The effect of sole reflexology (Reflex Zone Therapy) on the intensity of premenstrual syndrome: A single-blinded randomized controlled trial

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Abstract
Introduction: Premenstrual syndrome is considered as one of the most common gynecological diseases and is also one of the most common disorders at fertility ages. Regarding the global expansion of using traditional medicine as complementary medicine and keeping the midwives along with modern methods and also considering the many advantages and low side effects of reflexology, the researcher decided to study its effect on reducing this syndrome among students at Tehran University of Medical sciences.

Materials & Methods: This research is a single blinded clinical trial which was done on 120 volunteer students in the University of Tehran. Having diagnosed the above syndrome by registering the form of daily status and having the requirements for entering the study during two menstrual cycles as randomly and using Rand List software, the research units were divided in to two groups of real and unreal reflex zone therapy (intervention and control group) and received this treatment for eight continuous weeks, for 30 minutes once a week. The data were statistically analyzed by Chi-square test and Fisher’s exact test for comparing the qualitative variables and by mean difference test and repeated measurement of ANOVA for comparing the quantitative variables with SPSS.15 software.

Results: The results of research in the two treatment groups show that real reflex zone therapy can reduce the behavioral symptoms by 20% though such reduction does not show a statistically significant difference (p=0.16).

Conclusion: According to the results, although the effect of this method of the behavioral part of this syndrome was not significant, regarding the results of other researches for the effectiveness of this method of decreasing the PMS, it is hoped to use for reducing the symptoms by more researches in this area of complementary medicine together with other common treatments in gynecological areas like other advanced countries.

Keywords: Sole Reflexology (Reflex Zone Therapy), Premenstrual Syndrome, Behavioral symptoms of premenstrual syndrome.

Introduction
Premenstrual syndrome is a mental-social problem which is accompanied with menstrual cycle biologically, psychologically and sociologically and undoubtedly is one of the unknown medical subjects which confused the physicians such as the endocrinologist, gynecologist and psychologists (1). Premenstrual syndrome is one common disorders at fertility ages which, is seen among 95% of women in different intensities and was first described by Hippocrates as premenstrual stressful behavior. These women experienced premenstrual physical and mental symptoms...
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periodically. This syndrome involved millions of women during fertility years which are defined by repeated symptoms during the secretion of the menstrual cycle. Many women and their families are affected by physical and mental distressing symptoms. These symptoms affect their behavior and quality of life (2).

Cultural differences and family relations are among the important and effective factors in incidence of premenstrual syndrome. Such syndrome is seen more among some people due to heredity. There seen a relationship in incidence of this syndrome among mothers and daughters. Family factors may interfere in incidence of these symptoms. A study among twins shows that genetic and environment factors are effective in incidence of premenstrual syndrome. It shall be noted that this syndrome is available among all cultures and races (3). The studies show that this syndrome has more incidence and intensity among educated women, which can be due to more psychological distress and also it is one of the factors which susceptible the women to depression especially during premenstrual, before delivery and during the menstrual duration (4).

This syndrome is a set of emotional symptoms including behavioral instability, marital incompatibility, depression, anxiety, confusion and physical symptoms such as headache, muscle pain, hyperorexia and general swelling of woman's body (5). Educated women are more prone to emotional response to negative life consequences, they got angry more and has more involvement compared to non-infected individuals (3). Intensifying many symptoms such as Migraine Headaches, Asthma attacks and allergy are among the other problems (6). Studies show that 89-90% of women in fertility ages experience different mental and physical symptoms premenstrual periodically, almost 50% of women reported moderate symptoms and 3-8% reported very severe symptoms such that it confuses the quality of their lives (4-5).

Gilli reported in this book entitled as “Women’s sexual health” related to the effects of this syndrome as 27.5% decreasing in people’s occupational efficiency, 23.1% disorder in work relations, 82.7% dispute with husband, 6% dispute with children and 41% disorder in social relations among the patients (7). There are 59% increasing in direct treatment expenses of these women which are spent to medical visits and doing laboratory tests and 433 USD was reported annually in indirect expenses resulted from decreasing the working hours, absence from work and reducing the production (4). Due to the uncertainty of the etiology of premenstrual syndrome for treating and preventing from it, several chemotherapy and clinical therapy were done in this regard (8). Premenstrual syndrome treatments shall cover a comprehensive program including training, psychological support, sport, nutrition evaluation and pharmaceutical interventions if necessary (3).

The study published by the American College of Gynecology (ACOG) in 2003 showed that one of the treatment methods for solving the CAM symptoms is a complementary medicine (6). One of the astounding indicators of complementary medicine is reflexology or reflex zone therapy. The reflexology is known for improving and diagnosing diseases and rejuvenescence and in this regard, it is said that any part of the body has a connection with foot by neural pathways and subtle energy paths (9-
According to reflexologists, reflex stimulation of the special parts of the foot affects the related organs and systems (12). It revives the coordination of the different parts of the body and quickens and facilitates the body motion toward health (13). Pressure on involuntarily parts of foot and sole can balance the body function.

Reflex zone therapy has a higher success in alleviating the symptoms of the pharmaceutical therapy by physicians in premenstrual symptom treatment. In a study in 1993 by William and Fooli showed that stimulating theses stress parts on food leads to reducing the symptoms in 46% of women during 8 weeks and reducing the symptoms in 42% by two months after discontinuation of initial treatment (14).

Kim and et.al showed the effect of sole reflex zone therapy on reducing the premenstrual syndrome and also decreasing the dysmenorrheal (15). Despite the efforts of researchers in this study for widely reviewing the texts related to the effect of reflex zone therapy on PMS, no study was seen in the country and a few studies were done in foreign countries. Regarding the high prevalence of PMS, side effects and costliness of pharmaceutical methods and ever-increasing tendency toward complementary medicine, and the necessity of ‘midwives’ being upgraded with modern treatment methods; the researchers were persuaded to do this study. On this way, The current study aims at studying the effect of sole reflex zone therapy on behavioral symptoms of premenstrual syndrome.

Materials and Methods

This study is a single blinded clinical trial which was done among female students residing in the dormitory of Tehran University of Medical Sciences. In this study, 96 samples were estimated for two groups using the formula for computing the sample and considering the exclusion, 60 samples were considered for each group.

The volunteers for participating in the research were requested to register and the questionnaires of recording daily symptoms (Dickerson) were given to them. The participants received the necessary explanations for being aware of the manner of doing study and finally the written letter of satisfaction was get. Then they were asked to record the daily symptoms and fill the symptoms sheet including 6 behavioral symptoms which is measured by Mild, Moderate, None, Strong scale for two continuous months. The behavioral symptoms in this questionnaire included fatigue, lack of energy, insomnia, changes in sexual behavior, difficulty in concentrating, increasing appetite and anorexia. Then 120 persons were randomly allocated from among those whose premenstrual syndrome were defined and were put in two intervention and control group by Rand List software (the group of receiving real reflex zone therapy and the group of receiving unreal reflex zone therapy). It should be noted that, in this study, the participants were not aware of the type of intervention. Written letter of satisfaction was gotten from all the research units (1).

Dickerson questionnaire is a questionnaire designed for recording the daily symptoms from the first day of menstrual to the last day of the menstrual cycle which was filled by research units during at least two menstrual
cycles of before treatments and in two cycles of treatment from mild to strong. The behavioral symptoms include six symptoms, the intensity of each class was computed for each month based on acquiring point and the mean of two months were considered as the intensity of PMS. Dickerson questionnaire was a standard questionnaire whose validity was approved during different studies. For studying the reliability, the r quantity was computed as 0.94 for each of questionnaire items using the alpha correlation coefficient.

Sole reflex zone therapy (pressure on special parts of sole by finger for coordinating the hypothalamus, pituitary, ovary axis) for eight weeks, once a week for half an hour in each meeting (without considering the menstrual phases) in studying groups by an educated person who had a valid certificate passing the training courses of reflex zone therapy in a proper place such that the special parts of food are related to the problems of premenstrual syndrome and included the parts related to ovary (outer part of ankle), parts related to womb (inner part of ankle), pituitary (on thumb), solar plexus (in middle part of sole), parts related to kidney, adrenal (in middle of sole), neural system (inner part of foot). At first, the participator was placed in a proper position (as semi-sitting on a flat and stiff surface, leaning on back such that the feet are put above the body surface).

At the first phase, the foot was massaged for 5 to 10 minutes from leg to below, then the mentioned parts became under defined pressure for at last 5 to 20 seconds for each part (related to desired part) and totally 30 minutes by thumb. The amount of pressure on different mentioned parts is defined based on the person’s response to the pressure in solar plexus and pituitary. The desired response can be the incidence of pain in person, incidence of changes in the face, changes in skin color, perspiration, and etc. the basic pressure is diagnosed be the onset of these symptoms and during the work, the participants were asked to report any feeling (whether desired or not). After termination of work, pass the urine for excretion of waste material. Increasing the volume of urine can be a good symptom of the excretion of poisons from the body. In the control group, the reflex zone therapy was performed simultaneously for eight meetings. The only difference was that in this group, the unrelated parts to PMS which are considered as harmless like the parts related to the shoulder, ear, mouth and etc. were undergone pressure or the pressures were done on major parts with lower or higher intensity which was ineffective (1). Not receiving the zone therapy for 10 days or more was considered as excluding the study (1). The participants were asked to record the symptoms during the treatment and inform the researcher for using any analgesics and sedatives for solving the symptoms of premenstrual syndrome. Totally 19 persons were excluded from the study due to non-continuous attendance in the research, consumption of drugs and unwillingness to continue.

Any of the available symptoms in the questionnaire was coded and the data were entered into the computer to receive the research results after collecting the questionnaires and before the treatment onset and in order to define the intensity of PMS. After doing the intervention in two groups of experimental and control group and completing the questionnaires in two groups which lasted for 8 weeks, the data were entered
to the computer and were analyzed by SPSS15 statistical software.

The data of the study was analyzed by statistical methods (descriptive and inferential), chi-square test or Fisher’s exact test for comparing the qualitative variables in two groups, mean difference test and repeated measurement of ANOVA for comparing the quantitative variables in two groups.

In several cases, where there was not the presupposition of using parametric tests, non-parametric equations were used. In this study, p<0.05 is considered as significant statistically.

**Ethical considerations**

Having done the legal and ethical procedures of the research, at first all the students at the dormitory who had the requirements for entering the study was taken part in the research. These requirements included the girls residing at the dormitory, not being infected with a special disease, not consumption of analgesics, having regular menstrual, not being infected with the diseases of the reproductive system, not consumption of drugs effective on PMS and contraceptive pills, not smoking, lack of stressful events like death of relatives and tendency to participate in the study.

**Results**

From among 120 participants in the study, 101 persons were statistically analyzed at last. 19 persons excluded the study during two-month intervention (5 due to the consumption of drugs during the study, 8 due to unwillingness for continuing, and 6 due to non-regular attending in the dormitory).

In this study, most of the participants in both groups range from 19-23 years old, the menarche age ranges from 12-14 and the distance between two menstrual were 26-30 days, the amount of menstrual bleeding was moderate, and duration of menstrual was 5-7 days. The mean of age, menarche age, distance between two menstrual, and menstrual duration did not have statistically significant difference between two groups (Table 1).

Studying the results of statistical tests for comparing the mean intensity of symptoms before intervention in both groups showed that there is not statistically significant difference between two groups before the intervention.

Studying the statistical test results showed that there is not statistically significant difference between mean differences of the intensity of behavioral symptoms in the research unit in real and unreal reflex zone therapy. That means, such that the real reflex zone therapy was not effective in decreasing the intensity of behavioral symptoms p<0.05

Studying the results of Post Hoc statistical tests showed that the intensity of behavioral symptoms was decreased to 20% after receiving the real reflex zone therapy and for 18.30% after receiving the unreal reflex zone therapy which is not considered statistically significant (Table 2).
Table 1: Demographic indicators of samples in two intervention and control groups

<table>
<thead>
<tr>
<th></th>
<th>Real reflex zone therapy</th>
<th>Unreal reflex zone therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Age</td>
<td>22.3±1.63</td>
<td>21.46±1.46</td>
</tr>
<tr>
<td>Menarche age</td>
<td>12.67±0.92</td>
<td>12.3±0.77</td>
</tr>
<tr>
<td>Distance between two menstrual</td>
<td>29.58±1.89</td>
<td>29.42±1.87</td>
</tr>
<tr>
<td>Menstrual duration</td>
<td>7.16±2.82</td>
<td>6.6±0.69</td>
</tr>
</tbody>
</table>

Table 2: Comparing the intensity of behavioral symptoms of research units before and after treatment in two real and unreal groups

<table>
<thead>
<tr>
<th>Symptoms group</th>
<th>Intervention</th>
<th>Control</th>
<th>p value of between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>0.31±0.26</td>
<td>0.25±0.19</td>
<td>&lt;0.16</td>
</tr>
<tr>
<td>After</td>
<td>0.26±0.26</td>
<td>0.22±0.18</td>
<td>&lt;0.02</td>
</tr>
</tbody>
</table>

Discussion

Having studied available resources and papers related to the effect of reflex zone therapy on reducing the premenstrual behavioral symptoms, it shall be said that there are many intervening variables that can be effective on the results of these researches. These variables include age, academic status, economical status, place of dwelling and amount of stress. In this studying, it is tried to eliminate the intervening variables as much as possible. Therefore, all the participants are selected from the range of 18-30 years old and regarding their academic status, they were all students at the department of medical sciences and had full awareness to the symptoms of this syndrome. The time of study was chosen when it was not examination season to reduce the stress and environmental anxiety.

American College of Gynecology (ACOG) has recommended reflex zone therapy for reducing the premenstrual syndrome. In a clinical trial, Olesonet.al in America studied the effect of sole reflex zone therapy in treating the behavioral symptoms of premenstrual syndrome among 38 patients. According to the results, real reflex zone therapy leads to improving the behavioral symptoms compared to unreal reflex zone therapy (p<0.05).

The study by KO et al in Korea showed that reflex zone therapy is effective in treating the PMS behavioral symptoms and this treatment can reduce the symptoms such as drowsiness and fatigue in the intervening group (15). The research by Jin et.al in Korea also verified the positive effect of reflex zone therapy on drowsiness and fatigue (16). The research by Pourghazning entitled as the effect of sole reflex zone therapy on the fatigue intensity...
among pregnant women reported the desirable and effective results (17). Kim in a research in Korea entitled as the effect of sole reflex zone therapy on the intensity of anxiety and depression among nursing students showed that using sole reflex zone therapy as a complementary method is effective in treating the mood symptoms such as anxiety and depression. The results of this research showed that between two groups after receiving 7 weeks treatment, a significant decrease in the symptoms was seen in the experimental group compared to the control group (18).

Meanwhile, Lee in a research in Korea entitled as the effect of sole reflex zone therapy on depression, stress and function of immunity system among middle-aged women which were a single-group experimental study among 46 participants showed that using sole reflex zone therapy can decrease the depression and stress among middle-aged women and improves the immunity system in these women (19). Won et al in Korea in a study entitled as the effect of sole reflex zone therapy on fatigue and behavioral symptoms among cancer patients receiving chemotherapy, showed that reflex zone therapy can improve the mood status of this group (p=0.007) (20).

The study which Bagheri et al has done about the effect of sole reflex zone therapy on fatigue of patients under gone coronary artery bypass surgery showed that there is not a significant difference between two experimental and control group safer doing the intervention (p=0.001) (21).

This study which was first done in Iran showed that zone therapy was not very effective in reducing the mean of behavioral symptoms resulted from PMS compared to other studies in foreign countries, the result of which can be due to different community in this research (girl students) with other communities in the available papers (mainly women) and different prevalence of behavioral symptoms in these two groups. It should be noted that regarding the side effects in the current study, only two slight spotting were reported. On the other hand, many of samples announced desired and satisfactory feeling during the treatment.

It is proposed to train health agents related to women such as midwives and gynecologists in reflex zone therapy, doing research with more samples, continuing the treatment for longer duration, following the treatment and also comparing the effects of this method with other complementary medicines and chemical treatment in PMS.

Conclusion
The current research showed that reflex zone therapy did not definitely improve the behavioral symptoms of premenstrual syndrome but regarding the limited side effects, good effectiveness and desirability of treatment, reflex zone therapy can be one of proper treatment phases in women with this syndrome.

Whereas this research was first clinically assessed in Iran, it is proposed to do more studying with more samples, different population, using more desired facilities and conditions and comparing it with other pharmaceutical and non-pharmaceutical treatments which are proposed for treating this syndrome.

Acknowledgement
I do express deep appreciation from the educational vice-president at Tabriz Faculty of Nursing and Midwifery and Student Vice-
chancellor at Tehran University of Medical Sciences for doing the coordination with desired dormitories and all girl students participated in this research and I ask the almighty ever-increasing prosperity for all of them. It shall be noted that this study has registered under code No. 201022213027N3 at the Iran Registry of Clinical Trials (irct.ir).

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