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Efficacy of rhythmical massage in comparison to heart rate variability biofeedback in patients with dysmenorrhea—A randomized, controlled trial

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ABSTRACT

Background: 20–90% of all women suffer from dysmenorrhea. Standard therapy of primary dysmenorrhea (PD) are NSAIDs and oral contraceptives, effective but not without possible side effects.
Objective: To examine the efficacy of rhythmical massage (Anthroposophic Medicine) and heart rate variability biofeedback compared to usual care (control group) on pain intensity in women with primary dysmenorrhea.
Methods: This was a three-arm randomized controlled study. Both interventions (rhythmical massage once a week or HRV biofeedback 15 min daily) were carried out over a period of three months. The third group (control) applied usual care. The primary outcome were between-group differences in mean pain intensity (detected by a Numeric Rating Scale, NRS) during menstruation after three months (post-assessment, t2). Secondary outcomes were the use of analgesics, quality of life (SF-12) and heart rate variability.
Results: The study involved 60 women, mean age 29.7 years, SD 8.0 (n = 23 rhythmical massage, n = 20 biofeedback, n = 17 control). For the primary outcome there was a significant difference between the groups after three months (p = .005). Bonferroni adjusted post-hoc tests revealed a significant difference between rhythmical massage and control group (mean difference: -1.61; 95 CI: -2.77/-0.44; p = .004; ES: -0.80). No significant differences were found between rhythmical massage and biofeedback (mean difference: -0.71; 95 CI: -1.82/0.40; p = .361; ES: -0.34) and between biofeedback and control group (mean difference: -0.90; 95 CI: -2.10/-0.30; p = .211; ES: -0.51). For the secondary outcomes no significant differences were found between the groups at t2. The drop-out rate was higher in the biofeedback group (n = 6) than in the massage (n = 2) or the control group (n = 4).
Conclusion: Preliminary evidence suggests that rhythmical massage might improve pain intensity after 12 weeks compared to usual care.

1. Background

Dysmenorrhea is considered the most common reason for short-term absence from school or work in adolescent girls and adult women.[1–3] Defined as cramp-like pain in the lower abdomen shortly before and during menstruation, it is often accompanied by back pain, nausea, headache or signs of emotional instability.[4–6] Women suffering from primary dysmenorrhea (PD) exhibit no organic anomalies or disorders such as endometriosis, cysts, polyps, which can be the underlying cause for secondary dysmenorrhea.[5] Menstruation itself is the trigger for the onset of PD. Although the pathophysiology is not yet entirely understood, an increased uterine prostaglandin-F2alpha-activity leading to ischemic pain seems to be responsible, probably along with genetic and mental factors.[6–8] Up to 90% of all women report the condition, the severity ranging from slight discomfort to severe pain and activity limitations. The present study focuses exclusively on primary dysmenorrhea.

Conventional PD pharmacotherapy is mainly based on NSAIDs and oral contraceptives (ovulation suppressors) which restrict PGF2alpha levels.[4,9,10] However, a considerable number of women seek alternative therapies due to a reported failure rate of up to 20% and possible adverse side effects.[11]

Complementary PD therapies comprise acupuncture, dietary, herbal and behavioral approaches, physical exercise, biofeedback, massage

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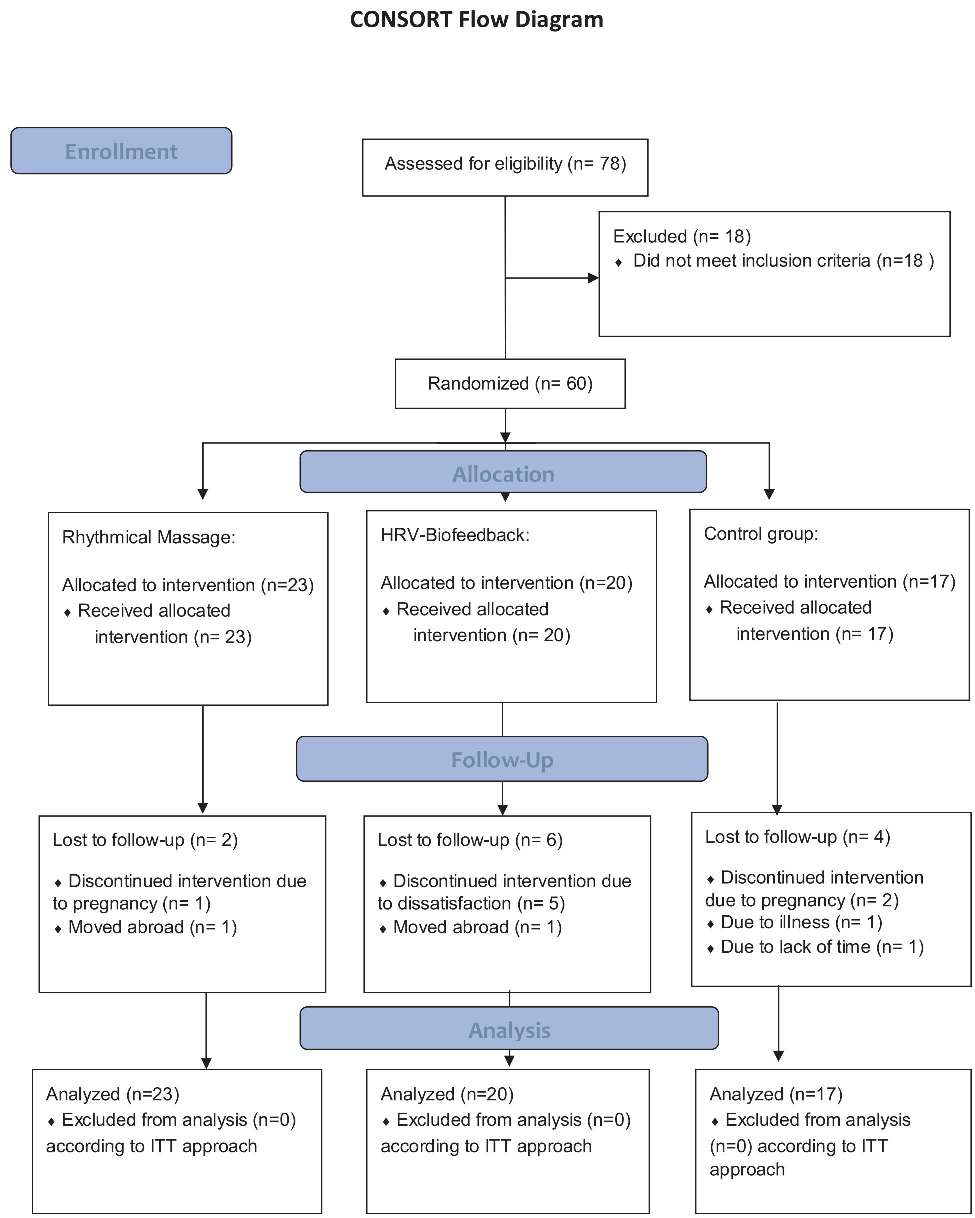

Fig. 1. CONSORT Flow Diagram.

and warmth as a traditional household remedy.[1,11–19] Massage therapy for PD has been evaluated by a limited set of studies. Positive effects were found with respect to pain intensity, possibly effected by normalized PGF2alpha levels and an improved uterine blood flow. However, the majority of these studies investigate Asian aromatherapy massage.[14,15,19–23] Rhythmical massage (RM), the approach explored in the present study, was derived from Swedish massage by Dr Ita Wegman in the 1920s, based on the principles of Anthroposophic Medicine (AM) with a holistic understanding of body, soul and "individuality".[24] Special RM techniques include gentle lifting and rhythmically undulating gliding movements, performed in complex movement patterns such as lemniscates. The approach is believed to have effects on the skin, subcutaneous tissues and muscles, promoting both general effects (e.g., enhancing physical vitality) and disease-specific effects. In a recent publication, Seifert et al. report positive effects of RM on the autonomic nervous system.[25] Rhythmical massage is applied by physiotherapists with an additional 1.5 to 3-year training according to a standardized curriculum.[26] Rhythmical massage therapy is used in patients of all ages for a wide range of indications in various medical fields [27] and can be applied as monotherapy or combined with other therapies.[28] Empirical observations suggest positive effects of rhythmical massage on pain reduction during menstruation. Biofeedback (BF) and its effect on PD has been the subject of previous research, confirming an effectiveness of biofeedback with EMG or Skin Temperature Training.[11,29,30] To the best of our knowledge, no randomized controlled trials have yet been published investigating rhythmical massage or heart rate variability biofeedback (HRV-BF), the approaches presented in the current study, for PD. Our objective was to compare rhythmical massage and HRV biofeedback as adjunct therapies with a control group (CG) that applied only usual care. Primary outcome was the self-reported pain intensity under rhythmical massage or biofeedback compared to control. Secondary outcomes were the use of analgesics, the sum-score of the SF-12 (health survey short form of SF-36), including the two sub-scores SF-12 mental and SF-12 physical, and parameters of a 24 h-HRV-measurement (ECG) before and after intervention or control phase.

2. Methods

2.1. Study design

We conducted a three-arm randomized controlled trial. Blinding was not possible due to the nature of the interventions. Patients who met the eligibility criteria were randomized to one of three groups (rhythmical massage, n = 23; HRV biofeedback, n = 20; control, n = 17 participants). Rhythmical massage took place at the Filderklinik or at two therapeutic facilities in Filderstadt and Tübingen, Germany. Biofeedback was carried out at home. The interventions were applied over a three-month period. Assessments with all three groups comprising completion of the SF-12 questionnaire and a 24 h-ECG-measurement were done prior to the first intervention (baseline, t1) and after the 12-week intervention period (post-assessment, t2). The women in all three groups wrote a menstrual pain diary throughout the intervention and control phases. Data collection and intervention took place for each participant individually. Thus, enrollment of participants was possible at different timepoints during the running study and was done between February 2012 and June 2013. The study was approved by the ethics committee of the University of Tübingen, Germany (No. 109/2012BO1) and registered at Clinical Trials (NCT03712800).

2.2. Participants

For enrollment we had contact with a total of 100 patients, 78 of whom were assessed for eligibility. Criteria required an age between 16 and 46 years, one year minimum of PD (physician-confirmed), a pain intensity on a numeric rating scale (NRS, ranging from 0 to 10, with 0 = no pain, 10 = worst pain imaginable) ≥ 5 on the day of maximal menstrual pain (this criterion was not revealed to the patients to avoid bias), written informed consent (also from parents of underage girls), menarche at least one year ago. Exclusion criteria were a reliable diagnosis of secondary dysmenorrhea, participation in another study, mental retardation, addiction. Of these 78 women 18 did not meet inclusion criteria which led to 60 women who were enrolled and randomized (Fig. 1). Patients were recruited externally through advertisements and physician referrals. They were not hospital inpatients.

2.3. Interventions

Rhythmical massage as an anthroposophic therapeutic approach aims at a recovery of self-regulation and self-healing forces, addressing not only the physical body but also mental and individual aspects. Empirical observations have suggested positive effects of the holistic rhythmical massage approach on PD. An intervention period of three months was determined corresponding to the anticipated onset of the therapeutic effect. Rhythmical massage therapy includes effleurage (gliding) with light, rhythmically undulating engagement into the tissues, kneading with circular, loop and lemniscate-shaped movements of harmoniously varying speed, depth and intensity, with gentle lifting and relieving qualities. The massaging movements are performed with a high level of awareness and concentration and are meant to stimulate self-healing forces rather than robust muscle pressure generating physical relaxation. A single therapy session takes about 30–45 minutes of massage followed by a rest period of 15–20 min. The patient is kept warm throughout the therapy, the body covered by blankets and only the massaged parts exposed.[24] In our study the rhythmical massage intervention consisted of 12 therapy sessions performed by certified, experienced RM therapists once a week.

Biofeedback uses auditory, visual or tactile feedback to make physiological processes such as heart rate or body temperature consciously perceptible as a precondition for the exertion of specific positive influence.[31] HRV biofeedback, one of various biofeedback approaches, gives a visual feedback of the user's heart rate variability. A high HRV is considered an indication of general health, physical and cognitive performance, self-regulation and a decreased risk of illness.[32–34] Indications have been found that autonomic dysregulation may be involved in PD because in a respective study PD-patients had a significantly decreased HRV compared to healthy controls.[35] Thus, one of our study objectives was an increase in HRV as an indication for an improved autonomic regulation. The HRV biofeedback device we used is the Qiu (BioSign GmbH, Ottenhofen, Germany), a battery-operated sphere with an integrated pulse sensor taking pulse measurements from the palm, the fingers or the earlobe (ear-clip). It is placed in the palm or in front of the user and guides them to breathe at resonant frequency (maximal respiratory sinus arrhythmia, RSA, attained at about 0.1 Hz) which is trainable for healthy and ill subjects. The degree of autonomic rhythmization reflecting HRV is visualized by changing colors. Prior to the beginning of the intervention participants in the biofeedback group underwent an instruction session. They were shown how to use the Qiu and the device was set corresponding to each woman's individual resonant breathing frequency. Training itself was to be done at home, 15 min daily. During the intervention period, booster sessions to verify correct use of the Qiu were held after one and three weeks of training and then every four weeks. Participants in the control group were advised to maintain their usual treatment which mainly consisted of analgesic medication, physical exercise and application of warmth (e.g. warm compresses). Following the intervention period, the control group also received 12 sessions of rhythmical massage for ethical and compliance reasons. During this time, the former intervention groups applied usual treatment. In a telephone or written follow-up interview three months after the end of the respective intervention phases (t3) we recorded pain intensity on the three days of maximal menstrual discomfort. In the present publication we report only analyses and results of the RCT parallel group phase (t1 and t2). In addition, we were interested in detailed patient perception of PD and the respective interventions; therefore, we conducted interviews with the participants for a qualitative evaluation. The results of the qualitative analysis will be published elsewhere ((Submitted to the same Journal and to be quoted here if accepted))

2.4. Outcome measures

After a preliminary information and medical history interview all the subsequent assessments and interviews were done according to each patient's menstrual cycle. Pain intensity during menstruation was documented by diary. The women were asked to indicate maximal pain intensity on the three days of maximal menstrual discomfort (usually the first three days), using the NRS. Our primary outcome was mean pain intensity at t2 (post-assessment). Secondary outcomes were maximum pain intensity at t2, the use of analgesics during menstruation, recorded by name and dosage in the pain diary and analyzed as the percentage of participants taking analgesics, HRV parameters obtained by 24 h-ECG-measurements at baseline and post-assessment, and pain-related limitations to daily life activities and quality of life as assessed by the SF-12 questionnaire. Resnick and Parker reported sufficient evidence for the internal consistency of the revised SF-12 with Cronbach alpha coefficients of 0.72 to 0.89 and a test retest reliability of r = 0.73-0.86.[36] Baseline demographic and case history information was obtained by the medical history form.

The 24-h-ECG was taken to generate HRV data. HRV can be assessed by various time or frequency domain measures. Time domain measures are derived from the mean R-R-interval in the ECG, SDNN (standard deviation of normal to normal beats) and RMSSD (root mean square of successive differences) being commonly used parameters. As a general rule there is a positive correlation between SDNN and HRV – a small SDNN corresponds to a low HRV. Frequency domain measures are obtained from spectral analysis of ECG recordings. The main spectral components are distinguished as HF (high frequency), LF (low frequency), VLF (very low frequency) and ULF (ultra-low frequency, additionally obtained from long-term recordings) components of heart rate variability.[37] They are related to specific sources of autonomic modulations. HF mainly reflects vagal activity while LF is affected by both the sympathetic and parasympathetic systems. LF/HF-ratio is rated as a parameter for autonomic balance. We used the SRM CardioScout Multi ECG System (Innovative Medical Solutions, Stuttgart, Germany). The data of a three-hour night phase after a clear decrease of the heart rate indicating the onset of sleep were used for HRV-analysis because they are the least affected by activity-induced heart rate variations.

2.5. Sample size

In the absence of RCTs investigating rhythmical massage or HRV biofeedback for PD, we made a sample size estimate based on a study on acupuncture for dysmenorrhea.[38] Taking into account a clinically relevant effect size (Cohen's $d = 1.15$) and a drop-out rate of 20%, we determined a sample size of 18 participants per group or 54 in total. Since this estimate was based on a different type of intervention, an exact calculation was not possible. We therefore decided to use a "convenient sample size" of 60 patients in total.

2.6. Randomization

Considering that menstrual pain and its response to therapy may be influenced by women's age and the intake of oral contraceptives, we used a permuted block system for the randomization procedure. Four boxes were prepared containing opaque envelopes with the allocations. The women took an envelope out of the box matching their individual status: "Age over 35, no oral contraceptives", "age over 35, taking oral contraceptives", "age under 35, no oral contraceptives", "age under 35, taking oral contraceptives". This led to differing group sizes of n = 23 (RM), n = 20 (HRV-BF) and n = 17 (CG) participants. Randomization was done at the second appointment (baseline) by Filderklinik staff otherwise not involved in the study.

2.7. Statistical analysis

Statistical analysis was done using the Statistical Package for the Social Sciences (SPSS) version 22.0. Missing values were replaced by the Markov chain Monte Carlo method (multiple imputation). The significance level for analysis was set at $\alpha = .05$ (two tailed). Baseline demography comparisons between the groups were calculated with analysis of variance (ANOVA) or Chi-square test according to distribution of data. For the primary outcome we applied an ANCOVA for differences between groups at the end of the intervention (t2), controlling for baseline as covariate. Bonferroni based post-hoc tests with alpha-correction were used to examine which groups differed from each other at t2. For all the secondary outcomes, we calculated group differences at t2 (post-assessment) and pre-post differences (within each group) with 95% confidence intervals. Effect sizes d were calculated and classified as small (0.21-0.5), medium (0.5-0.8) and large (> 0.8) according to Cohen (1988).[39] With respect to the use of analgesics we calculated the percentage of participants taking analgesics at t1 and t2. We conducted the analyses without and with missing imputation (Markov chain Monte Carlo).

3. Results

Demographic data are summarized in Table 1. There were no significant group differences in terms of age, height and weight whereas gynecological history revealed statistically significant differences between groups. Ovulation pain was most frequently reported in the massage group, the highest number of pregnancies occurred in the biofeedback group, age at menarche was lowest in the control group (Table 1). No significant differences were found at baseline with respect to the primary outcome (mean pain intensity) and to the secondary outcomes quality of life (SF-12 sum-score, sub-scores mental and physical) and heart rate variability parameters SDNN, RMSSD, Ratio LF/HF (Table 1).

Concerning the primary outcome there was a significant difference between the groups at the post-assessment t2 (p = .005). Bonferroni adjusted post-hoc tests revealed a significant difference between rhythmical massage and control group (mean difference: -1.61; 95 CI: -2.77/-0.44; p = .004; ES: -0.80). No significant differences were found between rhythmical massage and biofeedback (mean difference: -0.71; 95 CI: -1.82/ 0.40; p = .361; ES: -0.34) and between biofeedback and control group (mean difference: -0.90; 95 CI: -2.10/-0.30; p = .211; ES: -0.51). For the secondary outcomes, no significant differences were found between the groups at t2 (Table 2). Concerning pre-post differences within the groups, quality of life parameters improved after rhythmical massage (SF-12 sum-score: mean difference: 6.9; 95 CI: 1.0 / 12.9; ES: 0.6) and after biofeedback (SF-12 sum-score: mean difference: 8.7; 95 CI: 3.5 / 13.8; ES: 0.6) mainly based on an improvement of the sub-score SF-12 physical (rhythmical massage: mean difference: 8.1; 95 CI: 3.3 / 12.8; ES: 1.1 and biofeedback: mean difference: 4.4; 95 CI: 0.4 / 8.5; ES: 0.5) (Table 3).

Regarding medication, the percentage of participants taking analgesics was lower after rhythmical massage (70% at t1 and 60% at t2) and higher after biofeedback (57% at t1 and 64% at t2) and in the post-assessment of the control group (54% at t1 and 62% at t2). The results did not differ between the analysis without and with missing imputation (Markov chain Monte Carlo). The results presented are based on the analysis with missing imputation.

Twelve participants (20%) dropped out of the study (Fig. 1), three of them (one in each group) due to moving abroad or lack of time. Three women in the massage (n = 1) and control group (n = 2) became pregnant. They had to discontinue their participation in the study as pregnancy at an early stage is a contraindication for rhythmical massage.[28] One woman in the control group fell ill (no further information given) and as a consequence decided to drop out of the study. Five participants in the biofeedback group discontinued the intervention and gave dissatisfaction with the biofeedback training as their reason.

4. Discussion

To the best of our knowledge, no randomized controlled trials have yet been published investigating rhythmical massage or HRV biofeedback, the approaches presented in the current study, for PD. In summary, the present study shows that the mean pain could be significantly reduced with rhythmical massage at the end of the 12-week therapy, compared to the control group. Both interventions promoted a significant improvement in quality of life within each group from t1 to t2 (SF-12 sum-score).

A reduction of pain in primary dysmenorrhea effected by massage has also been shown in other studies. J.-S. Kim et al. report a pain reduction in women with dysmenorrhea after abdominal meridian massage 5 min daily on 6 days from the fifth day before until the first day of menstruation. The control group didn´t receive any treatment. Limitations of this study are that the intervention was applied only during one menstrual cycle and that the groups were not randomized.[14] Azima et al. conducted a randomized controlled trial comparing lavender oil effleurage massage with isometric exercises and with usual care (control group). Both interventions led to a significant reduction of pain intensity in PD. In contrast to the study at hand, the massage was only applied on the days of menstrual pain maximum.[23] The authors do not report effect sizes, which makes it difficult to compare the results with the present study. Y.-J. Kim et al. analyzed the effect of self-aromatherapy massage in women with dysmenorrhea compared to a placebo and to a non-treatment control group. Although the authors report a significant pain reduction after massage therapy the results can only be compared to a limited extent with our study as Kim et al. did not randomize the groups and analyzed only 24-h short-term effects.[40]

Table 1
Demographics and gynecological history at baseline.

Variable	MG (n = 23)	BFG (n = 20)	CG (n = 17)	statistical significance		
	M (SD)	M (SD)	M (SD)	F/X²	df	p
Demographics						
Age (years)	30.22 (7.72)	31.56 (7.44)	26.65 (8.4)	1.963	2	0.150
Height (m)	1.66 (0.07)	1.68 (0.08)	1.66 (0.05)	0.574	2	0.566
Weight (kg)	64.22 (15.05)	63.6 (21.27)	59.47 (9.43)	0.468	2	0.629
Gynecological history						
Contraceptive pills				1.921	2	0.383
yes	1	2	3			
no	22	18	14			
Cycle length (days)	28.22 (2.1)	28.22 (1.51)	28.09 (2.75)	0.023	2	0.977
Menstrual period (days)	5.15 (1.27)	5.35 (1.48)	5.29 (1.59)	0.114	2	0.890
Ovulation pain				6.340	2	0.042*
yes	13	5	4			
no	10	15	13			
Pregnancy	0.26 (0.54)	0.7 (1.13)	0 (0)	4.371	2	0.017*
Prevalence 0	18	13	17			
1	4	3	0			
2	1	1	0			
3	0	3	0			
Miscarriage	0.04 (0.21)	0.1 (0.31)	0 (0)	0.966	2	0.387
Prevalence 0	22	18	17			
1	1	2	0			
Bleeding intensity (score)	4.26 (0.75)	3.65 (1.14)	4.24 (0.66)	3.110	2	0.052
Day of max. pain	1.41 (1.09)	1.23 (0.7)	1.21 (0.69)	0.366	2	0.695
Age at menarche	13.04 (1.48)	13.2 (1.58)	12.0 (1.12)	3.806	2	0.028*
Mean pain intensity (0-10)	4.59 (2.12)	4.49 (1.85)	4.48 (1.54)	0.020	2	0.981
Max. pain intensity (0-10)	6.45 (1.79)	6.44 (2.19)	6.27 (1.26)	0.061	2	0.941
SF-12 mental	50.62 (10.26)	45.39 (10.65)	44.45 (8.15)	2.380	2	0.102
SF-12 physical	39.58 (8.22)	40.46 (9.65)	44.17 (8.52)	1.432	2	0.247
SF-12 sum-score	90.15 (10.99)	85.91 (14.15)	88.62 (12.89)	0.607	2	0.548
SDNN	101.85 (35.41)	82.28 (19.69)	96.97 (28.47)	2.565	2	0.086
RMSSD	52.76 (21.61)	43.74 (18.61)	54.18 (33.32)	1.032	2	0.363
LF/HF-Ratio	3.00 (2.17)	2.83 (2.21)	3.31 (2.46)	0.215	2	0.807

MG = massage group, BFG = biofeedback group, CG = control group, M = mean value, SD = standard deviation. In column depending on the type of variable (metric or categorial) F/χ, indicates either the F-value of a univariate ANOVA or the χ2–value of a χ2-test by Pearson. SDNN = Standard deviation of normal to normal; RMSSD = Root mean square of successive differences; LF/HF-Ratio = Ratio of two bands from frequency domain analysis: LF band (0.04-0.15 Hz) indicating sympathetic and parasympathetic activity, HF band (0.15-0.40 Hz) indicating parasympathetic activity.

So far there are only a few studies on rhythmical massage.[24,25,27,28] Wälchli et al. explored effects of rhythmical massage on body surface temperature (infrared imaging, IRI) and heart rate variability (ECG) in 18 in- and outpatients who received RM for any indication. The IRI measurements were taken before and after each massage treatment. The ECG recording ran from the beginning to the end of each therapy session. The authors found an immediate as well as a longer-term progressive improvement of warmth distribution and regulation of the resting HRV. The informative power of this study may be limited by the small number of participants and by uncontrolled factors such as other therapies and medications.[27] Hamre et al. studied clinical outcomes (Disease and Symptom Scores and SF-36) over a period of 48 months in 85 outpatients referred to rhythmical massage for various chronic diseases. The authors report a long-term reduction of chronic disease symptoms and an improvement of quality of life following the RM therapy. Possible confounders such as selection, other therapies and medications or psychologic factors are mentioned. Some of them were excluded by statistical analyses. Moreover, as RM was evaluated as a therapy package, the question of specific therapy effects versus non-specific effects was not an issue of the study.[28] Kanitz, Seifert and colleagues applied a single rhythmical massage with either aroma oil or a neutral oil, compared to a sham massage, on 118 healthy adults and assessed the efficacy of the intervention on several dimensions of well-being (standardized questionnaires MDBF, Bf-S, B-L and visual analog scales), salivary cortisol and heart rate variability (24 h ECG). The massage was rendered following exposition to an experimental stressful situation (Trier Social Stress Test, TSST). The authors found no differences between the treatment groups with respect to self-reported well-being and salivary cortisol. However, RM caused a specific and marked stimulation of the autonomic nervous system which was considerably more pronounced in the RM groups than in the sham massage group. Unfortunately, as the authors report, there was a baseline difference between the groups with no identifiable cause, as the trial had been planned and conducted on a methodologically sound basis.[24,25] These studies on rhythmical massage differ considerably from our trial e.g., with respect to study design, type and population. The first two studies are cohort studies without control groups and none of the studies focused on dysmenorrhea. Therefore, it is difficult to place them in a common context with the results of our study. It would be desirable to have more randomized controlled trials focusing on rhythmical massage in the future with similar designs. This would allow better comparability of the results and would increase the evidence base in this field of integrative medicine.

With respect to analgesics we monitored the use to rule out distorted pain reduction results due to increased medication intake and to detect possible analgesics reduction connected with positive intervention effects. Many women have been used to taking analgesics during menstruation for years and have made the experience that taking them early on before pain maximum results in better pain control. This might lead to a certain reluctance in analgesics reduction despite positive intervention effects. Nevertheless, the pain reduction in the massage group is in line with the decrease in analgesics reported for this group.

As mentioned above, both intervention groups experienced an improvement in quality of life. This is congruent with other biofeedback studies. The positive effects of the HRV biofeedback might be related to the breathing technique adopted from the training and to a rise in self-

Table 2
Mean differences between groups at t2 (post-assessment).

Outcome	Groups	Diff.	95 CI (L / H)	*ES*
Mean pain intensity	MG v CG	**−1.61**	**(−2.77/−0.44)**	**−0.80**
	BFB v CG	−0.90	(−2.10/0.30)	−0.51
	MG v BFB	−0.71	(−1.82/0.40)	−0.34
Maximum pain intensity	MG v CG	−1.31	(−2.73/0.10)	−0.60
	BFB v CG	−0.72	(−2.18/0.74)	−0.40
	MG v BFB	−0.59	(−1.94/0.76)	−0.23
SF-12 mental	MG v CG	0.75	(−5.64/7.14)	0.08
	BFB v CG	3.05	(−3.34/9.43)	0.33
	MG v BFB	−2.29	(−8.36/3.77)	−0.26
SF-12 physical	MG v CG	4.51	(−1.33/10.34)	0.59
	BFB v CG	1.44	(−4.53/7.41)	0.17
	MG v BFB	3.07	(−2.39/8.53)	0.40
SF-12 sum-score	MG v CG	5.56	(−3.36/14.48)	0.40
	BFB v CG	6.13	(−3.09/15.35)	0.41
	MG v BFB	−0.57	(−9.18/8.03)	−0.04
SDNN	MG v CG	3.08	(−12.49/18.64)	0.13
	BFB v CG	−0.38	(−16.72/15.96)	−0.02
	MG v BFB	3.46	(−12.01/18.92)	0.17
RMSSD	MG v CG	6.11	(−6.12/18.35)	0.28
	BFB v CG	0.80	(−11.99/13.60)	0.05
	MG v BFB	5.31	(−6.53/17.15)	0.30
LF/HF-Ratio	MG v CG	−0.29	(−1.31/0.73)	−0.18
	BFB v CG	0.44	(−0.62/1.50)	0.26
	MG v BFB	−0.73	(−1.71/0.25)	−0.65

MG: Massage; BFB: HRV-Biofeedback; CG: Control Group; v: versus; SF-12 (Quality of life questionnaire with the sum-score and the two sub-scores mental and physical); SDNN = Standard deviation of normal to normal; RMSSD = Root mean square of successive differences; LF/HF-Ratio = Ratio of two bands from frequency domain analysis: LF band (0.04-0.15 Hz) indicating sympathetic and parasympathetic activity, HF band (0.15-0.40 Hz) indicating parasympathetic activity; ES: Effect sizes (Cohen's *d*); Diff: mean difference between groups at t2 (post); numbers in bold are indicating 95% confidence intervals which do not include 0.

regulation capacity. These factors have been discussed as possible “mechanisms” for pain reduction through yoga and biofeedback.[41–44]

Comparing the control group with the two intervention groups, pain reduction was significantly higher in the massage group at t2. This was not the case for the biofeedback group. Possible reasons are that the regular appointments with the massage therapists and the treatment being administered through actual human touch resulted in a higher level of commitment. Many patients in the massage group might also have appreciated the monetary value, since a single session costs approx. 50 €. Thus, with 12 therapy sessions the patients received a therapy worth approx. 600 €. Another reason might be that compared to the rhythmical massage the personal contact with the patients was less frequent in the biofeedback group (3–5 booster sessions after introduction to the device in comparison to 12 massage appointments). This might also explain the comparatively high drop-out rate in this group: Five out of six drop-outs indicated dissatisfaction with the biofeedback training (Fig. 1). However, the biofeedback intervention was significantly more cost-effective compared to rhythmical massage. HRV biofeedback devices can be bought for 150–180 € and can then be used any time for several years.

One limitation of the study is that no exact sample size calculation could be performed due to a lack of studies on rhythmical massage or HRV biofeedback so that the present results should be interpreted as results of a pilot study. Furthermore, there is a limitation concerning an adequate measurement of HRV. It would have been desirable to record the HRV directly on the day of maximal menstrual pain, which unfortunately was not feasible in every case, so that some measurements were taken up to three days later. Another limitation is the lack of blinding which remains a difficult task for this type of intervention.

With respect to generalizability, on the one hand the study results can be transferred to a large number of women as the data have been raised from women of different ages, socio-economic backgrounds, number of pregnancies and drug therapy. On the other hand, the generalizability is limited: Our study population is heterogeneous, but does not represent all women with PD, given the exclusion criteria. The

Table 3
Mean differences between pre- (t1) and post-assessment (t2).

			pre		post				
Group		N	mean	(sd)	mean	(sd)	Diff	95 CI (L / H)	*ES*
Massage	Mean pain intensity	23	4.6	(2.1)	3.6	(2.4)	**−1.0**	(−1.6/−0.5)	**−0.5**
	Max. pain intensity	23	6.4	(1.8)	5.3	(2.9)	**−1.1**	(−2.0/−0.2)	**−0.5**
	SF-12 mental	23	50.6	(10.3)	49.8	(9.0)	−0.9	(−5.1/3.4)	−0.1
	SF-12 physical	23	39.6	(8.2)	47.6	(6.8)	**8.1**	(3.3/12.8)	**1.1**
	SF-12 sum-score	23	90.1	(11.0)	97.1	(13.8)	**6.9**	(1.0/12.9)	**0.6**
	SDNN	23	101.8	(35.4)	101.0	(26.7)	−0.8	(−15.0/13.4)	0.0
	RMSSD	23	52.8	(21.6)	55.5	(24.2)	2.7	(−6.0/11.4)	0.1
	LF/HF-Ratio	23	3.0	(2.1)	2.7	(1.0)	−0.3	(−1.3/0.7)	−0.2
HRV-Biofeedback	Mean pain intensity	20	4.5	(1.9)	4.2	(1.9)	−0.3	(−1.2/0.6)	−0.2
	Max. pain intensity	20	6.4	(2.2)	5.9	(2.2)	−0.5	(−1.4/0.3)	−0.2
	SF-12 mental	20	45.4	(10.7)	49.4	(8.9)	4.1	(−0.3/8.4)	0.4
	SF-12 physical	20	40.5	(9.6)	44.9	(8.5)	**4.4**	(0.4/8.5)	**0.5**
	SF-12 sum-score	20	85.9	(14.1)	94.6	(15.4)	**8.7**	(3.5/13.8)	**0.6**
	SDNN	20	82.3	(19.6)	91.5	(14.0)	9.2	(−0.2/18.6)	0.5
	RMSSD	20	43.7	(18.6)	46.0	(11.1)	2.2	(−4.3/8.8)	0.2
	LF/HF-Ratio	20	2.8	(2.2)	3.4	(1.2)	0.5	(−0.2/1.3)	0.3
Control Group	Mean pain intensity	17	4.5	(1.5)	5.1	(1.6)	0.6	(0.0/1.2)	0.4
	Max. pain intensity	17	6.3	(1.3)	6.5	(1.4)	0.2	(−0.4/0.9)	0.2
	SF-12 mental	17	44.4	(8.2)	45.9	(9.8)	1.5	(−2.6/5.6)	0.2
	SF-12 physical	17	44.2	(8.5)	44.8	(8.4)	0.7	(−2.6/3.9)	0.1
	SF-12 sum-score	17	88.6	(12.9)	90.4	(14.2)	1.8	(−2.9/6.5)	0.1
	SDNN	17	97.0	(28.5)	96.4	(20.9)	−0.5	(−15.1/14.1)	0.0
	RMSSD	17	54.2	(33.3)	50.0	(18.7)	−4.2	(−17.5/9.2)	−0.2
	LF/HF-Ratio	17	3.3	(2.5)	3.1	(2.2)	−0.2	(−1.2/0.7)	−0.1

Mean pain intensity (0–10); Maximum pain intensity (0–10); SF-12 (Quality of life questionnaire with the sum-score and the two sub-scores mental and physical; HRV = Heart Rate Variability; SDNN = Standard deviation of normal to normal; RMSSD = Root mean square of successive differences; LF/HF-Ratio = Ratio of two bands from frequency domain analysis: LF band (0.04-0.15 Hz) indicating sympathetic and parasympathetic activity, HF band (0.15-0.40 Hz) indicating parasympathetic activity; ES: Effect sizes (Cohen's *d*); Diff: mean difference between post and pre (numbers in bold are indicating 95% confidence intervals which do not include 0).

results of the present study do not provide any information about long-term effects. With regard to rhythmical massage, there is a further restriction because it can only be applied by experts in this specific massage technique. Biofeedback training, however, is easy to learn; smartphone-based HRV biofeedback applications are now available so that this kind of intervention can be made available to many people at relatively low cost.

In summary, preliminary evidence suggests that rhythmical massage might improve pain intensity after 12 weeks compared to usual care. For future studies, a longer observation period would be desirable, as experience shows that menstrual complaints can persist for many years and the effect of pain reduction in the present study has been investigated over a relatively short period of time.

Conflict of interest

The authors report no conflicts of interest. The funding sources had no role in the conduct of research or preparation of article.

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