinence (SUI) in women (scientific evidence level 1). Currently, hypopressive abdominal gymnastics (HAG) has been used in clinical practice without evidence for this purpose. To verify the superiority of an experimental treatment in relation to a positive control (gold standard) for the treatment of SUI and PFM function in climacteric women. A non-inferiority clinical trial was conducted with 31 climacteric women with SUI who were sexually active. They were allocated into two groups: 16 in the PFMT group and 15 in the HAG group. Both groups received 26 sessions twice per week and individual care. All participants were assessed twice, at the beginning and at the end of interventions. The primary outcome was assessed using the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) and the secondary were given by PFM function assessed via bidigital palpation. The methods used to analyze the

results were the two-way repeated measures analysis of variance (ANOVA), followed by the Tukey post-hoc test, when necessary. PFMT was better in improving SUI in the primary outcome (p=0.01). The groups showed no significant difference in force of contraction, time of sustained PFM, and fast and slow repetitions at the time of analysis. Regarding the symptoms of SUI, PFMT performed better than HAG.

**Keywords** | Women's Health; Sexuality; Pelvic Floor; Urinary Incontinence.

**RESUMO** | O treinamento dos músculos do assoalho pélvico (TMAP) é recomendado como primeira linha no tratamento do nível 1 de evidência da incontinência urinária de esforço (IUE). Atualmente, a Ginástica Abdominal Hipopressiva (GAH) tem sido utilizada na prática clínica com este propósito. Este estudo tem como objetivo verificar a superioridade de um tratamento experimental em relação ao tratamento padrão-ouro para IUE e função do assoalho



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pélvico em mulheres na menopausa. Foi conduzido um ensaio clínico randomizado de não inferioridade com 31 mulheres climatéricas, sexualmente ativas e com IUE. Elas foram alocadas em dois grupos, em que: 16 foram submetidas ao TMAP e 15 à GAH. Ambos receberam 26 sessões, duas vezes por semana, em atendimentos individuais. Todas as voluntárias foram avaliadas em dois momentos, no início e ao término das intervenções. O desfecho primário foi avaliado pelo Questionário (ICIQ-SF) e o secundário pela avaliação bidigital do assoalho pélvico. Para a análise estatística, foram utilizados o teste ANOVA de duas vias, seguido do pós-teste de Tukey, quando necessário. O TMAP foi superior na melhora da IUE (p=0.01). Não houve diferença entre os grupos em relação a força de contração, tempo de sustentação, repetições rápidas e lentas. Em relação à melhora dos sintomas de IUE, concluiu-se que o TMAP é superior a GAH.

**Descritores** | Saúde da Mulher; Sexualidade; Assoalho Pélvico; Incontinência Urinária.

**RESUMEN |** El entrenamiento muscular del suelo pélvico (EMSP) se recomienda como tratamiento de primera línea para las pruebas de nivel 1 de incontinencia urinaria de esfuerzo (IUE). Actualmente, se utiliza la gimnasia abdominal hipopresiva (GAH) en la práctica clínica con este fin. Este estudio tuvo por objetivo comprobar la superioridad de un tratamiento experimental en comparación con el tratamiento de referencia para la IUE y la función del suelo pélvico en mujeres menopáusicas. Se realizó un ensayo clínico aleatorizado de no inferioridad con 31 mujeres climatéricas sexualmente activas y con IUE. Las participantes se distribuyeron en dos grupos: 16 se sometieron a EMSP y 15 a GAH. Ambos recibieron 26 sesiones, dos veces por semana, en sesiones individuales. Todas las voluntarias fueron evaluadas en dos momentos, al principio y al final de las intervenciones. El resultado primario se evaluó mediante el cuestionario ICIQ-SF, y el resultado secundario mediante la evaluación bidigital del suelo pélvico. Para el análisis estadístico se utilizó la prueba ANOVA de dos vías, seguida de la prueba posterior de Tukey cuando necesario. El EMSP tuvo un mejor resultado en la mejora de la IUE (p=0,01). No hubo diferencias entre los grupos en cuanto a la fuerza de contracción, el tiempo de mantenimiento y las repeticiones rápidas y lentas. En cuanto a la mejora de los síntomas de IUE, se concluyó que el EMSP es superior a la GAH. Palabras clave | Salud de la Mujer; Sexualidad; Suelo Pélvico;

Incontinencia Urinaria.

#### INTRODUCTION

The climacteric period is a biological phase in a woman's life marked by the transition from the end of the female reproductive cycle, which is characterized by estrogen deprivation<sup>1</sup>. Some women experience uncomfortable symptoms during menopause that can negatively affect their quality of life and lead them to seek treatments<sup>2</sup>. At least 80% of women experience some degree of psychological or physical symptoms at menopause, including vasomotor symptoms, weight gain, osteoporosis, sleep disturbance, sexual dysfunction, and depression<sup>3</sup>.

This leads to anatomical and functional changes in the urethra and vagina, such as thinning of the epithelium and weakening of the pelvic floor muscle (PFM)<sup>4</sup>. These changes increase the rate of stress urinary incontinence (SUI). SUI is the involuntary loss of urine during increased abdominal pressure<sup>5,6</sup>. This dysfunction affects health services worldwide and decreases quality of life in social, sexual, hygienic, psychological, and financial aspects<sup>7</sup>. Its prevalence worldwide ranges from 10% to 40%, depending on the age group<sup>8,9</sup>.

Pelvic floor muscle training (PFMT), first described by Arnold Kegel in 1948 and applied to women after labor, aims to strengthen muscles via contractions of this muscle group. Today, it is considered a gold standard in the treatment of SUI<sup>10,11</sup>. Many physical therapists have been using alternative exercises to PFMT in their clinical practice as an adjuvant or even a substitute for PFMT in the treatment of SUI. One of these new approaches, hypopressive exercises use a postural technique that decreases or at least does not increase intra-abdominal pressure<sup>12</sup>.

The scientific literature on hypopressive abdominal gymnastics (HAG) is still scarce. This training aims to achieve a reflex pelvic floor muscle contraction against abdominal muscle recruitment. Some randomized clinical trials demonstrated that the addition of hypopressive exercises to regular PFMT programs does not improve PFM function or the cross-sectional area compared with PFMT alone<sup>13,14</sup>.

On the other hand, some studies reported benefits in PFM strength and endurance, as well as postural control, deep trunk muscle activation, and ventilatory capacity<sup>15,16</sup>. This technique is related to a decrease in intra-abdominal pressure in the thoracic, abdominal, and perineal compartments, and may play an important role in the activation of the striated muscle fibers of the PFM and deep trunk muscles<sup>17</sup>. However, although this technique has been widely used as a therapeutic exercise for PFM, its clinical efficacy in the treatment of SUI still causes controversy, since quality of life and PFM function can increase with PFMT, making it better than HAG<sup>18</sup>.

Notably, no clinical trial compares the efficacy of HAG alone to treat SUI in climacteric women.

Therefore, this study aimed to compare the efficacy of HAG with PFMT to improve SUI and sexual function in women in the climacteric period.

#### METHODOLOGY

#### Study design

This is a single-blind randomized controlled trial. It was approved by the Human Research Ethics Committee of the Universidade Federal de Mato Grosso do Sul (UFMS) (CAAE 37846614.2.0000.0021, protocol number 867426) and registered in the Brazilian Registry of Clinical Trials (REBEC; code RBR-9GF79B).

The recruitment of participants and data collection were performed at the Climacteric Outpatient Clinic of the UFMS's Maria Aparecida Pedrossian University Hospital. The study was conducted from May 2019 to December 2021, in accordance with CNS Resolution 466, which provides for procedures that ensure the confidentiality and privacy, image protection, and nonstigmatization of participants. All participants provided written consent prior to the assessments.

#### Participants and randomization

Women were included in the study if they met the following eligibility criteria: age 41 to 65 years; at least two climacteric symptoms (amenorrhea or changes in the menstrual cycle, hot flashes, mood swings); complaints of involuntary leakage of urine when coughing, laughing, or straining; at least one sexual intercourse (with penile penetration) in the last four weeks; absence of neurological diseases or sensory changes in the perineal region; history of abdominal or pelvic surgeries in the last six months; active infection in the lower urinary tract; obstructive or restrictive respiratory disease.

The exclusion criteria were use of antimuscarinic medication; presence of genital prolapse; urinary tract infection; previous history of pelvic floor exercise, urogynecological surgery, arterial hypertension, cardiovascular disease, gastroesophageal reflux, and abdominal herniation; musculoskeletal diseases (multiple sclerosis, myasthenia gravis, poliomyelitis, spina bifida, or stroke); grade III obesity (body mass index > 40 kg/m<sup>2</sup>); elite athletes; alcoholism or drug addiction; cognitive impairment; and illiteracy. Women who did not attend at least 75% of the sessions were also excluded.

#### Interventions

Women were allocated to the following two groups: positive control group (G1; women who underwent supervised PFMT) or experimental group (G2; women who underwent supervised HAG).

PFMT consisted of three to four series of eight to 12 maximal voluntary contractions (MVC) sustained for five to 10 seconds, followed by five fast contractions. The interval between contractions was six seconds and one minute after each series. The protocol was performed in three positions: supine, sitting, and standing<sup>19,20</sup>.

The exercise sessions were supervised twice per week for 13 weeks by a trained physical therapist specialized in women's health who was not involved in the assessments. Participants were instructed to perform the PFMT protocol daily at home, except on the days of supervised training. The strategy used to improve adherence to the protocol was weekly telephone contact to clarify doubts and encourage exercise at home. Women were allowed to perform recreational physical activities but were prohibited from performing any other form of physical therapy or structured physical activity during the trial. All outcome measures were assessed at baseline and 13 weeks later.

The HAG protocol was performed in accordance with the basic foundations of the exercise proposed by Caufrie<sup>21</sup>. The exercise sessions were supervised twice per week for 13 weeks by a physical therapist with expertise in HAG. The degree of difficulty of the exercises increased over the weeks. Participants were trained to perform three slow, successive diaphragmatic inspirations, followed by full expiration and apnea. Each apnea lasted 10 to 25 seconds, respecting the rhythm of each participant. Activation of the serratus major, intercostal, and transversus abdominis muscles, and relaxation of the diaphragm with activation of the abdominal band were performed simultaneously. Chart 1 describes the HAG protocol. All outcome measures were assessed at baseline and 13 weeks later.

Exercise	Description	Repetitions	Set	Breathing
Preparatory	Standing, arms in internal rotation, elbows and wrists neutral, feet parallel with a palmar distance between feet. Keep the body aligned, the spine erect, the scapulae as far apart as possible, and the hands towards the floor, maintaining axial growth.	10-15	1	Diaphragmatic breathing/ apnea in full expiration, from 10 to 25 s
Orthostatic I	Start with the preparatory posture, then flex your wrist (posture 1), raise your arms towards your middle finger at 45° (posture 2); then at 90° (posture 3), and do an internal rotation (posture 4). Next, lean your body slightly forward en bloc and place your hands on the iliac crests (AIS), keeping them parallel to the ground. Push your elbows outwards in isometric contraction, fully opening the scapulae. Knees in semiflexion, keeping the weight vertical.	10-15	1	Diaphragmatic breathing/ apnea in full expiration, from 10 to 25 s
Orthostatic II	Starts with the Orthostatic I posture, then place your hands on the iliac bone, keeping them parallel to the ground. Internally rotate your shoulders and push your elbows outwards in isometric contraction, keeping the scapulae open.	10-15	1	Diaphragmatic breathing/ apnea in full expiration, from 10 to 25 s
Orthostatic III	Start with the Orthostatic I exercise. Then raise your arms in flexion and internal rotation above eye level, with your hands parallel to the ceiling and maintaining full abduction of the scapulae.	10-15	1	Diaphragmatic breathing/ apnea in full expiration, from 10 to 25 s
Orthostatic IV	Start with the Orthostatic I exercise. Then, raise your arms in flexion and rotation at shoulder height, keeping the palm of the hand outwards, internally rotate the shoulders, and push your elbows outwards in isometric contraction, maintaining full abduction of the scapulae.	10-15	1	Diaphragmatic breathing/ apnea in full expiration, from 10 to 25 s
Intermediate I	Start with an en bloc inclination of the body, with one lower limb semiflexed and the other extended. Then, perform the Orthostatic I, II, III and IV exercises and bring your hands in front of the iliac crests (AIS). Moving from this position to half-kneeling, flex your hip and lower limb, bringing it backwards, and remain in a kneeling position.	10-15	1	Diaphragmatic breathing/ apnea in full expiration, from 10 to 25 s
Kneeling	Start in a kneeling position, feet in dorsiflexion, body slightly leaned forward, arms, elbows, and wrists neutral. Then, perform the Orthostatic I, II, III and IV exercises and bring your hands in front of the iliac crests (AIS). Raise your arms in flexion and internal rotation above eye level, with flexion of the elbows, extension of the wrists, hands parallel to the ceiling, and full abduction of the scapulae.	10-15	1	Diaphragmatic breathing/ apnea in full expiration, from 10 to 25 s

#### Chart 1. Hypopressive Aabdominal Gynastic protocol

# OUTCOMES

Firstly, personal data, such as age, weight, height, body mass index (BMI), parity, schooling level, self-reported ethnicity/skin color, and date of the last menstrual period, were collected.

The primary outcomes were urinary incontinence (UI) and PFM function. The International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) assessed UI. This self-applicable questionnaire, validated for Portuguese by Tamanini et al.<sup>22</sup>, ranges from 2 to 21 points. The higher the score, the worse the severity and impact of UI. Prior explanation and acceptance by the participants answered the ICIQ-SF. PFM function was assessed by bidigital palpation (with two fingers). Participants received detailed information on the location, function, and dysfunction of the PFM and how to correctly contract and relax these muscles using images of the pelvic floor and individualized instructions at the first assessment, following the steps recommended by Bø and Sherburn<sup>19</sup>.

After consenting, participants underwent the PFM assessment in supine position, with the hip and knee semiflexed. The examiner requested a PFM contraction and observed the performance. The participant was oriented to breathe normally and then the examiner, wearing gloves and lubricant gel, carefully inserted the index and middle fingers into the vaginal canal, inquiring about discomfort. Then, the pubcoccygeus muscle was palpated on each side of the vagina and the participant was asked to perform a maximal PFM contraction, as if to interrupt the urinary flow, and to squeeze the examiner's fingers as hard as possible, in order to lift it. The examiner discouraged contractions of accessory muscles, such as the abdomen, glutes, and hip adductors.

The response was graded according to the PERFECT scheme, in which muscle power (P) is scored from 0 to 5 (0 = no contraction; 1 = flickering contraction; 2 = weak contraction; 3 = moderate contraction; 4 = good contraction; 5 = contraction with maximal resistance)<sup>23</sup>.

Endurance (E) refers to the time the patient can keep a maximal contraction in seconds (from 0 to 10 seconds). Repetitions (R) refers to the number of times the slow contraction can be repeated while maintaining the power and endurance previously assessed. Fast contractions (F) refers to the maximal fast contractions recorded and, finally, every contraction timed (ECT) complete the acronym<sup>17</sup>. The rest interval between each contraction was 12 seconds.

Physical assessments were conducted by a physical therapist with over 13 years of experience in the area. The questionnaires were applied by another researcher, who was blinded to the results of the PFM assessment.

## Secondary Outcome

The secondary outcomes were sexual function, assessed by the Female Sexual Function Index (FSFI) a version translated into and validated for Portuguese and quality of life, assessed by the Utian Quality of Life (UQOL) questionnaire.

The FSFI was used to assess sexual function. This questionnaire was translated into Portuguese and culturally adapted and validated for Brazil<sup>24,25</sup>. It is selfexplanatory and consists of 19 questions grouped into six domains, which measure desire, arousal, lubrication, orgasm, satisfaction, and pain/discomfort<sup>26</sup>. Each domain is scored on a scale of 0 to 5, with higher scores representing better function. Only pain-related questions are scored inversely, with higher scores representing less pain/discomfort. The total FSFI score is obtained as the sum of the weighted scores for each domain. A total score of 26.5 points refers to sexual dysfunction.

#### Randomization sequence, allocation, and blinding

Participants agreed to participate without knowing the specific group they would be allocated. After assessment, a simple randomization procedure was performed using an opaque envelope, with 38 numbers. From 1 to 19, women were allocated to G1 (PFMT) and from 20 onwards, to G2 (HAG). The randomization list was generated by an assistant researcher who was not involved in any other part of the study. The examiners were blinded regarding groups allocation and the physical therapists who conducted the intervention were blinded to the results of the assessment.

#### Sample size

To determine the sample size of the groups, the difference considered in this study between the PFMT and HAG groups for incontinence control (difference between the initial and final analysis) was 4.5 points relative to UI, estimated by the ICIQ-SF. The number found was 15 per group, with a 0.80 power and a 0.05 alpha. The statistical program SigmaPlot version 12.0 was used.

#### Statistical analysis

Student's t-test was used to compare the experimental groups regarding age and BMI of the women who participated in this study. The association between experimental groups and the categorical variables analyzed was assessed using the Chi-square test. The multifactorial assessment of the experimental groups and the time of analysis, in relation to the variables force of contraction, time of sustained PFM, number of slow and fast repetitions, ICIQ-SF score, was performed by the two-way repeated measures analysis of variance (ANOVA), followed by the Tukey's post-hoc test, when necessary. The other results of this study were presented as descriptive statistics or tables. The statistical analysis was performed using the statistical program SPSS, version 24.0, considering a 5% significance level<sup>27</sup>.

## RESULTS

Participants were screened and eligibility assessed in the Climacteric Outpatient Clinic of the Maria Aparecida Pedrossian -University Hospital of the Universidade Federal do Mato Grosso do Sul (HUMAP/UFMS). The interventions took place in the gymnasium of the UFMS Integrated Training Clinic.

We recruited 98 women from May 2019 to December 2021. Of these, 38 (38.7%) met the inclusion criteria

and were randomized into one of the two groups: G1 (PFMT) and G2 (HAG).

In G1, three women dropped out during treatment. Two claimed personal problems and one contracted the COVID-19 infection. In G2, four participants did not continue follow-up, all of whom claimed personal problems, according to the flowchart shown in Figure 1.

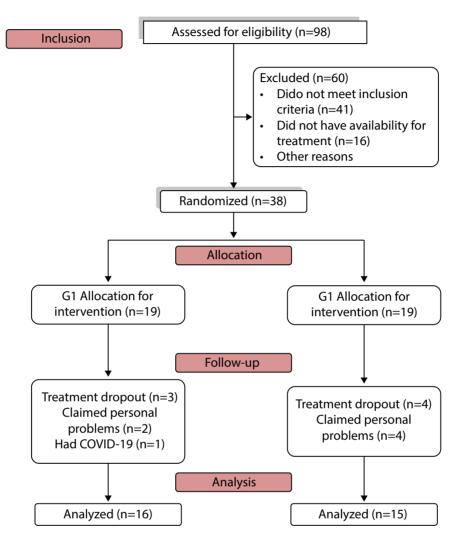


Figure 1. Flowchart of the participants included and analyzed in the study, in accordance with the Consolidated Standards of Reporting Trials (CONSORT), following the steps recommended by Moher et al.<sup>28</sup>

Among the 38 participants that were randomized, 16 completed the follow-up in G1 and 15 in G2. Participants' mean age ranged from 41 to 64 years, with mean age of  $52.39\pm0.98$  years (mean± standard error of the mean) and the mean BMI of  $24.96\pm0.83$  Kg/m<sup>2</sup>, with no difference between groups regarding age (t-student test, p=0.278) and BMI (p=0.074). As to skin color, 44.0% (n=11) of the women were White, 40.0% (n=10) of them were Mixed-race (*pardo*), 12.0% (n=3) were Black, and only one of them (4.0%) was Yellow. Six women evaluated in this study preferred not to state their skin color. Most participants were married (74.2%; n=23), had complete secondary education (35.7%; n=10) and family income above one minimum wage (77.4%; n=24). As to the number of pregnancies, only one participant was nulliparous (3.2%). Most participants had more than one pregnancy (90.3%; n=28). In total, 17 women (54.8%) had undergone one or two vaginal childbirths, while 16 (51.6%) had undergone one or two Cesarean sections. The great majority of the women (93.5%; n=29) did not take hormone replacement during the study.

There was no significant association between experimental group and skin color, marital status, education

level, family income, pregnancies, mode of delivery, and hormone replacement variables among the women assessed in this study (Chi-square test, p value ranging 0.075–0.926), which evinces the homogeneity between both experimental groups, in relation to these variables. Results of the comparison between experimental groups relative to age, BMI, skin color, civil state, education, family income, pregnancies, type of labor, and hormone replacement, between the women assessed in this study, are presented in Table 1.

Table 1. Results of the comparison between experimental groups relative to age, body mass index, skin-color, marital status, education level, family income, pregnancies, mode of delivery, and hormone replacement among the women assessed in the study

Parameter	Treatment		P-value	Total
	PFMT	HAG		
Age (41 to 64 years)	53.44±1.58	51.27±1.13	0.278	52.39±0.98
BMI (Kg/m2	26.38±1.34	23.44±0.84	0.074	24.96±0.83
Skin-color				
White	41.7 (5)	46.2 (6)		44.0 (11)
Mixed-race ( <i>pardo</i> )	41.7 (5)	38.5 (5)		40.0 (10)
Black	8.3 (1)	15.4 (2)	0.709	12.0 (3)
Yellow	8.3 (1)	0.0 (0)		4.0 (1)
Not stated	4	2		6
Marital status:				
Single	6.3 (1)	6.7 (1)		6.5 (2)
Married	68.8 (11)	8 no 0.0 (12)	0.070	74.2 (23)
Divorced	12.5 (2)	6.7 (1)	0.878	9.7 (3)
Widow	12.5 (2)	6.7 (1)		9.7 (3)
Education				
Up to high school	84.6 (11)	46.7 (7)		64.3 (18)
Higher education	15.4 (2)	53.3 (8)	0.090	35.7 (10)
Not stated	3	0		3
Family income				
Up to 1 MW	37.5 (6)a	6.7 (1)b	0.105	22.6 (7)
More than 1 MW	62.5 (10)a	93.3 (14)a	0.105	77.4 (24)
Number of pregnancies				
None	0.0 (0)	6.7 (1)		3.2 (1)
1	12.5 (2)	26.7 (4)		19.4 (6)
2	37.5 (6)	20.0 (3)		29.0 (9)
3	43.8 (7)	40.0 (6)	0.451	41.9 (13)
4	0.0 (0)	0.0 (0)		0.0 (0)
5	6.3 (1)	0.0 (0)		3.2 (1)
More than 5	0.0 (0)	6.7 (1)		3.2 (1)
Vaginal childbirth				
None	31.3 (5)	46.7 (7)		38.7 (12)
1	25.0 (4)	13.3 (2)		19.4 (6)
2	43.8 (7)	26.7 (4)	0.435	35.5 (11)
3	0.0 (0)	6.7 (1)		3.2 (1)
4	0.0 (0)	6.7 (1)		3.2 (1)
Cesarean section				
None	43.8 (7)	33.3 (5)		38.7 (12)
1	12.5 (2)	53.3 (8)	0.075	32.3 (10)
2	31.3 (5)	,7 (1)	0.075	19.4 (6)
3	12.5 (2)	6.7 (1)		9.7 ()
Hormone replacement				
Yes	6.3 (1)	6.7 (1)	0.926	6.5 (2)
No	93.8 (15)	93.3 (14)	0.520	93.5 (29)

Table 2 presents the results of the evaluation of the association between experimental groups and the dystopia, voluntary contractions, effort test, dermatome sensitivity, anal cutaneous reflex, and Achilles reflex variables among the women assessed in this study.

Among the 31 women, 48.4% (n=15) did not have pelvic organ prolapse. On the other hand, 41.9% of the participants (n=13) had degree 1 dystonia and only 9.7% of them (n=3) had degree 2 dystonia. Most participants had voluntary contraction (93.5%; n=29), positive effort test (87.1%; n=27), normal dermatome sensitivity (7.7%; n=21), normal anal cutaneous reflex (87.1%; n=27), and normal Achilles reflex (96.8%; n=30).

There was no significant association between experimental group and dystonia, voluntary contraction, effort test, dermatome sensitivity, anal cutaneous reflex, and Achilles reflex variables among the women assessed (chi-square test, p-value ranging 0.131–0.901), also evidencing the homogeneity between both groups, in relation to these variables.

Table 2. Results of the evaluation of the association between experimental groups and the dystonia, voluntary contractions, effort test, dermatome sensitivity, anal cutaneous reflex, and Achilles reflex variables among study participants

Parameter	Parameter Treatment		P-value	Total
	PFMT	HAG		
Pelvic Organ Prolapse				
Without	56.3 (9)	40.0 (6)		48.4 (15)
Degree 1	31.3 (5)	53.3 (8)	0.450	41.9 (13)
Degree 2	12.5 (2)	6.7 (1)		9.7 (3)
Voluntary contraction				
Present	100.0 (16)	86.7 (13)	0.131	93.5 (29)
Absent	0.0 (0)	13.3 (2)	0.131	6.5 (2)
Effort test				
Positive	93.8 (15)	80.0 (12)	0.254	87.1 (27)
Negative	6.3 (1)	20.0 (3)	0.234	12.9 (4)
Dermatome sensitivity				
Normal	68.8 (11)	66.7 (10)	0.901	67.7 (21)
Altered	31.3 (5)	33.3 (5)	0.901	32.3 (10)
Anal cutaneous reflex				
Normal	93.8 (15)	80.0 (12)	0.254	87.1 (27)
Altered	6.3 (1)	20.0 (3)	0.234	12.9 (4)
Achilles reflex				
Normal	100.0 (16)	93.3 (14)	0.294	96.8 (30)
Altered	0.0 (0)	6.7 (1)	0.234	3.2 (1)

Results are presented in relative frequency (absolute frequency). P-value in the chi-square test.

Table 3 presents the results of the multifactorial assessment of the effect of the time of analysis, experimental group, or interaction between these two variables. Also, it shows the comparison between groups, difference between

the two times of analysis, as to the variables contraction force, sustaining time, number of slow and fast repetitions, score in International Consultation on Incontinence Questionnaire -Short Form ICIQ-SF), among study participants.

Table 3. Results of the multifactorial assessment of the effect of the time of analysis, experimental group, or interaction between these two variables, as well as of the comparison between groups, of the difference between the two times of analysis, as to the variables power, endurance, number of slow and fast repetitions, score in International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF), among this study participants.

Parameter/	Treat	ment	P-value
time	PFMT HAG		P-value
Contraction force			
Initial	2.13±0.81Aa	2.13±0.99 Aa	Time: <0.001 Group: 0.559
Final	3.63±0.81Ba	3.27±1.33Ba	Time x group: 0.378
Difference	1.50±0.20a	1.13±0.36a	0.378
			(continues)

#### Table 3. Continuation

Parameter/	Treatment		P-value		
time	PFMT	HAG	F-Value		
Sustaining time					
Initial	2.94±2.38Aa	2.47±2.85Aa	Time: <0.001		
Final	5.38±2.63Ba	6.47±3.58Ba	Group: 0.710 Time x group: 0.221		
Difference	2.44±0.89a	4.00±0.88a	0.221		
Slow repetitions					
Initial	2.13±1.45Aa	1.40±1.72Aa	Time: <0.001		
Final	7.94±3.13Ba	5.13±3.02Bb	Group: 0.005 Time x group: 0.125		
Difference	5.81±0.98a	3.73±0.87a	0.125		
Fast repetitions					
Initial	4.81±3.64Aa	4.80±3.88Aa	Time: <0.001 Group: 0.723		
Final	8.56±2.56Ba	7.87±3.44Ba	Time x group: 0.638		
Difference	3.75±0.99a	3.07±1.04a	0.638		
International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF)					
Initial	13.25±0.88Aa	12.87±0.67Aa	Time: <0.001 Group: 0.093		
Final	2.25±1.06Bb	6.53±1.28Ba	Time x group: 0.011		
Difference	-11.00±1.32a	-6.33±1.06b	0.011		

Results are presented in mean±standard error of the mean. P-value in the two-way repeated measures ANOVA (between times and groups) or in the Student's t- test (difference between groups). Different capital letters in the column indicate significant difference between times in the same group (Tukey's post-test, p<0.05). Different lowercase letters in the same line indicate significant difference between groups for the same time of analysis (Tukey post-test or Student's t-test, p<0.05).

There was a significant effect of the time of analysis (two-way repeated measures ANOVA, p<0.001), yet, with no effect of the experimental group (p=0.559) or interaction between the time and group variables (p=0.378), relative to contraction force. There was no difference between the experimental groups considering the difference between final time and that initial for this same variable (Student' t-test, p=0.378).

Also, a significant effect of the time of analysis (twoway repeated measures ANOVA, p<0.001) was found, yet, no effect of the experimental group (p=0.710) nor interaction between the time and group variables (p=0.221) relative to sustaining time was found. The experimental groups did not differ considering the difference between final and initial time for this same variable (Student's t-test, p=0.221).

There was significant effect of the time of analysis (twoway repeated measures ANOVA, p<0.001), significant effect of the experimental group (p=0.005), yet, with no interaction between the time and group variables (p=0.125), regarding the number of slow repetitions, i.e., the number of slow repetitions at the final time was higher than that at the initial time, regardless of assessed group. Notably, the number of slow contractions in the PFMT group was higher than that observed for the HAG group, regardless of the time of analysis. However, there was no difference between the experimental groups considering the difference between final and initial time for this variable (Student's t-test, p=0.125).

There was significant effect of the time of analysis (two-way repeated measures ANOVA test, p<0.001), yet, with no effect of the experimental group (p=0.723) or interaction between the time and group variables (p=0.638) regarding the number of fast repetitions. There was also no difference between the experimental groups considering the difference between final and initial time for this variable (Student's t-test, p=0.638).

There was significant effect of the time of analysis (twoway repeated measures ANOVA test, p<0.001), but no effect of the experimental group (p=0.093). An interaction between the time and group variables (p=0.011) relative to the score in ICIQ-SF was found. The ICIQ-SF was lower at the final time compared to the initial time, regardless of the assessed group. However, the ICIQ-SF score in the PFMT group was lower than that observed for the HAG group, at the final time (Tukey's post-hoc test, p<0.05). Moreover, the ICIQ-SF score difference between the final time and that initial was more negative in the PFMT group than that for the HAG group (Student's t-test, p=0.011). Table 4 presents the results of the multifactorial evaluation of the effect of the time of analysis, the experimental group, or even the interaction between these times and the experimental group, in relation to the score in the domains and the total score, in the Female Sexual Function Index (FSFI), among the women evaluated in this study.

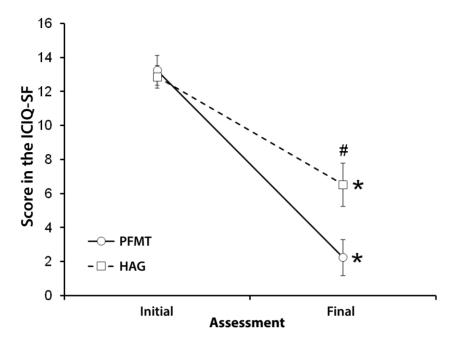


Figure 2. Graph presenting the score of the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) at the initial and final time of analysis in each experimental group. Each symbol represents the mean and the bar the standard error of the mean. \*: Significant difference regarding the initial time (Tukey's post-hoc test, p<0.05). #: Significant difference regarding the PFMT group (Tukey's post-hoc test, p<0.05).

Both in the sexual desire, sexual arousal, vaginal lubrication, orgasm, sexual satisfaction, and pain domains, as well as in the total FSFI score, there was a significant effect of the time of analysis (two-way repetitive measures ANOVA, p-value ranging from 0.010 and <0.001), however, without effect of experimental group (p-value from 0.066 to 0.623) and without interaction between time and experimental group (p-value from 0.335 to 0.857).

Table 4. Results of the multifactorial evaluation of the effect of the time of analysis, the experimental group, or even the interaction between time and experimental group, in relation to the score in the domains and the total score, in the Female Sexual Function Index (FSFI), among the studied women

Mariah la (Airea	Treat	ment	Duchus
Variable/ time	PFMT	HAG	P-value
Female Sexual Function Index (FSFI)			
Desire			
Initial	2.93±0.29Aa	2.52±0.32Aa	Time: <0.001
Final	3.86±0.41Ba	3.88±0.31Ba	Group: 0.623 Time x group: 0.439
Diference	0.94±0.44a	1.36±0.31a	0.439
Arousal			
Initial	3.45±0.37Aa	2.78±0.38Aa	Time: <0.001
Final	4.52±0.27Ba	4.16±0.40Ba	Group: 0.230 Time x group: 0.600
Difference	0.79±0.46a	1.38±0.38a	0.335
Lubrication			
Initial	3.41±0.47Aa	3.18±0.56Aa	Time o: <0.001
Final	5.14±0.24Ba	4.14±0.46Ba	Group: 0.300 Time x group: 0.210
Difference	1.41±0.53a	0.96±1.28a	0.488
			(continue:

#### Table 4. Continuation

Variable / time	Treatment		Duralua
Variable/ time	PFMT	HAG	P-value
Orgasm			
Initial	3.35±0.42Aa	3.01±0.45Aa	Time: <0.001
Final	5.04±0.17Ba	4.03±0.48Ba	Group: 0.160 Time o x group: 0.117
Difference	1.38±0.57a	1.013±0.30a	0.587
Satisfaction			
Initial	4.08±0.29Aa	3.41±0.34Aa	Time o: <0.001
Final	5.09±0.20Ba	4.43±0.40Ba	Group: 0.075 Time x group: 0.914
Difference	0.700±0.44a	1.01±0.42a	0.610
Pain			
Initial	3.50±0.42Aa	2.67±0.48Aa	Time o: 0.010
Final	2.72±0.44Ba	1.84±0.29Ba	Group: 0.125 Time x group: 0.867
Difference	-0.95±0.49a	-0.83±0.35a	0.842
Escore total			
Initial	20.71±1.47Aa	17.57±1.65Aa	Time o: <0.001
Final	26.63±1.03Ba	23.91±1.32Ba	Group: 0.066 Time x group: 0.859
Difference	4.26±2.20a	4.74±1.40a	0.857

Results are presented as means±standard error of the mean. P-value in the two-way repetitive measures ANOVA (between time of analysis and groups). Differente uppercase letters in the same column indicate significant difference between times of analysis within groups (Tukey's post-hoc test, p<0.05). Same lowercase letters in the rows indicate no significant difference between groups at the same time of analysis (Tukey's post-hoc test, p<0.05).

#### DISCUSSION

This study aimed to verify the superiority of an experimental treatment in relation to a positive control (gold standard) for SUI treatment and sexual function of women in the climacteric period. Groups proved to be homogeneous regarding anthropometric and sociodemographic data. This outcome is important as it confirms initial similarity and makes it possible to analyze, reliably, findings generated between the groups.

Similarly, the groups were homogeneous regarding functionality and integrity of the pelvic floor. Most participants were able to voluntarily contract the pelvic floor (Oxford >2), and presented sensitivity of sacral dermatome, and normal anal cutaneous and Achilles reflexes. Most women had a positive result in the effort test and absence of vaginal dystopia.

Regarding PFM evaluation, both groups improved the measurements in the pre-and post-intervention comparison relative to contraction force, sustaining time, and fast and slow contractions. However, in the comparison between groups, there was not statistically significant difference for this outcome. In the UI score, Group 1 had better improvement in this outcome when compared to Group 2 (p=0.011).

This suggests that both training protocols promoted an increase in the PFM force, endurance, resistance, and power.

PFMT is composed of a series of exercises that promote isolated and voluntary contraction of pelvic floor muscles, having greater specificity in training these fibers<sup>29</sup>. The HAG does not require direct activation of the PFM, but it is believed that their activation happens due to the synergy between the PFM and the abdominal and respiratory musculature. Previous studies demonstrated by surface electromyography that the PFM are activated during the performance of hypopressive exercises<sup>30-32</sup>. However, this activation of pelvic floor muscles was not sufficient to reduce the degree of incontinence, when compared to Group 1. Thus, it is believed that the HAG-produced muscle activation is not sufficient for it to replace PFMT in treating female stress urinary incontinence.

A recent systematic literature review compared training modalities that promise increasing PFM strength. The study included seven randomized clinical trials and concluded that the Pilates Method, the Paula Method, and hypopressive exercises are ineffective in increasing the muscle strength of the pelvic floor, unless they are performed in association with PFMT<sup>33</sup>. A systematic review by Cochrane recommended that PFMT should be the first line of treatment for urinary incontinence with level 1 of evidence and degree A of recommendation<sup>9</sup>.

Other studies obtained findings similar to ours. In one of them, conducted by José-Vaz et al.<sup>33</sup> which compares hypopressive abdominal technique (HAT) with PFMT in

improving stress urinary incontinence in 90 women, the ICIQ-SF questionnaire, modified Oxford scale, for vaginal palpation, and manometry via Peritron were used. In this study, participants underwent 24 sessions throughout 12 weeks and the intervention was carried out in groups of two to three women. The study showed improvements in both groups. However, PFMT presented a better performance when compared to HAT in all domains.

Although pelvic floor muscle training is widely recommended in the literature as the gold standard for the treatment of pelvic floor dysfunctions, such as urinary incontinence, interest in other exercise regimens is increasing. A systematic review showed that hypopressive exercises or Pilates performed alone do not increase pelvic floor muscle strength. Pelvic floor muscle training continues to be the gold standard for increasing pelvic muscle strength<sup>34</sup>.

The UI-related problems cause psychological impact and substantially reduce patients' quality of life. Often, they feel discomfort, low self-esteem, emotional lability, and sense of helplessness. QoL affects the personal, professional, economic, and social spheres of life. Out of longing and shame, they end up changing their lifestyle, which in turn, has a negative impact on socialization and contributes to social isolation, changes in sexual activity, and even develop depression and anxiety disorders as evidenced in some studies<sup>35,36</sup>.

In our study of the analysis of sexual function, it was observed that both groups improved in the domains of sexual function comparing the moments before and after treatment. There was no statistically significant difference between the groups. Female sexual function involves biological and psychosocial factors. However, concerning the organic aspect, ischiocavernosus and bulbospongiosus muscles, part of the corpus cavernosum of the clitoris, have facilitators action on the sensorymotor reflex (involuntary contractions), local blood flow, and clitoral sensitivity, which potentiates arousal and vaginal lubrication, increases vaginal elasticity, as well as provides greater proprioception and conscience of the perineal region, favoring sexual desire<sup>37</sup>. The female sexual response involves an increased PFM contractility to form the orgasmic platform, elevation of uterine position, and consequently rhythmic contractions of the musculature (orgasm) and later relaxation (resolution)<sup>38</sup>. In other studies, improvement was observed in some domains of sexual function after PFMT<sup>39</sup>. The literature is still not clear, but it indicates that any intervention that effectively treat pelvic floor disorders tends to improve sexual function, as studies associate PFM dysfunction

with worse sexual function<sup>40</sup>. As for the role of HAG, there are no randomized clinical trials available that investigate the improvement of sexual function with the use of this technique.

## Limitations

We achieved relevant outcomes in this study. However, some limitations must be pointed out.

One limitation occurred in the practice of postures in the HAG. Some women showed greater difficulty in their performance due to poor body awareness and motor coordination to perform the postures. Other participants complained of articular pain specially in the upper limbs. Beside this, the HAG group had greater drop out treatment. And, no doubt, the most limiting factor in carrying out the research was the COVID-19 pandemic, which made participants insecure of even starting treatment and sample loss of seven patients resulting in relatively small sample size. This may have been sufficient for great differences not to be detected between the groups.

## CONCLUSION

Results of this study reinforce the benefits of pelvic floor muscle training on stress urinary incontinence in the climacteric women. Therefore, hypopressive abdominal gymnastics should not be indicated for patients to treat female stress urinary incontinence. Regarding sexual function, there was no difference between the evaluated modalities.

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