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# Application of psycho-educational intervention to reduce menstrual-related distress among adolescent girls: a randomized controlled trial

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#### Abstract

Objectives: The objective of the present study was to investigate the effect of psycho-educational intervention on severity of menstrual distress symptoms among adolescents with primary dysmenorrhea.

Methods: A randomized controlled trial was conducted from August 2019 to April 2020 comprising 120 adolescent girls. The study settings were high schools in Qazvin City. Participants were randomly assigned to intervention (n=60) and control groups (n=60) using a cluster randomization method. The intervention included three 60- to 90-min group psychoeducational sessions based on Leventhal's self-regulatory method. The sessions took place over three consecutive weeks with each group comprising 8-10 individuals. Menstrual distress (as the primary outcome), and illness perception and severity of dysmenorrhea (as the secondary outcomes), were assessed at four time points (pre-intervention, and three postintervention assessments [one month, two months, and three months]).

Results: A total of 54 individuals from the intervention group and 60 from the control group completed all follow-up measurements. Menstrual distress in the pre-menstruation phase significantly decreased among the intervention group at the three follow-ups (-5.41, -5.45, -4.97; all p<0.001). Menstrual distress in the menstruation phase significantly

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decreased among the intervention group at the three followups (-11.75, -12.49, -12.38; all p<0.001). Dysmenorrhea pain intensity significantly decreased among the intervention group at the three follow-ups (-2.90, -3.49, -3.30; all p<0.001). Illness perception of dysmenorrhea significantly decreased among the intervention group. Mean differences of between group comparison (intervention vs. control) through follow-ups were -19.74, -22.56, -22.71 (all p<0.001). Based on the result of the RM ANOVA-ANCOVA model, the group effect was significant (p<0.001) with the intervention explaining 36.3% of variance for change in menstrual distress in the pre-menstruation phase, 75% of change in mean scores of menstrual distress in the menstruation phase, 78.5% of variance for change in mean scores of dysmenorrhea, and 74.8 % of variance for change in mean scores of illness perception.

**Conclusions:** This intervention improved adolescent girls' menstrual distress, severity of dysmenorrhea, and illness perception regarding dysmenorrhea.

Keywords: menstrual distress; dysmenorrhea; disease perception; psycho-educational intervention

Clinical Trial Code: IRCT20190625044002N1

# Introduction

The menstrual cycle is a biopsychosocial phenomenon in which a normal physiological process can affect women's psychological status and social activity [1]. One of the most prevalent issues related to menstrual cycles among reproductive age women is dysmenorrhea [2]. Dysmenorrhea (i.e., painful menstruation or period pain) is an acute pelvic pain during menstruation comprising two types based on presence or absence of pathological and anatomical conditions (e.g., endometriosis and pelvic inflammatory disease, uterine leiomyoma) [3, 4]. In the absence of underlying pelvic pathology, period pain is referred as primary dysmenorrhea (PD), in which pain commonly starts within three years after the first menstrual period [5].

PD occurs due to increased production of prostaglandin by the endometrium through physiologic ovulatory menstrual

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cycles which leads to increased contraction activity of the uterus and subsequently uterine muscle hypoxia and pain [6-8]. PD (as the most prevalent form of chronic pelvic pain) might be experienced for at least six months and is severe enough to disrupt an individual's daily life activities, and lead to treatment seeking [9]. PD is the most prevalent cause of period pain among young women of school and university age who are under 25 years [10]. Based on a systematic review by Armour et al. [11] which synthesized evidence from 38 studies (comprising 21,573 young women from countries with different income levels), the prevalence of dysmenorrhea was 71.1% (95% CI: 66.6-75.2) irrespective of the countries' economic status. No significant difference was found in prevalence of dysmenorrhea among students at school and at university (72.5 vs. 74.9%). With 20.1% absence rate from school or university, and 40.9 % negatively affected classroom performance or concentration due to dysmenorrhea, the impact of dysmenorrhea was significant [11].

Similar to other chronic pains, period pain can act as a stressor and exacerbate psychological distress in combination with menstrual physical symptoms [4]. Menstrual distress (MD) refers to the physical and psychological symptoms related to primary dysmenorrhea which may occur before, during, and after menstruation [12]. General weakness, lethargy, abdominal pain, breast tenderness, skin disorders, palpitations, nausea, vomiting, and back pain are the physical symptoms of menstrual distress, and irritability and loneliness are among the psychological symptoms of menstrual distress [13]. MD is a prevalent problem experienced by 40 %-50 % of adolescents with geographical variation due to cultural differences [14, 15]. Because menstruation is a stigmatized issue in some cultures, many female adolescents hide their menstruation and do not tell anyone about their menstrual pain and distress [15]. This might lead to an underestimation of the prevalence of menstrual-related issues including MD [16].

MD can lead to different health problems affecting daily activities (e.g., housework, working time and doing job-related duties, school attendance, and academic performance) [17]. To alleviate symptoms of MD, reduce its socioeconomic consequences, and increase the individual's productivity, effective measures should be taken [18]. The most frequent measure for managing menstrual distress and menstrual-related pain are medications such as nonsteroidal anti-inflammatory drugs (NSAIDs) [19]. However, these medications are not suitable as a long-term solution because they have risks for decreased effectiveness and increasing dependency [20]. In this regard, non-pharmacologic treatments are the preferred approach to manage menstrual-related pain and distress to avoid unwanted side effects of medication [21].

There are many misconceptions regarding menstruation and how its related problems (such as MD) should be managed [15]. The challenges for managing menstrual-related issues are of importance in lower income settings due to limited available resources, lower socio-economic status, low reproductive knowledge, lack of formal education, local traditions, and cultural beliefs [22]. These perceptions can affect the consequences of a health condition such as menstruation [23]. Most females believe that their cyclic changes (including menstruation and its related problems) is a kind of sickness [24, 25]. Understanding a disease can affect individuals' required health-related adaptive behaviors to manage their health related problems/disease [26]. Therefore, interventions are needed to improve perceptions regarding menstrual changes and best practices to manage menstrual-related problems such as MD [24, 25].

The self-regulatory model (SRM) is a cognitive model which helps individuals understand their illness/disease. The SRM was developed by Leventhal et al. in the 1980s [27]. Based on this model, disease perception is based on bidirectional interaction between the emotional and cognitive components which alter the perception of disease threat. In this model, patients can actively play role in controlling their disease by taking action towards the change of behavior [27]. Perception of the disease responds to the symptoms and signs of the disease and guides coping strategies. This is achieved by creating cognitive and emotional experiences of the specific health condition [28, 29]. Patients' cognitive perceptions involve beliefs about (i) identity (ideas about names and symptoms), (ii) ideas about the causes of disease, (iii) the impacts of disease on various aspects of life, (iv) timing of disease-related events (ideas about duration), and (v) treatment or control (ideas for treatment and improvement). In addition, emotional components of disease perceptions include emotional reactions such as anxiety, fear, anger, and sadness toward disease. Disease perceptions derived from the SRM of health behavior shape a useful framework for assessing both individuals' cognitive perceptions concerning the disease and behavioral responses to manage outcomes [30]. Illness perception is a significant determinant of patients' self-care behaviors [31]. Training based on Leventhal's SRM can raise awareness, reduce individuals' anxiety and worry [32], and help individuals to change their behavior in order to better manage their health related condition [33].

Dysmenorrhea and MD are prevalent among Iranian adolescents [14, 34]. With its chronic and cyclic nature, it can disrupt young women's quality of life and social activities, and it is often associated with increased costs relating to medicine and medical care [17]. Individuals' strategies to manage menstrual-related issues and coping with them are mainly influenced by their knowledge and perception [22].

Based on results of a recent systematic review, health education regarding menstrual-related issues lack critical health literacy skills for female adolescents [35]. Another recent systematic review, synthetizing evidence from studies published between 2014 and 2020 regarding interventions with younger adolescent girls aged 10-14 years old as the target group, concluded that educational interventions were effective in improving the menstrual knowledge and self-management competencies of young adolescents to manage their menstruation and its related issues more comfortably [36]. While interventions based on Leventhal's SRM have shown a positive impact in improving perception and self-management practices among individuals with different health conditions such as breast cancer [37, 38], depression [39], rheumatoid arthritis [40] and diabetes [38], its effectiveness for managing MD has not been well studied. Therefore, the present study was designed to assess the effect of psycho-educational intervention using Leventhal's SRM on menstrual-related distress among female adolescent experiencing primary dysmenorrhea.

Based on the aforementioned literature, it was hypothesized that among female adolescents experiencing PD, the psycho-educational intervention using Leventhal's SRM would be effective in reducing (i) menstrual distress ( $H_1$ ), (ii) dysmenorrhea pain intensity ( $H_2$ ), and (iii) menstruationrelated perception (illness perception) ( $H_3$ ).

# Methods

## Study design

A randomized controlled trial study was conducted between August 2019 to April 2020. The protocol of present study was approved by the Research Ethics Committee at Qazvin University of Medical Sciences (decree code of IR.QUMS.REC. 1398.043). It was registered and approved in the Iranian Registry of Clinical Trials (code IRCT20190625044002N1). The related study protocol has been published elsewhere [41]. The report of the study was prepared based on suggested items in the CONSORT reporting guidelines [42].

## Setting

Qazvin province is one of the 31 provinces of Iran. It is in the northwest of the country, with the city of Qazvin as its capital. Based on Statistical Yearbook of Qazvin Province, in 2022, the student population in Qazvin city (both urban and rural areas) was 117,765 of which 10,758 were girls studying at high schools [43]. The study setting was urban high schools in Qazvin City.

#### Participants

Adolescent girls aged 14–19 years old, with regular menstruation cycles, experiencing moderate to severe dysmenorrhea for two consecutive months (intensity of menstrual pain rate of 4 or more based on the pain assessment Visual Analogue Scale) were recruited. Exclusion criteria included (i) being diagnosed with secondary dysmenorrhea due to endometriosis, pelvic inflammatory disease, congenital pelvic abnormalities and/or cervical stenosis, (ii) suffering from ovarian cysts, (iii) having a history of known mental illness, (iv) using psychoactive drugs (e.g., antidepressants), and (v) having a history of gynecological surgery. Written informed consent from was acquired from adolescents and their parents after explaining the study aims, their right to participate, and the anonymity of their responses.

#### Sample size estimation

Base on study of Wong et al. [44], sample size was estimated. Considering the mean score of MD for the intervention group as  $23.96 \pm 4.79$  and for the control group as  $26.61 \pm 1.5$ , as well as  $\alpha$ =0.05, study power of 80 % ( $\beta$ =0.2), and 20 % attrition, the required sample size was estimated to be 60 individuals for each group.

### Randomization

To minimize the chance of information leakage among students at the same school, a two-stage cluster sampling was implemented. From 34 eligible girls' schools in Qazvin city, 12 were randomly selected (six for the intervention group and six for the control group). In the study, cluster randomization was conducted using a simple random method. More specifically, all the school names were written on pieces of paper and placed inside sealed envelopes. Then, six envelopes were randomly selected for schools in the intervention group and six envelopes were randomly selected for schools in the control group. Then, one class from each school was randomly selected using a simple random method. Ten participants were then selected via simple random sampling. If the number of eligible participants in the selected classroom was more than ten (i.e., if there were more than ten eligible individuals in one class), their names were

written on paper, put into sealed envelope, and ten were Table 1: Details of educational content prepared for each session. then randomly selected.

#### Recruitment

To recruit participants, the required license was acquired. One of research team members (who was responsible for sampling and conducting interventions) attended the randomly selected schools. The researcher attended the selected classes and after explaining the study aims and assuring participants and their parents regarding the confidentiality and privacy of the data, informed consent was acquired. Students in the selected classrooms were then interviewed to determine if they met the eligibility criteria or not. Potentially eligible students were asked to complete the VAS for two consecutive months. Following this, eligible individuals were identified. After data collection, a small gift (colored pens) was given to participants to acknowledge their participation.

#### Intervention group

#### **Educational content**

The educational content was developed based on Leventhal's SRM (details provided in Table 1) to promote illness perception by improving cognition as well as controlling emotional responses. The SRM provides conscious personal management to guide an individual's thoughts, behaviors, and feelings to achieve goals. To achieve this goal, training materials were developed by the research team for participants over three sessions.

In addition to face-to-face educational sessions, a booklet was developed to ensure that sufficient information regarding the cognitive and psychological dimensions of menstruation and dysmenorrhea was provided. The booklet aimed to improve illness perceptions related to menstruation by providing simple explanations and relevant illustrations. The content included a definition of menstrual distress, misconceptions about the menstrual cycle, activities that can be engaged in during menstruation (e.g., eating more white meat, dairy products, eggs, and fresh vegetables; doing suitable exercises during menstruation) and those that cannot (e.g., avoiding strenuous exercise, limiting the eating of red meat and fried foods), and tips regarding personal hygiene, nutrition, physical activity, stress management techniques, and relaxation. The booklet was reviewed and approved by ten faculty members in the nursing and midwifery school at Qazvin University of Medical Sciences. Five female students were asked to read the booklet and assess its suitability for use

Session	Aims	Content	Activities
1	Assessment of adolescents' cognitive and emotional perceptions regarding menstrual distress and its physical and psychological symptoms based on SRM components	1. Acquaintance, introduction, statement of goals 2. Explanation of the nature, cause and symptoms of menstrual distress 3. Discussing aggravating factors from the patient's point of view 4. Focus on correct- ing things that the teenager has a wrong understand- ing of. 5. Questions and answers	Training in tech- niques including self-control, verbal encouragement, feedback, behavioral assessment, and ways to successfully control illness experiences
2	To change the negative and untrue percep- tions of the illness	<ol> <li>Discussing teen- agers' beliefs about the consequences of menstrual distress</li> <li>Talking about how to control and treat menstrual distress</li> <li>Questions and approprint</li> </ol>	Repeating the tech- niques from the first session Training stress and relaxation strategies
3	Establishing self-care program	1. Providing a self-care program to stabilize informa- tion and manage menstrual distress 2. Evaluating the impact of trainings and solving existing problems and obstacles 3. Questions and answers	Repeating the exercises from the previous sessions

by adolescents. During the sessions, the booklet was provided to the intervention group. In addition, the researcher's contact information was provided to the adolescents in case they had any further questions.

#### **Educational sessions**

For the intervention group, three 60-to-90-min sessions over three consecutive weeks (one session per week) were conducted in groups of 10 [45]. In total, there were six educational groups and 18 educational sessions were held within a two-month period. Additionally, individual counseling sessions regarding adolescents' reproductive common problems were held.

## **Control group**

Participants in control group did not receive any educational content during study phases. Upon completion of the study (when the study was finished for both groups and all data were collected) and based on their willingness, the counseling sessions were provided to the control group. The same person conducted the counseling sessions for the control group. It should also be noted that there were no restrictions on using other analgesics and NSAIDs by participants, but they were asked to inform the research team if they were using other sedatives in order to investigate any confounds.

### Intervention fidelity

One of the research team members (who had degrees in BSc Midwifery and MSc Counseling in Midwifery) conducted all the intervention sessions. In Iran, those with an MSc Counseling in Midwifery degree have to pass theoretical and clinical courses in counselling which prepare them for being a counselor in reproductive health issues including menstrualrelated problems. The content used in the present study was assessed by faculty members of the midwifery group and its content validity was confirmed. To ensure the fidelity of the counselling sessions conducted, the first five sessions were conducted in presence of study advisors, all of whom had PhDs in reproductive health. After ensuring the competency of the person conducting the counselling sessions, the rest of sessions were conducted independently.

#### Study outcomes and measures

Menstrual distress was assessed as the primary outcome, and illness perception and severity of dysmenorrhea were the secondary outcomes. These outcomes were assessed before conducting the intervention, one, two, and three months after completing the intervention using the following measures:

 Demographic and menstrual characteristics including age, menarche age, body mass index, menstrual cycle characteristics (menstrual duration, bleeding volume), family history of dysmenorrhea, and use of painkillers for dysmenorrhea (assessed at baseline and all three follow-ups) were assessed.

- 2. The severity of dysmenorrhea was assessed using *Visual Analog Scale (VAS)* which is a valid and reliable measure for evaluating dysmenorrhea [46]. The VAS is a 10-cm line where no pain is rated as zero and the most severe pain is rated as 10 [47]. The participants mark their experience regarding severity of the pain using this scale.
- General complaints regarding menstruation-related symptoms was assessed using the modified *Moos Menstrual Distress Questionnaire (MMDQ)*, which is a valid and reliable measure [48, 49]. The MMDQ assesses physical and psychological symptoms of distress during pre-menstruation, menstruation, and post-menstruation. Responses are rated from 1 (*experienced no symptoms*) to 4 (*experienced most severe and debilitating symptoms*) [48]. The psychometric properties of MMDQ Persian version have been confirmed [50]. In the present study, the MMDQ had acceptable reliability.
- 4. The brief *Illness Perception Questionnaire (IPQ)* is a nineitem scale for assessing the perception of the disease [51]. The *IPQ* assesses individuals' emotional and cognitive aspects of illness/disease-related perceptions. Responses are rated on a 10-point Likert scale with higher scores indicating more negative cognitive and emotional representations of illness [51]. The validity and reliability of the Persian version has been confirmed [52].

### Data collection

Data were collected in-person using a paper-and-pencil method and the surveys were self-completed by the participants.

#### Data analysis

The data were analyzed using SPSS.24 (IBM SPSS, New York, USA). To assess normality distribution of variables, Kolmogorov-Smirnov and Shapiro-Wilks tests were used. Independent *t*-tests and chi-square tests were used to evaluate differences between the group scores. The effect of intervention on menstrual distress, illness perception, and menstrual pain were assessed using repeated measures analysis of variance-covariance (RM ANOVA-ANCOVA) at a significance level of p<0.05.

# Results

In the present study, 120 adolescent girls who were eligible for inclusion participated in the study. A total of 60 participants were randomly assigned to each group. In the intervention group, six did not complete the surveys due to the study follow-up times interfering with the end-ofsemester exams. Therefore, 54 participants in the intervention group and 60 in the control group completed the study. Figure 1 shows the CONSORT flow diagram of the study.

The mean age of the participants was 15.45 years (SD=0.68) in control group and 15.54 years (SD=0.61) in intervention group. The mean age of participants' menarche age was 12.38 years (SD=1.06) in control group and 12.81 years (SD=1.07) in intervention group. The distribution of demographic characteristics was balanced in the two groups (see Table 2) except for age of menarche which was controlled for as a covariate.

#### **Menstrual distress**

Menstrual distress in the pre-menstruation phase significantly decreased among the intervention group (Table 3). The mean differences of between group comparison (intervention vs. control) at the three follow-ups were -5.41, -5.45, -4.97 (all p<0.001) with large effect sizes (Cohen's *d*=-1.39, -1.49, -1.37, respectively). Based on the result of the RM ANOVA-ANCOVA model, the group effect was significant (p<0.001) and explained 36.3 % of variance for change in mean scores of menstrual distress in the pre-menstruation phase. Menstrual distress in the menstruation phase significantly decreased among the intervention group (Table 3). Mean differences of between group comparison (intervention vs. control) at the three follow-ups were -11.75, -12.49, -12.38 (all p<0.001) with large effect sizes (Cohen's *d*=-3.05, -3.34, -3.53, respectively). Based on the result of the RM ANOVA-ANCOVA model, the group effect was significant (p<0.001) and explained 75 % of variance for change in mean scores of menstrual distress in the menstruation phase.

#### Dysmenorrhea pain intensity

Dysmenorrhea pain intensity significantly decreased among the intervention group (Table 4). Mean differences of between group comparison (intervention vs. control) at the three follow-ups were -2.90, -3.49, -3.30 (all p<0.001) with large effect sizes (Cohen's d=-3.16, -3.42, -3.77, respectively). Based on the result of the RM ANOVA-ANCOVA model, the group effect was significant (p<0.001) and explained 78.5 % of variance for change in mean scores of menstrual distress in the menstruation phase.

### Illness perception regarding dysmenorrhea

Illness perception regarding dysmenorrhea significantly decreased among intervention group (Table 5). Mean differences of between group comparison (intervention vs.



Figure 1: CONSORT flow diagram.

Table 2: Summary of participants' demographic characteristics.

		Control (n=60) Mean, SD	Intervention (n=54) Mean, SD	p-Value of between group comparison
Age, years		15.45 (0.68)	15.54 (0.61)	0.47
The age of menarche, in years		12.38 (1.06)	12.81 (1.07)	0.03
The length of the menstrual cycle, in da	ys	29.23 (2.88)	30.00 (3.82)	0.23
The duration of menstrual bleeding, in	days	6.47 (1.28)	6.52 (1.45)	0.84
Duration of menstrual pain, in days		2.78 (1.32)	3.07 (1.27)	0.23
Body mass index, kg/m <sup>2</sup>		20.80 (2.83)	21.67 (2.91)	0.11
Qualitative variables		No (%)	No (%)	
Economic status of the family	Medium	27 (45)	32 (59.3)	0.18
-	Good	33 (55)	22 (40.7)	
Family history of menstrual cramps	Yes	32 (53.3)	33 (61.1)	0.40
	No	28 (46.7)	21 (38.9)	
The severity of menstrual bleeding	Mild	29 (48.3)	25 (46.3)	0.54
	Severe	31 (51.7)	29 (53.7)	
Need to relieve menstrual pain	No	1 (1.7)	1 (1.9)	0.94
•	Yes	59 (98.3)	53 (98.1)	
Menstrual pain relief method	Pharmacological	7 (11.7)	3 (5.6)	0.57
	Non-pharmacological	25 (41.7)	20 (37)	
	Both	27 (45)	30 (55.6)	

Table 3: Results of repeated measure analysis of variance-covariance (RM ANOVA-ANCOVA) to investigate the effect of intervention on menstrual distress.

Variable of interest	Time	Intervention n=54	Comparison n=60	Mean difference 95 % CI	p-Value	Cohen's <i>d</i> (95 % CI)	Results of RM ANOVA-ANCOVA		
	point						Effect	F (p)	Partial η²
Menstrual distress: pre- menstruation phase	Before	12.70 (5.51)	9.75 (6.81)	2.95 [0.64; 5.27]	0.13	0.47 [0.10; 0.85]			
,	Follow 1	5.23 (3.90)	10.64 (3.89)	-5.41 [-6.89; -3.92]	<0.001	–1.39 [–1.80; –0.98]	Time	0.21 (0.77)	0.002
	Follow 2	5.58 (3.66)	11.03 (3.65)	-5.45 [-6.85; -4.05]	<0.001	-1.49 [-1.91; -1.08]	Group	61.08 (<0.001)	0.363
	Follow 3	5.59 (3.64)	10.56 (3.63)	-4.97 [-6.36; -3.58]	<0.001	-1.37 [-1.78; -0.96]	$Time \times Group$	0.75 (0.45)	0.007
Menstrual distress: menstruation phase	Before	23.74 (7.36)	20.37 (8.94)	3.37 [0.32; 6.43]	0.031	0.38 [0.01; 0.75]			
	Follow 1	10.30 (3.86)	22.05 (3.85)	–11.75 [–13.22; –10.28]	<0.001	-3.05 [-3.59; -2.51]	Time	0.49 (0.62)	0.005
	Follow 2	10.20 (3.75)	22.69 (3.74)	-12.49 [-13.92; -11.06]	<0.001	-3.34 [-3.90; -2.77]	Group	320.865 (<0.001)	0.750
	Follow 3	10.16 (3.51)	22.54 (3.50)	-12.38 [-13.72; -11.04]	<0.001	–3.53 [–4.12; –2.95]	Time × Group	2.42 (0.09)	0.022

(all p<0.001) with large effect sizes (Cohen's d=-2.70, -3.71, -3.65, respectively). Based on the result of the RM ANOVA-

control) at the three follow-ups were -19.74, -22.56, -22.71 ANCOVA model, the group effect was significant (p<0.001) and explained 74.8 % of variance for change in mean scores of illness perception.

Table 4: Results of repeated measure analysis of variance-covariance (RM ANOVA-ANCOVA) to investigate the effect of intervention on dysmenorrhea pain intensity.

Variable of interest	Time point	Intervention n=54	Comparison n=60	Mean difference 95 % CI	p-Value	Cohen's <i>d</i> (95 % CI)	Results of RM ANOVA-ANCOVA		
							Effect	F (p)	Partial η²
Dysmenorrhea pain intensity	Before	7.72 (1.23)	7.43 (1.60)	0.29 [-0.24: 0.81]	0.28	0.20			
	Follow-up 1	4.55 (0.92)	7.44 (0.91)	-2.90 [-3.24; -2.55]	<0.001	-3.16 [-3.71; -2.61]	Time	0.42 (0.65)	0.004
	Follow-up 2	4.10 (1.02)	7.59 (1.02)	-3.49 [-3.88; -3.11]	<0.001	-3.42 [-4.00; -2.85]	Group	390.98 (<0.001)	0.785
	Follow-up 3	4.20 (0.87)	7.50 (0.88)	-3.30 [-3.64; -2.97]	<0.001	-3.77 [-4.38; -3.16]	$Time \times Group$	10.99 (<0.001)	0.093

**Table 5:** Results of repeated measure analysis of variance-covariance (RM ANOVA-ANCOVA<sup>a</sup>) to investigate the effect of intervention on illness perception regarding dysmenorrhea.

Variable of interest	Time	Intervention	Comparison	Mean differ-	p-Value	Cohen's d	Results of RM ANOVA-ANCOVA		
	point	n=54	n=60	ence 95 % CI		(95 % CI)	Effect	F (p)	Partial η²
Illness perception regarding dysmenorrhea	Before	50.31 (9.78)	45.93 (12.97)	4.38 [0.14; 8.62]	0.04	0.38 [0.01; 0.75]			
	Follow- up 1	27.56 (7.33)	47.30 (7.30)	–19.74 [–22.52; –16.96]	<0.001	–2.70 [–3.21; –2.19]	Time	0.73 (0.46)	0.007
	Follow- up 2	24.67 (6.09)	47.23 (6.07)	–22.56 [–24.88; –20.25]	<0.001	–3.71 [–4.32; –3.11]	Group	318.16 (<0.001)	0.748
	Follow- up 3	24.09 (6.22)	46.79 (6.21)	–22.71 [–25.07; –20.34]	<0.001	–3.65 [–4.25; –3.05]	$Time \times Group$	16.83 (<0.001)	0.136

<sup>a</sup>Adjusted for pre-intervention baseline scores for each variable of interest and age of menarche and need to use painkillers.

#### Need to use painkillers for dysmenorrhea

The need to use painkillers for dysmenorrhea significantly decreased through the measurement time-points (Table 6) in the intervention group (p=0.02 for time trend in the

Table 6: Need to use painkillers for dysmenorrhea.

Measurement time point	Intervention (n=54)	Control (n=60)	p-Value for between group comparison using Fisher's exact test		
Baseline	53 (98.1)	59 (98.3)	0.94		
First follow-up	51 (94.4)	60 (100)	0.10		
Second follow-up	49 (90.7)	59 (98.3)	0.06		
Third follow-up	48 (88.9)	59 (98.3)	0.05		
p-Value for within group comparison using Cochran's <i>Q</i> test	0.02	0.39			

intervention group). Between group comparison showed that the decreased need for painkillers among intervention group was not significant at the first follow-up (p=0.10), marginally non-significant at the second follow-up (p=0.06), and significant at the third follow-up (p=0.05).

## **Potential confounders**

All analyses were adjusted for related scales' baseline scores, age of menarche, and need to use painkillers for dysmenorrhea.

# Discussion

In the present study, the effect of a psycho-educational intervention developed based on Leventhal's self-regulation model on menstrual distress (as primary outcome), and illness perception and severity of dysmenorrhea (as the secondary outcomes) among female adolescents was investigated. The menstrual cycle is a normal biopsychosocial process which is often accompanied with pain and distress, and can affect women's physical and psychological health as well as their social activity [1]. There are many misconception regarding menstruation and how its related problems such as menstrual distress should be managed [15]. The self-regulatory model (SRM) is a cognitive model which can help individuals to shape their perception regarding disease or health condition based on the emotional and the cognitive components. Consequently, they can actively manage their symptoms by changing their behavior [27].

Results of present study showed that the mean scores of menstrual distress in the premenstrual and menstrual phase were significantly reduced after the intervention at all three follow-up times for the intervention group in comparison to the control group (supporting H<sub>1</sub> that the psycho-educational intervention using Leventhal's SRM would be effective in reducing MD among female adolescents experiencing primary dysmenorrhea). It is noteworthy that the reduction of menstrual distress in the menstrual phase was greater in comparison with the pre-menstrual phase. This finding is consistent with results of previous studies. Kabirian et al. [53] reported that self-care education promoted self-care and reduced the intensity of menstrual distress among 74 college girls with dysmenorrhea (mean age=21 years). Tang et al. [54] reported that 391 female college students (mean age=19 years old) suffering from dysmenorrhea benefited from a self-care education program. Moreover, they found that self-care behavior training was as a suitable option for reducing the intensity of menstrual pain and improving the quality of life among females experiencing dysmenorrhea [54].

The present study found there was a significant reduction in the mean scores of menstrual pain severity after the intervention (supporting  $H_2$  that the psycho-educational intervention using Leventhal's SRM would be effective in reducing dysmenorrhea pain intensity among female adolescents experiencing PD). Similarly, Ozkan-Sat and Isık [55] reported that psychoeducation based on Leventhal's SRM was effective in reducing the severity of dysmenorrhea pain and its functional and emotional impact among 66 nursing students (aged 18–30 years) [55]. Moreover, results of a systematic review comprising five trial studies (comprising 213 women of reproductive age), found that behavioral therapy (using adaptive coping strategies, challenging irrational beliefs, and muscle relaxation) reduced menstrual pain severity after treatment [56].

Consistent with the present study, a reduction in menstrual pain severity was reported in previous studies in which adolescent girls were educated about menstruation and proper self-care behaviors [53, 54, 57]. This significant reduction in the mean scores of menstrual pain severity after intervention can be attributed to adolescent girls' utilizing techniques such as using heat therapy to control menstrual pain. Hosono et al. [58] reported the efficacy of heat- and steam-generating sheets for the relief of symptoms of primary dysmenorrhea among 34 female university students (mean age 20 years) [58]. As a result of the intervention, the misconceptions of the participants were corrected and the wrong methods that they used to reduce pain were removed and replaced with the right methods. Consequently, menstrual pain reduction was observed in all three follow-ups in experimental group.

The other key finding of present study was significant improvement in the perception of menstrual distress among adolescent girls in the intervention group at all three followups in comparison to the control group (supporting H<sub>3</sub> that the psycho-educational intervention using Leventhal's SRM would be effective in reducing menstruation-related perception [illness perception] among female adolescents experiencing PD). Although Ozkan-Sat and Isık [55] used psychoeducation based on Leventhal's SRM among 66 nursing students (aged 18-30 years) and reported its effectiveness in reduced pain intensity, they did not assess illness perception as an outcome [55]. Based on Leventhal's SRM, the perception of disease in each individual is unique, which can affect health outcomes [27]. The positive role of self-regulatory educational interventions in health behaviors can have positive functional consequences and psychological adjustment among individuals [59, 60]. There is a dynamic relationship between illness perception and psychological health indicators [61]. Improving illness perception can reduce negative disease symptoms by correctly understanding the components of the disease, correcting unrealistic perceptions about the disease, and using proper self-management techniques.

#### **Study implications**

The overall results of the present study showed that the psychoeducational intervention based on Leventhal's SRM was effective in reducing menstrual distress and menstrual pain intensity among Iranian adolescent girls and improved their perception regarding menstruation and how they managed menstrual-related problems. This education program consisted of (i) introduction to cognitive and emotional components regarding menstruation, dysmenorrhea, and menstrual distress, (ii) physical and psychological symptoms related to menstrual distress, (iii) changing the negative and untrue perceptions related to menstruation and its related problems, and (iv) establishing a self-care program. Improving menstrual knowledge and learning self-care and menstrual pain management behaviors among adolescents can help them to pass through their reproductive age more healthily and with less problems.

In Iran, there is no comprehensive sexuality and relationships education in school curricula [62]. This formal education gap results in low menstrual-related knowledge and improper self-care practices among Iranian female adolescents [63, 64]. Therefore, Iranian adolescent girls should be empowered by receiving proper education regarding reproductive and sexual knowledge including menstrual issues [65]. Roux et al. developed a holistic school-based menstrual health literacy program, for 94 Grade 9 students (aged 14–15 years) in Australia. They reported that this program improved participants' menstrual health literacy [66]. Therefore, a good way to provide menstrual health educations with different methods including SRM for adolescents is its integration into school curricula to ensure that all female adolescents can benefit from such education.

Based on a recent systematic review by Rastogi et al. [67] which synthesized the evidence of the effectiveness of 27 interventions aimed at improving menstrual health among young girls in different countries, some key elements contributing to effectiveness of these interventions were providing information, sensitization to beliefs, involving stakeholders, providing a supportive environment, and culturally sensitive communication [67]. Existence of the socio-cultural beliefs and taboos regarding menstruation in society might be barriers of menstrual health-related interventions. Including mothers and teachers in menstrual health interventions can enable adolescents to be more successful in menstrual health management.

## Limitations

A number of limitations should be noted when interpreting the study's findings. First, there were differences at baseline in all outcome measures, with the intervention group consistently worse than the control group. While the research team tried to statistically reduce the effect of baseline differences by adding baseline scores as covariates, there was still the issue of selection bias. While the baseline demographic and reproductive characteristics (Table 2) had a balanced distribution, the baseline scores of study variables appeared to show some differences. This might have occurred due to using cluster level randomization. Second, the participants were adolescents from urban areas. Therefore, further studies including adolescents from rural settings are also needed. Third, the assessment of outcomes used self-report measures which have well-known biases (e.g., social desirability, memory recall). The

target population in present study were students and other stakeholders (mothers, teachers, nurses) were not involved. In future studies, the effectiveness of this method could be compared with other educational methods including mothers and teachers in educational sessions, and the duration of follow-up could be longer (e.g., six months or one year). Moreover, qualitative research would add depth to future studies.

#### Conclusions

The overall results of the present study showed that the psychoeducational intervention based on the Leventhal's SRM was effective in reducing menstrual distress and menstrual pain intensity among adolescent Iranian girls and is non-pharmacological, easy to use, and a low-cost pain relief intervention.

**Research ethics:** The present study was conducted in accordance with the Declaration of Helsinki. The protocol of present study was reviewed and approved by the Research Ethics Committee at Qazvin University of Medical Sciences under decree code of IR.QUMS.REC. 1398.043. It was also registered and approved with the code IRCT20190625044002N1 in the Iranian Registry of Clinical Trials. Informed consent was obtained from all participants and their parents during the study. **Informed consent:** Written informed consent was obtained from all participants and their parents before commencing data collection.

**Author contributions:** N.B. & M.A.A. contributed to the conception, Z.A., N.B. & M.A.A. contributed to the design of the study, S.A. contributed in data collection in supervision of N.B. & Z.A. Z.A. contributed in data analysis, Z.A. & N.B. interpretation of data. Z.A., N.B., M.A.A. and S.A. drafted the manuscript. M.D.G. and Z.A. provided contributions to the literature review and discussion and prepared the final version of the manuscript. M.D.G. revised the manuscript and copy-edited the manuscript. All authors revised the integrity and accuracy of the study, and read and approved the final version of the manuscript to be published. All the authors met the criteria for authorship, and they are listed as co-authors on the title page.

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