



RESEARCH PAPER

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Management of sleep disorders in females diagnosed with the polycystic ovarian syndrome: A systematic review

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Abstract

Females diagnosed with polycystic ovarian syndrome (PCOS) are more likely to exhibit obstructive sleep apnoea (OSA), difficulty falling asleep, difficulty in maintaining sleep, poor sleep quality, daytime sleepiness and restless leg syndrome. Presence of sleep disturbances or sleep disorders results in poor day time work performance, lack of attention, memory and overall feeling of well-being. The present systematic review focus on interventions for management of sleep disorders in PCOS females. Online literature search of relevant studies across databases of PubMed, Directory of Open Access Journals (DOAJ), Google Scholar and Physiotherapy Evidence Database (PEDro) from beginning to June 2022 was performed (PROSPERO:CRD42022347538). The methodological quality of included RCT was assessed using Cochrane ROB tool and pre-post study was assessed using NIH quality assessment tool. Results of review were reported using qualitative synthesis. One RCT and one pre-post study was included and analysed in this review. Age range of participants in the study was from 18-40 years. The studies reported 8 weeks' interventions of continuous positive airway pressure (CPAP), melatonin tablets with magnesium oxide and melatonin tablets alone. Sleep outcomes were assessed subjectively by Stanford Sleepiness Scale and Iranian version of the Pittsburg Sleep Quality Index and objectively by polysomnographic recordings. Qualitative synthesis of included studies indicated positive results of interventions on sleep outcomes in PCOS females though with limited evidence. CPAP, melatonin-magnesium co-supplementation; and melatonin alone for 8 weeks have beneficial effects on some sleep outcomes in PCOS females. Moreover, there is need to conduct more good quality research trials.

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Introduction

Polycystic ovarian syndrome is a multidimensional endocrine disorder of reproductive age females with a prevalence of 8% to 13% worldwide depending upon the diagnostic criteria (Wolf *et al.*, 2018; Naz *et al.*, 2019; Teede *et al.*, 2018). Irregular menses, hyperandrogenism, polycystic ovarian morphology (PCOM), hirsutism, acne, alopecia, dyslipidemia, insulin resistance, hyperinsulinemia, impaired glucose tolerance test (IGT), eating disorders, anxiety, body dissatisfaction, depression are most common features encountered by these females (Jakhar *et al.*, 2022).

Diagnostic criteria used for PCOS are evolving and no single criterion is used across the world. According to the National Institutes of Health (NIH) guidelines (1990)

PCOS is diagnosed when both criteria are met: (i) Clinical and/or biochemical hyperandrogenism and (ii) chronic anovulation (after excluding other causes of hyperandrogenism and anovulatory subfertility). According to the European Society for Human Reproduction and Embryology and American Society for Reproductive Medicine (ESHRE/ASRM) or Rotterdam guidelines (2003) PCOS is diagnosed when two out of three criteria are met: (i) Oligo-ovulation and/or anovulation (ii) clinical and/or biochemical hyperandrogenism (iii) polycystic ovaries on ultrasound (after excluding other causes of hyperandrogenism and anovulatory subfertility). According to the Androgen Excess and PCOS Society (AEPCOS) guidelines (2006) PCOS is diagnosed when both criteria are met: (i) hyperandrogenism: hirsutism and/or biochemical hyperandrogenism (ii) ovarian dysfunction: oligo-anovulation and/or polycystic ovaries (after excluding other causes of hyperandrogenism and anovulatory subfertility) (Rao *et al.*, 2020; Dennett *et al.*, 2015).

These females are also at risk of gestational diabetes, spontaneous abortion in first trimester, infertility, endometrial cancer, type 2 diabetes, heart attack, cardiovascular diseases (CVD), metabolic syndrome

and suicidal attempts as compared to their healthy counterparts (Jakhar *et al.*, 2022). Its features include metabolic disturbances, chronic inflammation, reproductive features, psychological stress, and lower quality of life (QoL). Its manifestation starts in early puberty and is present throughout the life (Prמודh, 2020). These females are also at increased risk of sleep disorders like insomnia, obstructive sleep apnoea (OSA) and sleep disturbances like delayed sleep onset, alteration in sleep duration or awakening early from sleep (Hung *et al.*, 2014; Tseng *et al.*, 2021). Recently, screening obstructive sleep apnoea (OSA) and related symptoms like daytime sleepiness, snoring, waking unrefreshed from sleep in these females are also recommended (Teede *et al.*, 2018). Work performance in day time activities and mood are adversely affected because of sleep disorders (Fernandez *et al.*, 2018). Moreover, OSA is risk factor for insulin resistance, type 2 diabetes, metabolic diseases and cardiovascular diseases (CVS) (Martins *et al.*, 2021). Otherwise, healthy females can also develop OSA during pregnancy because of weight gain and oedema of upper airway. Literature suggests mild OSA can also result in preeclampsia, gestational diabetes, and hypertensive disorders during pregnancy and also results in poor neonatal outcomes (Bui *et al.*, 2022).

In a study of tertiary hospital, 23.3% PCOS females met restless leg syndrome (RLS) criteria and 31.5% of PCOS females had significantly higher risk of OSA than control group (Caltekin *et al.*, 2021). In an observational cross-sectional study conducted at University Hospital Coventry (United Kingdom) 38.5% of PCOS females had OSA (Kahal *et al.*, 2020). A meta-analysis reported 35% prevalence of OSA in PCOS (Kahal *et al.*, 2020).

Studies have concluded that continuous sleep insufficiency results in IR and diabetes in healthy population (Lim *et al.*, 2016). IR is also inevitably linked to gain in weight, obesity, metabolic disorders and cognitive disorder (Barber *et al.*, 2021). The sleep disorders have 8 main categories: Sleep-

related breathing disorders like OSA, circadian rhythm sleep disorders, insomnia, hypersomnia, parasomnia, sleep related movement disorders like restless leg syndrome, normal variants and isolated symptoms and various subcategories. But 90% of practitioners who manage PCOS females are not adequately trained for sleep disorders in these females (Bahman *et al.*, 2018).

PCOS can result in metabolic syndrome (MS) which is strongly associated with central obesity and IR. Sleep has multiple characteristics of quantity, quality and timing correlated with circadian rhythm. Lifestyle modification program including fibre rich diet and regular exercises along with improved sleep quality and quantity may play crucial role in improving metabolic features in PCOS (Mehra *et al.*, 2020).

Presence of any one or two of these factors together can result in or aggravate the co-morbidities independently caused by any of these factors. Hence the planning and cost of treatment and overall health can be negatively affected. To our knowledge no systematic review has been done on management of sleep disorders in PCOS females. A review on this topic is important as it will provide evidence-based management strategies in this population. Moreover, it will help in reducing the cluster of symptoms for these females. Therefore, the present systematic review aimed to provide the evidence to support the management strategies on sleep outcomes among PCOS females.

Materials and Methods

The review is registered in PROSPERO (CRD42022347538). The systematic review is done and presented as per PRISMA (Preferred Reporting Items for Systematic Reviews and Meta- Analyses) guidelines in Fig. 1.

Eligibility criteria for articles

Freely available full text randomized controlled trials (RCTs), pre-post study including human studies in English language for management of sleep disorder in polycystic ovarian syndrome were included.

Reviews, qualitative studies, case studies and abstracts were excluded.

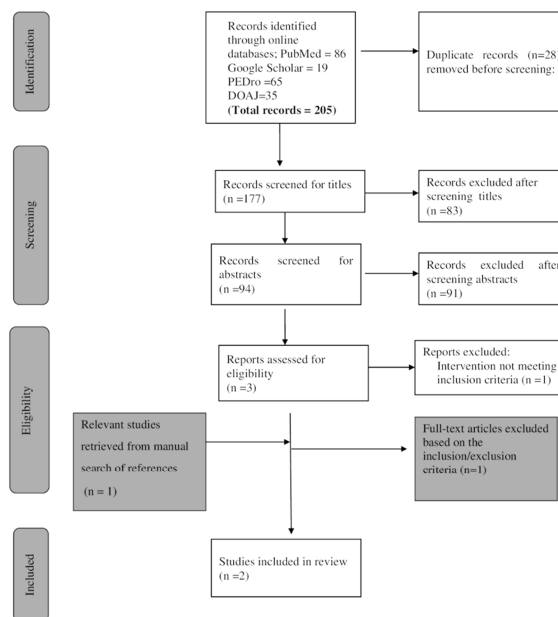


Fig. 1. PRISMA flow chart of the review

Search method

Two independent reviewers searched the PubMed, Directory of Open Access Journals (DOAJ), Google Scholar and Physiotherapy Evidence Database (PEDro) from beginning to June 2022. In PubMed search was done using MeSH term and full text (Table 1). Combination of sleep, polycystic ovarian syndrome and PCOS was used for search in PEDro, DOAJ and Google scholar. Studies were included on basis of inclusion criteria. Also, references of included articles were searched for eligible articles.

Selection of articles

All searched articles from PubMed, Goggle Scholar and PEDro were transferred to Mendeley online. All articles from DOAJ were first downloaded and then added to Mendeley. Thereafter, all the duplicates were removed. Initially, title and abstract of remaining articles were screened by two independent reviewers. Freely available full text articles on basis of inclusion criteria were retrieved. These articles were included on basis of following inclusion criteria:

1. Females of any age group diagnosed with polycystic ovarian syndrome.

2. Participants receiving any kind of intervention for management of sleep disorder like Positive Airway Pressure (PAPs), pharmacological treatment or non-pharmacological treatment such as physical activity, lifestyle modification, yoga or exercises but not any surgical intervention.
 3. Have a control group or comparator group which does not receive same intervention as experimental group.
 4. Reporting sleep outcomes using appropriate sleep assessment tools.
 5. Articles showing pre and post intervention results of sleep outcomes.
 6. Full text article available in English language.
- The data from included studies was extracted in a Microsoft Excel sheet by first author and was rechecked by second author.

Table 1. Search strategy for PubMed database

SL	Query	Sort by	Filters	Search details	Pubmed results
1	"pcos" or "polycystic ovarian syndrome" or "polycystic ovarian morphology" or "polycystic ovaries"	Free full text	English	("pcos"[All Fields] OR "polycystic ovarian syndrome"[All Fields] OR "polycystic ovarian morphology"[All Fields] OR "polycystic ovaries"[All Fields]) AND ((ffrft[Filter]) AND (english[Filter]))	5,626
2	"pcos" or "polycystic ovarian syndrome" or "polycystic ovarian morphology" or "polycystic ovaries"[MeSH Terms]	Free full text	English	("pcos"[All Fields] OR "polycystic ovarian syndrome"[All Fields] OR "polycystic ovarian morphology"[All Fields]) AND ((ffrft[Filter]) AND (english[Filter]))	5,451
3	(#1) OR (#2)	Free full text	English	((("pcos"[All Fields] OR "polycystic ovarian syndrome"[All Fields] OR "polycystic ovarian morphology"[All Fields] OR "polycystic ovaries"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language])) OR (("pcos"[All Fields] OR "polycystic ovarian syndrome"[All Fields] OR "polycystic ovarian morphology"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language]))) AND ((ffrft[Filter]) AND (english[Filter]))	5,626
4	"sleep" or "sleep disturbances" or "sleep disorders" or "insomnia" or "daytime sleepiness"	Free full text	English	("sleep"[All Fields] OR "sleep disturbances"[All Fields] OR "sleep disorders"[All Fields] OR "insomnia"[All Fields] OR "daytime sleepiness"[All Fields]) AND ((ffrft[Filter]) AND (english[Filter]))	92,648
5	"sleep" or "sleep disturbances" or "sleep disorders" or "insomnia" or "daytime sleepiness"[MeSH Terms]	Free full text	English	("sleep"[All Fields] OR "sleep disturbances"[All Fields] OR "sleep disorders"[All Fields] OR "insomnia"[All Fields]) AND ((ffrft[Filter]) AND (english[Filter]))	92,456
6	(#4) OR (#5)	Free full text	English	((("sleep"[All Fields] OR "sleep disturbances"[All Fields] OR "sleep disorders"[All Fields] OR "insomnia"[All Fields] OR "daytime sleepiness"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language])) OR (("sleep"[All Fields] OR "sleep disturbances"[All Fields] OR "sleep disorders"[All Fields] OR "insomnia"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language]))) AND ((ffrft[Filter]) AND (english[Filter]))	92,648
7	(#3) AND (#6)	Free full text	English	((("pcos"[All Fields] OR "polycystic ovarian syndrome"[All Fields] OR "polycystic ovarian morphology"[All Fields] OR "polycystic ovaries"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language])) OR (("pcos"[All Fields] OR "polycystic ovarian syndrome"[All Fields] OR "polycystic ovarian morphology"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language])) AND ((("sleep"[All Fields] OR "sleep disturbances"[All Fields] OR "sleep disorders"[All Fields] OR "insomnia"[All Fields] OR "daytime sleepiness"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language])) OR (("sleep"[All Fields] OR "sleep disturbances"[All Fields] OR "sleep disorders"[All Fields] OR "insomnia"[All Fields]) AND ("loattrfree full text"[Filter] AND "english"[Language]))) AND ((ffrft[Filter]) AND (english[Filter]))	86

Table 2. Table of included studies and their characteristics

Author names/ year of publication	Study design	Sample and sample size	Study setting	Intervention group/ Comparator group	Sleep assessment tools and sleep assessed	outcome and outcomes	Main conclusion
Tasali <i>et al.</i> , 2011	Pre-post study without control group	PCOS Women who have OSA (diagnosed by AHI; at least 5 events per hour during sleep). 19 females completed 8 weeks' intervention.	Endocrinology, Diabetes, and Metabolism Clinics at University of Chicago. Assessments were obtained over a 2-day inpatient study.	Intervention group: Home CPAP treatment for 8 weeks; minimum of 4 h of CPAP usage over the 2-day intervention period. Comparator group: No CPAP control group	Tools: Polysomnographic recordings at Stanford Sleep Scale Outcomes: Sleep efficiency Wake after sleep onset REM sleep N1 sleep N2 sleep N3 No AHI ODI Arousal index	CPAP successfully and subjective sleepiness and sleep quality at night in Stanford PCOS females.	treatment reduced daytime improved sleep quality at night in PCOS females.
Alizadeh <i>et al.</i> , 2021	RCT	PCOS females with age between 18 and 40 and BMI ≤ 35 . Sample size=84	Alzahra Bahman and Tabriz, Iran	29 4 groups: One group- melatonin + magnesium (n=22), second group- melatonin only (n=21), third group- magnesium only(n=21), fourth group- placebo(n=20)	Tool: Iranian version of the Pittsburgh Sleep Quality Index (PSQI) Outcome: Sleep quality	Melatonin supplementation alone or melatonin combined with magnesium reduces PSQI score in PCOS subjects and improves sleep quality.	

Data extracted from studies

Details including author names, year of publication, sample and sample size, study setting, intervention group, sleep outcome assessment tools, pre and post intervention sleep outcomes and conclusion were extracted from full text to the Excel sheet (Table 2).

Assessment of included studies

Included RCT was assessed with Cochrane Risk of Bias tool for Randomised Controlled Trials and NIH quality assessment tool for before-after (pre-post) study without control group was used for before-after study. However, data synthesis was based on all the included studies to summarize management strategies used for sleep disorders in PCOS females so far. The assessment of studies was done independently by both authors and later the results were discussed in a meeting. Both researchers agreed about included studies without approaching third researcher.

Results

Study selection and evidence synthesis

A total of 205 potential studies were identified from online searches of four databases. 19, 35, 65 and 86

records were obtained respectively from Google scholar, DOAJ, PEDro and Pubmed. After removing duplicates 184 articles were left. All the records were transferred to Rayyan where remaining duplicates were removed automatically (n=6) and by the authors (n=1). 177 records were assessed for eligibility. After screening titles 83 records were removed. The records were excluded because of not meeting the study design and population given in inclusion criteria. After screening the abstracts of remaining 94 records, 91 records were excluded on following basis:

- 1) Full text article not freely available (n=1)
- 2) Study design did not meet inclusion criteria (n=41)
- 3) No sleep outcome assessed (n=48)
- 4) Full text not available in English language (n=1)

After full text reading of remaining 3 articles, further 1 article was excluded because intervention did not meet inclusion criteria.

The remaining 2 articles were included. References of included studies were also searched for relevant articles. 1 article was found to be relevant but could not be included on basis of inclusion criteria and hence excluded.

Study and sample characteristics

1 randomised controlled trial (RCT) and 1 pretest-posttest study without control was included. RCT published in 2021 and was conducted in Alzahra and 29 Bahman hospitals of Tabriz, Iran. Pre-post study published in 2011 and was conducted at the Endocrinology, Diabetes, and Metabolism Clinics at the University of Chicago. Two studies had included females of 18-40 years of age and 103 PCOS females.

Interventions used in included studies

In the RCT conducted by Alizadeh *et al.* (2021), participants were randomly allocated 4 groups. One group received two melatonin tablets each of 3 mg plus one 250 mg magnesium oxide tablet; second group received two melatonin tablets each of 3 mg plus one magnesium placebo; third group received one 250 mg magnesium oxide tablet plus two melatonin placebos; and fourth group received two melatonin placebos plus one magnesium placebo for 8 consecutive weeks. Participants were instructed to continue their usual diet intake and physical activities.

In other study conducted by Tasali *et al.* (2011) 8 weeks of home CPAP (continuous positive airway pressure) treatment is given after adjusting its optimum settings for each individual with requirement of at least 4 hours of nightly CPAP throughout this study period.

Subjectively, sleep quality was the sleep outcome measured in RCT using Pittsburg Sleep Quality Index (PSQI), Iranian version and daytime sleepiness was assessed as sleep outcome using Stanford sleepiness scale in other study. Objectively, one study did polysomnographic recordings to provide REM (rapid eye movement) sleep, obstructive respiratory events, arousals, AHI (apnoea-hypopnea index), arousal index and oxygen desaturation index (ODI).

Qualitative synthesis

Subjective sleep outcomes

According to one study, after 8 weeks of supplementation sleep quality improved in

magnesium-melatonin co-supplementation group as well as in melatonin only group with significant reduction in mean score of PSQI. Another study reported that after 8 weeks of CPAP treatment mean Stanford sleepiness scale reduced and hence there was reduced daytime sleepiness.

On basis of the quality of included studies, the evidence to support effectiveness of CPAP, magnesium-melatonin co-supplementation and melatonin alone on subjective sleep outcomes in PCOS females is limited.

Objective sleep outcomes

Only one study recorded sleep outcomes objectively using polysomnographic recordings. After using CPAP, markers of OSA severity along with AHI and ODI decreased remarkably, sleep fragmentation was lower and stage 3 sleep was increased significantly.

On basis of the quality of included studies, the evidence to support effectiveness of CPAP on objective sleep outcomes in PCOS females is limited.

Discussion

The aim of present review was to provide the evidence to support the management strategies on sleep outcomes among PCOS females of 18-45 years of age. However, only two studies met inclusion criteria of this review. Subjective sleep outcomes-daytime sleepiness and sleep quality and objective sleep outcomes using polysomnographic recordings are reported. It indicates heterogeneity of data in included studies.

Iranian version of Pittsburg Sleep Quality Index (PSQI) includes 7 components namely subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleeping medications and daytime dysfunction disorder. It is reported to have a potential to differentiate poor sleepers (Khosravi *et al.*, 2021). Stanford sleepiness scale (SSS) is a single-item measurement tool where responder selects one of seven statements corresponding to their level of perceived sleepiness at a specific time point (Broughton *et al.*, 1982; Connor *et al.*, 2002).

Both the studies have short term intervention of 8 weeks and there was no follow up reported. CPAP compliance is defined as use of CPAP more than 4 hours at night and poses challenge for successful treatment for OSA. In the trial conducted by Tasali *et al.* (2011) females completing the study used nightly CPAP for approximately 6.6 hours on an average and couldn't use CPAP for approximately for 3.4 days on an average in 8 weeks treatment protocol. However, after CPAP treatment, mean score of Stanford Sleepiness Scale decreased, apnoea hyperpnoea index (AHI) and oxygen desaturation index (ODI) reduced, arousal index was lowered by 53% and amount of deep non-REM sleep became higher by 22%. On other hand in study conducted by Alizadeh *et al.* (2021) supplementation of melatonin and magnesium combined and supplementation of only melatonin for 8 weeks resulted in reduction of PSQI mean score but this study didn't include polysomnographic recording for objective sleep outcome.

Limitations and strength of the study

The review brings attention to the fact that interventions focusing on sleep outcomes in PCOS females are very limited. Hence, only two studies could be included for evidence synthesis. Both the trials had different type of interventions and used different questionnaires for subjective sleep outcomes. Only trial conducted by Tasali *et al.* (2011) used polysomnographic recordings for objective sleep outcomes. Hence, there is need to conduct trials using similar interventions with same subjective as well as objective assessment tools in PCOS females which can yield strong evidence. Moreover, total sample size of both studies is relatively small, totalling only 103. Finally, the findings of this review are important to healthcare practitioners dealing with PCOS females.

Conclusion

CPAP, melatonin-magnesium co-supplementation; and melatonin alone for 8 weeks have beneficial effects on some sleep outcomes in PCOS females. Currently, body of evidence is very limited. Hence, need to conduct more good quality research trials on the topic area is warranted.

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