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Mindfulness-based body scan training in multimodal physiotherapy for vulvodynia – a randomized controlled feasibility study

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ABSTRACT

This randomized controlled trial explored the feasibility and preliminary effectiveness of integrating mindfulness-based body scan (MBBS) interventions into multimodal pelvic floor physiotherapy for vulvodynia treatment. Participants received ten sessions of standardized physiotherapy. The mindfulness intervention group was instructed to additionally perform home-based audio-file guided MBBS five times a week. The primary study endpoint was feasibility. The effect on pain intensity, pain characteristics and sexuality were assessed with Numeric Rating scales (NRS), the McGill-Melzack Pain Questionnaire (MPQ), the Female Sexual Distress Scale (FSDS) and Female Sexual Function Index (FSFI) and digital assessment of pelvic floor. Thirty-three women were randomized and completed the end-of-treatment assessments and 26 (79%) attended the follow-up. 15 of 17 participants of the intervention group (88%) performed the body scans more than ten times and the feasibility criteria were achieved. The intervention group showed significantly better improvements in NRS of average pain, MPQ subscales and FSDS total score. Pelvic floor assessment showed a significant improvement of myofascial pressure points over time with no difference between study groups. Integration of MBBS trainings into multimodal pelvic floor physiotherapy for vulvodynia is feasible and well accepted and may improve pain reduction and sexual function.

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Vulvodynia; physiotherapy; mindfulness-based stress reduction; body scans; pelvic floor

Introduction

Vulvodynia is a chronic, complex pain disorder which affects between 8 and 10% of women of all ages [1]. Despite its high prevalence rate and medical burden, the condition is still under-recognized and under-treated. Vulvodynia is defined as vulvar pain of at least three months duration without a clear identifiable cause, and commonly negatively impacts on sexuality and health-related quality-of-life (HrQoL) [1]. According to 2015 Consensus Terminology of the International Society for the Study of Vulvovaginal Disease (ISSVD), the International Society for the Study of Women's Sexual Health (ISSWSH) and the International Pelvic Pain Society (IPPS), vulvodynia can be further characterized as localized or generalized, provoked or not provoked, and primary or secondary, or mixed [2]. The etiology is not well understood, but alterations in pelvic floor muscles and abnormal neurologic pain perception have been discussed [1]. Neurologic, psychiatric, urologic or gastrointestinal comorbidities are common [3] and an integrative diagnostic and therapeutic approach is recommended. Treatment involves pelvic floor therapy, psychological interventions, local and oral pain modulating treatment and- in refractory cases – vestibulectomy. Treatment is challenging and the need for further trials on multimodal treatment has been emphasized [4].

Pelvic floor therapy is considered a first line treatment [5] and recommended for all forms of vulvodynia, with primary or secondary onset [6]. Especially multimodal pelvic floor physiotherapy, which involves educational components, different manual techniques and biofeedback, has been shown to be effective [4].

Vulvodynia patients commonly show high levels of physical and psychological stress with increased cortisol levels [7]. Chronic stress may dysregulate the central nervous system leading to central sensitization in women with vulvodynia [8]. Integration of Mindfulness-based stress reduction (MBSR) or yoga

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into physical therapy addresses the biopsychosocial components of female sexual pain and may enhance treatment benefits [9]. Several clinical studies were able to demonstrate that mindfulness-based approaches are effective in the treatment of chronic pain [10–12], but only few studies studied the effect of MBSR in patients with vulvodynia [7].

Mindfulness-based body scan (MBBS) is a single essential part of MBSR which combines stress regulation and body awareness in an accepting, nonjudgmental manner. Patients are guided to focus on the different parts of their body and to consciously perceive and accept their present body sensations. A randomized trial found MBBS to be an effective method for achieving immediate pain reduction in female patients with a variety of chronic pain [13].

The purpose of our study was to explore the feasibility of combining home-based guided MBBS with multimodal pelvic floor physiotherapy for patients with vulvodynia.

Materials and method

Participants

This randomized, controlled feasibility trial was conducted at a private physiotherapy center, which provides specialized multimodal pelvic floor physiotherapy for female patients with pelvic pain. Women with previously diagnosed vulvodynia, who were referred for pelvic floor therapy, were invited to participate in the study. Inclusion criteria were age above 18 years, any type of vulvodynia and dyspareunia, and at least one pelvic floor muscle showing overactivity on baseline examination. Exclusion criteria were pregnancy, current vulvovaginal or urinary tract infection, recent surgery of the pelvic organs and myofascial physiotherapy in the last two years. Severe pelvic pain, a history of unresolved trauma or mental illness, were further reasons for exclusion, if vaginal palpation or questionnaire assessment were thought to be unfeasible During the study period all patients with vulvodynia were assessed for study inclusion and exclusion criteria and eligible patients were informed about MBBS and the clinical trial. The study was approved by the Ethics Committees of the Medical University of Vienna (1102/2019). All participants provided written informed consent before randomization.

Procedures

Eligible and consenting patients were randomized to MBBS plus pelvic floor physiotherapy (intervention group) or pelvic floor physiotherapy only (control group). Randomization was performed with sealed envelopes at a ratio of 1:1. Pelvic floor physiotherapy was performed in a standardized multimodal approach, which combines myofascial therapy, manual therapy and specific local pelvic floor therapy for increased pelvic floor awareness and desensitization of painful areas. This was complemented with pain management strategies, endurance and stability training and general lifestyle advice. All participants were scheduled for 10 therapy sessions, with a duration of 60 min each, over a period of 10 weeks.

Participants randomized to the intervention group were introduced to MBBS training during their first physiotherapy session. Using a standardized text patients were taught to scan different parts of their body in an accepting, nonjudgmental manner. An MP3 file recording of the 25 min text was then handed out for further home training. Participants were instructed to perform the body scan five times a week over 10 weeks and to document their exercises in a study diary.

Measures

Four of eight dimensions of feasibility [14] were addressed to evaluate the feasibility of the MBBS intervention: integration, implementation, acceptability, and preliminary effectiveness. First of all, it was tested how many patients with vulvodynia, who were referred to pelvic floor physiotherapy, would be interested and willing to perform MBBS and participate in the trial. Integration of the MBBS into the physiotherapy program would be judged as feasible if at least 70% of eligible patients would agree to participate. Implementation was evaluated through attendance and study compliance. If at least 70% of participants attended all 10 physiotherapy sessions and the follow-up evaluation, study compliance would be rated as successful. The acceptability of the MBBS intervention was assessed by participants' adherence and feedback. Participants would be considered adherent to the intervention if they performed a minimum of 10 home-based MBBS interventions. Study diaries were used to monitor the times and number of performed body scans. Open-ended questions were used to assess participants' subjective experiences, perceived benefits and challenges. Participants answers were analyzed and grouped in different categories according to the principles of Qualitative Content Analysis, described by Mayring [15] The preliminary effectiveness was evaluated with a range of patient reported outcome measures (PROMs) at baseline, at the end-of-treatment (after 10 sessions) and at follow-up (8–12 weeks after study completion). Average pain-intensity in the past seven days and average pain during

penetrative sexual intercourse was assessed with a Numeric Rating Scale (NRS) ranging from 0 to 10, with 0 referring to "no pain" and 10 referring to "worst imaginable pain". The following validated self-administered questionnaires were used for the assessment of pain characteristics and sexuality: the McGill-Melzack Pain Questionnaire (MPQ) [16] (sensory pain index: 11 items; affective pain index: 4 items; pain intensity: 1 item); the 13- item Female Sexual Distress Scale (FSDS) [17]; the 19-item Female Sexual Function Index (FSFI) [18].

Pelvic floor examinations were performed in a standardized method for objective assessment of myofascial pain [19]. Patients were placed in a supine position with legs at a 45-degree angle. The intravaginal digital palpations were carried out with disposable gloves using lubricant. The pelvic floor muscles were localized in a clockwise orientation and assessed for painful areas. The number of myofascial pain areas (maximum 18) and the average pain intensity, rated on a NRS scale from 0 to 10, was then recorded.

Statistical analysis

The study was designed as a feasibility study and no *a priori* sample size calculation was performed. Based on clinicalexperience a sample of at least 30 patients was anticipated. Patient characteristics are presented as mean and standard deviation. The feasibility outcomes were assessed as percentage of participating patients, attended physiotherapy appointments and performed MBBS sessions.

The analysis of study effectiveness was done *via* calculating two-way mixed ANOVAs with the between-subject factor group (intervention vs. control) and the within-subject factor time-point (baseline vs. end-of-treatment vs. follow-up). Greenhouse-Geisser correction was applied when sphericity assumptions were violated. Significant interactions were followed up with Tukey post-hoc tests. For all tests, two-sided *p*-values $p<0.05$ were considered statistically significant. Statistical analysis was performed using Jamovi 2.3.28 [20].

Results

During the study period 54 patients were assessed for eligibility, and 33 of 37 eligible patients (89%) consented to participate in the clinical trial. Of these, 17 patients were allocated to the MBBS intervention group and 16 patients were allocated to the control group (Figure 1). All study participants were women and white Europeans with a mean age of 29 years (see Table 1). Twenty-five patients were referred with the diagnosis "provoked localized vulvodynia" and eight patients with "generalized vulvodynia", with an overall mean symptom duration of 6.1 years (SD = 3.8). Four participants (2 control group, 2 intervention group) were additionally diagnosed with mild forms of lichen planus or lichen simplex, which may have contributed to vulvar pain symptoms All 33 participants attended the 10 scheduled pelvic floor treatment sessions during the study period. The follow-up assessment after study completion was attended by 26 (79%) participants ($n=15$ intervention group, $n=11$ control group). Out of the 17 patients randomized to the MBBS intervention, 15 (88%) reported to have performed the home-based body scan more than ten times, at a mean of 27.9 times, during the study period. The predefined study criteria for recruitment, compliance and adherence were achieved, and the feasibility dimensions integration, implementation and acceptability were fulfilled. Analysis of the open questions regarding benefits and challenges of body scan training showed that integration into daily routine helped participants to cope with stress and feel more relaxed. The possibility of taking an active part in therapy was commonly regarded as empowering and beneficial. Some patients reported that being tired and stressed out made it harder to focus and concentrate, sometimes resulting in falling asleep during body scan training.

Follow-up assessments were completed by 79% of included participants (Figure 1). Main reasons for missing assessments were difficulties with questionnaire completion and reluctance to undergo vaginal palpation. The changes in outcome measures from baseline to end-of-treatment and follow-up in the two study groups, including p-values to report main and interaction effects of the respective ANOVA models, are shown in Table 2. The groups differed significantly from each other in the total score and the subscales "pain" and "satisfaction" of the FSFI, where individuals from the body scan group had higher scores, i.e. better function, than the control group. Significant changes over time were observed in a range of outcomes assessing pain experience. Importantly, some of these time effects were qualified by a significant interaction effect with the factor group. The interaction effect of the outcome "Average pain in the last 7 days", ($F(1.76,21.2) = 4.28$ $p=0.025$ $\eta_p^2 = 0.16$), was driven by significant decreases in reported pain in the intervention group from baseline to end-of-treatment ($p=0.010$) and from baseline to follow-up ($p<0.001$), while no significant changes were observed in the control group. Significant interaction effects were found for the "Sensory pain index", ($F(1.74, 41.7) = 3.87$, $p=0.034$, $\eta_p^2 = 0.14$), and the "Pain intensity score", ($F(1.91, 45.8) =$

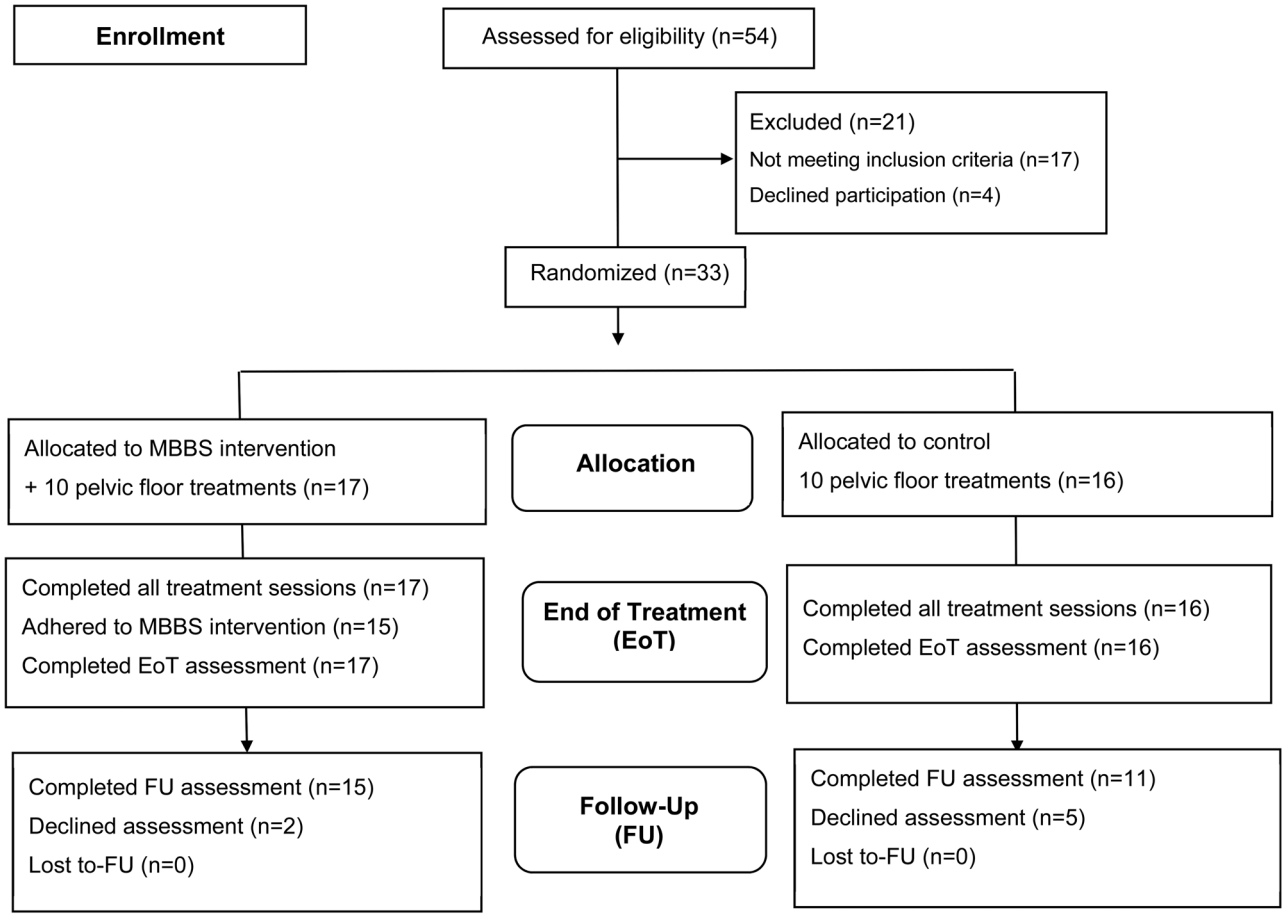

Figure 1. Consort flow diagram of study population.

Table 1. Patient characteristics.

	MBBS Group ($n=17$)	Control Group ($n=16$)	Total ($n=33$)
Age (years)	29.2 (6.3)	28.6 (5.2)	28.9 (5.9)
Education			
Tertiary education (University)	10 (59%)	9 (56%)	19 (58%)
Secondary education (High school)	5 (29%)	6 (38%)	11 (33%)
Primary education	2 (12%)	1 (6%)	3 (9%)
Current Relationship status			
In partnership	14 (82%)	12 (75%)	26 (79%)
Single	3 (18%)	4 (25%)	7 (21%)
Sexual Orientation			
homosexual	0	0	0
bisexual	1 (6%)	1 (6%)	2 (6%)
heterosexual	16 (94%)	15 (94%)	31 (94%)
Type of vulvodynia			
Provoked localized vulvodynia	12 (71%)	13 (81%)	25 (76%)
Generalized vulvodynia	5 (29%)	3 (19%)	8 (24%)
Primary onset	6 (35%)	11 (69%)	17 (52%)
Secondary onset	11 (65%)	5 (31%)	16 (49%)
Duration of symptoms (years)	5.4 (4.1)	6.8 (3.4)	6.1 (3.8)
Previous Psychotherapy	10 (59%)	7 (44%)	17 (52%)

Data is given as number (percent) or mean (standard deviation).
MBBS: Mindfulness-based body scan.

3.83, $p=0.031$, $\eta_p^2 = 0.14$), of the MPQ. The MBBS intervention group rated "sensory pain characteristics" and "pain intensity" lower at end-of-treatment than at baseline, and lower at follow-up than at baseline (all p-values <0.01). No significant changes were observed in the control group for these outcomes. A time by group interaction was also found for the FSDS, ($F(1.81, 41.6) = 5.32$, $p=0.011$, $\eta_p^2 = 0.19$). Again, the effect was driven by lower ratings of sexual distress in the intervention group from baseline to end-of-treatment ($p=0.008$), and from baseline to follow-up ($p<0.001$). Digital assessment of pelvic floor muscles showed a significant improvement of myofascial pressure points and pain intensity over time, with no difference between study groups.

Discussion

This randomized controlled feasibility trial assessed the potential benefits and challenges of combining guided MBBS exercises with pelvic floor physiotherapy for patients with vulvodynia. In our trial the home-based MBBS were well accepted and performed at regular intervals, and the predefined feasibility criteria were fulfilled. Furthermore, a beneficial effect of adding MBBS training to multimodal pelvic floor therapy was observed. Patient reported outcome measures showed significant improvements in pain perception and

Table 2. Subjective and objective study outcomes.

	MBBS Intervention Group			Control Group					
	Baseline ($n=17$)	End-of-treatment ($n=17$)	Follow-up ($n=14$)	Baseline ($n=16$)	End-of-treatment ($n=16$)	Follow-up ($n=11$)	Main effect timepoint	Main effect group	Interaction timepoint x group
NRS (0–10)									
Average pain last 7 days	5.0 (2.2)	2.5 (1.7)	2.1(2.0)	3.3 (2.4)	3.1 (2.8)	3.2 (2.5)	**$p<0.001$**	$p=0.515$	**$p=0.025$**
Pain during sexual intercourse	9.3 (1.7)	3.0 (2.4)	1.9 (2.1)	8.5 (1.9)	5.9 (1.9)	2.7 (2.3)	**$p=0.004$**	$p=0.451$	$p=0.160$
MPQ*									
Sensory pain index	13.2 (6.8)	8.8 (6.2)	6.6. (4.0)	11.4 (5.7)	9.5 (5.7)	10.5 (5.7)	**$p=0.002$**	$p=0.689$	**$p=0.034$**
Pain intensity score	3.4 (0.7)	2.1 (1.4)	2.0 (1.4)	3.0 (1.1)	2.6 (1.2)	2.9 (1.4)	**$p<0.001$**	$p=0.855$	**$p=0.031$**
Affective pain index	3.2 (4.3)	1.5 (2.0)	1.3 (2.4)	2.7 (2.6)	2.0 (1.9)	2.4 (2.2)	$p=0.198$	$p=0.650$	$p=0.435$
FSFI**									
Total score	17.1 (7.4)	22.8 (8.7)	23.1 (9.6)	14.0 (7.0)	17.3 (8.3)	18.7 (7.8)	**$p=0.048$**	**$p=0.036$**	$p=0.806$
Pain	1.4 (1.7)	2.5 (2.3)	3.1 (2.2)	1.2 (1.4)	1.2 (1.4)	1.7 (1.3)	$p=0.241$	**$p=0.039$**	$p=0.309$
Desire	3.2 (0.9)	3.9 (2.1)	4.5 (2.4)	2.3 (1.0)	3.1 (1.2)	3.0 (1.3)	**$p=0.013$**	$p=0.051$	$p=0.602$
Arousal	3.1(2.1)	3.4 (2.5)	3.7 (1.8)	2.2 (1.8)	3.1 (1.8)	3.6 (1.9)	$p=0.269$	$p=0.268$	$p=0.533$
Lubrication	3.4 (2.5)	3.8 (2.1)	4.2 (2.0)	2.7 (2.4)	3.6 (2.2)	3.9 (2.09	$p=0.307$	$p=0.472$	$p=0.878$
Orgasm	3.0 (2.3)	4.1 (2.1)	4.0 (1.8)	3.2 (2.3)	3.4 (2.3)	3.7 (1.8)	$p=0.215$	$p=0.421$	$p=0.623$
Satisfaction	2.7 (2.0)	3.9 (1.8)	4.2 (1.6)	2.6 (1.6)	2.9 (1.9)	3.0 (1.8)	$p=0.135$	**$p=0.031$**	$p=0.683$
FSDS™*	35.3 (10.3)	24.3 (13.8)	17.0 (13.3)	31.3 (8.9)	27.7 (10.1)	28.5 (11.2)	**$p=0.001$**	$p=0.376$	**$p=0.011$**
Pelvic Floor Assessment									
Average pain intensity on palpation (NRS 0–10)	5.5 (2.0)	3.3 (3.1)	2.1 (3.1)	4.1 (2.0)	2.3 (2.0)	3.3 (2.1)	**$p=0.001$**	$p=0.333$	$p=0.067$
Number of myofascial pressure points	5.0 (2.5)	2.2 (2.1)	1.2 (2.0)	4.5 (2.1)	1.8 (2.2)	2.0 (1.8)	**$p<0.001$**	$p=0.925$	$p=0.500$

Data is given as mean (SD). *Lower score indicates less pain or less sexual distress, **Higher scores indicate better sexual function. Significant p-values are depicted in bold font. MBBS_ Mindfulness-based body scan; NRS_ Numeric Rating Scale; MPQ_ McGill-Melzack pain questionnaire;FSFI_ Female Sexual Function Index; FSDS_ Female Sexual Distress Scale.

sexual dysfunction in patients performing the body-scans interventions. Clinically meaningful improvements of pelvic pain and sexuality from baseline to follow-up could be observed in both study groups, strongly supporting that pelvic floor physiotherapy is an effective intervention for patients with vulvodynia [21,22]

Positive effects of MBSR for patients with vulvodynia have been described before. In a wait-list controlled study of 85 women with provoked vulvodynia an integrated mindfulness program was applied. During four sessions of group treatment patients received comprehensive information on the current state of the science regarding the pathophysiology of vulvodynia and were introduced to mindfulness skills. Positive effects on pain management and acceptance were observed in the intervention group, supporting the use of a mindfulness-based program for distressing genital pain [7]. A comparison of mindfulness-based cognitive therapy with cognitive behavioral therapy in the treatment of provoked vestibulodynia showed that the mindfulness approach was equally effective in most pain- and sexuality-related study endpoints [23]. Similarly, a randomized trial comparing a mindfulness-based group cognitive behavior with an education support group found both group therapies to be effective in reducing pain and distress. However, women in the mindfulness-based group cognitive behavior therapy program showed greater improvement in certain secondary outcomes, indicating that the mindfulness based approach may offer advantages in reducing distress associated with vulvodynia [24]. Despite these positive reports, a systematic review on effectiveness of mindfulness-based interventions for patients with chronic pain concluded that there is still limited evidence for effectiveness, stressing the need for further well conducted studies [25]

To our knowledge, our trial was the first study evaluating a mindfulness based intervention as part of specialized physiotherapy for pelvic pain. An important strength of our feasibility study was the randomized controlled design and the broad range of study outcomes, including validated PROMs, study diaries, and the standardized assessment of pelvic floor muscles. The digital pelvic floor assessments were performed consistently by a single trained physiotherapist which likely enhanced intra-rater reliability and may be considered as a considerable strength of our feasibility trial. The study has several limitations that need to be mentioned. Pelvic floor treatments, introduction to MBBS and assessment of study outcomes were performed by the same physiotherapist and therefore blinding was not possible. The possibility of measurement bias, especially in the assessment of pelvic floor muscle outcomes, must be considered. Furthermore, multimodal physiotherapy can only be standardized to a certain extent and a tailored individual approach was taken. The generalizability of our results may be limited by the fact that our study participants were mostly highly educated and primarily white European descendants, who were referred to a private freelance physiotherapy practice.

Integrating home-based MBBS in multimodal pelvic floor physiotherapy has several benefits. Women with vulvodynia are commonly referred to pelvic floor physiotherapy as a standard part of multimodal therapy. Pelvic floor therapy does not only treat painful myofascial trigger points but also involves recognizing and respecting physical pain limits. The mindfulness-based approach supports body awareness and enables patients to accept their pain thresholds. Women with a history of pain and/or sexual abuse may be encouraged to pursue non-penetrative sexuality, as introital pain may be regarded as an unspoken "no" MBBS is thought to benefit chronic-pain patients by a distinct mode of action which differs from the manual techniques applied by physiotherapists. Myofascial treatments are helpful in releasing muscle tensions and facial restrictions but also increase body awareness and function. MBBS is thought to complement these positive effects by inducing desensitization of the pain-generating nervous systems and reducing sympathetic nervous system activity. A special advantage of audio-guided MBBS is the readily availability of treatment which allows patients to actively take control and may increase their empowerment. In our study several patients reported that they continued performing MBBS after the end of study treatment, which may explain the ongoing positive effects observed during follow-up assessments.

In our study the MBBS was designed as a general body scan and included only few sentences on pelvic floor and genitals. Using a MBBS text addressing mainly the pelvic floor may have more specific effects on muscle overactivity and pain. Future studies may explore the effect of MBBS focusing on the pelvic region in patients with vulvodynia and other gynecologic pain symptoms.

In conclusion, our trial demonstrates that integration of MBBS trainings into multimodal pelvic floor physiotherapy for vulvodynia is feasible and well accepted and may improve pain reduction and sexual function.

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Author contributions

CRediT: **Heidi Halbedl**: Conceptualization, Methodology, Investigation, , Writing - Original Draft; **Daniela Melitta Pfabigan**: Formal analysis, Methodology, Writing – review & editing; **Irene Ebhardt**: Conceptualization, Supervision, Writing – review & editing; **Gerda Trutnovsky**: Conceptualization, Methodology, Supervision, Writing – review & editing.

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