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Original Reports

A randomized controlled trial investigating feasibility, acceptability and effects of dry needling for provoked vestibulodynia

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ABSTRACT

This study aimed to investigate the feasibility, acceptability, and effects of dry needling in women with provoked vestibulodynia. Forty-six women diagnosed with provoked vestibulodynia were randomized to receive six weekly sessions of either real or sham dry needling (DN). Participants, investigators and data analysts were blinded. Feasibility outcomes (adherence to treatment, questionnaire completion and dropout rate) and side effects were measured throughout the study. Pain intensity during intercourse (0−10 numeric rating scale) was measured at baseline and posttreatment, and acceptability (questionnaire) was assessed at posttreatment. Women in the realDN group attended 99% of the planned treatment sessions, compared to 91% in the shamDN group. Additionally, 100% of the questionnaires were completed in the realDN group, compared to 93% in the shamDN group. All participants in the realDN group completed the study. In contrast, two participants in the shamDN group withdrew. For the main side effects, 96% of the participants in the realDN group and 52% in the shamDN group experienced muscle aches ($p<.001$). Moreover, 35% experienced autonomic reactions in the realDN group, while these were not observed in the shamDN group ($p<.001$). All participants reported high levels of acceptability across all dimensions, with no significant difference between groups. The realDN group showed a significant decrease in pain intensity compared to the shamDN group (mean difference between groups 2.4; 95%CI 1.4–3.3; $p<.001$). Our findings support the feasibility and acceptability of dry needling to treat women with provoked vestibulodynia and showed a significant effect in reducing pain.
Perspective: This article presents the results of a novel study examining the feasibility and acceptability of using dry needling to treat women suffering from provoked vestibulodynia and lays the groundwork to inform a future randomized controlled trial.

Introduction

Vulvodynia is a chronic and often overlooked pain condition affecting the vulvar area, with lifetime prevalence estimates ranging from 8% to 16% among women of reproductive age.[1] This condition is associated with significant psychological distress, including depression and anxiety, while also disrupting sexual function, and greatly diminishing quality of life.[2] Furthermore, vulvodynia imposes a considerable

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economic burden on both patients and society.[3]

Provoked vestibulodynia (PVD) is the most prevalent subtype of vulvodynia.[1] It is characterized by pain upon pressure on the vulvar vestibule or during attempts at penetration, lasting more than three months.[4] The etiology of PVD is multifactorial, with various contributors proposed.[5,6] Women with PVD have shown increased tone[7] and tenderness of the pelvic floor muscles,[8] when compared to asymptomatic women. Moreover, the presence of myofascial pain, characterized by palpable taut bands and hypersensitive spots, has been reported in the muscles of the hip, lower back and abdominal wall among the chronic pelvic pain population, including PVD.[9–12]

Increased pelvic floor muscle tone has been proposed to play an important role in the development and maintenance of vestibular pain, resulting in an ongoing cycle involving pain and further muscle tension.[13,14] Increased tone has also been associated with a lower reduction in pain after physical therapy, thereby suggesting a lower response to treatment.[15] This matter prompts the need to develop new treatment modalities specifically targeting the increased tone of the pelvic floor muscles.

Dry needling differs from the traditional acupuncture paradigm in that it focuses on circulating energy through meridians and predetermined points, and is gaining popularity among clinicians to treat patients suffering from chronic musculoskeletal conditions.[16] Dry needling consists of inserting thin monofilament needles into muscles without any injectate to manage a variety of musculoskeletal pain syndromes.[17] One of the most commonly used and well-supported dry needling technique involves inserting needles into taut bands of muscles,[18] aiming to elicit peripheral and central physiological effects.[16,17,19]. Recent systematic reviews and meta-analyses have established the efficacy of dry needling in reducing muscle tone and pain, as well as improving function in various conditions, such as the neck, shoulder and lower back pain.[20–22] Furthermore, randomized controlled trials have demonstrated that dry needling can effectively reduce tone in lower back muscles, as assessed by shearwave elastography[23,24] and in neck muscles, as measured with a myotonometer.[25,26] Since dry needling has been shown to be effective in reducing tone and alleviating pain,[22] it could serve as a promising intervention to treat women suffering from PVD. However, to date, dry needling has not been studied in this population. The primary objective of this study was to assess the feasibility and acceptability of using dry needling for women with PVD. The secondary objective was to explore the effects of real dry needling (realDN), compared to sham dry needling (shamDN), on pain intensity during intercourse, sexual function, and patients' impression of change.

Material and methods

Study design

A parallel-group randomized prospective feasibility and acceptability clinical trial was conducted. Feasibility outcomes were determined in accordance with the Consolidated Standards of Reporting Trials (CONSORT) extension for feasibility studies.[27] To document feasibility of dry needling techniques, we adhered to the recommendations outlined in the CONSORT framework for acupuncture trials.[28] Acceptability was evaluated according to the Theoretical Framework of Acceptability in Healthcare Interventions.[29,30] Patient partners were involved throughout the course of the project, providing input on the study design, as well as participating in the testing of the study procedures. This study received approval from the institutional ethics committee (research ethics board of the Research Center of the Centre hospitalier universitaire de Sherbrooke #2023–4686), and all participants provided written informed consent. Additionally, the study was registered on ClinicalTrials.gov (NCT05797480) prior to the initiation of recruitment.

Participants

Participants were recruited between February 2023 and May 2024 through posters displayed in the hospital and university settings, social media advertising, and referrals from health professionals. Participants were included if they met the eligibility criteria, as determined by an interview and a gynecological assessment. The gynecological assessment was conducted in accordance with current guidelines (i.e., performing differential diagnosis, such as ruling out infections, and obtaining a positive cotton swab test).[31] Participants were eligible if they met the following criteria: nulliparous individuals assigned female at birth (referred to as "women" throughout this manuscript for clarity and consistency); aged 18–45 years old; reporting moderate to severe pain ($\geq$ 5/10 on a numerical rating scale) during sexual intercourse or attempted penetrations, present in at least 90% of vaginal penetration, and persisting for over three months. In this preliminary investigation of dry needling to treat PVD, parous women were excluded to minimize potential confounding effects of childbirth on myofascial structures and pain. Exclusion criteria were having received dry needling or acupuncture treatments in the past; previous history of other urogynecological conditions (e.g., dermatological issues, unprovoked pain, and deep dyspareunia); history of surgery in the vulvar area; refusal to abstain from other treatments related to vulvar pain during the study; reporting of any medical conditions that could interfere with the study procedures, and any contraindications to receive punctures (e.g., anticoagulation, hemophilia, metal allergies and immunosuppression).

Randomization and blinding

Participants were randomized in a 1:1 ratio to receive either realDN or shamDN. Allocation was carried out using a computer-generated list created by an independent research associate, utilizing random permuted blocks of sizes 2–4. An independent person managed the concealed list and assigned participants to their respective groups. The gynecologists, participants, investigators and the data analyst remained blinded to group allocations. Only the physical therapist delivering the intervention was not blinded due to the nature of the dry needling treatment.

Interventions

The treatment consisted of six consecutive weekly sessions of either realDN or shamDN, with each session lasting between 15 and 40 min. The treatment protocol (i.e., which muscles to treat, needle calibers, appropriate needling technique to ensure security) was developed based on the current literature on PVD and dry needling,[12,26,32] as well as expert consultations. The expert group consisted of two researchers with an expertise in myofascial pain and pelvic floor physical therapy, one experienced clinician trained in dry needling and pelvic floor physical therapy, one international dry needling expert, and two patient partners. Through discussions and consideration of the available literature, the group reached a consensus on the dosage and number of treatment sessions, which were tailored to the novel nature of this treatment approach for PVD. All sessions were conducted by the same experienced physical therapist, who has over 20 years of experience and is certified in both dry needling and women's health.

In the first treatment block (sessions 1–3), the muscles of the hip, lower back and abdominal wall were examined and treated, as these muscles can present with taut bands and chronic pain,[9–12] and are likely to refer pain to the pelvic floor area.[18] In the second treatment block (sessions 4–6), the dry needling techniques specifically targeted the pelvic floor muscles.

At the beginning of each treatment session, the therapist performed a palpation examination of the targeted muscles. In order for a muscle to be considered for treatment, it needed to meet at least two of the three diagnostic criteria established in the literature for myofascial pain,[18]

namely, the presence of a taut band, a hypersensitive spot (also referred to as trigger point by some authors),[32–34] and/or referred pain. Additionally, if palpation of the muscles elicited a symptom recognized by the participant, those muscles were also considered for dry needling.[18]

Throughout the study, the dry needling procedure adhered to standard infection control practices, including handwashing, using latex-free exam gloves, and preparing the skin with 70% isopropyl alcohol swabs prior to treatment. Sterile, single-use, coated-acupuncture dry needles (Asiamed TeWa, Wujiang city, China) of varying calibers (25 mm x 0.30–100 mm x 0.35) were utilized. In the shamDN group, the needle introducer tube was sealed with glue at the bottom[35,36] and rewrapped in its original packaging (Fig. 1). To ensure blinding, identical gestures and verbal cues were used for both groups.[37] The physical therapist unwrapped the needle in front of the participant, in both groups, to show that it came from an unopened package. After positioning the needle introducer tube against the skin over the hypersensitive spot, the physical therapist gently tapped the top of the needle to insert it and stated, "It is going to pinch." For the shamDN group, the physical therapist slightly twisted the introducer tube in the skin while applying constant pressure. Then, the needle was moved within the tube to simulate realDN needle manipulation. To standardize the pressure applied to the tube, the physical therapist was trained with a force sensor before each sham treatment session. The sham needle was pressed against the force sensor, with the therapist blinded to the sensor reading, until approximately 200 g of pressure were consistently reproduced three times in a row. This procedure was repeated before each sham treatment. In the realDN group, the physical therapist inserted the needle into the skin, removed the introducer tube, and advanced the needle deep enough to reach the taut muscle band. The goal was to produce referred pain, deep pressure, or a sensation of pain that the participant recognized. Depending on each participants' tolerance level, the needle was manipulated using pistoning or rotation maneuvers. While producing a local twitch response was not a primary goal, attempts were made to elicit one when the participant could tolerate it. Finally, in both groups, the needles and the introducer tubes were disposed of in a biohazard container.

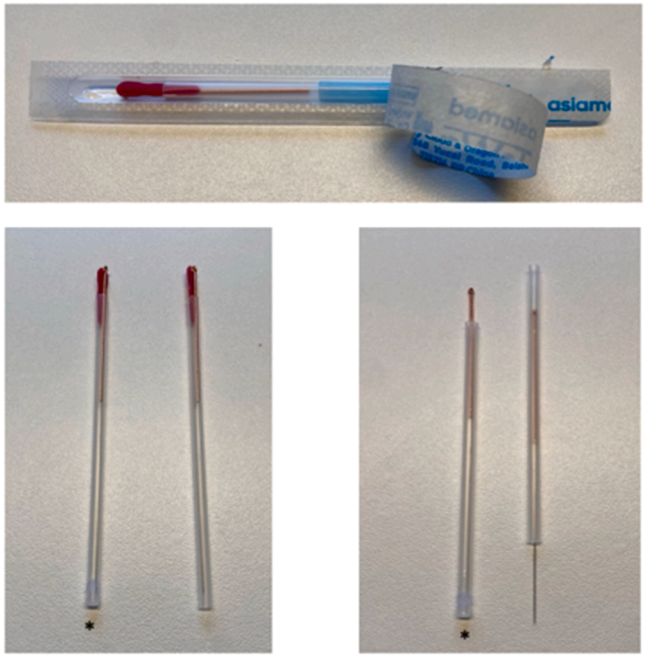

Fig. 1. Sham needle. The real and shamDN appeared nearly identical, as both were packaged in their original envelopes. However, the introducer tube of the sham needle was sealed* at the bottom, preventing the needle from being inserted into the skin, even when the needle was struck or manipulated inside the tube.

Feasibility outcomes

Primary feasibility outcomes included: 1) adherence rate to treatment sessions (calculated as the number of treatment sessions completed divided by the total number of treatments possible, multiplied by 100; 2) adherence rate to questionnaire completion (defined as the number of completed questionnaires divided by the total possible questionnaires, multiplied by 100); and 3) retention rate (the number of participants completing posttreatment questionnaires divided by the total number of participants randomized, multiplied by 100). The recruitment rate (number of participants included divided by the number of participants screened, multiplied by 100) with barriers of participation was measured throughout the study, along with the daily diaries adherence rate (number of diaries completed divided by the total possible diaries, multiplied by 100).

To further document feasibility, dry needling outcomes were also collected through the patient medical record over the course of the study and consisted of: 1) the list and frequency (calculated as the number of times a muscle was treated divided by the total number of treatment opportunities, multiplied by 100) of muscles treated; 2) the average number of needles inserted per session; 3) the average pain intensity measured with numerical rating scale (0−10) reported during dry needling (i.e., pain was scored for each needle inserted and then, average per treatment session was calculated); 4) the treatment session duration (in minutes); 5) the number of local twitch responses elicited per session; 6) the side effects; and 7) the blinding integrity. During the sessions, the physical therapist recorded any side effects directly in the patient record. Between sessions, participants reported delayed or persistent side effects daily in paper diaries, using open-ended text boxes to describe their experiences in their own words. Each week, the physical therapist reminded participants to bring their paper diary to the following session. Diaries were to be completed from the day of the first treatment session until two weeks after the final treatment. Side effects were classified based on the severity scale proposed by Boyce et al. in 2020,[38] which divided them into two categories: "minor side effects" and "major side effects". They defined "minor side effects" as short-term, mild, non-serious events with intact function that lasted from a few hours to several days (e.g., bruising and pain). They described "major side effects" as medium to long-term, moderate to severe events that may require further treatment, could be serious, and last days or weeks (e.g., nerve injury, infection or excessive symptom exacerbation). To assess the blinding integrity, participants were asked in their post-treatment questionnaire, "In which treatment group do you think you were randomized?" (see Fig. 2).

Acceptability outcomes

Acceptability was measured at posttreatment using a questionnaire developed based on the Theoretical Framework of Acceptability in Healthcare Interventions[29,30] (see Supplementary material 1). This framework defines acceptability as a *"multi-faceted construct that reflects the extent to which people receiving the intervention consider it to be appropriate based on cognitive and emotional responses."* While the questionnaire encompasses seven dimensions, we retained the following components relevant to this research: 1) burden (the perceived effort required to participate in the intervention); 2) affective attitude (participants' feelings about the intervention); 3) ethicality (the extent to which the treatment aligns with personal values); 4) intervention coherence (whether the intervention is logical and understandable); 5) perceived effectiveness (participants' belief that the intervention achieved its intended outcomes); and 6) global acceptability. The dimensions of opportunity costs and self-efficacy (dimensions 6 and 7 of the original construct) were not included, as they were not relevant to the context. Consistent with Sekhon et al. (2022), an additional question

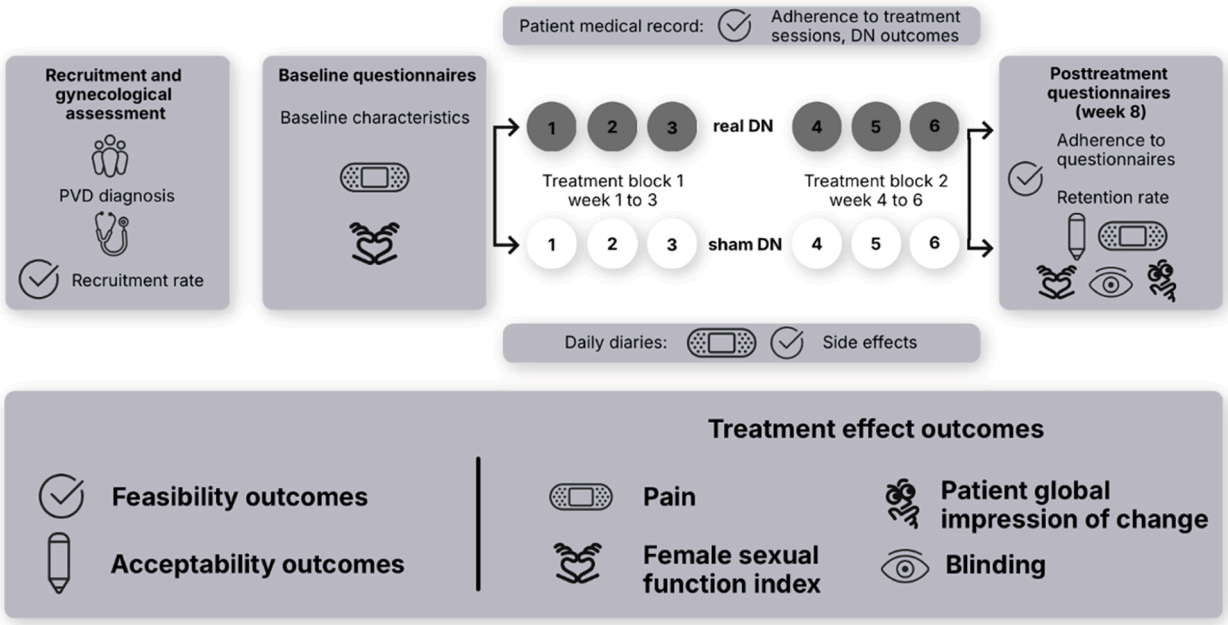

Fig. 2. Timeline. DN, dry needling.

regarding the perception of global acceptability (designated as dimension 6 in this work) was added. The authors suggest incorporating this item to allow a direct assessment of overall acceptability, since it remains unknown which TFA dimensions most strongly influence participants' overall judgments (the questionnaire can be found in the supplementary materials).

Treatment effect outcomes

Treatment effect outcomes were selected following the recommendations of the Initiative on Methods, Measurements and Pain Assessment (IMMPACT),[39] which were adapted for PVD.[40] The average pain intensity during intercourse was measured using the numerical rating scale and recorded posttreatment. The Female Sexual Function Index, a validated self-administered questionnaire, was used to measure sexual function at baseline and posttreatment (see Fig. 2). This 19-item questionnaire evaluates desire, arousal, lubrication, orgasm, satisfaction and pain.[41] The score can range from 2 to 36; higher scores indicate greater sexual function.[41] The cutoff score for the presence of a sexual dysfunction is $\leq$ 26.5.[42] The Patient Global Impression of Change was measured at posttreatment. This questionnaire consists of a single item that assesses participant's overall perception of change in pain on a 7-point Likert scale ranging from 1 (no change) to 7 (very much improved). It was also used in the posttreatment assessment.[39] All the aforementioned questionnaires were completed using a secure web-based platform (Research Electronic Data Capture (REDCap)). Participants received a link to access the questionnaires on the scheduled day, and a reminder was sent if they had not completed them within three days. An additional email reminder was sent after one week, followed by a phone call, if necessary.

Sample size calculation

A priori size calculation was conducted based on hypothesis testing of key feasibility objectives.[43] Predetermined upper (acceptable and feasible) and lower (unacceptable) cutoff thresholds guided the calculation. The feasibility benchmarks were selected based on previous studies on PVD[44–46] and dry needling,[26,47–49] as well as through expert consultations. The sample size was calculated based on adherence rate to treatments and questionnaire completion (rate greater than 70%), as well as retention (greater than 85%). Calculations utilized a one-sample, one-sided test with a 5% alpha level and a power of 80%, employing the normal approximation method[43] (further details on sample calculation are available in the supplementary material section). Anticipating a potential dropout rate of 10% at follow-up and informed by previous studies on PVD,[45,50,51] a total of 46 participants were recruited for the study.

Statistical analysis

Baseline sample characteristics, feasibility outcomes, acceptability and global impression of change were analyzed using descriptive statistics and Chi-square tests to determine the differences between groups. Wilcoxon's sum of rank tests was employed to compare groups for continuous feasibility data pertaining to dry needling outcomes (e.g., number of needles inserted, duration of treatment, pain during treatment, number of local twitch responses). Exploratory linear mixed models were conducted using an intention-to-treat approach, to examine the effects of dry needling on pain and sexual function. In these models, the intensity of pain during intercourse and the total score on the Female Sexual Function Index served as dependent variables, while the fixed effects included group, time and group interaction term (time*group). All statistical assumptions were met for the mixed model including linearity, independence, homoscedasticity, and normality of residuals. The statistical significance level for all tests was set at $p<.05$. All analyses were performed using SPSS, version 27.

Results

Participants

Of the 77 cisgender women interested in participating, 46 were found eligible and randomized to either the realDN group (n=23) or the shamDN group (n=23), see Fig. 3. Baseline sociodemographic characteristics were similar between the 2 groups (Table 1).

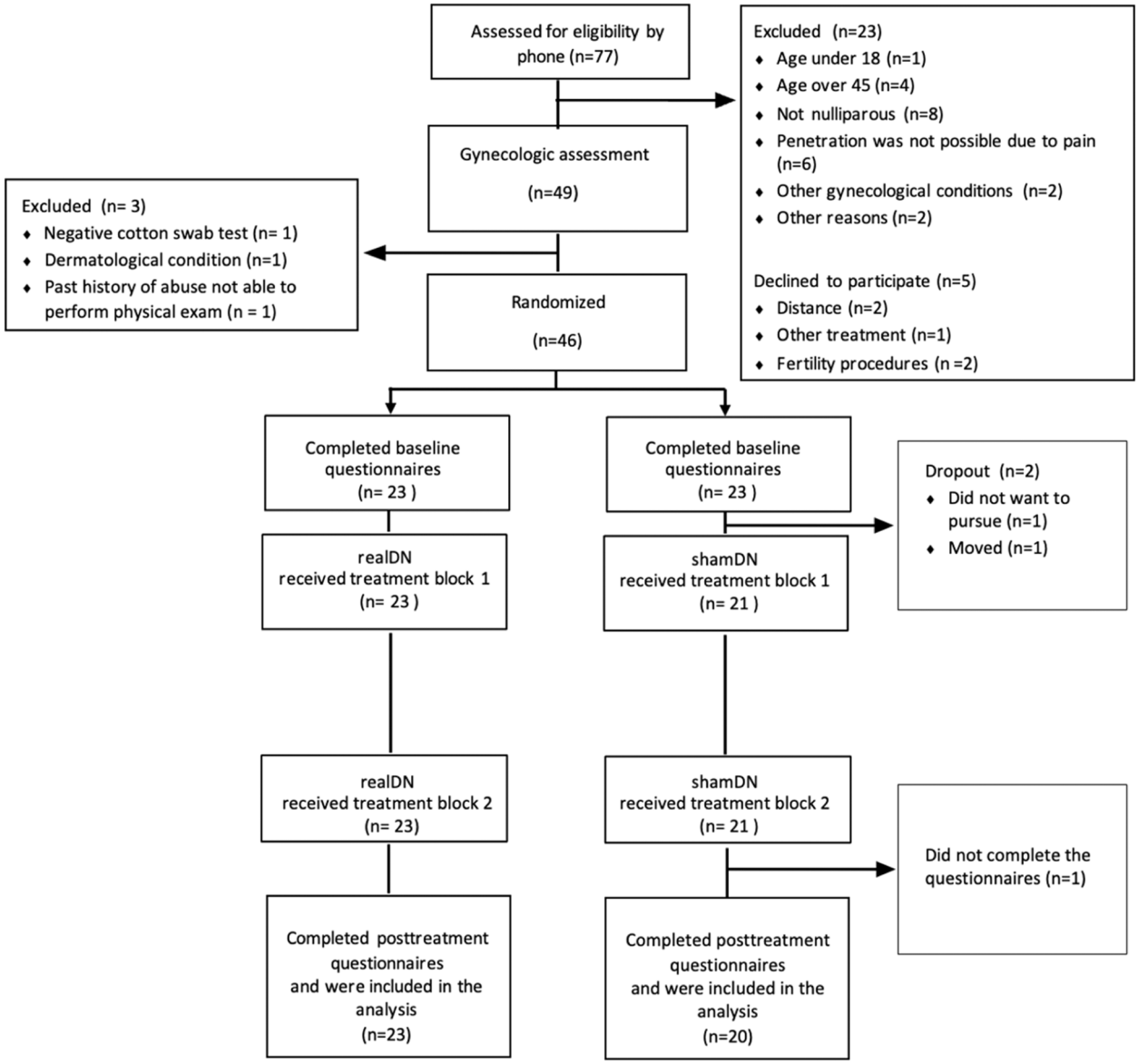

Fig. 3. Consort flowchart. DN, dry needling.

Feasibility outcomes

Interestingly, among the women screened over the phone interview, none declined to participate due to the nature of the treatment (see Fig. 3 for a flowchart of participants throughout the study). Regarding adherence to treatments, 99% (137/138) of the planned realDN sessions were delivered compared to 91% (126/138) in the sham group (p=.14). Two participants in the sham group discontinued participation after randomization: one relocated too far away and the other chose not to continue. In the realDN group, two participants experienced discomfort during pelvic floor muscles treatment in one session of the second treatment block. This required changing the targeted muscles from those in the first treatment block. One participant did not received her last real DN treatment because she was satisfied with the results obtained. One hundred percent of questionnaires (46/46) were completed in the realDN group, while 93% (43/46) were completed in the sham group (p=.07). The retention for the realDN group was 100% (23/23), whereas the sham group had a retention of 87% (20/23) (p=.08). One participant in the shamDN group chose not to complete the posttreatment questionnaires, mentioning that the questions were too intimate, but she participated in all the treatments and filled out all her diaries throughout the study. Our recruitment rate was 60%, with barriers to participation including travel distance, being on a waiting list to get involved in fertility procedures and other ongoing physical therapy treatments. Finally, 100% of the daily diaries were completed in the realDN group, while 91% were completed in the shamDN group (p=.59).

Regarding dry needling outcomes, there was no significant difference between groups in terms of the frequency of muscles treated. In the first treatment block, the most frequently targeted muscles were the quadratus lumborum (91% in the realDN group and 100% in the shamDN group, p=.61) and the gluteus minimus (96% in the realDN group and 95% in the shamDN group, p=.51). In the second treatment block, the puborectalis was the most frequently treated muscle (96% in the realDN group, 95% in the shamDN group, p=.30) (see Table 2).

There was no difference between the realDN and shamDN group regarding the number of needles inserted per session, the mean pain reported during dry needling techniques, or treatment duration. The only notable difference was the presence of local twitch responses in the realDN group during needle insertions compared to the shamDN group (p<.001) (Table 3). As for the main side effects reported (Table 4), 96% of participants in the realDN group experienced muscle aches, compared to 52% in the shamDN group (p<.001). Additionally, 35% (8) of the

Table 1
Characteristics of the participants at baseline according to the treatment group.

Characteristics	realDN (n=23)	shamDN (n=23)	*p*-value
Age, years	23 (21–25)	23 (22–28)	.69
Place of birth			.50
North America	21 (91)	20 (87)	
Europe and Asia	2 (9)	3 (13)	
Education			.29
High school	3 (13)	1 (4)	
College	8 (35)	6 (26)	
University-graduate	12 (52)	16 (70)	
Annual income, Canadian $			.75
0–9999	4 (17)	5 (22)	
10,000–19,999	7 (30)	9 (39)	
20,000–39,999	7 (30)	5 (22)	
≥40,000	5 (23)	4 (17)	
Relationship status			.54
Married	1 (4)	3 (13)	
Civil union (living with a partner ≥ 2y)	3 (13)	3 (13)	
In relationship	19 (83)	17 (74)	
Sexual orientation			.12
Heterosexual	20 (87)	13 (57)	
Homosexual	3 (13)	9 (39)	
Other	0 (0)	1 (4)	
Relationship duration, years	2 (1–5)	5 (2–6)	.66
Pain intensity during intercourse (NRS)	7 (7–8)	7 (6–8)	
Type of PVD			.41
Primary (pain since first sexual intercourse)	18 (75)	19 (83)	
Secondary (acquired after a pain-free period)	5 (25)	4 (17)	
Duration of pain, years	5 (3–7)	4 (2–10)	.98
Intercourse frequency (per week)	4 (1–7)	3 (1–4)	.61
Use of hormonal contraceptive	23 (100)	19 (83)	.11

Data are reported as median (interquartile range) or number (percentage). NRS, numeric rating scale; DN, dry needling. Wilcoxon's sum of rank test; $p \leq .05$ difference between groups for continuous data. χ^2 tests; $p \leq .05$ differences between groups for categorical data. For cells with a count of less than 5, Fisher's exact test was considered.

participants in the realDN group experienced transient autonomic reactions of short duration (< 15 min), such as sweating, nausea, tremors and fatigue, which were not observed in the shamDN group ($p<.001$). Adherence with diary completion was high in both groups. In the realDN group, adherence was 100% whereas in the shamDN group, 91% of the diaries were completed ($p=.21$) The only participants (2) who did not complete the diaries were those who had dropped out before receiving the first treatment session.

In the shamDN group, 19% of the participants reported redness at the site where the introducer tube was pressed, a side effect not reported in the realDN group ($p<.05$). Treatment blinding was proven to be effective, with 90% of the participants in the shamDN group believing they had received realDN treatment, and only two participants correctly identifying their treatment group. In the realDN group, 91% of the women accurately identified which treatment they had received.

Acceptability outcomes

All participants reported high levels of acceptability across all 6 dimensions, with no significant difference between groups (Fig. 4).

Treatment effect outcomes

Fig. 5 presents the mean values and standard deviations of pain during intercourse from baseline to posttreatment for both groups. Pain decreased in both groups from baseline to posttreatment as revealed by statistically significant within-group slopes (realDN $p<.001$ and

Table 2
Frequency of muscles treated per group and blocks.

Muscles treated	realDN (n=23)	shamDN (n=21)	*p*-value
Treatment block 1	**n (%)**	**n (%)**	
Adductor brevis	9 (39)	7 (33)	.68
Adductor longus	20 (87)	13 (62)	.21
Adductor magnus	20 (87)	18 (86)	.09
External obliques	7 (30)	8 (38)	.12
Gluteus maximus	0 (0)	3 (14)	.08
Gluteus medius	20 (87)	16 (76)	.55
Gluteus minimus	22 (96)	20 (95)	.51
Hamstrings	2 (9)	0 (0)	.27
Iliacus	6 (26)	2 (10)	.20
Iliocostalis	15 (65)	15 (71)	.42
Internal oblique	4 (17)	5 (24)	.31
Internal obturator	19 (83)	15 (71)	.26
Longissimus	7 (30)	7 (33)	.54
Multifidus	1 (4)	1 (5)	.37
Pectineus	8 (35)	8 (38)	.18
Piriformis	18 (78)	15 (71)	.87
Psoas	1 (4)	0 (0)	.45
Quadratus femoris	5 (22)	4 (19)	.63
Quadratus lumborum	21 (91)	21 (100)	.61
Quadriceps	0 (0)	0 (0)	.99
Rectus abdominis	1 (4)	2 (10)	.44
Tensor fasciae latae	7 (30)	8 (38)	.12
Trochanteric muscles	4 (17)	5 (24)	.51
Treatment block 2			
Bulbospongiosus	17 (74)	14 (67)	.47
Coccygeus	19 (83)	18 (86)	.63
Iliococcygeus	12 (52)	7 (33)	.55
Ischiocavernosus	18 (78)	11 (52)	.36
Perineal body	5 (22)	4 (19)	.59
Puborectalis	22 (96)	20 (95)	.30
Transverse perineal	22 (96)	19 (90)	.50

Values are in number (percentage). χ^2 tests; $p \leq .05$ differences between groups.

Table 3
Needle parameters per session and per treatment group.

	realDN (n=23)	shamDN (n=21)	*p*-value
Number of needles inserted			
S1	6 (6–7)	6 (6–8)	.51
S2	8 (8–9)	8 (6–9)	.22
S3	8 (7–9)	8 (6–8)	.15
S4	4 (3–4)	4 (3–4)	.17
S5	5 (4–6)	5 (4–6)	.88
S6	5 (4–7)	4 (4–6)	.21
Average pain intensity (NRS) during DN			
S1	4 (3–5)	5 (4–6)	.06
S2	4 (3–6)	5 (3–6)	.86
S3	4 (3–6)	5 (4–6)	.20
S4	3 (3–7)	4 (2–5)	.28
S5	5 (4–6)	5 (3–7)	.76
S6	4 (3–5)	5 (3–6)	.45
Duration of the treatment session (minutes)			
S1	38 (37–41)	38 (31–41)	.52
S2	24 (25–33)	27 (23–31)	.11
S3	25 (22–30)	23 (20–27)	.06
S4	18 (13–23)	16 (12–20)	.28
S5	17 (14–18)	18 (13–19)	.72
S6	17 (12–20)	14 (12–17)	.18
Number of observed LTRs			
S1	2 (1–4)	0 (0)	<.001
S2	3 (1–4)	0 (0)	<.001
S3	2 (1–4)	0 (0)	<.001
S4	0 (0–1)	0 (0)	<.001
S5	0 (0–1)	0 (0)	.07
S6	1 (0–1)	0 (0–1)	.38

Values represent the median and interquartile range. Wilcoxon's sum of rank test; $p \leq .05$ difference between groups. DN, dry needling; SD, standard deviation; Sx, treatment session; LTR, local twitch response.

Table 4
Side effects by treatment group.

	realDN (n=23)	shamDN (n=21)	*p*-value
Muscle ache	22 (96)	11 (52)	<.001
Bruise	11 (48)	10 (48)	.89
General fatigue	9 (39)	12 (57)	.23
Autonomic reaction*	8 (35)	0 (0)	<.001
Fear	4 (17)	1 (5)	.22
Numbness	2 (9)	0 (0)	.54
Dizziness	1 (4)	1 (5)	.72
Burning at site of insertion	1 (4)	2 (10)	.72
Feeling an electrical shock	1 (4)	1 (5)	.72
Heaviness sensation in muscle	1 (4)	2 (10)	.72
Redness at site of DN	0 (0)	4 (19)	.04

Values are in number (percentage). DN, dry needling. χ^2 tests; $p \leq .05$ differences between groups. For cells with a count of less than 5, Fisher's exact test was considered. *Autonomic reaction includes heavy sudden sweating, nausea, face redness, tremors and shivering, sudden soft legs.

shamDN $p=.05$). The realDN group showed a greater effect compared to shamDN in reducing pain intensity according to slope difference ($p<.001$) and mean difference at posttreatment (2.4 [95%CI 1.4; 3.3]; $p<.001$) (Table 5).

In Fig. 6, the mean values and standard deviations of the sexual function scores from baseline to posttreatment are presented for both groups. Sexual function improved only in the realDN group from baseline to posttreatment, as indicated by a statistically significant within-group slope (realDN: $p=.02$, shamDN: $p=.12$). However, there was no statistically significant difference between groups at posttreatment, nor between group slopes (Fig. 6 and Table 5).

For the Patient Global Impression of Change at posttreatment, 56% of participants in the realDN group reported being "much improved" to "very much improved", compared to 39% in the shamDN group ($p=.75$) (Fig. 7).

Discussion

This novel study examined the feasibility, acceptability, and effects of dry needling in treating PVD. The high adherence to treatment sessions and questionnaire completion, along with a very low dropout rate, surpassed all predetermined feasibility benchmarks. Both real and shamDN were well-tolerated, and the overall perception of acceptability of dry needling for treating PVD was notably high in both groups. Overall, these findings support the feasibility and acceptability of using dry needling to treat women suffering from PVD. Furthermore, a significant reduction in average pain intensity during intercourse was observed in the realDN group compared to the shamDN group. These results provide a foundation for planning a future large-scale randomized controlled trial aimed at determining the effectiveness of dry needling in this population.

Our high adherence and retention rates demonstrate feasibility, aligning with comparable dry needling studies in other painful musculoskeletal conditions affecting the neck, shoulder and heel.[52–57] Specifically, the adherence reported in these studies, which involved 2–10 treatment sessions, ranged from 95% to 100% for groups receiving dry needling, with the exact same range of rates observed for the comparator groups. Similarly, this study reported 99% adherence rate for the realDN group and 91% for the shamDN group. The retention rates for dry needling groups in these studies ranged between 98% and 100%, while the comparator groups had rates from 95% to 100%. Our realDN group also achieved 100% retention, whereas the shamDN group was slightly lower at 87%, which is slightly below the rates reported for the comparator groups. These findings confirm that dry needling in the pelvic floor muscles, an area that could be particularly sensitive, is a feasible treatment approach for PVD.

We were able to recruit about six participants per month, which is consistent with what is typically observed in the laboratory setting for this population.[45] Among the 77 women that were contacted to participate, most (60%) proceeded with the study, resulting in a screen failure rate of 40%. This rate falls within the highest brackets published in PVD studies, which range from 24% to 70%.[45,46,51,58–60] Since, no women declined to participate due to the nature of the intervention, it seems that the dry needling approach did not deter participation.

Similar to what is reported in the literature,[38,61,62] no "major side effects" occurred; only "minor side effects" were reported. In the realDN group, the most frequently reported effect was pain during the procedures, followed by muscle soreness and bruising. These findings are consistent with previous studies on dry needling for other

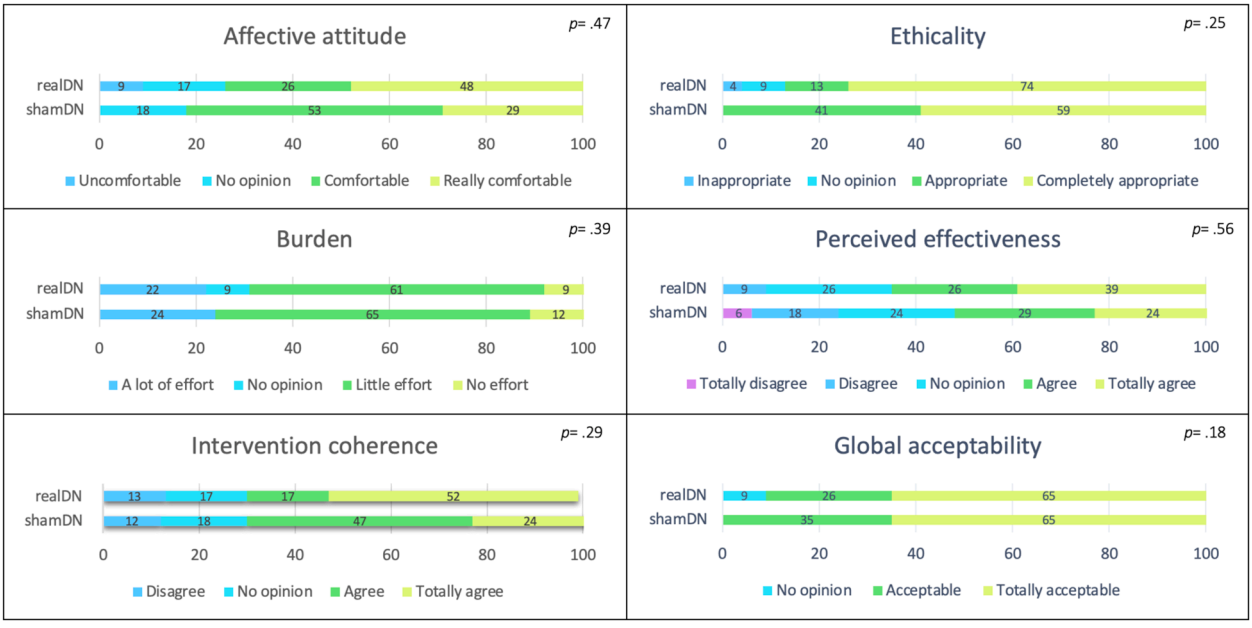

Fig. 4. Posttreatment acceptability for each group and dimension. For acceptability, percentages are presented for each dimension. χ^2 tests $p>.05$ between groups for all dimensions. For cells with a count of less than 5, Fisher's exact test was considered.

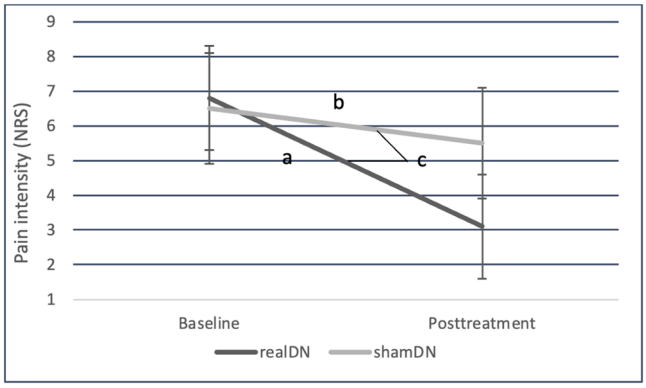

Fig. 5. Pain intensity from baseline to posttreatment according to treatment groups. Mean estimated values over time according to treatment groups. The mean pain intensity was measured with the NRS. Mean estimated values and *p*-values were derived from the linear mixed models. The letter "a" represents significant within-group slope in the realDN group, $p \leq .001$, "b" denotes significant within-group slope for shamDN group, $p < .05$, "c" represents between-group slope significant difference, $p \leq .001$.

Table 5
Pain and sexual function at baseline, and posttreatment, and mean differences between groups.

Study measure	realDN (n=23)	shamDN (n=21)	Mean difference between groups (95%CI)	*p*-value
Pain intensity (NRS)				
Baseline	6.8 (1.4)	6.5 (1.6)	0.3 [−1.3; 0.6]	.05
Posttreatment	3.1 (1.5)	5.5 (1.7)	2.4 [1.4; 3.3]	<.001
Sexual function (FSFI)	**(n=23)**	**(n=20)**		
Baseline	18.3 (7.3)	19.2 (8.0)	1.0 [−3.6; 5.5]	.67
Posttreatment	23.8 (8.0)	22.7 (7.5)	1.2 [−5.8; 3.5]	.62

Data shown are the mean estimated scores and standard errors derived from linear mixed models according to treatment group and mean difference between groups (95%CI). DN, dry needling; CI, confidence interval; NRS, numeric rating scale; FSFI, Female Sexual Function Index.

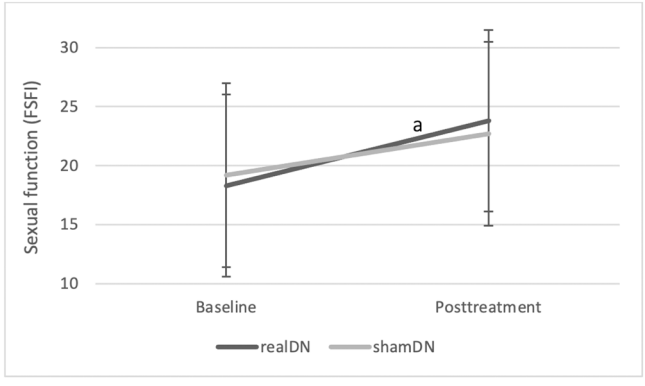

Fig. 6. Sexual function from baseline to posttreatment according to treatment groups. Mean estimated values over time according to treatment groups. Sexual function was assessed with the Female Sexual Function Index (ranges 2–36; higher values are related to better sexual function). Mean estimated values and *p*-values were derived from the linear mixed models. The letter "a" is associated with a significant within-group slope in the realDN group $p \leq .05$.

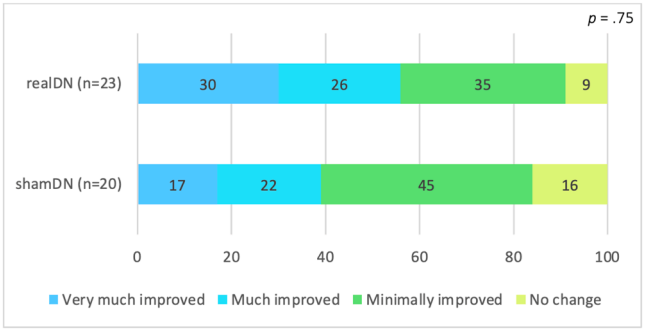

Fig. 7. Patient Global Impression of Change. For PGIC, percentages are presented for perceived improvement. *P*-value denotes between-group difference. PGIC, Patient Global Impression of Change; DN, Dry needling.[a] Fisher's exact test; $p \leq .05$ differences between groups.

musculoskeletal conditions.[38,61,62] Post-needling soreness has been attributed to tissue micro-damage caused by the needle, which often leads to minor local bleeding and an inflammatory response.[63] Furthermore, multiple needle insertions and the elicitation of local twitch responses have been linked to post-needling muscle soreness.[64] Notably, a higher percentage of transient autonomic reactions, such as sweating, shivering and fatigue, were reported exclusively among participants in the realDN group. These autonomic responses were monitored and resolved in-person during study visits and had completely subsided by the participants' departure from the research center. The observed increase in parasympathetic responses was consistent with findings documented in the musculoskeletal literature.[65,66] Although some studies have reported more severe autonomic reactions, including instances of loss of consciousness[65,66] such events did not occur in this study. Interestingly, these autonomic reactions were observed exclusively during treatment of the pelvic floor muscles in the realDN group in eight participants. Specifically, five participants experienced these reactions while inserting a needle into the perineal body. Two participants had similar reactions during needling of the bulbospongiosus muscle, and one during the needling of the transverse perineal muscle. Research indicates that women with PVD often exhibit a heightened fear of pain[67] and that in response to painful stimuli, they may show increased activity in certain areas of the central nervous system related to fear-avoidance behaviors.[68–70] Studies have demonstrated that exposure to fearful stimuli or anticipation of pain may activate the sympathetic nervous system, resulting in measurable physiological changes such as increased heart rate, sweating and peripheral vasomotor responses.[71,72] Furthermore, the association of actual needle insertion with pain or discomfort can amplify fear and anxiety.[73] Finally, it is well established that realDN elicits an immediate activation in the sympathetic nervous system, compared to shamDN.[73] Since the second treatment block involved needling muscles located in the surroundings of the painful area, it is plausible that dry needling in this zone associated with pain may have contributed to the higher occurrence of autonomic responses observed in this treatment block.

Reporting acceptability is key in studies, investigating a new modality or applying a known treatment to address a specific condition for the first time. It enables researchers to explore the extent to which individuals receiving the intervention deem it appropriate based on their cognitive and emotional responses.[30] However, it appears that no dry needling studies examined participants' perceptions of dry needling across various pathologies or anatomical areas. Exploring acceptability was particularly important in this study, given the sensitive and private nature of the anatomical area involved. At first glance, the prospect of receiving needle punctures in the pelvic floor may appear daunting. However, the majority of participants in the study reported that dry needling was "comfortable", "ethically acceptable," and "globally acceptable" for treating PVD.

This study demonstrated that realDN had a statistically significant greater reduction in pain intensity during intercourse compared to shamDN. Importantly, this reduction is also clinically meaningful given that both the within-group change in the realDN group (54% reduction in pain intensity, mean change −3.7 (SD 1.5)) and the mean between-group difference (2.4, [95%CI 1.4; 3.3]), which exceeded the clinically important threshold of 1.0 point on the numerical rating scale for between-group differences applied in other trials on chronic pain.[75]

The realDN group showed a significant improvement in sexual function, but the difference between groups was not statistically significant. One possible explanation for this finding may be a lack of statistical power. This sample size was determined based on feasibility outcomes and may not have been sufficient to detect between-group differences for effect outcomes. Another plausible explanation lies in the fact that the women participating in this study did not benefit from a comprehensive educational psychosexual program, which is typically included in a multimodal physical therapy approach. The absence of this key component may have limited effectiveness of the intervention in addressing psychosexual outcomes, such as sexual function.[45] In the field of dry needling, combining dry needling with a contemporary pain neuroscience approach is recognized as a way to enhance and prolong treatment effects.[33] This may partly explain why participants in the study reported a lower perception of change at posttreatment. In contrast, a large-scale randomized controlled trial treating PVD with multimodal physical therapy, which included a psychosexual educational program, found that 79% of participants in the physical therapy group reported feeling "very much" or "much improved" at posttreatment, supporting the importance of incorporating an educational program into treatment strategies.[45]

Strengths and limitations

The main strengths of this study included its sham-controlled randomized design, the blinding of both participants and data analysts, meticulous eligibility criteria that involved a standardized gynecological examination to confirm the diagnosis of PVD and rule out potential confounding variables, as well as a high adherence rate. Regarding limitations, certain aspects should be acknowledged as potential constraints to the generalizability of the findings. First, this study was conducted at a single site and involved only one therapist, which may limit the external validity. Second, we did not collect data on participants' race and ethnicity, potentially restricting the applicability of the results to diverse populations. Finally, only short-term effects were assessed, future research should explore whether these effects are sustained over a longer duration.

Conclusions

The findings of this study demonstrated that using dry needling to treat women with PVD is both feasible and acceptable. Importantly, the results revealed a statistically and clinically significant improvement in pain during intercourse associated with the realDN treatment compared to shamDN. While it is essential to further validate the effectiveness of dry needling with a large scale randomized controlled trial, the data gathered from this study will be instrumental in shaping and designing future research efforts.

CRediT authorship contribution statement

Melanie Roch: Conceptualization, methodology, software, formal analysis, investigation, writing original draft, visualization, project administration, funding acquisition. **Nathaly Gaudreault:** Conceptualization, methodology, resources, writing-review and editing, supervision, funding acquisition. **Josianne Paré:** Investigation, review and editing, funding acquisition. **Marie-Elisabeth Bouchard:** Investigation, review and editing, funding acquisition. **Melanie Morin:** Conceptualization, methodology, resources, data curation, writing-review and editing, supervision, project administration, funding acquisition. **Malgorzata Starzec-Propserpio:** Methodology, review and editing, supervision, funding acquisition. **Jan Dommerholt:** Conceptualization, methodology, review and editing, funding acquisition. **Nathalie J Bureau:** Methodology, review and editing, funding acquisition. **Marie-Helene Mayrand:** Review and editing, funding acquisition. **Sophie Bergeron:** Review and editing, funding acquisition. **Marie-France Dubois:** Methodology, review and editing, funding acquisition.

Data sharing

The methodological materials supporting this study, as well as the data underlying the findings, are available from the corresponding author upon reasonable request.

Disclosures

MR and JD received lecturing/teaching fees from various professional associations and educational organizations for dry needling courses. JD received royalties from published books on dry needling. The remaining authors have nothing to disclose. This work was funded by the *Partenariat de recherche clinique en physiothérapie* of the *Ordre professionnel de la physiothérapie du Québec/ Réseau provincial de recherche en adaptation-réadaptation* and the *National Women's Health Research Initiative of the Canadian Institutes of Health Research*. Mélanie Roch received a doctoral scholarship and Mélanie Morin, a salary award from *Fonds de recherche du Québec – Santé*.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jpain.2025.105596.

References

1. Harlow BL, Kunitz CG, Nguyen RHN, Rydell SA, Turner RM, MacLehose RF. Prevalence of symptoms consistent with a diagnosis of vulvodynia: population-based estimates from 2 geographic regions. *AJOG*. 2014;210(1):1–40. https://doi.org/10.1016/j.ajog.2013.09.033.
2. Bergeron S, Likes WM, Steben M. Psychosexual aspects of vulvovaginal pain. *Best Pr Res Clin Obstet Gynaecol*. Oct 2014;28(7):991–999. https://doi.org/10.1016/j.bpobgyn.2014.07.007.
3. Xie Y, Shi L, Xiong X, Wu E, Veasley C, Dade C. Economic burden and quality of life of vulvodynia in the United States. *Curr Med Res Op*. 2012;28(4):601–608.
4. Bornstein J, Goldstein AT, Stockdale CK, et al. 2015 ISSVD, ISSWSH, and IPPS consensus terminology and classification of persistent Vulvar Pain and Vulvodynia. *J Low Genitl Trac Dis*. 2016;20(2):126–130. https://doi.org/10.1097/LGT.0000000000000190.
5. Falsetta ML, Foster DC, Bonham AD, Phipps RP. A review of the available clinical therapies for vulvodynia management and new data implicating proinflammatory mediators in pain elicitation. *BJOG*. 2017;124(2):210–218. https://doi.org/10.1111/1471-0528.14157.
6. Thibault-Gagnon S, Morin M. Active and passive components of pelvic floor muscle tone in women with provoked vestibulodynia: a perspective based on a review of the literature. *JSM*. 2015;12(11):2178–2189. https://doi.org/10.1111/jsm.13028.
7. Morin M, Binik YM, Bourbonnais D, Khalifé S, Ouellet S, Bergeron S. Heightened pelvic floor muscle tone and altered contractility in women with provoked vestibulodynia. *J Sex Med*. 2017;14(4):592–600. https://doi.org/10.1016/j.jsxm.2017.02.012.

8. Gentilcore-Saulnier E, McLean L, Goldfinger C, Pukall CF, Chamberlain S. Pelvic floor muscle assessment outcomes in women with and without provoked vestibulodynia and the impact of a physical therapy program. *J Sex Med*. 2010;7(2 Pt 2):1003–1022. https://doi.org/10.1111/j.1743-6109.2009.01642.x.
9. Pastore EA, Katzman WB. Recognizing myofascial pelvic pain in the female patient with chronic pelvic pain. *J Obstet Gynecol Neonatal Nurs JOGNN*. 2012;41(5):680–691. https://doi.org/10.1111/j.1552-6909.2012.01404.x.
10. Moldwin RM, Fariello JY. Myofascial trigger points of the pelvic floor: Associations with urological pain syndromes and treatment strategies including injection therapy (Article.) *Curr Urol Rep*. 2013;14(5):409–417. https://doi.org/10.1007/s11934-013-0360-7.
11. Meister MR, Sutcliffe S, Ghetti C, et al. Development of a standardized, reproducible screening examination for assessment of pelvic floor myofascial pain. *Am J Obstet Gynecol*. 2019;220(3):255.e1–255.e9. https://doi.org/10.1016/j.ajog.2018.11.1106.
12. Sanses TV, Chelimsky G, McCabe NP, et al. The pelvis and beyond: musculoskeletal tender points in women with chronic pelvic pain. *Clin J Pain*. 2016;32(8):659–665. https://doi.org/10.1097/ajp.0000000000000307.
13. Bergeron S, Rosen NO, Morin M. Genital pain in women: beyond interference with intercourse. *Pain*. Jun 2011;152(6):1223–1225. https://doi.org/10.1016/j.pain.2011.01.035.
14. Zolnoun D, Hartmann K, Lamvu G, As-Sanie S, Maixner W, Steege J. A conceptual model for the pathophysiology of vulvar vestibulitis syndrome. quiz 423 *Obstet Gynecol Surv*. 2006;61(6):395–401. https://doi.org/10.1097/01.ogx.0000219814.40759.38.
15. Bélanger C, Dumoulin C, Bergeron S, et al. Pain characteristics, fear-avoidance variables and pelvic floor function as predictors of treatment response to physical therapy in women with provoked vestibulodynia, 8 *Clin J Pain*. 2022;38(5):360–367. https://doi.org/10.1097/AJP.0000000000001030.
16. Cagnie B, Dewitte V, Barbe T, Timmermans F, Delrue N, Meeus M. Physiologic effects of dry needling. *Curr Pain Headache Rep*. 2013;17(8):348. https://doi.org/10.1007/s11916-013-0348-5.
17. Dommerholt J. Dry needling: peripheral and central considerations. *J Man Manip Ther*. 2011;19:223–234.
18. Fernández-de-Las-Peñas C, Dommerholt J. International consensus on diagnostic criteria and clinical considerations of myofascial trigger points: a Delphi study. *Pain Med*. 2017;19. https://doi.org/10.1093/pm/pnx207.
19. Fernández-de-las-Peñas C, Dommerholt J. Myofascial trigger points: peripheral or central phenomenon? *Curr Rheuma Rep*. 2014;16(1):395. https://doi.org/10.1007/s11926-013-0395-2.
20. Callejas-Marcos I, Torrijos-Bravo A, Torres-Chica B, Ortiz-Gutiérrez RM. [Efficacy of dry needling in neck pain compared with other physiotherapy techniques: a systematic review]. Eficacia de la punción seca en la cervicalgia en comparación con otras técnicas de fisioterapia: una revisión sistemática *Rehabil (Madr)*. 2019;53(3):189–197. https://doi.org/10.1016/j.rh.2018.11.004.
21. Dunning J, Butts R, Mourad F, Young I, Flannagan S, Perreault T. Dry needling: a literature review with implications for clinical practice guidelines. *Phys Ther Rev*. 2014;19(4):252–265.
22. Sánchez-Infante J, Navarro-Santana MJ, Bravo-Sánchez A, Jiménez-Diaz F, Abián-Vicén J. Is dry needling applied by physical therapists effective for pain in musculoskeletal conditions? A systematic review and meta-analysis. *Phys Ther*. 2021;101(3). https://doi.org/10.1093/ptj/pzab070.
23. Koppenhaver SL, Weaver AM, Randall TL, et al. Effect of dry needling on lumbar muscle stiffness in patients with low back pain: a double blind, randomized controlled trial using shear wave elastography. *J Man Manip Ther*. 2021:1–11. https://doi.org/10.1080/10669817.2021.1977069.
24. Maher RM, Hayes DM, Shinohara M. Quantification of dry needling and posture effects on myofascial trigger points using ultrasound shear-wave elastography. *Arch Phys Med Rehabil*. 2013;94(11):2146–2150. https://doi.org/10.1016/j.apmr.2013.04.021.
25. Sánchez-Infante J, Bravo-Sánchez A, Jiménez F, Abián-Vicén J. Effects of dry needling on muscle stiffness in latent myofascial trigger points: a randomized controlled trial. *Pain*. 2021;22(7):817–825. https://doi.org/10.1016/j.jpain.2021.02.004.
26. De Meulemeester KE, Castelein B, Coppieters I, Barbe T, Cools A, Cagnie B. Comparing trigger point dry needling and manual pressure technique for the management of myofascial neck/shoulder pain: a randomized clinical trial. *J Manip Physiol Ther*. 2017;40(1):11–20. https://doi.org/10.1016/j.jmpt.2016.10.008.
27. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355:i5239. https://doi.org/10.1136/bmj.i5239.
28. MacPherson H, Altman DG, Hammerschlag R, et al. Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): Extending the CONSORT statement. *PLOS Med*. 2010;7(6), e1000261. https://doi.org/10.1371/journal.pmed.1000261.
29. Sekhon M, Cartwright M, Francis JJ. Development of a theory-informed questionnaire to assess the acceptability of healthcare interventions. *BMC Health Serv Res*. 2022;22(1):279. https://doi.org/10.1186/s12913-022-07577-3.
30. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Serv Res*. 2017;17(1):88. https://doi.org/10.1186/s12913-017-2031-8.
31. Bergeron S, Reed BD, Wesselmann U, Bohm-Starke N. Vulvodynia (Primer). *Nat Rev Dis Prim*. 2020;6(1). https://doi.org/10.1038/s41572-020-0164-2.
32. Fernández-De-Las-Peñas C, Plaza-Manzano G, Sanchez-Infante J, et al. Is dry needling effective when combined with other therapies for myofascial trigger points associated with neck pain symptoms? A systematic review and meta-analysis. *Pain Res Manag*. 2021, 8836427. https://doi.org/10.1155/2021/8836427.
33. Fernández-de-Las-Peñas C, Nijs J. Trigger point dry needling for the treatment of myofascial pain syndrome: current perspectives within a pain neuroscience paradigm. *J Pain Res*. 2019;12:1899–1911. https://doi.org/10.2147/jpr.S154728.
34. Dommerholt J, Gerwin RD. Contracture Knots vs. Trigger Points. Comment on Ball et al. Ultrasound Confirmation of the Multiple Loci Hypothesis of the Myofascial Trigger Point and the Diagnostic Importance of Specificity in the Elicitation of the Local Twitch Response. *Diagnostics (Basel)*. 2022;12(10). https://doi.org/10.3390/diagnostics12102365.
35. Tough EA, White AR, Richards SH, Lord B, Campbell JL. Developing and validating a sham acupuncture needle. *Acupunct Med*. 2009;27(3):118–122. https://doi.org/10.1136/aim.2009.000737.
36. Cushman DM, Holman A, Skinner L, Cummings K, Haight P, Teramoto M. Validity of a sham dry needling technique on a healthy population. *Int J Sports Phys Ther*. 2021;16(1):49–56.
37. Braithwaite FA, Walters JL, Li LSK, Moseley GL, Williams MT, McEvoy MP. Effectiveness and adequacy of blinding in the moderation of pain outcomes: systematic review and meta-analyses of dry needling trials. *Peer J*. 2018;6, e5318. https://doi.org/10.7717/peerj.5318.
38. Boyce D, Wempe H, Campbell C, et al. Adverse events associated with therapeutic dry needling. *Int J Sports Phys Ther*. 2020;15:103–113. https://doi.org/10.26603/ijspt20200103.
39. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*. 2005;113(1-2):9–19. https://doi.org/10.1016/j.pain.2004.09.012.
40. Pukall CF, Bergeron S, Brown C, Bachmann G, Wesselmann U. Recommendations for self-report outcome measures in vulvodynia clinical trials. *Clin J Pain*. 2017;33(8):756–765. https://doi.org/10.1097/ajp.0000000000000453.
41. Rosen CB J, Heiman S, Leiblum C, et al. The female sexual function index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. *J Sex Marital Ther*. 2000;26(2):191–208.
42. Wiegel M, Meston C, Rosen R. The female sexual function index (FSFI): cross-validation and development of clinical cutoff scores. *J Sex Marital Ther*. 2005;31(1):1–20. https://doi.org/10.1080/00926230590475206.
43. Lewis M, Bromley K, Sutton CJ, McCray G, Myers HL, Lancaster GA. Determining sample size for progression criteria for pragmatic pilot RCTs: the hypothesis test strikes back!. *Pilot Feasibility Stud*. 2021;7(1):40. https://doi.org/10.1186/s40814-021-00770-x.
44. Ventegodt S. New trends in the treatment of vulvodynia and other chronic female disorders: a review. *J Pain Manag*. 2020;13(1):19–25.
45. Morin M, Dumoulin C, Bergeron S, et al. Multimodal physical therapy versus topical lidocaine for provoked vestibulodynia: a multicenter, randomized trial. *Am J Obstet Gynecol*. 2021;224(2):189.e1–189.e12. https://doi.org/10.1016/j.ajog.2020.08.038.
46. Bergeron S, Binik YM, Khalifé S, et al. A randomized comparison of group cognitive–behavioral therapy, surface electromyographic biofeedback, and vestibulectomy in the treatment of dyspareunia resulting from vulvar vestibulitis. *Pain*. 2001;91(3):297–306. https://doi.org/10.1016/s0304-3959(00)00449-8.
47. Luan S, Zhu Z-M, Ruan J-L, et al. Randomized trial on comparison of the efficacy of extracorporeal shock wave therapy and dry needling in myofascial trigger points. *Am J Phys Med Rehabil*. 2019;98(8):677–684. https://doi.org/10.1097/PHM.0000000000001173.
48. Cagnie B, Barbe T, De Ridder E, Van Oosterwijck J, Cools A, Danneels L. The influence of dry needling of the trapezius muscle on muscle blood flow and oxygenation. *J Manip Physiol Ther*. 2012;35(9):685–691. https://doi.org/10.1016/j.jmpt.2012.10.005.
49. Turo D, Otto P, Hossain M, et al. Novel use of ultrasound elastography to quantify muscle tissue changes after dry needling of myofascial trigger points in patients with chronic myofascial pain. *J Med Ultrasound*. 2015;34(12):2149–2161. https://doi.org/10.7863/ultra.14.08033.
50. Bergeron S, Khalifé S, Dupuis MJ, McDuff P. A randomized clinical trial comparing group cognitive-behavioral therapy and a topical steroid for women with dyspareunia. *J Consult Clin Psychol*. 2016;84(3):259–268. https://doi.org/10.1037/ccp0000072.
51. Bergeron S, Vaillancourt-Morel MP, Corsini-Munt S, et al. Cognitive-behavioral couple therapy versus lidocaine for provoked vestibulodynia: a randomized clinical trial. *J Consult Clin Psychol*. 2021;89(4):316–326. https://doi.org/10.1037/ccp0000631.
52. Arias-Buria JL, Fernandez-de-Las-Penas C, Palacios-Cena M, Koppenhaver SL, Salom-Moreno J. Exercises and dry needling for subacromial pain syndrome: a randomized parallel-group trial. *J Pain*. 2017;18(1):11–18.
53. Gallego-Sendarrubias GM, Rodríguez-Sanz D, Calvo-Lobo C, Martín JL. Efficacy of dry needling as an adjunct to manual therapy for patients with chronic mechanical neck pain: a randomised clinical trial. *Acupunct Med*. 2020;38(4):244–254. https://doi.org/10.1136/acupmed-2018-011682.
54. Cotchett MP, Munteanu SE, Landorf KB. Effectiveness of trigger point dry needling for plantar heel pain: a randomized controlled trial. *Phys Ther*. 2014;94(8):1083–1094. https://doi.org/10.2522/ptj.20130255.
55. Valiente-Castrillo P, Martín-Pintado-Zugasti A, Calvo-Lobo C, Beltran-Alacreu H, Fernández-Carnero J. Effects of pain neuroscience education and dry needling for the management of patients with chronic myofascial neck pain: a randomized clinical trial. *Acupunct Med*. 2021;39(2):91–105. https://doi.org/10.1177/0964528420920300.
56. Sterling M, Vicenzino B, Souvlis T, Connelly LB. Dry-needling and exercise for chronic whiplash-associated disorders: a randomized single-blind placebo-

controlled trial. *Pain*. 2015;156(4):635–643. https://doi.org/10.1097/01.j.pain.0000460359.40116.c1.
57. Stieven FF, Ferreira GE, Wiebusch M, de Araújo FX, da Rosa LHT, Silva MF. Dry needling combined with guideline-based physical therapy provides no added benefit in the management of chronic neck pain: a randomized controlled trial. *JOSPT*. 2020;50(8):447–454. https://doi.org/10.2519/jospt.2020.9389.
58. Morin A, Leonard G, Gougeon V, et al. Efficacy of transcranial direct-current stimulation in women with provoked vestibulodynia. *Obstet Gynecol Surv*. 2017;72(8):477–478.
59. Hess Engström A, Bohm-Starke N, Kullinger M, et al. Internet-based treatment for vulvodynia (EMBLA) - a randomized controlled study. *J Sex Med*. 2022;19(2):319–330. https://doi.org/10.1016/j.jsxm.2021.11.019.
60. Bardin MG, Giraldo PC, Martinho N. Pelvic floor biometric changes assessed by 4D translabial ultrassound in women with vulvodynia submitted to physical therapy: a pilot study of a randomized controlled trial. *J Sex Med*. 2020;17(11):2236–2246. https://doi.org/10.1016/j.jsxm.2020.07.020.
61. Kearns GA, Brismée JM, Riley SP, Wang-Price S, Denninger T, Vugrin M. Lack of standardization in dry needling dosage and adverse event documentation limits outcome and safety reports: a scoping review of randomized clinical trials. *J Man Manip Ther*. 2023;31(2):72–83. https://doi.org/10.1080/10669817.2022.2077516.
62. Brady S, McEvoy J, Dommerholt J, Doody C. Adverse events following trigger point dry needling: a prospective survey of chartered physiotherapists. *J Man Manip Ther*. 2014;22(3):134–140. https://doi.org/10.1179/2042618613Y.0000000044.
63. Domingo A, Mayoral O, Monterde S, Santafé MM. Neuromuscular damage and repair after dry needling in mice. *Evid Based Complement Altern Med*. 2013;2013,260806. https://doi.org/10.1155/2013/260806.
64. Butts R, Dunning J, Perreault T, Mourad F, Grubb M. Peripheral and spinal mechanisms of pain and dry needling mediated analgesia: a clinical ressource guide for healthcare professionals. *Int J Phys Med Rehabil*. 2016;4(2). https://doi.org/10.4172/2329-9096.1000327.
65. Halle JS, Halle RJ. Pertinent dry needling considerations for minimizing adverse effects-part two. *Int J Sports Phys Ther*. 2016;11(5):810–819.
66. DiLorenzo L, Traballesi M, Morelli D. Hemiparetic shoulder pain syndrome treated with deep dry needling during early rehabilitation: a prospective, open-label, randomized investiguation. *J Musculoskel Pain*. 2004;12(2):25–34.
67. Thomtén J, Linton SJ. A psychological view of sexual pain among women: applying the fear-avoidance model. *Women's Health (Lond)*. May 2013;9(3):251–263. https://doi.org/10.2217/whe.13.19.
68. Pukall CF, Strigo IA, Binik YM, Amsel R, Khalifé S, Bushnell MC. Neural correlates of painful genital touch in women with vulvar vestibulitis syndrome. *Pain*. 2005;115(1-2):118–127. https://doi.org/10.1016/j.pain.2005.02.020.
69. Hampson JP, Reed BD, Clauw DJ, et al. Augmented central pain processing in vulvodynia. *J Pain*. 2013;14(6):579–589. https://doi.org/10.1016/j.jpain.2013.01.767.
70. Gupta A, Rapkin AJ, Gill Z, et al. Disease-related differences in resting-state networks: a comparison between localized provoked vulvodynia, irritable bowel syndrome, and healthy control subjects. *Pain*. 2015;156(5):809–819. https://doi.org/10.1097/01.j.pain.0000461289.65571.54.
71. Yoshihara K, Tanabe HC, Kawamichi H, et al. Neural correlates of fear-induced sympathetic response associated with the peripheral temperature change rate. *Neuroimage*. 2016;134:522–531. https://doi.org/10.1016/j.neuroimage.2016.04.040.
72. Cook TE, Fergus TA, Young DA, Williams SE, Ginty AT. Stressor-evoked heart rate, perceived physiological arousal, and anxiety symptoms in young adults. *J Affect Disord*. 2025;376:454–462. https://doi.org/10.1016/j.jad.2025.02.011.
73. Lazaro-Navas I, Lorenzo-Sanchez-Aguilera C, Pecos-Martin D, et al. Immediate effects of dry needling on the autonomic nervous system and mechanical hyperalgesia: a randomized controlled trial. *Int J Environ Res Public Health*. 2021;18(11):6018. https://doi.org/10.3390/ijerph18116018.