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Effects of a web based lifestyle education on general health and severity of the symptoms of Premenstrual Syndrome (PMS) among female students: a randomized controlled trial

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Abstract

Context: Premenstrual syndrome (PMS) is a range of physical, emotional and behavioral symptoms. **Objectives:** A randomized controlled trial was conducted to determine the effects of a web based education on general health in students. **Methods:** A total of 104 women with PMS participated in the study and were randomly assigned to two groups. The instrument for data collection was a questionnaire. **Results:** The experimental group improved significantly general health ($P \leq 0.001$) as well as emotional, behavioral and physical components of PMS symptoms ($P = 0.007$, $p = 0.04$, and $p = 0.01$ respectively) after intervention. **Conclusions:** The web-based training can lead to post-intervention improvements in general health and relief of PMS in female university students.

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Keywords: Premenstrual syndrome (PMS), General Health, Web Based Education

1. Introduction

Studies indicate that the frequency of women with premenstrual symptoms (PMS) is not small (Chandraratne & Gunawardena, 2011). Epidemiological data on PMS in Iran suggest that as many as 60% to 90% of women experience PMS (Shahpoorian, Mahmoody, Bastani, Parsaei, & Hosseini, 2005, Kiani Asiabar, Heidary, Mohammadi tabar & Faghih Zadeh 2009). PMS include a range of physical, behavioral, and emotional features (Berek, 2007). The symptoms associated with poor general health and reduction in health-related quality of life (Mahmoodi, Shahpoorian, Bastani, Parsay, & Hoseini 2010). PMS continues to be poorly understood and in many cases inadequately managed (Rieck, & Fiander, 2006). The unknown etiology of PMS has led to many treatments being suggested as possible therapies (Prilepskaya, Ledina, Tagiyeva, & Revazova, 2006). One of the effective wide ranges of treatment options is lifestyle modifications (Indusekhar, Bose Usman & O'Brien, 2007, Stevinson & Ernst, 2001). The lifestyle treatments, including adequate rest, physical activity and exercise, regular hot baths,

nutritional strategies (reduced intake of caffeine as well as sugar, reduced salt intake, avoidance of alcohol) plus intake of calcium and magnesium, and reduction in factors causing excessive stress (Greenfield & Blythe 2006, Greydanus, Tsitsika & Gains 2007), are recommended for women with PMS (Schulman, 2010). However, the efficacy of the treatments are not reported yet (Lete, Dueñas, Serrano, Doval, Martínez-Salmeán, Ezequiel Pérez-Campos & Arbat 2011). To date, we have found no publication of systematic reviews of randomized controlled trials (RCTs) of lifestyle education on general health and the symptoms management in women with PMS. This randomized controlled trial study attempts to determine the effectiveness of our web based lifestyle intervention on improving general health and relieving the severity of PMS symptoms among female university students.

2. Method

2.1. Study design and Participants

A prospective, randomized controlled trial design was employed in this study for allocating control and experimental groups and to obtain an equal probability of selection and minimize bias. The population of this study was all female university students in their reproductive age with PMS. Potential subjects were recruited by advertisements in a large Women's University in Tehran, Iran. The participants of this study were under-graduate and post graduate of non-medical sciences university students. Based on the results of a previous study (Mahmoodi, Shahpoorian, Bastani, et al. 2010) and according to power analysis, the minimal valid sample size was estimated to be 104 women as university students considering a normal distribution for the main dependent variables, when the power, effect size, and alpha were set as 0.80, 0.20, and 0.5, respectively (Polit & Hungler, 2003). Therefore, a total of 104 students whose prospective daily ratings for two complete menstrual cycles confirmed the diagnosis of PMS were placed on a randomized controlled trial and were randomly assigned to one of two groups of experimental and control (52 participants in each group). Of 104 participants, 21 failed to complete the trial and were excluded, leaving a total of 83 students in the study for data analysis.

2.2. Data collection instruments

Data were collected by self-administered questionnaires. The participants in both groups completed personal form as well as pre- and post-intervention questionnaires assessing healthy behaviors (focused on nutrition and exercise/physical activity), general health and severity of PMS symptoms. The personal form was developed by the researchers in lay-Persian to gather information about the participant's age, Body Mass Index (BMI), educational situation, and menstrual history. The health behaviors regarding nutrition, exercise and general health of the participants were measured by using a validated lifestyle questionnaire (Samimi, 2005) which consists of 14, 9 and 28 items on a Likert-type scale respectively. The items of the healthy nutrition and exercise were on the 5-point Likert-type, with the scores of 0 (never) to 4 (always), with the range of (0-56) and (0-36) respectively. General health were on the 4-point Likert-type, ranging from never (0) to very often (3) including four domains of physical, emotional, social and mental health respectively (each section consisted of 7 items).

For content and face validity of the different parts of the lifestyle questionnaire, a group of Iranian scholars and experts assessed the questionnaire to detect any unclear, misleading, or highly sensitive questions. Following their comments, the researchers made minor revisions to the wording of the questionnaire. Internal consistency of the questionnaire was assessed and the Cronbach's alpha for the subscales of healthy nutrition, exercise/physical activity and general health included 0.70, 0.73, and 0.78, respectively.

Regarding PMS, many methods exist for diagnosis of PMS that are used in different studies. Premenstrual syndrome diary (PMSD), a self-assessment symptom rating scale, which provides good tools for measuring PMS symptoms, was used to diagnose PMS. The PMS symptoms suggested to be prospectively confirmed by daily ratings during at least two consecutive cycles (Shahpoorian, Mahmoodi, Bastani, Parsaei, & Hosseini, 2005, Kiani Asiabar, Heidary, Mohammadi tabar & Faghieh Zadeh 2009). Therefore, potential subjects were given the PMSD for two cycles before intervention. The questionnaire has been used in studies of (Derman, Kanbur, Tokur, & Kutluk, 2004). The PMSD is a concise questionnaire consisting of 17 items of Diagnostic and Statistical Manual of Mental Disorders-IV (DSM-IV) criteria for evaluating PMS, adapted from the American Psychiatric Association (American Psychiatric Association, 1994).

The PMSD consisted of the statements describing various emotional, behavioral and physical symptoms. The questionnaire was a single page questionnaire using statements scored on a 4-point scale of increasing intensity, from “not at all” to “very much so” (with the scores of 0–3, respectively). In this study, severity of disabling global PMS symptoms was also measured through the use of Visual Analogue Scale (VAS), based on a modified version of the PMS-screening tool developed by Di Carlo (2001) and Shinohara (2000). The students in both groups completed the VAS of global symptoms of PMS in the last menstrual cycle at pre-post intervention. The reliability and validity of VASs in the measurement of the symptoms has been well documented (McCormack, Horne, & Sheather, 1988). VASs have been also found to be an effective tool in measuring changes over time for symptoms especially emotional PMS symptoms (Sundström & Bäckström, 1998)

2.3. Procedure

The study was conducted between July 2008 to November 2009 and the investigators relied upon Internet technology to implement the educational project. After confirmation of eligibility, the students included in the study met the inclusion criteria for PMS and were randomly allocated to experimental or control groups. Eligibility criteria included 1) understood and agreed with the aims of this study; 2) healthy women with fertile age, 18–30 years; 3) a diagnosis of PMDD according to the Diagnostic and Statistical Manual, 4th edition, or DSM-IV (American Psychiatric Association, 2000); 4) had experience in Internet use 5) expressed a strong commitment to the completion of this study 6) no depressive, anxiety, eating, and drug/alcohol use disorders during the last 2 years; 7) no oral contraceptive pill use for the 3 months prior to study entry; 8) no concurrent therapy for PMDD; 9) regular menstrual cycles of 22–35 days ; and 10) no current pregnancy. In the study, the exclusion criteria consisted of 1) pregnancy or lactation during the trial; 2) menstrual cycle irregularity; 3) unstable medical illness; 4) major psychiatric disorders; 5) intake of hormonal contraceptives; and 6) any treatment of PMS.

The independent variable was a web based lifestyle education program for female university students with PMS. All instruments were administrated at pre-treatment (i.e., last cycle prior to the start of the intervention) and at post-treatment (i.e., the last cycle after the intervention had ended). Data were analyzed using descriptive and inferential statistics. The analysis was performed with SPSS version 14 (SPSS, Chicago, IL, USA). The descriptive data summarized the number of students, the mean, standard deviation, minimum and maximum of the experimental and control groups. We compared the main dependent variables differences between the two groups using t-tests, chi-squared tests and or Fisher's Exact Test.

All 104 students have signed the consent form to participate in this study. The individuals attended the informative meetings held in their institutions at predetermined time. The orientation was given to students enrolled in the study to explain the study design and protocol for diagnosis of PMS prospectively. The orientation session was performed as a single session of 50–60 min guided participants through the process of PMS diagnosis in two cycles prospectively. During the session, the individuals were informed about the website and how they were supposed to use the website and the interactive form; individuals' questions were also answered.

Participants who completed the orientation session were given PMS form and sent individual e-mails as well as cell phone messages containing an assigned username and password to be used for the duration of the study and a link providing access to the online pretest. The education program was given to the experimental group after the collection of the pretest data and receiving another orientation on an overview of the web-based learning as well as a direction for using a web browser. Participants in the control group did not receive any form of educational intervention. Though, after the posttest, the control group was trained and accessed to the web based lifestyle education for four weeks, because of ethical considerations. The intervention was designed by the principal investigator, a midwife and a software engineer. The on line educational contents were available at www.womenhealth-pms.ir over the server hired for one year from the HOSTIRAN Company in Iran. The fundamental information on the website was available with the scope and contents of the training consisted of essential knowledge about PMS and healthy lifestyle. All study procedures were approved by the Ethical Committee of Tehran University of Medical Sciences Review Board in Tehran, Iran.

3. Results

In this study, the mean age of 104 students who were screened and met the criteria and entered the trial, was 22.12 (SD = 3.4; range, 18-30 years). Mean BMI was (22.75) kg/m². with regular menstrual bleeding 3 to 10 days (7.42 ± 1.23) and menstrual cycles of 22 to 35 days (27.92± 2.94). Most participants (65.38%) had dysmenorrhea with moderately severe emotional, behavioral and physical components of PMS symptom. The findings showed that the baseline characteristics of the experimental and control groups did not differ significantly (p<0.05). In this study, from 104 participants, a total of 83 women completed all phases of the study. Twenty one women excluded from the study because of illness or injury, pregnancy, were away for a significant period of time, not have time to continue participating, and using oral contraceptive pill during the study. The key data regarding the comparison of the main dependent variables (lifestyle and general health) and severity of PMS symptoms before and after intervention (last cycle after post-intervention) are summarized in Table 1-4 respectively.

Table 1. Frequency distribution of components of PMS symptoms in the participants at the last cycle before intervention

PMS symptoms		Experimental group No. (%)	Control group No. (%)	p†
Emotional	mild	11 (23.9%)	7 (18.9%)	0.86
	Moderate	22 (47.8%)	19 (51.4%)	
	sever	13 (28.3%)	11 (29.7%)	
Behavioral	mild	12 (26.1%)	7 (18.9%)	0.50
	Moderate	25 (54.3%)	19 (51.4%)	
	sever	9 (19.6%)	11 (29.7%)	
Physical	mild	11 (23.9%)	5 (13.5%)	0.49
	Moderate	24 (52.2%)	22 (59.5%)	
	sever	11 (23.9%)	10 (27.0%)	

†statistical significance assessed using the χ^2 test.

Table 2. Frequency distribution of components of PMS symptoms in the participants at the last cycle after intervention

PMS symptoms		Experimental group No. (%)	Control group No. (%)	p†
Emotional	mild	27 (58.7%)	9 (24.3%)	0.007
	Moderate	14 (30.4%)	20 (54.1%)	
	sever	5 (10.9%)	8 (21.6%)	
Behavioral	mild	19 (41.3%)	6 (16.2%)	0.04
	Moderate	20 (43.5%)	22 (59.5%)	
	sever	7 (15.2%)	9 (24.3%)	
Physical	mild	26 (56.5%)	9 (24.3%)	0.01
	Moderate	14 (30.4%)	20 (54.1%)	
	sever	6 (13.0%)	8 (21.6%)	

†statistical significance assessed using the χ^2 test.

Table 3. Comparison of the health behaviors and general health in participants at pre intervention*

Variables	Experimental group	Control group	p†
Healthy Nutrition	32.60± (10.99)	34.13±(12.80)	0.56
Exercise/Physical Activity	23.45± (4.19)	24.40± (4.11)	0.30
General Health	47.96± (12.84)	48.63 ± (10.84)	0.773

*Data are presented as mean and standard deviation; †statistical significance assessed using the independent t test.

Table 4. Comparison of the health behaviors and general health at the last second cycle after intervention *

Variables	Experimental group	Control group	p†
Healthy Nutrition	39.28± (2.993)	35.02± (3.905)	0.001
Exercise/Physical Activity	25.13± (3.263)	19.86± (3.787)	0.001
General Health	68.19 ± (11.38)	60.29± (6.641)	0.001

*Data are presented as mean and standard deviation; †statistical significance assessed using the independent t test.

As shown in the tables, the intervention group varied considerably across the trials. In other words, compared with the control group, the experimental group improved significantly healthy nutrition, exercise/physical activity, and general health ($P \leq 0.001$) after intervention. There were also significant differences regarding emotional, behavioral and physical components of PMS symptoms and the scores of VAS global PMS symptoms in the experimental group after intervention compared to the control group ($P=0.007$, $p=0.04$, $p=0.01$ and $p=0.004$ respectively).

4. Discussions

PMS affects millions of women at reproductive age and has been described as one of the most common disorders in women (Takeda, Koga, & Yaegashi, 2010). The PMS rate is prevalent among students with a high negative influence on their daily life (Chandraratne & Gunawardena, 2011). This study provides new information that has not been available from Asian students in the world literature on the effect of a web based randomized controlled trial of healthy lifestyle education on improving general health and reducing PMS symptoms in university students. The trial was performed on 104 non- medical students of a large Women's University in Tehran. In this study, the majority of the students in the experimental and control groups were young women with a range of 18-23 years old (the mean age of 22.12 ± 3.4). Most participants (65.39%) had dysmenorrhea with moderately severe emotional, behavioral and physical components of PMS symptom. It is suggested that, students with PMS who have unhealthy diet and who have dysmenorrhea, are more vulnerable to adverse life quality (Pinar, Colak, & Oksuz, 2011).

At pre-intervention, no significant differences regarding demographic, presence of dismenorrhea, and other main dependent variables (health behaviors) were found between two groups (Table 1 & 3). Whereas, the findings at post intervention, (Table 2 & 4) showed that, the students who were recipients of the educational program, varied considerably across the trials. Interestingly, the students in experimental group improved significantly healthy nutrition, exercise/physical activity, and general health, compared to the control group ($P \leq 0.001$) with reduction of severity of PMS symptoms after intervention. According to the inclusion criteria, the participants were healthy students and none of them recruited in the study had any significant medical history that could be adversely affected by lifestyle (healthy nutrition high in calcium, magnesium and fruit/vegetable consumption as well as regular exercise) or any symptoms that could lead to incorrect findings.

Since, PMS is a complex psychosomatic problem in women, it is important to manage it as a chronic disorder with low incidence of side effects and continuation until menopause. Therefore, the preventive, educational and consultancy roles of the health and medical staff become more highlighted to alleviate the PMS symptoms in women, particularly in students. According to the study of Keely, et al. (2011) there are significant correlations among education, cognitive variables and health behaviors, including attitudes and intended choices that can be related to physical activity as well as the intake of healthy diet leading to improving general health in women. Based on the assumption that PMS is a multifactorial medical disorder and must not, therefore, have a definable cause (Richardson, 1995). and female students have poor dietary habits and low level of exercise compared to male students (Wyffels, 2002) the condition was investigated using a healthy lifestyle education program for female students.

Considering that women, use the Internet for obtaining health information more frequently (Hanifah, Ahmada, Wana, & Jianga, 2010), therefore, the internet seems to be an important resource for effective health education for women, to create, foster, deliver and facilitate learning, anytime and anywhere (Lenert, Muñoz, Stoddard J, et al. , 2003). Therefore, in this study, the participants as university students who have access to Internet, were considered an significant target group to be provided a web based health education program to improve their general health and consequently to reduce the severity of their PMS symptoms. Interestingly, according to the study findings, the

hypotheses (1 to 3), in terms of the scores of healthy behaviors of “healthy nutrition, exercise” as well as general health in the experimental group will be significantly increased compared with the control group, after the web based education” were confirmed.

Despite the significant health and economic consequences of PMS in women (Glasgow, McCaul, & Fisher, 1993) studies of the intervention on health behaviors as a mediator on reducing the PMS symptoms in women and particularly female students seldom appear in the recent literature (Hallal, Victora, Azevedo, & Wells, 2006). It is well established that healthy lifestyle such as eating habits and regular exercise in women provide many advantages and are directly linked to prevent health consequences such as osteoporosis, obesity, hyperlipidemia, and diabetes (Ross & Steiner, 2003). Regarding significant reduction of severity of the emotional, behavioral and physical components of PMS symptoms in experimental group compared to the control group after the intervention (Table 2), the last hypothesis in terms of “The scores of severity of the PMS symptoms in the experimental group will be significantly reduced compared with the control group, after the web based lifestyle education” was confirmed too.

Today, most current therapeutic interventions (e.g., drugs, vitamin supplements, and psychotherapy) have been found to be ineffective, to have undesirable side effects, or to have low individual treatment satisfaction (Schulman, 2010). Other strategies including complementary/alternative therapies as well as traditional medicine appear to offer, at best, a 25% to 50% reduction in PMS symptoms, the treatment may have substantial side effects. Therefore, developing successful holistic interventions for management of physical, emotional and behavioral symptoms of PMS has been challenging. Considering that many lifestyle strategies (eg, regular exercise, avoiding certain foods, and consumption of high calcium diet) can be appropriate alternative to relieve the PMS symptoms (Choi & Salmon, 1995), and frequently are utilized, but their efficacy is not reported yet (Freeman, 2010).

It seems that empowering women to foster healthy lifestyle, by educational programs, assist them to have better self management and self control of PMS symptoms. As an innovated method of education, web-based training has recently become a part of health education/ health promotion programs for general population. It has been reported to be effective for modifying health behaviors such as nutrition education (Oenema, Brug, & Lechner, 2001). Despite that healthy lifestyle is one of the least frequently used interventions and its effectiveness on PMS is not fully understood (Derman, Kanbur, Tokur, & Kutluk, 2004), we can conclude that in this study, the intervention successfully increased general health in students with PMS and significantly decreased the severity of the symptoms. However, it must be pointed out that there are some limitations. In this study, such an educational program and learning approach may not be suitable to all women. Women may have different background, especially in terms of their knowledge and computer skills, and needs, so they may exhibit various levels of engagement in the web based education. Also in this study, our population was primarily educated women (mostly undergraduate university students) they were not a representative sample of all women with PMS; the results of this study may not be generalizable to other populations that are less educated and culturally dissimilar. Another limitation is that we did not evaluate objective behavioral outcomes and the frequency of practice of the healthy lifestyle was based on unverified, subjective self reports from each participant in the experimental group. However, all participants in this study were volunteer and more motivated to take part in the trial actively and practice the health behaviors. In general, the findings suggest that the web-based healthy lifestyle education, focused on healthy nutrition and exercise, can lead to improvements in general health and consequently substantial symptomatic relief of PMS in university students. Consequently, it is hoped that health professionals will find this study’s result useful and will be able to build on these findings in their future research.

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