Patient Education and Counseling 105 (2022) 3279–3286

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.journals.elsevier.com/patient-education-and-counseling

Effects of health education and progressive muscle relaxation on vasomotor symptoms and insomnia in perimenopausal women: A randomized controlled trial

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ARTICLE INFO

Keywords:
Perimenopausal women
Vasomotor symptoms
Insomnia
Health education
Progressive muscle relaxation

ABSTRACT

Objectives: This study aims to determine the effects of health education (HE) and progressive muscle relaxation (PMR), individually or combined, on vasomotor symptoms and insomnia in perimenopausal women.
Methods: This study is a single-center, pretest-posttest, randomized controlled trial with a factorial design. The research sample consists of 108 women who were randomly divided into three groups: HE + PMR group (n = 36), PMR group (n = 36) and control group (n = 36). 90 women completed the study. The data were collected in three steps by using instruments of Personal Information Form, Visual Analog Scale and a diary for vasomotor symptoms, Women's Health Initiative Insomnia Rating Scale.
Results: Hot flash and night sweats frequency and severity scores/24 h, the VAS scores for hot flashes and night sweats, and the WHIIRS scores significantly improved more in the intervention groups compared to the control group ($p < 0,05$). Compared to the group PMR, the group PMR + HE had a greater improvement with larger effect size in all measurements.
Conclusions: PMR and HE counseling by nurses benefit perimenopausal women who suffer from insomnia and vasomotor symptoms.
Practice implications: PMR combined with HE or PMR alone is effective in managing vasomotor symptoms and insomnia; therefore, they can easily be integrated into clinical practice.

1. Introduction

Vasomotor symptoms and sleep problems commonly appear during perimenopause [1]. Previous studies have shown that there is strong correlation between vasomotor symptoms and sleep quality; sleep problems negatively affect women's quality of life and daily life activities, and vasomotor symptoms negatively affect their sleep quality [2–4]. It has also been suggested that health education is an appropriate strategy to manage symptoms of menopause [5,6]. Particularly, mind-body based therapies appear to be safe and economical interventions to cope with the symptoms. Progressive muscle relaxation (PMR) is among these effective interventions. Various studies have demonstrated that PMR is effective in managing vasomotor symptoms and improving sleep quality [7–9].

Healthcare professionals may help manage the common perimenopause problems, vasomotor symptoms and insomnia, by providing perimenopausal women with appropriate care. There are many studies that investigate the ways to manage vasomotor symptoms and improving sleep quality in perimenopausal women [7–9]; however, there is no study that examines the effects of PMR combined with health education on vasomotor symptoms and insomnia. Accordingly, this study aims to expose the effects of health education and progressive muscle relaxation, combined or alone, on vasomotor symptoms and insomnia in perimenopausal women.

2. Method

2.1. Design

This study is a single-center, pretest-posttest, randomized controlled trial with a factorial design, which is registered on ClinicalTrials.gov, with number NCT04808232. The design, procedures, and reporting

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https://doi.org/10.1016/j.pec.2022.07.015
Received 30 January 2022; Received in revised form 19 July 2022; Accepted 22 July 2022
Available online 28 July 2022
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phases of the study conforms with the criteria of the 'CONSORT 2010 checklist of information to include when reporting a randomized trial' (Supplementary file: CONSORT 2010 checklist).

2.2. Population and sample

The study population consists of 1830 women of 40–55 ages who were enrolled patients of a Family Health Center (FHC). We carried out a pilot study to determine the sample size. The pilot study was conducted on 18 women; one third of whom were assigned to the group PMR + HE (n = 6), another to the group PMR (n = 6), and the last third to the group C (n = 6). A sample size of at least 84 women, as 28 in each group were required to perform a power analysis for the study. Taking into account a dropout rate of 25 %, which is referred to in the study by Garcia et al. [10], we included 36 women in each group. The data were collected between February 17th, 2019 and April 2nd, 2020 (Fig. 1: Consort flowchart).

2.2.1. Inclusion criteria

- Placing at the STRAW (Stages of Reproductive Aging Workshop) stages + 1 or + 2,
- Experiencing natural menopause,
- Rating above 10 on the Women's Health Initiative Insomnia Rating Scale,
- Rating above 3 on the Visual Analog Scale for vasomotor symptom severity score,
- Experiencing moderate or severe hot flash more than 3 times a day,
- Using a smart mobile phone (IOS and Android) effectively.

2.2.2. Exclusion criteria

- Receiving or previous experience of hormone replacement therapy,
- Diagnosis with any psychiatric disorder,
- Use of alcohol,
- Use of sleep medications,

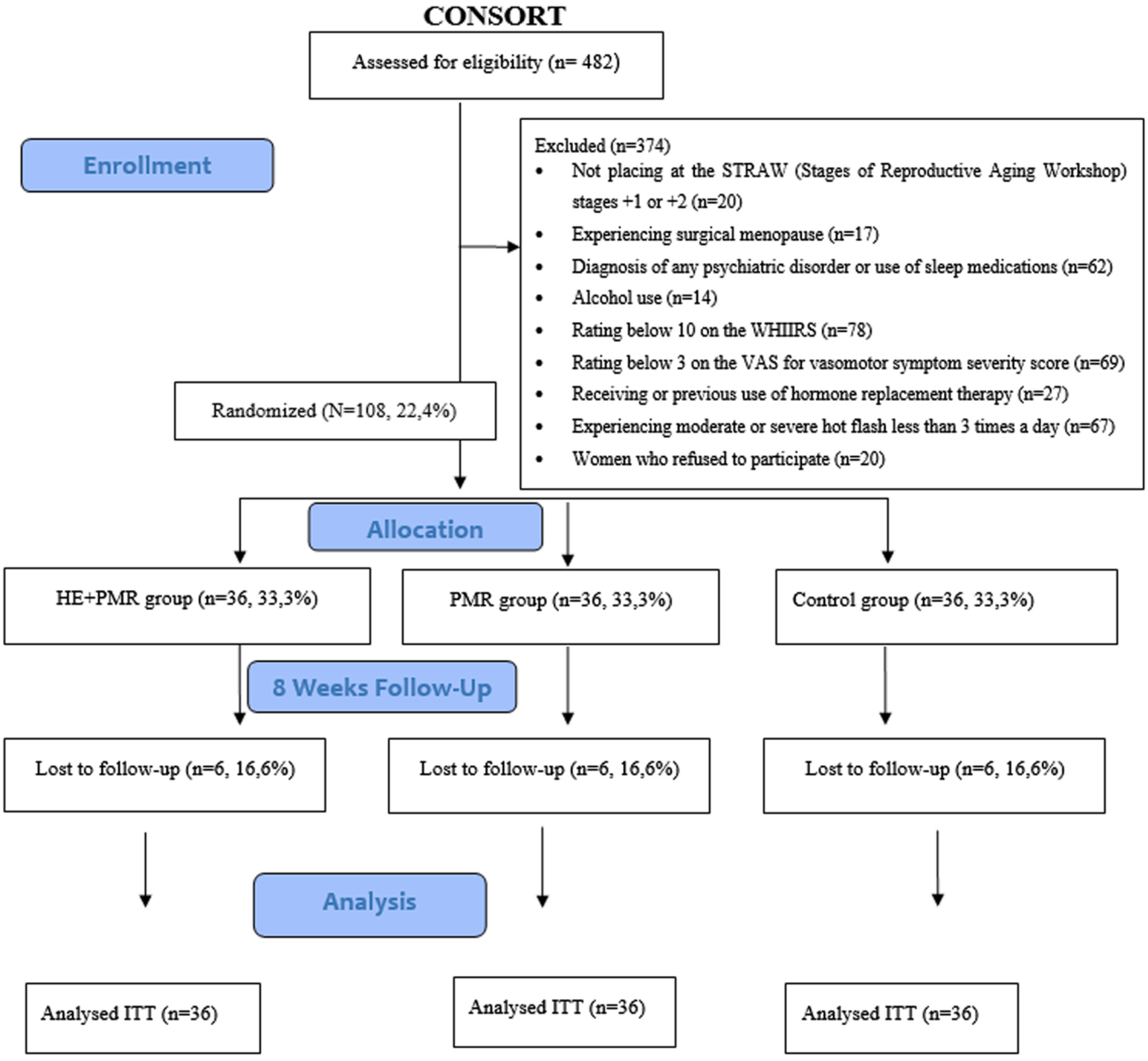

Fig. 1. Consort flowchart.

- Practicing any other techniques of mind-body based therapies (meditation, hypnosis, yoga, mindfulness, guided imagery),
- Diagnosis of any disorder that may cause vasomotor symptoms or insomnia, and receiving medical treatment for a chronic disease (thyroid diseases, heart failure, neurological disorders).

2.3. Instruments

2.3.1. Personal information form

This form consists of 12 items including women's age, education level, marital status, working status, income level, characteristics of vasomotor symptoms and insomnia, status of smoking and regular physical activity.

2.3.2. Visual Analog Scale (VAS) for vasomotor symptoms

A VAS was used to determine the severity of complaints of hot flashes and night sweats. A horizontal scale of "1"–"10" was used for each vasomotor symptom. The women were asked to rate the severity of their symptoms on the scale where "1" indicated no symptom and "10" indicated the most severe symptom.

2.3.3. Women's Health Initiative Insomnia Rating Scale (WHIIRS)

The WHIIRS was developed by Levine et al. to analyze and interpret symptoms of insomnia. It was adapted into Turkish by Timur and Hotun Şahin. The WHIIRS has 5 questions with answers on a 5-point, Likert-type scale (from 0 to 4). A total score of 10 or above on this scale indicates that the individual suffers from insomnia [11,12]. Cronbach's alpha of the scale was found 0.94 in our study.

2.3.4. Diary for vasomotor symptoms

This diary was developed by Guttuso et al. [13]. It is a weekly schedule rating frequency and severity (mild, moderate, severe, or none) of hot flashes and night sweats within 24 h. In our study, women were asked to record their vasomotor symptoms, and rate their severity on the diary for 9 weeks. They were also asked to record night sweats when they woke up.

2.3.4.1. Calculation of frequency of hot flashes and night sweats. An average hot flash and night sweats frequency for each group was calculated from the numbers of hot flashes and night sweats recorded per week.

2.3.4.2. Calculation of severity of hot flashes and night sweats. A weekly severity score was calculated for each group as follows: number of mild hot flashes × 1; number of moderate hot flashes × 2, and number of severe hot flashes × 3. An average severity score in a period of 24 h was also obtained from the severity scores that were weekly calculated.

We calculated the frequency and severity mean scores during the 7-day baseline period as well as the end of the 4th and 8th week of intervention.

2.3.5. Tracking chart for PMR practice

This chart was created to track the women's practice of PMR. It included name of the participant and the starting date of PMR practice. The chart was created for eight weeks throughout which the practice would be in progress. The women filled out the chart to reveal whether or not they practiced PMR on a daily basis.

2.3.6. Tracking chart for health education

This chart demonstrates the name of the participant and the starting date of health education at the top. It includes the eight-week implementation period. The women were asked to fill in the chart whether they implemented the education for each day. The women were asked to adapt the information they received to their daily lives in order to cope with the vasomotor symptoms and insomnia they learned during the health education. For instance: The women were asked to mark each day whether they adjusted themselves to such issues as not consuming excessive amount of spicy food or taking regular showers.

2.4. Materials

2.4.1. Health education booklet

A draft was prepared based upon the literature, which provided women with information about common perimenopausal symptoms of hot flashes, night sweats and insomnia, and certains ways of how to manage them [9,14,15]. A total of 9 academic experts on the subject were consulted for the content suitability of the draft. Then, a health education booklet of 30 pages was ready to be delivered to the women. Contents of the booklet contained transition to menopause, menopause period, common problems in this period, hot flashes and night sweats, tips for managing hot flashes, insomnia, tips to sleep better, sleep hygiene education and information for progressive muscle relaxation.

2.4.2. Progressive muscle relaxation CD

"Audio Records of Relaxation Techniques CD" prepared by the Turkish Psychologists Association was converted to MP3 and delivered to the participants. In the direction of PMR audio records, each muscle group is tensed while taking a deep breath, and then the muscle groups are relaxed while gradually releasing the breath. Relaxation period lasts for 10–20 s before the next muscle group is tensed. All the muscles in our body are tensed and relaxed from face to hands, arms, neck, shoulder, chest, abdomen, hips, feet and finally fingers. Participants were asked to practice PMR every day of the week for the best effect. In cases where this was not possible, they were expected to apply at least 4 days a week.

2.5. Data collection

Before collecting the data, we conducted a pilot study with a total of 18 women, 6 of whom were divided into three different groups. After the pilot study, we didn't need to make any changes in the instruments or in the study process. The women participating in the pilot study were not included in the current study.

2.5.1. Randomization

Women who met the inclusion criteria were informed about the study purpose and process, and those who agreed to participate in the study provided informed consent forms. Pretests were administered to these participants. The sample of 108 women were stratified according to their status of smoking and physical activity, and assigned to one of the three groups by sealed envelope system. A nurse working in the FHC where the study was carried out randomly allocated the women from the same strata to group PMR + HE, group PMR and group C. To test whether distributions were equal, we performed chi-square test for homogeneity. We found that the distribution of counts was homogeneous across the groups in terms of stratification criteria ($p < 0.05$).

2.5.2. Validity-reliability

In the study, the Cochrane Risk of Bias Tool (RoB 2 tool) was used to evaluate the risk of bias [16].

Inclusion criteria were set to avoid *Selection Bias.*

No blinding is used to avoid *performance bias*, as the researcher herself implemented the interventions and no placebo intervention was used in the study.

An individual other than the researcher administered pretests and implemented the random allocation of the participants to avoid *detection bias*.

The study data were grouped into three categories (A–C) and entered into the SPSS program. The data analysis was carried out by an independent statistician out of the research team to avoid *reporting bias*.

Intention-to-treat analysis was performed to handle dropouts or incomplete data at posttests to avoid *attrition bias.*

2.5.3. Procedure

2.5.3.1. 1st assessment (baseline). Before first implementation, women enrolled in the FHC were evaluated according to inclusion criteria of the study by a nurse who was working in the institution. Then they were asked to fill out the instruments Personal Information Form, the VAS for vasomotor symptoms and the WHIIRS. After evaluating the forms, those who met the inclusion criteria, were randomly assigned to the interventions and control groups by means of sealed envelope system. The women involved in the study sample were given the diary developed to determine the characteristics of vasomotor symptoms they experienced.

After one week, the researcher divided the women in the intervention groups into groups of three. She phoned to invite them to health education with details of date, place, time, and the comfortable dress code of the event. The researcher first provided the women in the group PMR + HE with a 30-minute theoretical knowledge, and then performed PMR. After a ten-minute break, the women performed PMR on their own. At the end of the implementation, they were given the booklet developed by the researcher. The women in group PMR were divided, contacted and invited likewise; however, they were not provided with theoretical knowledge. They were asked to perform PMR at the institution after the researcher had showed how to practice it.

Once the first implementation was complete, the PMR instruction with music was installed on the women's phones so that they could do the exercise at home. The women in the intervention groups were sent messages through WhatsApp (chat groups) per day to implement the interventions and fill out the forms.

2.5.3.1.1. The control group. No intervention was implemented to the women in the control group although a Whatsapp group was created so that a reminder massage could be sent to them per day to fill out the forms.

2.5.3.2. 2nd and 3rd assessment. At the end of the 4th and 8th weeks of intervention, all of the women included in the sample submitted the VAS for vasomotor symptoms and the WHIIRS they filled out to the nurse working in the FHC where the study was carried out. Schedule of application of measurement tools can be observed in Supplementary table (Supplementary material Table 1).

2.6. Data analysis

The SPSS 24 (IBM SPSS Statistics 24) package program was used to store and analyze the data. The data were analyzed using frequency tables, descriptive statistics, ANOVA test, Repeated Measures test, Kruskal-Wallis H test, Friedman test and cross tabulation with chi-square test. The ANOVA F-test was performed to detect the effect size between groups ($f = 0.10 <$ small < 0.25, $0.25 >$ medium < 0.40, $0.40 <$ large), and partial eta-squared within groups ($\eta 2 = 0.01 <$ small < 0.06, $0.06 <$ medium < 0.14, $0.14 <$ large) [17].

2.7. Ethical considerations

We obtained written permits from Ethics Committee for Non-Interventional Studies and the institution where the study would be carried out before the start of the study. In addition, written informed consent was obtained from all women who were willing to participate in the study. After the study was completed, the health education booklet was delivered to the group PMR. Similarly the PMR mp3 and the booklet were given to the group C. They were also informed that all questions were going to be answered, and those who requested would be provided with the health education. As completion of this study coincided with the Covid-19 pandemic, no participant requested the education.

3. Results

3.1. Demographic and clinical characteristics of women

A total of 108 women were randomized, but due to a variety of reasons, the study was completed with a total of 90 women. A total of 12 women from intervention groups and 6 women from control group were excluded from the study during the follow-up.

3.2. Demographic and clinical characteristics of women in the intervention groups and control groups ($n = 108$)

The mean age of the women in the PMR + HE group was 50.38 ± 3.61, 49.61 ± 2.99 in the PMR group, and 50.22 ± 3.61 in the control group. 91.7 % of women in the PMR + HE group, 88.9 % in the PMR group and 94.4 % in the control group were married. 38.9 % of women in the PMR + HE group, 38.9 % in the PMR group and 27.8 % in the control group were university graduates. 8.3 % of women in PMR + HE group and control group, 19.4 % of women in PMR group are working in any job. In all groups, almost half of the women stated that their economic status equalled to medium, about a quarter stated they smoked, and about one-third of the women stated they regularly exercised. We found no significant difference among the groups in regards to their age, marital status, education level, working status, income level, smoking and regular physical activity status.

3.3. Primary outcomes results of women

There was no significant difference among the groups at the first assessment in regards to hot flash frequency/24 h. At the second and third assessment however, hot flash frequency/24 h in the group PMR + HE showed a significant decrease, compared to the group C, and the effect size was larger for the group PMR + HE (p = 0.000, f:0,235 f:0,406). In the control group, it became clear that hot flash frequency/24 h increased significantly in the second and third assessments. There was no significant difference between the groups in night sweats frequency/24 h at the first assessment; however, there were significant differences at the second and third assessments. At the second assessment, night sweats frequency/24 h was significantly lower in the group PMR + HE compared to the group C; and at the third assessment, night sweats frequency/24 h was significantly lower in the group PMR + HE and group PMR compared to the group C. The effect size was larger for the group PMR + HE (p = 0,000, f:0.336, f:0,453) (Table 1). Distribution graph of hot flashes frequency and night sweats frequency /24 h of women by groups and weeks can be seen in the Supplementary figures (Supplementary material Fig. 2–3).

The mean VAS score for hot flashes was significantly lower in the group PMR + HE and in the group PMR compared to the group C at the second and third assessments, and the effect size was larger for the group PMR + HE (p < 0.05, f:0,237, f:0,560). The mean VAS score for night sweats was also significantly lower in the group PMR + HE and in the group PMR compared to the group C at the second and third assessments, and the effect size was larger for the group PMR + HE, as well (p < 0.05, f:0.391, f:0.436) (Table 2)

The mean severity scores for hot flushes in a 24-hour period were significantly lower in the group PMR compared to the group C at the second assessment. The effect size was larger for the group PMR (p = 0,024, f:0,182). The mean severity scores for hot flushes in a 24-h period were significantly lower in the group PMR + HE and in the group PMR compared to the group C at the third assessment. The effect size was larger for the group PMR + HE (p = 0,000, f:0488) (Table 3).

The mean severity scores for night sweats in a 24-h period were significantly lower in the group PMR + HE and in the group PMR compared to the group C at the second and third assessments. The effect size was larger for the group PMR + HE (p = 0,000, f:0,357, f:0,530) (Table 3). Distribution graph of hot flashes severity scores and night

sweats severity scores /24 h of women by groups and weeks are shown in the Supplementary figures (Supplementary material Fig. 4–5).

The group PMR + HE and the group PMR showed significant decreases in the mean WHRIIS scores at the second and third assessments, compared to the group C. The effect size was larger for the group PMR + HE (p = 0.000, f:0,467, f:0,731) (Table 4).

4. Discussion and conclusion

4.1. Discussion

It was found that the nurse-led health education and counseling program (health education+PMR, or alone PMR) helped to reduce vasomotor symptoms and insomnia. There was some evidence in the literature that PMR alone could alleviate vasomotor symptoms and insomnia [7–9]. In our study, we combined health education for one of the PMR groups, because we thought that vasomotor symptoms and insomnia could be managed more easily by a nurse-led training. Accordingly, at the end of the study, we checked whether combining health education with PMR would make a difference. Group learning method was used in the application of our research where women participated in three-person training groups. Therefore, it is possible to suggest that there is a Hawthorne effect in the training sessions of our study. Thus, the motivation and sharing of women may have increased.

Vasomotor symptoms are commonly experienced by menopausal women and negatively affect quality of life [18]. In our study, hot flash frequency/24 h and night sweats frequency/24 h were significantly improved in the group PMR + HE and in the group PMR ($p < 0.05$). And the effect size was larger for the group PMR + HE. Studies conducted on this subject generally had two groups of subjects (PMR and control groups), and have revealed that PMR decreases the vasomotor symptoms night sweats and hot flashes [7,8,10,19,20]. In the study of Zaborowska et al. [8], it is clear that relaxation exercise provided a significant reduction in night sweats and hot flashes in women compared to placebo after 12 weeks of application. Nedstrand et al. [7] declared that hot flash frequency/24 h at the beginning of the study in postmenopausal women who underwent relaxation exercise decreased significantly in the PMR group at the end of 12-week follow-up. Thus, a 72 % decrease was achieved in hot flash frequency/24 h compared to baseline [7]. The study conducted by Lindh-Astrand and Nedstrand revealed that relaxation exercises given to postmenopausal women for 12 weeks reduced the frequency of hot flashes by 55 % [19]. Kaur et al. [20] reported that relaxation exercises provide significant improvement in psychological, vasomotor and somatic symptoms in perimenopausal women. Garcia et al. [10] stated that an eight-week mindfulness-based relaxation initiative in postmenopausal women provided a significant reduction in vasomotor symptoms. We believe that one strength of our study derives from that it has two intervention groups, PMR + HE and PMR groups. And our finding that the effect size is larger in the group PMR + HE highlights the importance of implementing PMR combined with health education.

It is reported that PMR may help relieve menopausal symptoms due to its reducing effects on sympathetic nervous system activity [21]. In the present study, hot flash severity and night sweats severity in a 24-h period, and VAS scores for hot flashes and for night sweats were all significantly improved in the group PMR + HE and in the group PMR. In addition, the effect size was larger for the group PMR + HE. There are studies showing that relaxation techniques significantly help to relieve the severity of night sweats and hot flashes in women [7,22,23]. Carmody et al. [22] stated that the women in the intervention group, where mindfulness-based relaxation was applied to cope with hot flashes, decreased their hot flash scores and increased sleep quality compared to the control group. Sood et al. [23], in the intervention group in which they applied deep breathing exercises for nine weeks, hot flash scores were significantly reduced compared to the control group. However, these studies consisted only of the exercise group. In our study, the PMR group demonstrated a significant improvement in the severity of symptoms, similar to these studies. However, the improvement provided by the PMR + HE group is more effective than the PMR group. It is, thus, possible to assert that the combination of education and PMR, unlike propositions of literature, offers a more effective way to cope with these symptoms.

PMR is recommended to be used for improvement of sleep quality and relief insomnia during menopausal period [24]. We found in our study that the mean WHRIIS score was significantly lower in the intervention groups compared to the control group, with a larger effect size in the group PMR + HE. Our findings support the suggestion of previous studies demonstrating that relaxation techniques help manage sleep

Table 1
Distribution of hot flash frequency/24 h and night sweats frequency/24 h (n = 108).

	PMR + HE group (n = 36) (1)		PMR group (n = 36) (2)		Control group (n = 36) (3)		Analysis	Difference	Effect size
Variables	$\overline{X} \pm S.D.$	Medyan [IQR]	$\overline{X} \pm S.D.$	Medyan [IQR]	$\overline{X} \pm S.D.$	Medyan [IQR]			
Hot Flush Frequency/24 h									
Baseline(1)	6,75 ± 4,43	6,0 [3,5]	6,77 ± 4,11	4,5 [3,2]	6,66 ± 3,91	5,7 [4,4]	$\chi^2 = 0,067$ p = 0,967	–	f:0,009
2. Assessment(2)	5,15 ± 3,40	4,1 [2,3]	5,78 ± 3,60	4,5 [3,1]	7,26 ± 3,98	7,0 [5,4]	**χ^2=8,072 p = 0,018**	**[1-3]**	f:0,235
3. Assessment(3)	4,24 ± 2,80	3,9 [2,8]	5,13 ± 3,03	3,8 [2,4]	7,63 ± 4,23	7,6 [4,8]	$\chi^2 = 21,334$ **p = 0,000**	**[1,2-3]**	f:0,406
Analysis	$\chi^2 = 32,493$ **p = 0,000**		$\chi^2 = 34,323$ **p = 0,000**		$\chi^2 = 24,709$ **p = 0,000**				
Difference	**[1-2,3] [2-3]**		**[1-2,3] [2-3]**		**[1-2,3]**				
Effect Size	η^2:0,290		η^2:0,308		η^2:0,216				
Night Sweats Frequency/24 h									
Baseline(1)	2,80 ± 1,80	3,2 [3]	3,22 ± 2,71	3,1 [3,3]	3,35 ± 2,16	3,8 [3,3]	F = 0,647 p = 0,724		f:0,066
2. Assessment(2)	1,62 ± 1,70	1,1 [2,6]	2,79 ± 2,35	2,4 [3,3]	3,75 ± 2,14	3,7 [2,6]	$\chi^2 = 16,370$ **p = 0,000**	**[1-3]**	f:0,336
3. Assessment(3)	1,48 ± 1,37	1,1 [2,5]	2,50 ± 1,90	2,3 [2,5]	3,79 ± 1,97	3,7 [2,7]	$\chi^2 = 25,538$ **p = 0,000**	**[1,2-3]**	f:0,453
Analysis	$\chi^2 = 31,091$ **p = 0,000**		$\chi^2 = 24,109$ **p = 0000**		$\chi^2 = 15,817$ **p = 0,000**				
Difference	**[1-2,3]**		**[1-2,3]**		**[1-2,3]**				
Effect Size	η^2:0,277		η^2:0,211		η^2:0,132				

Table 2
Distribution of mean visual analog scale scores for vasomotor symptoms (n = 108).

Variables	PMR + HE group (n = 36) (1)		PMR group (n = 36) (2)		Control group (n = 36) (3)		Analysis	Difference	Effect size
	$\overline{X} \pm S.D.$	Medyan [IQR]	$\overline{X} \pm S.D.$	Medyan [IQR]	$\overline{X} \pm S.D.$	Medyan [IQR]			
Hot Flush									
Baseline(1)	6,30 ± 1,82	6,0 [3,0]	6,38 ± 1,79	7,0 [3,7]	6,44 ± 2,14	6,0 [4,7]	χ2 = 0,543 p = 0,762	–	f:0,009
2. Assessment(2)	5,09 ± 1,80	5,0 [2,0]	5,05 ± 2,15	4,0 [0,2]	6,41 ± 1,61	6,0 [2,7]	χ2 = 14,921 **p = 0,001**	**[1,2-3]**	f:0,237
3. Assessment(3)	3,81 ± 1,62	4,0 [2,8]	4,13 ± 2,26	4,0 [1,6]	6,34 ± 1,57	6,0 [2,3]	χ2 = 29,002 **p = 0,000**	**[1,2-3]**	f:0,560
Analysis	χ2 = 37,984 **p = 0,000**		χ2 = 19,090 **p = 0,000**		F= 1,175 p = 0,556				
Difference	**[1-2,3] [2-3]**		**[1,2-3] [2-3]**						
Effect Size	η2:0,343		η2:0,163		η^2:0,008				
Night Sweats									
Baseline(1)	5,81 ± 2,60	4,0 [3,0]	6,00 ± 1,95	5,0 [3,0]	5,91 ± 2,33	5,0 [3,0]	χ2 = 0,045 p = 0,978	–	f:0,030
2. Assessment(2)	4,18 ± 2,15	4,0 [2,5]	4,38 ± 2,57	4,0 [2,5]	6,02 ± 2,45	6,5 [3,7]	χ2 = 11,940 **p = 0,003**	[1–3]	f:0,391
3. Assessment(3)	3,27 ± 3,73	3,0 [2,1]	3,83 ± 2,38	3,0 [2,1]	5,83 ± 2,28	6,0 [2,6]	χ2 = 24,400 **p = 0,000**	[1–3]	f:0,436
Analysis	χ2 = 49,463 **p = 0,000**		χ2 = 35,871 **p = 0,000**		F = 0,935 p = 0,627				
Difference	**[1-2,3] [2-3]**		**[1-2,3] [2-3]**						
Effect Size	η2:0,452		η2:0,323		η2:0,01				

Table 3
Distribution of mean severity scores for hot flashes/24 h and night sweats/24 h (n = 108).

Variables	PMR + HE group (n = 36) (1)		PMR group (n = 36) (2)		Control group (n = 36) (3)		Analysis	Difference	Effect size
	$\overline{X} \pm S.S$	Medyan [IQR]	$\overline{X} \pm S.S$	Medyan [IQR]	$\overline{X} \pm S.S$	Medyan [IQR]			
Hot Flush Severity Score/24 h									
Baseline(1)	15,03 ± 1,23	11 [11,5]	13,33 ± 1,16	8,6 [8,5]	14,19 ± 8,90	10,8 [12,2]	χ^2 = 1,983 p = 0,371	–	f:0,053
2. Assessment(2)	12,06 ± 1,08	8,1 [12]	12,12 ± 1,07	8,7 [9,9]	16,22 ± 1,07	12,2 [13,2]	χ^2 = 7,422 **p = 0,024**	**[2-3]**	f:0,182
3. Assessment(3)	8,03 ± 8,70	5,8 [4,0]	9,41 ± 8,78	5,8 [8,1]	16,59 ± 1,06	15,6 [10,7]	χ^2 = 25,440 **p = 0,000**	**[1,2-3]**	f:0,488
Analysis	χ^2 = 31,091 **p = 0,000**		χ^2 = 24,109 **p = 0,000**		χ^2 = 15,817 **p = 0,000**				
Difference	**[1-2,3] [2-3]**		**[1-2,3] [2-3]**		**[1-2,3] [2-3]**				
Effect Size	η^2:0,277		η^2:0,211		η^2:0,132				
Night Sweats Severity Score/24 h									
Baseline(1)	5,58 ± 4,11	4,5 [7,6]	7,05 ± 6,91	4,5 [5,4]	8,36 ± 4,46	8,5 [7,3]	χ^2 = 3,795 p = 0,150	–	f:0,214
2. Assessment(2)	3,72 ± 3,88	3,0 [5,1]	5,50 ± 6,02	4,0 [5,0]	8,73 ± 4,94	8,6 [8,3]	χ^2 = 18,244 **p = 0,000**	**[1,2-3]**	f:0,357
3. Assessment(3)	3,03 ± 3,11	2,1 [4,3]	5,02 ± 5,07	3,0 [4,8]	8,73 ± 4,73	8,8 [6,3]	χ^2 = 26,442 **p = 0,000**	**[1,2-3]**	f:0,530
Analysis	χ^2 = 36,690 **p = 0,000**		χ^2 = 19,514 **p = 0,000**		F= 6,183 **p = 0,045**				
Difference	**[1-2,3] [2-3]**		**[1-2,3] [2-3]**		**[1-3]**				
Effect Size	η^2:0,330		η^2:0,167		η^2:0,04				

problems and insomnia in women [9,10,22,25,26]. Duman and Timur Taşhan [9] found that PMR and sleep hygiene training with postmenopausal women were effective in reducing sleep problems in postmenopausal women with insomnia. Garcia et al. [10] stated that an eight-week mindfulness-based relaxation initiative in postmenopausal women resulted in a significant reduction in menopausal symptoms and improvement in menopausal-specific sleep quality. Carmody et al. [22] stated that women in the mindfulness-based relaxation group had higher quality of life and sleep quality compared to the control group. The present study contributes to a growing body of evidence by suggesting that PMR is more effective in managing vasomotor symptoms and insomnia during menopausal period when combined with health education for the symptoms and sleep hygiene.

4.2. Conclusion

As previously stated as the purpose of the current research, it is now possible to state that PMR combined with health education or PMR alone is an effective way to improve insomnia and reduce vasomotor symptoms. Our findings have also revealed that the group PMR + HE has a greater improvement with larger effect size in all measurements, compared to the group PMR. The findings of the study suggest that PMR and health education counseling by nurses would benefit perimenopausal women who suffer from insomnia and vasomotor symptoms.

4.3. Practice implications

Responsibility will be given to patients to maintain health and

Table 4
Distribution of mean Women's Health Initiative Insomnia Rating Scale scores (n = 108).

Variables	PMR + HE group (n = 36) (1)		PMR group (n = 36) (2)		Control group (n = 36) (3)		Analysis	Difference	Effect size
	$\overline{X} \pm S.D$	Medyan [IQR]	$\overline{X} \pm S.D$	Medyan [IQR]	$\overline{X} \pm S.D$	Medyan [IQR]			
Baseline(1)	14,77 ± 3,37	14,0 [6]	14,25 ± 4,90	13,5 [5,7]	14,05 ± 2,86	14,0 [4]	$\chi^2 = 1,309$ p = 0,520	–	f:0,072
2. Assessment(2)	9,94 ± 3,80	10,0 [6,7]	10,97 ± 4,29	10,0 [5]	14,27 ± 3,17	15,0 [5,5]	$\chi^2 = 22,824$ **p = 0,000**	**[1,2-3]**	f:0,467
3. Assessment(3)	7,79 ± 2,99	9,0 [5]	9,09 ± 4,15	8,0 [3,2]	13,87 ± 2,91	14,0 [4,7]	$\chi^2 = 50,209$ **p = 0,000**	**[1,2-3]**	f:0,731
Analysis	$\chi^2 = 53,465$ **p = 0,000**		$\chi^2 = 42,304$ **p = 0,000**		F= 3,709 p = 0,156				
Difference	**[1-2,3] [2-3]**		**[1-2,3] [2-3]**						
Effect Size	η^2:0,490		η^2:0,384		η^2:0,016				

exercise behaviors and participate in symptoms management in order to reduce adverse disease outcomes, increase their functional capacity and improve their quality of life. Without the need for pharmacological methods, with appropriate education and counseling, women's compliance with healthy lifestyle behaviors and PMR, reduce vasomotor symptoms and insomnia in the perimenopausal period. Taking into account the benefits of health education and PMR on vasomotor symptoms and insomnia, and its practicality, it can well be used as an appropriate education and counseling program in the clinical field.

5. Limitations

The findings in this study are limited to perimenopausal women in the sample. The data are based on self-reports and subjective measurements. The researcher or the subjects were not blinded. Interaction between the subjects was not controlled, as the women in the intervention and control groups were selected from the same institution, since women who drink alcohol are excluded. The effect on women who use alcohol cannot be generalized.

Funding

No funding from an external source supported the publication of this study.

Ethical approval

We acquired written permissions from Ethics Committee for Non-Interventional Studies and the institution where the study would be carried out before start of the study (date-reference no.: 21/12/2018-E.168846).

CRediT authorship contribution statement

Sıdıka Pelit Aksu: Conceptualization, Methodology, Software, Resources, Validation, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization, Funding acquisition. **Ayten Şentürk Erenel:** Conceptualization, Methodology, Writing – review & editing, Supervision, Project administration. All authors accept responsibility for the entire content of this submitted manuscript and approved submission.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2022.07.015.

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