Randomized Controlled Study of Premenstrual Symptoms Treated With Ear, Hand, and Foot Reflexology

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Objective: **To determine whether reflexology therapy—the application of manual pressure to reflex points on the ears, hands, and feet that somatotopically correspond to specific areas of the body—can significantly reduce premenstrual symptoms compared to placebo treatment.**

Methods: **Thirty-five women who complained of previous distress with premenstrual syndrome (PMS) were randomly assigned to be treated by ear, hand, and foot reflexology or to receive placebo reflexology. All subjects completed a daily diary, which monitored 38 premenstrual symptoms on a four-point scale. Somatic and psychological indicators of premenstrual distress were recorded each day for 2 months before treatment, for 2 months during reflexology, and for 2 months afterward. The reflexology sessions for both groups were provided by a trained reflexology therapist once a week for 8 weeks, and lasted 30 minutes each.**

Results: **Analysis of variance for repeated measures demonstrated a significantly greater decrease in premenstrual symptoms for the women given true reflexology treatment than for the women in the placebo group.**

Conclusion: **These clinical findings support the use of ear, hand, and foot reflexology for the treatment of PMS.** ***(Obstet Gynecol 1993;82:906–11)***

In 1931, Frank[1] observed that many women suffer varying degrees of discomfort in the days preceding the onset of menstruation. Nader[2] found that most subsequent studies estimated the prevalence of premenstrual syndrome (PMS) at 30–40%. One survey[3] of 1826 women reported that 85% of the respondents complained of one or more premenstrual symptoms. Nonetheless, the etiology and treatment of PMS remain controversial. Because the physical and psychological symptoms reported by women are most severe during the late luteal phase of the menstrual cycle, one proposed mechanism for PMS has been related to progesterone levels. However, several controlled studies have failed to find progesterone administration to be more effective than placebo. A randomized, controlled, double-blind, crossover study of 168 women showed that progesterone suppositories did reduce premenstrual symptoms, but this decrease was not significantly greater than with placebo administration.[4] In a 1-year follow-up of these women,[5] only 27% of the original subjects were still taking the progesterone medications, and there was no significant difference in premenstrual symptoms between women taking and those not taking progesterone.

Other double-blind, randomized, placebo-controlled studies of PMS treatment have examined various gonadotropin-releasing hormone agonists[6,7] and different oral contraceptives.[8,9] In each of these investigations, the active medications were shown to alleviate some of the physical symptoms of PMS significantly more than placebos, but less consistent results were found for the mood changes that often precede menstrual flow. Conversely, placebo-controlled studies of anxiolytic[10,11] and antidepressant[12–14] medications have shown significant improvement in mood-related premenstrual symptoms compared to the effects of placebo medications, but less pronounced results with somatic symptoms.

A different approach to the treatment of PMS has been reduction of stress by procedures other than psychotropic medications. Goodale et al[15] demonstrated significantly greater alleviation of premenstrual symptoms in women trained to produce Benson's relaxation response than in women who participated in a reading control group or in women who just charted their symptoms. The degree of improvement was highest for women with the most severe PMS.

The present study sought to investigate whether reflexology therapy can reduce premenstrual distress.

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Reflexology involves the manual stimulation of reflex points on the ears, hands, and feet that correspond somatotopically to specific areas and organs of the body. In his review of the reflexology literature, Dale[16] noted the occurrence of several "cutaneo-organ reflex points" on the foot, which were first described by Fitzgerald in 1917. Dale further delineated the microacupuncture reflex systems found on the ears, hands, feet, nose, tongue, and teeth, which are "holographic reiterations of the anatomy of the body." Although acupuncture points on the auricle were known by ancient Chinese physicians, Nogier first described the inverted fetus topology of reflex points represented on the external ear in 1957.[17] Oleson et al[18] conducted a double-blind evaluation of these auricular points to demonstrate the diagnostic validity of the somatotopic representation of particular parts of the body at specific ear reflex points. The present investigation is believed to be the first placebo-controlled trial of the effect of reflexology treatment on any clinical condition.

Materials and Methods

From October 1988 to November 1990, women reporting premenstrual symptoms were recruited using newspaper advertisements and were then given a telephone interview. After all research procedures were presented, subjects who agreed to participate were required to give written informed consent. Potential participants were disqualified if they were pregnant, reported a serious physical or psychiatric illness, had extensive prior experience with reflexology, or were taking estrogen or progesterone specifically for PMS. All subjects were interviewed by a clinical psychologist to exclude individuals with severe psychological disturbance.

Each subject was asked to keep a daily record of PMS symptoms, consisting of 19 somatic symptoms such as sensations of breast tenderness, abdominal bloating, and menstrual cramps, and 19 psychological symptoms, including feeling anxious, depressed, irritated, and critical. These items were selected from several previous research questionnaires on PMS.[4,6,10] The daily diary also provided a space for the women to indicate when they experienced their monthly menstrual flow. Subjects rated each symptom on a four-point rating scale[19] using the following values: 0 (none), 1 (mild), 2 (moderate), and 3 (strong). The premenstrual score for each symptom was the sum of the symptom scores for the 7 days before menstruation, a time period used in several previous studies.[4,8,10] A 7-day symptom score on the 0–3 scale could range between 0–21. Although for most items a high score indicated severe premenstrual distress, three measures of positive mood—feelings of well-being, energy, and excitement or alertness—were scored in the reverse direction and their value subtracted from 21.

Somatic, psychological, and total symptom scores were obtained by deriving the sum of the daily scores for the 7 days before the onset of menses and computing the mean value across all items. Alpha coefficients for these three principal measures indicated high internal consistency during the baseline charting period: 0.92 for the total PMS scale, 0.82 for the somatic symptoms scale, and 0.94 for the psychological symptoms scale. Comparing the first two menstrual periods for all subjects, there was high test-retest reliability for the total PMS scale ($r = 0.87$), and these premenstrual scores were highly correlated to the Health Distress Index ($r = 0.62$). A separate study of 12 untreated women who were asked to complete the same daily PMS diary revealed that these premenstrual distress scores remained stable over time for 6 consecutive months ($F = 2.26$, $P > .1$, one-way repeated-measures analysis of variance).

After they had recorded premenstrual symptoms each day for at least two menstrual cycles before the first treatment, all participants were randomly assigned, using a random numbers table, to either the true reflexology group or the placebo group according to the order of their first reflexology session appointment.[20] The subjects were informed that they would receive one of two types of reflexology therapy, each of which had the potential to relieve premenstrual symptoms. They did not know which treatment they received. The subjects continued the daily charting for 2 more months while receiving weekly reflexology sessions and then for another 2 months after treatment.

Participants in both the true and placebo reflexology groups attended 30-minute, individual reflexology sessions once a week for 8 weeks. The subjects lay supine on a treatment table while one of several trained reflexology therapists touched specific areas of their ears, hands, and feet. True reflexology therapy consisted of manual pressure to the areas of the ears, hands, and feet that correspond to specific areas of the body. The reflex points considered appropriate for the treatment of PMS include points on the hands and feet for the ovary, uterus, pituitary gland, adrenal gland, kidney, celiac or solar plexus, and sympathetic nervous system.[16] In addition to these regions, manual pressure to the ear was also applied to the Chinese auricular reflex point *shen men*,[17] and the Chinese acupuncture point on the hand known as *hoku* or large intestine 4.[16] Figure 1 illustrates the precise locations of these reflex points on the ears, hands, and feet. Appropriate reflex points tend to be more sensitive to

applied pressure than the surrounding tissue, and thus they were manipulated firmly yet soothingly.

Subjects in the placebo reflexology group were given uneven tactile stimulation to areas of the ears, hands, and feet not considered appropriate for the treatment of PMS. The reflex points considered inappropriate for menstrual problems included the nose, ear, shoulder, upper arm, elbow, abdomen, and mouth. The different locations of these placebo reflex points are shown in Figure 2. Manual pressure applied in the placebo treatment was either overly light or very rough. Nonetheless, every effort was made to make the placebo reflexology sessions appear similar to the true reflexology treatment with regard to the manner in which the therapy was provided. During these sessions, all placebo subjects reported that they found the treatment relaxing and pleasant, although a few participants did complain that the manual pressure was sometimes too light. All subjects indicated that they felt they were receiving actual reflexology therapy.

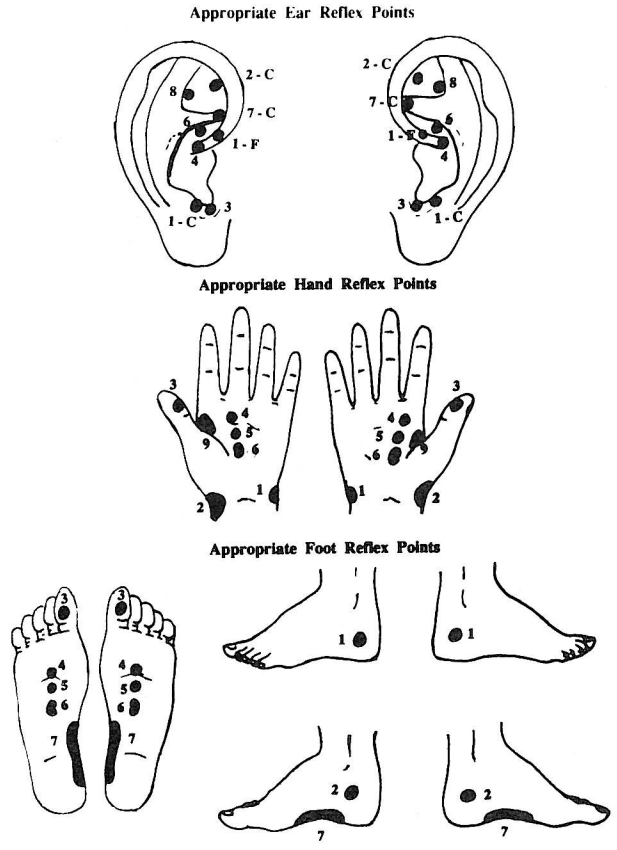

Figure 1. Location of appropriate ear, hand, and foot reflex points[16] where manual pressure was applied to participants in the true reflexology group. Numbers indicate the part of the body to which that reflex point somatotopically corresponds: 1 = ovary; 2 = uterus; 3 = pituitary gland and endocrine system; 4 = solar plexus (point zero on the ear); 5 = adrenal gland; 6 = kidney; 7 = sympathetic nervous system; 8 = Chinese ear point *shen men*; 9 = Chinese meridian point *hoku* or large intestine 4. Where there is a difference in the location of auricular points between Chinese and French charts,[17] the Chinese representation is indicated by the extension "C"; the French representation is indicated by the extension "F".

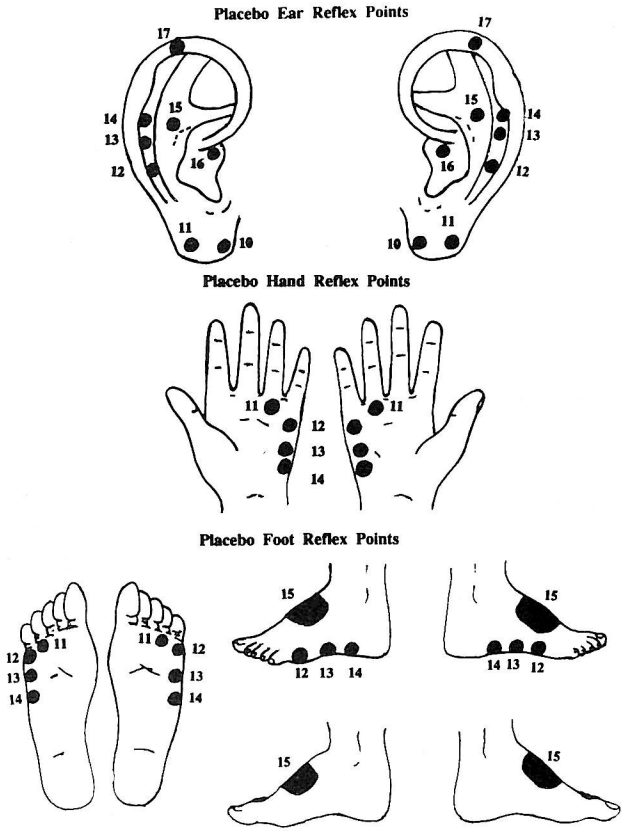

Figure 2. Location of inappropriate ear, hand, and foot reflex points where manual pressure was applied to participants in the placebo reflexology group. Numbers indicate the part of the body to which that reflex point somatotopically corresponds: 10 = nose; 11 = ear; 12 = shoulder; 13 = upper arm; 14 = elbow; 15 = abdomen; 16 = mouth; 17 = helix point represented on Chinese ear charts.

The mean of the first two premenstrual periods recorded during the baseline charting period was compared to the mean of the two premenstrual periods examined during the 8 weeks of reflexology sessions and the mean of the two premenstrual periods following treatment. Statistical differences between the true reflexology and placebo reflexology groups were analyzed by two-way analysis of variance with repeated measures, using as independent factors the type of treatment and the PMS charting period. In addition, a percent decrease in PMS was obtained by dividing the difference between the baseline and treatment periods by the baseline period.

Results

All subjects who passed the initial telephone screening were sent packets of demographic questionnaires and

Table 1. Characteristics of Participants at Entry

	True reflexology	Placebo reflexology
Mean age (y)	37.2	32.7
Ethnic status		
White	17 (94%)	12 (71%)
Hispanic	1 (6%)	2 (12%)
Black	0	2 (12%)
Other	0	1 (6%)
Marital status		
Single	10 (56%)	10 (59%)
Married	3 (17%)	5 (29%)
Divorced	5 (28%)	2 (12%)
No. of children		
None	11 (61%)	12 (71%)
One	2 (11%)	4 (23%)
Several	5 (28%)	1 (6%)
Education level		
High school	1 (6%)	2 (12%)
Some college	10 (56%)	6 (35%)
Bachelor's degree	2 (11%)	6 (35%)
Graduate degree	5 (28%)	3 (18%)
Annual income		
$1000–15,000	1 (6%)	3 (18%)
$16,000–25,000	5 (28%)	4 (23%)
$26,000–40,000	7 (39%)	8 (47%)
$41,000–60,000	3 (17%)	2 (12%)
≥$61,000	2 (11%)	0

several copies of the premenstrual symptoms diary. Thirty-three of the 83 women who began daily charting of PMS symptoms failed to complete the first 2 months of baseline measurements. Further attrition occurred after the subjects were randomly assigned to one of the two treatment groups; seven participants in the true reflexology group and eight in the placebo reflexology group dropped out of the study for various reasons. The high attrition rate is not surprising in a study with such a long evaluation phase and treatment period, despite our efforts to keep all volunteers in the study. The mean age of the 35 women in the two treatment groups was 35.6 years, ranging from 24–47. Most of the women were white (83%), single (57%), and childless (66%), had some college or had received a Bachelor's degree (69%), and earned an annual income of $16,000–40,000 (69%). Table 1 shows the demographic variables for each treatment group. The diagnosis of PMS was considered appropriate if the mean total score in the premenstrual phase was at least twice that for the week after menstruation. All participants fulfilled this criterion, exhibiting a progressive rise in premenstrual symptoms 3–10 days before the onset of menstrual flow and a pronounced decrease in these symptoms on the third or fourth day after menstruation began.

Table 2 shows the mean and standard deviation (SD) for the total PMS scale, somatic symptoms scale, and psychological symptoms scale for the true reflexology and placebo reflexology groups for the three time periods. For each of these three measures, premenstrual scores were similar for the two groups during baseline charting, showed greater reduction for the true reflexology group during the treatment period, and rose only slightly for each group during the post-treatment period. Two-way analysis of variance for repeated measures revealed a significant interaction between treatment groups and times of measurement. Statistical analyses of the interaction effect showed that treatment varied significantly with period for total PMS scale ($F = 6.70$, $P < .01$), somatic symptoms scale ($F = 8.71$, $P < .001$), and psychological symptoms scale ($F = 3.50$, $P < .05$). With regard to the total PMS scale of the true reflexology and placebo reflexology groups, there was a significant repeated-measures analysis of variance group-by-period interaction effect with paired comparisons of the baseline and reflexology treatment periods ($F = 13.2$, $P < .001$) and the baseline and post-treatment periods ($F = 7.7$, $P < .01$). Thus, the greater decrease in premenstrual symptoms by true reflexology was highly significant during the 8 weeks of reflexology sessions and for the next 2 months after treatment was terminated.

For the separate measures of somatic and psychological symptoms, the pattern was similar. The repeated-measures analysis for the somatic symptoms scale was statistically significant for group-by-period interactions comparing the baseline period to the treatment period ($F = 19.6$, $P < .001$) and for paired comparisons of the baseline period to the post-treatment period ($F = 8.3$, $P < .01$). Likewise, the repeated-measures analysis

Table 2. Changes in Premenstrual Syndrome Across Treatment Periods by Reflexology Group

Scale	Reflexology group	Placebo group	*F*
Total PMS			
Baseline	6.6 ± 2.7	6.3 ± 2.8	
Treatment	3.6 ± 1.9	5.0 ± 2.4	13.2*
Post-treatment	4.1 ± 2.6	5.2 ± 2.5	7.7*
Somatic symptoms			
Baseline	7.0 ± 2.2	6.0 ± 2.6	
Treatment	4.0 ± 2.0	4.9 ± 2.1	19.6*
Post-treatment	4.6 ± 2.4	5.1 ± 2.3	8.3*
Psychological symptoms			
Baseline	6.2 ± 3.7	6.6 ± 3.3	
Treatment	3.1 ± 2.1	5.2 ± 3.0	6.4†
Post-treatment	3.6 ± 3.0	5.4 ± 2.9	4.2†

PMS = premenstrual syndrome.
Data are presented as mean ± SD.
* $P < .01$.
† $P < .05$.

for the psychological symptoms scale showed a significant interaction effect between the treatment groups for the difference between the baseline and reflexology periods ($F = 6.4$, $P < .05$) and between the baseline and post-treatment periods ($F = 4.2$, $P < .05$).

The greatest mean percent change in the total PMS scale scores from the baseline conditions to the treatment period was the 46% reduction shown by the true reflexology group, which remained relatively the same (41%) during the post-treatment period. The 19% change from baseline conditions for the placebo reflexology group was less than half that shown by the true reflexology subjects. Similar patterns were also demonstrated by the percent changes in somatic and psychological symptoms. The respective decreases from the baseline to the treatment periods shown by the true reflexology and placebo reflexology groups were 43 and 17% for the somatic symptoms scale and 50 and 22% for the psychological symptoms scale, respectively. Examining individual participants, 15 (83%) of the 18 women in the true reflexology group showed at least a 30% decrease in total PMS scores during the 8-week reflexology treatment period, whereas only four (24%) of the 17 women in the placebo reflexology group exhibited such a reduction. This difference between the groups is significant by χ^2 test ($\chi^2 = 10.8$, $P < .01$).

Discussion

This randomized controlled study showed that true reflexology treatment led to a significantly greater reduction in premenstrual symptoms than did placebo reflexology. Though there was a larger percent reduction in premenstrual symptoms during the treatment period, the significant difference between the treatment groups also persisted for 2 months after treatment for both somatic and psychological symptoms. Previous studies of medical management of PMS by pituitary gonadotropin hormones[6,7] and oral contraceptives[8,9] showed that these drugs significantly reduced physical premenstrual symptoms as compared to placebo treatment, but they were not as effective with psychological symptoms and often produced pronounced side effects when used on a long-term basis. Although psychotropic drugs improved mood-related premenstrual symptoms significantly more than placebo substances,[10–14] they have not proved as reliable in reducing the somatic symptoms that accompany PMS, and they also produce unwanted side effects. No negative side effects were reported with reflexology therapy; instead, most subjects found the treatment pleasant and relaxing.

Although no previous study has examined the role of reflexology in the treatment of premenstrual distress, Helms[21] conducted a randomized, controlled clinical trial on the effectiveness of acupuncture in managing primary dysmenorrhea. Over twice as many women showed a pronounced reduction in dysmenorrhea-related pain in the real acupuncture group as compared to a placebo acupuncture group, a standard medical treatment group, or a visitation control group. The participants in the real acupuncture group also reported a significantly greater reduction in analgesic medication use than subjects in the other groups. As in previous research, Helms postulated that the benefits of acupuncture might be related to alterations in adrenal, gonadal, and pituitary activity, as well as to possible acupuncture-induced changes in sympathetic autonomic nervous system activity, endogenous opioid release, and prostaglandin levels. Because Dale[16] noted that the micro-acupuncture systems on the ear, hand, and foot correlate to the macro-acupuncture systems described by the Chinese, similar physiologic mechanisms may account for the clinical benefits of acupuncture and reflexology.

The theoretical rationale for the study of Goodale et al,[15] which examined the physiologic mechanisms for the effectiveness of relaxation therapy, may also apply to the present study. Goodale et al proposed that relaxation training reduces the psychophysiologic response to stress and that reduction of stress helps alleviate PMS. Even though baseline serum cortisol levels are relatively stable over the menstrual cycle, Marinari et al[22] found that women tested premenstrually exhibited greater adrenocortical reactivity to psychological distress than those tested at mid-cycle. As acupuncture has been shown to reduce plasma ACTH and cortisol levels,[23] reflexology could also serve to attenuate adrenocortical stress reactivity. It is not as obvious why the benefits of reflexology were maintained for 2 months post-treatment, but one possibility is that the brain mechanisms[24] related to acupuncture and to the reflexology micro-systems can be altered permanently by the treatment.

The primary benefit reported by the women receiving true reflexology therapy was the experience of profound relaxation. Many of the women fell asleep during the 30-minute reflexology session and reported having more energy the next day. This finding corresponds to the extensive survey by Pullon et al,[3] which noted that some type of massage therapy was the single most effective self-help treatment reported by women for relief of premenstrual symptoms. Massage, rest, and exercise received a higher rating of success for alleviating PMS than did the medications prescribed by physicians.

One of the greatest experimental difficulties in designing this research was the development of a credi-

ble placebo control group. Every effort was made to present the placebo reflexology session as a potentially beneficial treatment, without actually providing therapeutically effective reflexology therapy. It was particularly difficult for the volunteer reflexology therapists not to touch appropriate areas of the ears, hands, and feet therapeutically when the women in the placebo control group complained of severe premenstrual distress. Even though the type of manual pressure given to the placebo subjects was either overly light or very rough, the participants in the placebo reflexology group consistently commented during their sessions that they found the therapy relaxing and pleasant. Many of these women reported that they enjoyed lying down for half an hour and having someone else attend to them. Although some of these placebo subjects stated that they thought the reflexology was "having an effect," their daily diaries did not indicate as large a reduction in premenstrual symptoms from baseline values as did the participants in the true reflexology group.

Some investigators[4,14] have suggested that there is a high placebo response for PMS patients, but other studies[8,10,12,13] have reported that the reduction in premenstrual symptoms for placebo subjects was less than 20%. This figure is comparable to the 19% change in PMS severity found for our subjects who received placebo reflexology. At the same time, other studies have indicated higher levels of benefit from the experimental treatment than was found for reflexology. The 46% reduction in premenstrual symptoms in the true reflexology subjects is lower than the 58% improvement found by Goodale et al[15] for women trained to produce the relaxation response. Moreover, medication management of PMS has achieved successes in 60–75%.[6,13] Unfortunately, all of these studies used different assessment measures for evaluating PMS. A clinically controlled comparison of several different therapies for women given the same PMS assessment form would be valuable future research.

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