



Effectiveness of exercise therapy on pain and quality of life of patients with primary dysmenorrhea: a systematic review with meta-analysis

Egzersiz tedavisinin primer dismenoreli hastaların ağrı ve yaşam kalitesi üzerine etkinliği:
Meta-analiz ile sistematik bir derleme

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ABSTRACT

Objectives: This study aims to gather robust evidence in relation to the effectiveness of exercise interventions in reducing pain and improving quality of life in individuals with primary dysmenorrhea.

Materials and methods: A systematic review of experimental studies was executed with a meta-analysis of randomized trials. Using the PEDro guideline for quality appraisal, 12 electronic databases were accessed that recorded studies on exercise interventions in women with primary dysmenorrhea using menstrual pain intensity and quality of life as primary and secondary outcomes, respectively. Data unsuitable for meta-analysis were reported as descriptive data in the systematic review.

Results: The search yielded 32 citations, from which eight studies were systematically reviewed, with four of the eight being eligible for meta-analysis. The systematic review showed moderate methodological quality with the mean of 5.65 out of 10 on the PEDro quality scale. Exercise therapy showed some evidence of pain reduction in primary dysmenorrhea.

Conclusion: Exercise therapy can be considered as a non-pharmacological option in the management of primary dysmenorrhea pain.

Keywords: Bodily activity; exercise therapy; exercise; physical activity; physical intervention; primary dysmenorrhea.

ÖZ

Amaç: Bu çalışma, primer dismenoreli bireylerde ağrının azaltılması ve yaşam kalitesinin artırılmasına yönelik egzersiz müdahalelerinin etkinliği ile ilgili sağlam kanıtlar toplamayı amaçlamaktadır.

Gereç ve yöntemler: Deneysel çalışmaların sistematik derlemesi randomize çalışmaların meta-analizi ile yürütüldü. Kalite değerlendirmesinde PEDro kılavuzu kullanılarak, primer dismenore olan kadınlarda egzersiz girişimlerine ilişkin verileri menstrüel ağrı yoğunluğunu ve yaşam kalitesini sırasıyla birincil ve ikincil sonuçlar olarak değerlendiren çalışmaları gösteren 12 elektronik veri tabanına erişildi. Sistematik derlemede meta-analiz için uygun olmayan veriler tanımlayıcı veri olarak rapor edildi.

Bulgular: Aramada sekiz araştırmanın sistematik olarak gözden geçirildiği 32 alıntı sonucuna ulaşıldı, sekiz tanesinin dördü meta-analiz için uygun bulundu. Sistematik inceleme PEDro kalite ölçeğine göre 10 üzerinden 5.65 ile orta derece metodolojik kalite gösterdi. Egzersiz tedavisi, primer dismenorede ağrı azalması ile ilgili bazı kanıtlar gösterdi.

Sonuç: Egzersiz tedavisi, primer dismenore ağrısının yönetiminde farmakolojik olmayan bir alternatif olarak düşünülebilir.

Anahtar sözcükler: Bedensel etkinlik; egzersiz terapisi; egzersiz; fiziksel aktivite; fiziksel müdahale; primer dismenore.

Dysmenorrhea constitutes a high health, social and economic burden. Absenteeism from school or work at least once, in response to the symptoms of primary dysmenorrhea have been reported in between one

third to one half of sufferers. Within this group, 5% to 14% report even more frequent absenteeism.^[1] One third to half of women with primary dysmenorrhea report moderate or severe symptoms^[2] that for

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many women negatively impact their quality of life (QoL).^[3-6] Exercise interventions have been advocated as a major non-medical intervention for the relief of dysmenorrhea.^[7-10] However, there is conflicting evidence regarding the salient issue of whether the different interventions are beneficial.^[11]

One of the major challenges for those studying the subject of primary dysmenorrhea and exercise therapy has been the subjective nature of the symptoms presentation coupled with the heterogeneity of the different protocols and levels of exercise.^[11] As such, variation in the quality, intensity and duration of the protocols in relation to menses remain a challenge to interpret.^[11]

A Cochrane systematic review in 2010^[11] concluded that there is a lack of available evidence to support the use of exercise as an intervention in the alleviation of symptoms associated with primary dysmenorrhea and called for further evidence from well-controlled, randomized trials before any definitive conclusions can be made. Four years down the line more trials are expected to have taken place. Therefore, the quality of the evidence needs to be re-examined to establish if exercise interventions can be advocated as a supplementary therapy for women with primary dysmenorrhea symptoms.

This study aims to scrutinize robust evidence from controlled trials for indications of the effectiveness or otherwise of exercise in the management of pain and improving QoL in women with primary dysmenorrhea, adding to literature on best practice of non-pharmacological intervention in primary dysmenorrhea. This information is essential to draw a consensus to promote non-pharmacological intervention as an important adjunct therapy for women with primary dysmenorrhea. This review also aims to serve as a reference point for future research on similar areas of study.

MATERIALS AND METHODS

The research design was a systematic review with meta-analysis. Only randomized trials were eligible for the meta-analysis, including crossover trials provided outcome data were available for each intervention before starting the crossover. Studies not published in English were excluded. Other experimental studies not eligible for meta-analysis were systematically reviewed.

Data was collected through a comprehensive search strategy which was conducted online identifying all relevant publications on exercise interventions for

management of primary dysmenorrheic pain and QoL of females with primary dysmenorrhea. Allied health, health-related, health science and medical data bases including Ovid Medline, Cochrane Library, Science Direct, PubMed, Scopus, Physiotherapy Evidence Database (PEDro), Web of Science, CINAHL, MANTIS, SCIENCE DIRECT, SCOPUS, PsyclINFO, Ovid Medline, AMED and EMBASE were used. The search was performed using the following key indexing terms independently; exercise therapy, exercise intervention, physical activity, 'physiotherapy', 'physical therapy', 'primary dysmenorrhea' 'quality of life' and 'physical intervention'. Also, a search strategy described by Brown and Brown^[11] was explored. Google search and a hand search of reference lists of existing articles was also conducted to find papers that did not appear in the main databases. The search covered literature from January 1970 to April 2014.

Published studies with focus on the efficacy, effectiveness, or effect of different exercise interventions on pain, and/or QoL of females with primary dysmenorrhea were searched using the following selection criteria. Only studies comprising cohorts of human female subjects within the selected reproductive age were included. Studies were limited to peer-reviewed journals and conference proceedings. All study abstracts meeting these broad criteria were initially included. In the case that a decision could not be made based on the title and abstract of the paper, the authors were contacted asking for any missing data in the included studies and the full text of the paper was obtained to be used when a decision was made. Case reports and clinical opinions were excluded (See details of excluded studies in Appendix 1).

Subsequent inclusion, based on the inclusion criteria, was then assessed independently by the first and the second authors. When a difference of opinion occurred, consensus was reached on inclusion or exclusion through discussion and reflection. Third author was called upon in the event of disagreement. Specifically, selection of trials was based on criteria earlier described by Brown and Brown^[11] in a similar systematic review.

Trials eligible for review conformed to the following inclusion criteria: primary dysmenorrhea (pain affecting daily activity or with a high baseline score ≥ 3 on visual analog scale (VAS) or equivalent tool); primary dysmenorrhea in the majority (>50%) of menstrual cycles; primary dysmenorrhea for at least one day of menses; of reproductive age; pain intensity and/or QoL as outcome measures. Trials which met

Table 1. Descriptive characteristics of studies on exercise versus control

Study	Design	Participants	Intervention	Control	Outcome measures
Abbaspour et al. ^[15]	RCT	n= 142 (Exp= 97, Cont= 45) Age= 15-18 years (16.56±1.12) Pain (0-10 cm) = Exp= 8.59 (1.21) Cont= 8.84 (0.893)	Exercise therapy	No therapy	VAS (0-10) cm
Mahvash et al. ^[14]	RCT	n= 50 (Exp= 25, Cont= 25) Age= Exp= 22.84±1.79, Cont= 23.84±2.91 Pain= Moderate to severe	PAE classes with physical activity protocol	PAE classes without physical activity protocol	Pain scales, PRI VAS PPI
Gamit et al. ^[16]	RCT	n= 30 (Exp= 15, Cont= 15) Age= 19-25 years Pain: VAS (Exp= 6 (1.30), Cont= 6.20 (1.65))	Active stretching exercise program	No exercises program (waiting period)	VAS (0-10) cm VMS (grade 0-3)
Shahr-Jerdy et al. ^[17]	RCT	n= 179 (Exp= 124, Cont= 55) Age= 15-17 years Pain (0-10 cm) = Exp= 7.65±1.94, Cont= 7.77±1.50	Stretching exercise	Avoided irregular physical exercise	VAS 10-10 cm Hrs for pain duration No of tablets (use of meds)
Onur et al. ^[18]	Pre-test post-test Design	n=45 Age= 25 (8), 16-39 VAS= 7.8	Home-based exercise program	No control group	Pain scale-> VAS (0-100 cm) Quality of life

Exp: Experimental group; Cont: Control group; VAS: Visual analog scale; PAE: Physical activity education; PRI: Pain rating index; PPI: Present pain intensity; VMS: Verbal Multidimensional Scoring System for Assessment of Dysmenorrhea Severity.

any of the following criteria were not included in the review: irregular or infrequent menstrual cycles (usually outside of the typical range of a 21 to 35 day cycle); use of intra-uterine contraceptive device or the taking of oral contraceptive pills.

The second author acted as the principal reviewer for data extraction and management, and was trained by the first author. The first author acted as the second reviewer to extract data from the included paper. Training sections included clarification of all data items and required elements of the quality appraisal tool. Standardization of the procedure was required for consistency in method of data extraction used by the reviewers. To this effect, before data extraction

began, a trial was conducted on two similar but unrelated papers and the result was discussed. The last author was consulted when there were disagreements between the first and second authors. The last author's opinion stimulated further discussion to arrive at a consensus. This data extraction method (double data extraction) has been shown to have a lower rate of error than simple data extraction.^[12] Pooling of data was undertaken where adequate homogeneity of results existed. Discrepancies were resolved through discussion. For each included trial, data was extracted regarding the participants (age range, eligibility criteria), the nature of the interventions and data relating to the outcomes specified above.

Table 2. Descriptive characteristics of studies on exercise versus other interventions

Study	Design	Participants	Intervention	Control	Outcome measures
Gupta et al. ^[19]	RCT	n=79 (Exp= 34, Cont= 30) Age= 17-19 years Pain. NRS (0-10), Exp= 5.09±2.33, Con= 5.13±1.99 MDQ Exp= 50.85±29.07 (0-4), Cont= 62.27±49.47	Active exercise and dry ginger powder (500 mg) 2x a day	Only active exercise	Pain scales: NRS: 0-10 MDQ: 0-4
Chaudhuri et al. ^[20]	RCT	n= 112 (Exp= 48, Cont= 64) Age= Median (14.0) VAS= Exp= 5.75, Cont= 5.16 MDQ= Exp= 14.53, Cont= 14.92	Exercise	Hot water bottle	Pain scales: VAS: 0-10 cm MDQ

Exp: Experimental group; Cont: Control group; NRS: Numeric rating scale; MDQ: Menstrual distress questionnaire; VAS: Visual analog scale.

Table 3. Descriptive characteristics of studies on yoga

Study	Design	Participants	Intervention	Control	Outcome measures
Nag et al. ^[21]	RCT	n= 113 (Exp= 60, Cont= 53) Age= 18-23 years NRS	Yoga intervention	No intervention	Pain scale: NRS; 0-10 Stress scale

Exp: Experimental group; Cont: Control group; NRS: Numeric rating scale.

Table 4. Physiotherapy Evidence Database quality appraisal of studies on exercise versus control

Study name of author	Random allocation	Concealed allocation	Groups similarat baseline	Participant blinding	Therapist blinding	Assessor blinding	<15% dropout	Intention to treat analysis reported	Between group difference	Paint estimate & variability reported	Total 0-10
Abbaspour et al. ^[15]	Y	N	Y	N	N	N	Y	Y	Y	Y	6
Mahvash et a. ^[14]	Y	N	Y	N	N	N	Y	N	Y	N	4
Gamit et al. ^[16]	Y	N	Y	N	N	N	Y	N	Y	N	4
Shah-jerdy et al. ^[17]	Y	N	Y	N	Y	N	Y	N	Y	N	5
Onur et al. ^[18]	N	N	Y	N	N	Y	Y	Y	Y	Y	6

Y: Yes; N: No.

Table 5. Physiotherapy Evidence Database quality appraisal of studies on exercise versus other interventions

Study name of author	Random allocation	Concealed allocation	Groups similarat baseline	Participant blinding	Therapist blinding	Assessor blinding	<15% dropout	Intention to treat analysis reported	Between group difference	Paint estimate & variability reported	Total 0-10
Gupta et al. ^[19]	Y	Y	Y	N	N	N	Y	Y	Y	Y	7
Nag et al. ^[21]	Y	N	Y	N	N	N	Y	Y	Y	N	5
Chaudhuri et al. ^[20]	Y	Y	Y	N	N	N	Y	Y	Y	Y	7

Y: Yes; N: No.

The data extraction form consisted of descriptive characteristics (Tables 1-3) and a quality appraisal tool (Tables 4 and 5). Data was extracted based on the elements of this form which are related to the research questions and aims of this systematic review.

The quality of each paper was appraised using the Physiotherapy Evidence Database (PEDro) quality appraisal tool.^[13] The PEDro is an 11-item scale in which the first item relates to external validity and the other ten items assess the internal validity of a clinical trial. One point was given for each satisfied criterion (except for the first item, which was given a YES or NO answer), yielding a maximum score of 10. The higher the score, the better the quality of the study and the following point scale was used: 9-10 (excellent); 6-8 (good); 4-5 (fair); <4 (poor). A point for a particular criterion was awarded only if the article explicitly reported that the criterion was met.^[13] A score of one was given for each yes answer and zero for no, unclear and not applicable (N/A) answers. The overall score was reported as a tally of all yes answers out of 10 based on the applicable answers for each study. Scores of individual items from the critical appraisal tool were added to present a total score.

This study was approved by ethical committee of University of Nigeria Teaching Hospital Health Research and Ethics Committee.

RESULTS

The initial searches identified a number of potential relevant papers. The flow of papers through the process of assessment of eligibility is indicated along with reasons for exclusion of papers at each stage of the process (Figure 1). The study authors were contacted when data was not reported in the format that allowed inclusion in the review. Where data could not be included in a suitable format, the paper was excluded.

In total, the eight included studies contributed data on 750 participants. However, only four trials (contributing data on 401 participants) met the criteria for inclusion into meta-analysis. The quality appraisal of the included trials is presented in Tables 1 to 3 while the level/grade of evidence for each outcome is presented in Tables 4 and 5 including trials with research conducted from January 1970 to April 2014.

The methodological quality of the included trials ranged from fair to good, with a mean PEDro score of 5.65 out of 10. Four trials were methodologically

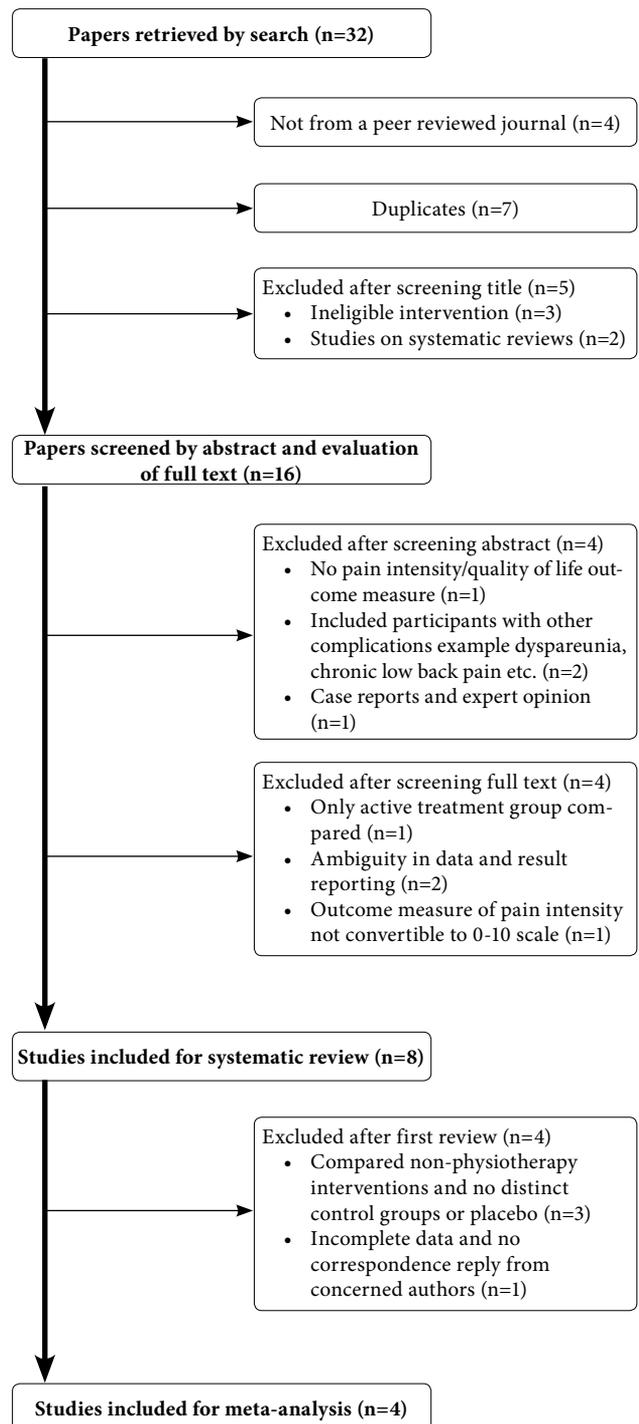


Figure 1. Flow of studies through the review.

of good quality (trials with scores ≥ 6). The individual PEDro items satisfied by almost all the trials were random allocation, groups similar at baseline, <15% dropout rate, and reporting of between-group difference. However, most of the studies did not satisfy

Table 6. Forest plot of weighted mean difference for pain intensity for exercise versus control

Study name	Cumulative statistics						Cumulative std diff in means (95% CI)		
	Point	Standard error	Variance	Lower limit	Upper limit	Z-value	p-value		
Abbaspour et al. ^[15]	-0.606	0.184	0.034	-0.967	-0.246	-3.296	0.001		
Mahvash et al. ^[14]	-0.595	0.155	0.024	-0.899	-0.291	-3.839	0.000		
Shahr-jerdy et al. ^[12]	-0.570	0.113	0.013	-0.792	-0.349	-5.054	0.000		
Gamit et al. ^[16]	-0.629	0.109	0.012	-0.842	-0.416	-5.784	0.000		
	-0.629	0.109	0.012	-0.842	-0.416	-5.784	0.000		

Std diff: Standard deviation difference; CI: Confidence interval.

one or more criteria based on participants, therapist or assessor blinding.

The level/grade of evidence was deemed complete based on the outcome data for each outcome which was adequately described in all the included studies in the meta-analysis. No other limitations, such as stopping early for benefit or use of invalidated outcome measures, were identified in any of the included studies. The summary of findings and evidence profile are presented in Tables 4 and 5. The overall grade of the evidence obtained for the outcome of exercise intervention trials was 'moderate'.

The sample sizes of the included trials ranged from 30 to 179. The mean age of participants in the included trials ranged from 14 to 39 years.

Four trials compared the effect of exercise versus control;^[14-17] one trial compared effect of exercise pre- and post-treatment;^[18] one trial compared exercise to consumption of ginger^[19] while one compared exercise to use of a hot water bottle.^[20]

All the trials included outcomes which measured pain intensity/severity as outcome measure with six trials using VAS, two trials using a numeric pain rating scale, two trials using menstrual distress questionnaires, one trial using a perceived stress scale and one trial using presenting pain intensity and pain rating intensity of the McGill's questionnaire. One trial assessed the QoL of the participants using the Health Related Quality of Life questionnaire SF-36.

Out of the eight studies included in the systematic review, four were excluded from meta-analysis. These four studies^[18-21] were excluded because they did not meet one or more of the inclusion criteria for meta-analysis which required randomized trials with control

or placebo groups, pain outcome measure convertible to VAS and/or QoL outcome measure).

Five trials examined exercise versus control or no intervention (Table 1). Four studies were of randomized controlled trials (RCT), and one pre-test post-test design. A total of 446 participants were involved with age range of 15-39 years and a baseline pain score ranging from 6-8.59. All the trials recorded pain as an outcome with VAS except Mahvash et al.^[14] using pain rating index convertible to a 0-10 VAS scale. Additional outcomes also included pain duration (in hours) and use of medication.

Data pooled from the four RCTs were methodologically of moderate-quality, providing moderate grade evidence of the effect of exercise compared with control (See Table 4). The four trials measured pain severity on a VAS and the analysis showed the effect was statistically significant, $p < 0.001$ (95% CI) as it tended to favor the exercise group (A) with a mean effect size of 0.629 (details in Table 6).

A total of three trials are reported in Table 2 and Table 3 with three trials using RCT design.^[19-21] The sample size contained in these studies was 304 participants with an age range of 14-23 years. The interventions included active exercise versus ginger, yoga intervention and exercise versus hot water bottle using numeric pain rating scale (NRS) as outcome for pain intensity.

The trial which compared the effect of yoga versus the control group^[21] collected data on pain using a numeric pain scale but which we converted to a 0-10 scale. The study showed a significant effect of yoga compared to control at the end of three months yoga intervention.

DISCUSSION

Through systematic review we identified and assessed several exercise interventions that caused a statistically significant reduction in pain severity and some other menstrual symptoms. Currently available data suggests that most of the exercise interventions had fewer side effects and were preferred to pharmacological treatments or herbal medicines for the reduction in pain. However, these results are limited because they contain some methodological flaws. Therefore, it is important to interpret the result with caution, considering the extent and quality of the evidence obtained, the details of the interventions provided, the estimates of the mean effect on pain obtained derived from the data and whether the confidence intervals around those estimates include clinically relevant or clinically worthwhile effects.

Meta-analysis of the trials on exercise therapy showed a significant effect of exercise in decreasing overall pain scores compared to the control, demonstrating a moderate effect size in favor of exercise. Abbaspour et al.^[15] in 2004 used a series of exercise activities for 20 minutes twice a day for four cycles and recorded a decrease in pain intensity starting in the fourth period. A similar decrease was recorded by Onur et al.^[18] whose participants were involved in a home-based exercise program for three cycles, though without a control group and Mahvash et al.^[14] who administered physical activity for eight weeks, three sessions a week and 90 minutes per session. Both studies recorded a decrease in symptoms during each cycle. Abbaspour et al.^[15] and Mahvash et al.^[14] noted additional outcomes including decrease in pain duration (in hours), decrease in rate and volume of bleeding, decrease in the use of sedative drugs, as well as decreases in total and present pain intensity. Onur et al.^[18] went further to check similar outcomes using the health related QoL questionnaire with significant improvement ($p < 0.012$) in all the eight domains. Two of the exercise trials^[16,17] utilized stretching exercise as their intervention, with both recording significant results in the use of stretching exercise for pain reduction.

The evidence about the use of yoga for pain management was assessed from one trial.^[21] The intervention assessed various Yoga poses (24 times). At the end of three months of yoga intervention, there was a significant ($p < 0.0001$) reduction in the pain perceived after yoga intervention. This result was derived from a single study with a PEDro score of 5, so

replication of this result in other studies of yoga and perhaps other exercise regimens should be sought. One study of a 15 minute exercise regimen practiced for three months for two sessions a day^[20] found a benefit for dysmenorrhea, although it was not eligible for this meta-analysis because of the absence of a control or placebo effect which was replaced with the use of hot water bottle in a control group. However, the study showed a statistically significant difference in pain scores between the two groups, with hot water bottle showing better results than exercise in reducing pain. A systematic review^[11] reported that exercise reduced menstrual symptoms though the results were limited to a single RCT of limited quality and had a small sample size.

Although the analgesic benefits of the different exercise regimens, yoga poses and stretching exercises were statistically significant, the evidence for each intervention came with minor caveats. The estimates were provided by one to two trials; the effect mean changes did not exclude the possibility that the clinical effect was trivial though with good quality. However, these interventions have relatively low costs and risks, so women with dysmenorrhea may wish to try them despite these uncertainties.

Evidence from review of one study^[18] showed that the exercise group had better physical and mental components of QoL compared to the control group. This study, however, was not included in the meta-analysis due to the use of a different modality (home-based exercise intervention), and defective design (pre-test post-test design).

This study had several limitations. The studies satisfying the inclusion criteria were clinically and methodologically heterogeneous with respect to the severity of pain, participants, the different types and techniques of intervention used in similar trials, control groups employed and outcomes examined. The follow-up length and timing of outcome assessment also varied, as did the treatment schedule and frequency. In addition, a possible publication bias was not excluded for this review, as majority of trials reported were those found readily available from journals and authors; and also a majority of those included indicated positive effects of the interventions in the treatment of primary dysmenorrhea.

Another possible limitation was the paucity of data on the interventions with similar techniques in use of the various interventions. This made it impossible to draw definite conclusions on interventions involving so few similar trials.

In conclusion, this study involved three reviewers who dependently and independently performed study selection, quality assessment and data extraction and management. Several interventions indicated statistical significance. Insights into effectiveness of each intervention were identified in each of the interventions in correlation to themselves and with each other. The systematic review highlighted promising evidence in the form of studies done to establish the effectiveness of exercise interventions in the management of primary dysmenorrhea. However, the results were limited with methodological flaws. The review identified that exercise can significantly reduce the pain associated with dysmenorrhea. The magnitude of these effects may or may not be clinically worthwhile, but as the costs and risks of this intervention are low, it could be considered for clinical use.

With this in mind, further research is merited, as the quality of the trials and the reporting of the trials methodologies reviewed in this study were overall moderate; further higher quality trials are needed to assess the effectiveness of the exercise interventions for the treatment of menstrual pain. To improve the trial design quality, level of performance and degree of reporting of clinical trials, future researchers should follow the basic guidelines for reporting clinical trials, such as PEDro guideline which provides specific guidelines for clinical trials.

Further studies should be conducted with blinded patients and/or assessors against a sham control intervention to allow for placebo effects. These studies should be of sufficient sample size and employ validated outcome measures of clinical effectiveness. Quality of life of participants should also be included as an outcome of interest in future research.

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