

The Effects of Melatonin Treatment on Chronic Insomnia in 1–3-Year-Old Children Undergoing Behavior Therapy

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Abstract

Background: Melatonin is effective as a treatment option for sleep disorders in children. Parents can develop positive sleep habits in children through behavior therapy. This study aimed to evaluate the effects of melatonin on children undergoing behavioral therapy.

Method: The present study was performed on 60 children (1–3-year-old, male and female). Thirty children were randomly selected as the treatment group, treated with melatonin. All of the participants in both treatment and control groups and their parents were taught how to observe sleep hygiene and behavior therapy through a graduated extinction method. The Pediatric Sleep Clinic Questionnaire Background Information (for 1–3-year-old children) was used in this research. Parents in both groups were educated on sleep hygiene and behavioral therapy. The data was analyzed through paired t-test and chi-square ($p < 0.05$) using SPSS 18 software program.

Result: Mean \pm SD (standard deviation) of age was 27.33 ± 8.99 months in the behavior therapy/melatonin-treated group, while it was 23.10 ± 10.76 months in the behavior therapy/non-melatonin-treated group. There was a significant difference between the two groups regarding breastfeeding ($p < 0.05$). Moreover, significant differences were observed between the two groups in terms of the average number of waking ups during the night, the length of wakefulness of a child at night (in minutes), the time of waking up in the morning, the average sleep time at night (in hours), and the relationship between sleeping in parents' bed and parents staying in the child's room after the lights were switched off ($p < 0.05$).

Conclusion: The quality of night sleep in the melatonin-treated group was better than that in the group that did not receive melatonin. Therefore, proper medical treatment along with psychological and behavioral therapies can be helpful for treating sleep disorders.

Key Words: Behavioral Therapy, Children, Graduated Extinction Method, Insomnia, Limit-setting, Melatonin, Sleep Disorders, Sleep-Onset Association.

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1. INTRODUCTION

Insomnia, by definition, includes sleep problems or difficulty starting or continuing sleep or having sleep instability, or poor sleep quality, even when there is enough time and opportunity for age-appropriate sleep. This disorder is especially important in children. Insomnia hurts mood, behavior, learning, and memory; and it leads to dysfunction in the child's daily life. Insomnia in young children will also cause sleep disorders in parents, which will lead to complications such as mood swings and daily life dysfunction (1, 2). The frequent occurrence of falling asleep and waking up at night is the most common type of sleep disorder in young children and accounts for about 20-30 % of sleep problems in infants. It is estimated that about 30% of children have some form of sleep problems. Studies have shown that sleep problems can persist for months and even years, causing chronic physical ailments such as asthma, seizures, and atypical dermatitis. Developmental disorders also hurt a child's sleep (3). Drug treatment of insomnia includes benzodiazepines, anti-anxiety, and antidepressant compounds. The United States Food and Drug Administration (FDA or USFDA) approved that medication for children is chloral hydrate. The use of compounds that are endogenously produced in the body and naturally play a role in the creation and control of sleep in healthy people seems to be more appropriate for treating insomnia. Melatonin is one of the most important natural and endogenous compounds, and it is a serotonin-dependent endogenous hormone. Melatonin secretion from the pineal gland is in response to darkness and is one of the important mechanisms of maintaining the circadian rhythm and controlling the sleep and wake cycle (4, 5).

The importance of insomnia in children and the administration of melatonin in its

treatment have been previously discussed. The safety and effectiveness of synthetic melatonin in the treatment of sleep problems in children with developmental disabilities showed that children fell asleep faster when receiving melatonin. No side effects have been reported. It is shown that synthetic melatonin reduces sleep latency in children with developmental disabilities. Therefore, this synthetic melatonin can be used as a safe and effective remedy in the control and treatment of insomnia (6). Since the effects of insomnia affect children's behavior and mental health, melatonin treatment improves health and reduces stress in children. According to a questionnaire filled out by parents, melatonin had a positive effect on children's behavior. Considering the importance of children's mental health, the treatment of insomnia is very important for children (7). Melatonin's efficacy and safety have been established for children with sleep disorders. But further trials are necessary to determine the optimal dose and safety of melatonin in children (8).

Sleep helps to rejuvenate the body, memorize better, strengthen the nervous and immune systems; and plays an important role in children's growth (children's bodies produce growth hormones during sleep), which is why children need healthy sleep at faster growth stages. Adequate and high-quality sleep at different ages and stages of development of children creates a body that acts mentally, psychologically, and emotionally healthier. On the other hand, as mentioned, melatonin is a natural substance in the body that helps regulate sleep hours in the body as well as blood pressure, body temperature, and cortisol levels, and helps to improve the functionality of the immune system. Melatonin is an endogenous and natural (non-synthetic) substance that causes sleep and has been used to treat insomnia in children. This study aimed to investigate

the effects of melatonin on the onset time of sleep, total sleep duration, sleep quality, and finally, daily performance in a population with insomnia.

2- METHODOLOGY

2-1. Design and sampling

The present study was a clinical trial (IRCT code: IRCT20180719040526N1). Participants of the study were selected through convenient sampling. They included 60 children (1-3-year-old males and females) who had visited the sleep clinic of Qazvin Children's hospital affiliated with Qazvin University of Medical Sciences, due to complaints about poor sleep (Code of Ethics: IR.QUMS.REC.1396.277). Initially, all children were examined by a physician, and children with no underlying disease were randomly divided into melatonin-treated and non-melatonin-treated groups. Colorful cards were used to randomize the patient selection. Green and blue cards were placed in a bag. Green was the color for the melatonin-treated group and blue was the color for the non-melatonin-treated group. Depending on what color was picked for the patient, they were placed in the allocated group.

2-1-1. Inclusion and exclusion criteria

Children with chronic insomnia were included in the study after being examined by a pediatric sleep specialist. According to the International Classification of Sleep Disorders, second and third editions (ICSD-3 and 2), behavioral insomnia in children includes three types of sleep-onset association, limit-setting, and a combination of sleep-onset association and limit-setting types.

Chronic insomnia disorders include those reported by a patient, a parent, or a babysitter regarding one or more of the following items: Difficulty starting sleep, difficulty continuing sleep, waking up early, resistance to a regular sleep

program, and inability to sleep without the intervention of a nurse or parents. In the current study, patients, parents, or babysitters reported one or more of the following: Fatigue, lethargy, decreased attention, concentration or memory, decreased social and family interactions, mood swings, daytime sleepiness, behavioral problems (for example, hyperactivity, aggression, and anger), decreased movement and energy, as well as worrisome or dissatisfied sleep. Moreover, there were no other items like not having enough time to sleep or suitable conditions such as a safe, dark, and quiet environment. Other cases for entering the study included: Sleep disorders and accompanying daily symptoms at least three times a week, and the symptoms should have lasted for at least three months. At the beginning of the study, complete blood count (CBC) and ferritin were obtained from the children. Children with hemoglobin > 12 g/dl and ferritin > 30 mcg/dl were included in the study (none of the children were iron deficient).

Exclusion criteria encompassed children with underlying neurological disorders, children with psychological disorders including attention deficit hyperactivity disorder (ADHD), and those with underlying diseases including cardiopulmonary and blood disorders, as well as children that had no drug use including antibiotics, antihistamines, and sleeping pills within the last month, and those with the presence of obvious clinical signs of anemia. Children whose parents were depressed or anxious were excluded from the study as well (1, 2).

2-2. Procedure and instrument

The Pediatric Sleep Clinic Questionnaire Background Information (for 1-3-year-old children) was used in this study. During this period, a researcher contacted the subjects by phone or met them in person once a week and asked about the side effects of the medication such as feeling

cold, hypotension, headache, nausea, vomiting, confusion, and restlessness. Furthermore, behavioral therapy on the child's sleep was explained to the parents so they could report any changes in the child's sleep. The effects of the drug on precocious puberty were also evaluated after one month, which was not observed in any of the subjects (9).

2-2.1. Sleep hygiene

The parents were advised to put their child to bed at 9 pm, with the child sleeping in a separate room (if possible) or on a separate bed in the parents' room. Parents were to try to get the child to sleep without their constant presence. When the child was sleeping, the lights should have been switched off, room temperature should have been favorable (about 25 degrees Celsius), and electrical appliances such as cell phones, televisions, and computers should have been removed from the child's bedroom. The child should not have fallen asleep from 6 pm until bedtime and must have avoided caffeine-containing substances, which could have been used either by the child or by the breastfeeding mother (10).

2-2-2. Behavioral therapy

The graduated extinction method was used in pediatric behavior therapy. Parents were taught that they should ignore the child's cries and awakenings, and respond to the child according to a fixed schedule. In this way, when the child wakes up and seeks the parents, they do not go to the child immediately. The parents were told to respond to the child after five minutes the first time, after ten minutes the second time, and from that point on, after 15 minutes, so that the child learns self-relaxation and can sleep alone again. Parents were to have the least amount of interference with the child's re-sleeping and spend the minimum possible time (for example, one minute) (10).

2-2-3. Clinical trial

Sixty patients were randomly divided into behavior therapy/melatonin-treated group (0.1 mg/kg -1 mg) (n = 29, during the study and consumption of melatonin, a 3-year-old child was excluded from the study due to headaches caused by melatonin) and behavior therapy/non-melatonin-treated group (n = 30). Each of these 60 patients and their parents was taught how to observe sleep hygiene and behavior therapy. The study was double-blind and the pills were given by an expert in charge of the hospital pharmacy without the knowledge of the project directors. The duration of drug administration and intervention was four weeks. All the children were required to take their medication at 9 o'clock. Neither group was allowed to take any other medication during melatonin administration. During the medication administration period, parents were required to complete a sleep log for evaluation purposes for one month including time of going to bed, sleep time, duration of nighttime sleep, number of night awakenings after going to sleep, and daily performance improvement (by completing a questionnaire that assessed sleep and wakefulness hours).

2-3. Data analysis

The groups were compared in terms of demographics, breastfeeding, variables related to children's sleep, as well as the variables concerned with sleep-related behaviors in children. Independent t-test and Chi-square test were performed for numerical and categorical data comparison between the groups and to determine the association between qualitative variables. Nonparametric variables were analyzed by the Mann-Whitney U test. Data was analyzed using SPSS software (version 24.0) (SPSS Inc, Chicago, USA) ($p < 0.05$).

3- RESULTS

The results of comparing the two groups in terms of age showed that the

mean \pm SD was 27.33 ± 8.99 months in the behavior therapy/melatonin-treated group and 23.10 ± 10.76 months in the behavior

therapy/non-melatonin-treated group (**Table 1**).

Table-1: Comparison of demographic variables and child nutrition in the two groups

Variables		Behavior therapy/non-melatonin-treated N=30 N (%)	Behavior therapy/melatonin-treated N=29 N (%)	P. value
Age (month) (Mean \pm SD)		23.10 \pm 10.76	27.33 \pm 8.99	0.10
Gender	Male	14 (46.70)	15 (51.70)	1.00
	Female	16 (53.30)	14 (48.30)	
Father's Education	Under Diploma	2 (6.60)	0	0.24
	Diploma	10 (33.30)	13 (44.82)	
	Bachelor Degree	14 (46.6)	16 (55.17)	
	Master's degree and higher	4 (13.30)	0	
Mother's Education	Under Diploma	1 (3.30)	0	0.40
	Diploma	10 (33.30)	8 (27.60)	
	Bachelor Degree	17 (56.6)	21 (72.40)	
	Master's degree and higher	2 (6.60)	0	
Number of Family Members (Mean \pm SD)		3.43 \pm 0.62	3.45 \pm 0.50	0.72
Feeding	Breast milk	21 (81.80)	9 (47.4)	0.00
	Milk powder	5 (19.20)	3 (15.80)	
	Both of them	0	7 (36.80)	

The mean \pm SD of the number of family members in the two behavior therapy/melatonin-treated and behavior therapy/non-melatonin-treated groups were 3.45 ± 0.50 and 3.43 ± 0.62 , respectively. The number of male child participants (15 (51.7%)) was higher in the behavior therapy/melatonin-treated group, while female child participants (16 (53.3%)) were more frequent in the behavior therapy/non-melatonin-treated group. In terms of the parent's educational level, the prevalence of a bachelor's degree among fathers in both behavior therapy/melatonin-treated (16 (55.170 %)) and behavior therapy/non-melatonin-treated (14 (46.60 %)) groups was higher

than other levels of education. In the case of the mothers, the prevalence of bachelor's degree level in both behavior therapy/melatonin-treated (21 (72.40 %)) and behavior therapy/non-melatonin-treated (17 (56.60 %)) groups was higher than the other levels of education. Most children in the behavior therapy/melatonin-treated (9 (47.40 %)) and the behavior therapy/non-melatonin-treated (21 (81.80 %)) groups were breastfed. There was a significant difference between the two groups regarding breastfeeding ($p < 0.001$). A comparison of the variables related to the children's sleep and night feeding is demonstrated in **Table 2**.

Table-2: Comparison of variables related to children's sleep and night feeding, in the two groups

Variables		Behavior therapy/non-melatonin-treated N=30 N (%)	Behavior therapy/melatonin-treated N=29 N (%)	P. value
Before Treatment	Times of breastfeeding during night	2.41±1.70	2.06±1.17	0.10
	Times of waking up during night	3.20±1.29	3.30±1.66	0.75
	Amount of sleep during night according to hour	9.70±3.28	9.91±3.87	0.13
	Duration the child sleeps (minutes)	85.21±61.61	87.32±60.59	0.61
	duration the child stays awake at night (minutes)	42.35±47.09	39.85±31.63	0.28
	time to wake up in the morning	9.55±1.53	10.39±1.37	0.06
	average nighttime sleep time (hour)	10.41±1.95	9.66±1.30	0.16
After Treatment	Times of breastfeeding during night	1.48±1.61	1.03±1.42	0.13
	Times of waking up during night	1.96±1.70	0.90±1.09	0.00*
	Amount of sleep during night according to hour	9.68±3.89	9.0±4.21	0.62
	Duration child sleeps (minutes)	37.58±34.11	39.33±59.66	0.48
	Duration child stays awake at night (minutes)	17.7±19.04	4.47±3.48	<0.00*
	Time to wake up in the morning	9.50±1.38	10.15±1.13	0.03
	Average nighttime sleep time (hours)	10.76±1.79	10.25±0.67	0.03

No significant change was observed in any of the studied variables related to the children's sleep and night feeding in the two groups before and after the treatment ($p < 0.05$).

After the treatment, the mean number of night awakenings in the behavior therapy/melatonin-treated group (0.90 ± 1.09) was less than that in the behavior therapy/non-melatonin-treated group (1.96 ± 1.70), and there was a significant difference between the two groups ($p < 0.001$). The duration of wakefulness of the children at night (minutes) in the behavior therapy/melatonin-treated group (4.47 ± 3.48) was less than that in the behavior therapy/non-melatonin-treated group (17.7 ± 19.04), and a significant difference was observed between the two groups ($p < 0.00$). Wake-up time in the morning (hour) was later in the behavior therapy/melatonin-treated group (10.15 ± 1.13) compared to the behavior therapy/non-melatonin-treated group (9.50 ± 1.38), and a significant difference was found between the two groups ($p = 0.03$). Average night sleep time (hour) in the behavior therapy/melatonin-treated group (10.25 ± 0.67) was less in the behavior therapy/non-melatonin-treated group (10.76 ± 1.79), and a significant difference was observed between the two groups ($p = 0.03$). Comparisons of the variables of sleep-related behaviors are shown in **Table 3**.

Before the treatment, no significant difference was observed in any of the studied variables of sleep-related behaviors between the groups ($p < 0.05$). After treatment, there were significant differences between the two groups regarding sleeping in the parent's bed ($p < 0.00$) and parents staying after the lights were switched off ($p = 0.03$). In the behavior therapy/non-melatonin-treated group, 21 children (77.70 %) never slept with their parents after treatment, while this number was 2 (7.40 %) before

treatment. In the behavior therapy/melatonin-treated group, 12 children (41.40%) wanted to sleep with their parents every night after the treatment, and this number was 13 (44.80%) before the treatment. In the behavior therapy/non-melatonin-treated group, after the treatment, 18 children (60.00 %) insisted that their parents stay with them every night after the lights went out, compared to 12 children (48.00 %), before the treatment.

4- DISCUSSION

Sleep disorders are very common in children and without proper treatment, they can become chronic and last for years (1). Drowsiness in children may manifest as irritability, behavioral problems, learning difficulties, and poor academic performance (11).

In this study, the effects of melatonin treatment were investigated on chronic insomnia in children aged one to three years, and various variables affecting it were measured. The results of comparing the two groups showed that the mean \pm SD of age in the behavior therapy/melatonin-treated group was 27.33 ± 8.99 months and in the behavior therapy/non-melatonin-treated group, it was 23.10 ± 10.76 months. Al Twaijri et al. in 2022, reported that the efficacy and side effects of using melatonin are significant in children with a mean age of 5.83 ± 3.07 years on developmental neurological disabilities that result in sleep disorders. In their study, out of 23 children, 15 (65.22 %) were male, which is similar to the present study. However, they had more males in the behavior therapy/melatonin-treated group (51.7 %) than girls (48.30 %). Nevertheless, in the behavior therapy/non-melatonin-treated group, female participants had a higher frequency (53.30 %) than the males (46.70 %) (12).

Table-3: Comparison of related variables of sleep-related behaviors in two groups

Variables			Behavior therapy/non-melatonin-treated N=30 N (%)	Behavior therapy/melatonin-treated N=29 N (%)	P. value
Before Treatment	Behavioral problems: sleep onset associations, parental difficulties with limit-setting, or both.	Never	14 (46.6)	15 (51.7)	0.75
		1-2 at the week	6 (20)	5 (17.2)	
		3-5 at the week	4 (13.3)	6 (20.3)	
		Every night	6 (20)	3 (10.3)	
	Sleeping in parent's bed	Never	2 (7.4)	3 (10.3)	0.34
		1-2 times in the week	12 (44.4)	13 (44.8)	
		3-5 times at the week	3 (11.1)	0	
		Every night	10 (37.1)	13 (44.8)	
	Parents stay after the lights went out	Never	9 (36.0)	12 (41.4)	0.91
		1-2 times at the week	1 (4.0)	0	
		3-5 times at the week	3 (12.0)	3 (10.3)	
		Every night	12(48.0)	14 (48.3)	
Daily Nap			26 (89.7)	25 (86.2)	1.00
After Treatment	Behavioral problems: sleep onset associations, parental difficulties with limit-setting, or both.	Never	12 (46.2)	11 (37.9)	0.08
		1-2 times at the week	14 (53.8)	13 (44.8)	
		3-5 times at the week	0	5(17.2)	
		Every night	0	0	
	Sleeping in parent's bed	Never	21 (77.7)	6 (20.7)	0.00
		1-2 times at the week	1 (3.7)	3 (10.3)	
		3-5 times at the week	0	8 (27.6)	
		Every night	6 (22.2)	12 (41.4)	
	Parents stay after the lights went out	Never	12 (40.0)	5 (17.2)	0.03
		1-2 times at the week	0	5 (17.2)	
		3-5 times at the week	0	0	
		Every night	18 (60.0)	19 (65.5)	
Daily Nap			21 (72.4)	26 (89.7)	0.17

Similar to the current research, Lewien et al. 2021, reported that sleep problems are a growing public health concern. They performed a study on 855 children aged four to nine and showed that it is important to get an overview of the specific problems of the most vulnerable children. In this regard, the effects of age and gender on various sleep-related problems have been proven in a study conducted by Lewien et al., in which 6.22 % of the children had sleep disorders. Due to gender differences, parasomnia was significantly more prevalent in boys than in girls. There is still skepticism about the relationship between gender and sleep problems. Research shows that in childhood, boys report more sleep problems than girls. One possible explanation for the present results may be that parents tend to evaluate sleep and behavioral problems to a lesser degree in boys than in girls. Boys are more likely to exhibit externalizing behaviors, while girls are more likely to exhibit internalizing behaviors. When children cannot sleep at night, boys may attract more attention with dramatic behaviors, while girls may be more adaptable and therefore attract less attention to them.

The present study reports sleep-related problems in childhood and adolescence. Gender differences can be seen in early childhood. It is important for pediatricians to be aware of these conditions and to identify sleep-related problems in particularly vulnerable individuals (13). However, a study conducted by Shoghy et al. in 2005, found that a child's age and gender, parents' educational level, parent-child relationship, and parental sleep problems were significantly associated with sleep disorders. Sleep disorders in children are affected by cultural differences, common disciplinary principles among families in different communities, and parental strategies for setting sleep patterns. Along with the increase in the level of parental literacy, a decrease was observed in the overall

incidence of sleep problems in the children under study, which may be the result of the implementation of disciplinary measures in this type of family or more awareness of educated parents about sleep and child-rearing issues (14).

Many of the children in the behavior therapy/melatonin (47.40 %) and the behavior therapy/non-melatonin (81.80 %) groups were breastfed. However, there was a significant difference between the two groups regarding breastfeeding. Similar to the current results, Touchette et al. 2005, reported that a factor strongly associated with an infant's sleep was breastfeeding (15). Melatonin concentrations are very low during the first three months of life and then increase suddenly, probably because melatonin in human milk has a clear circadian curve and stabilizes the rhythm of the infant's sleep and wakefulness until their circadian system has matured (11). The results of the current study also showed that the mean frequency of waking up at night and the average number of minutes of the children's wakefulness at night in the melatonin-treated group were lower than those in the behavior therapy/non-melatonin-treated group. Al Twaijri et al., in 2020, also showed that among children aged four to nine years treated with melatonin, average sleep time in the afternoon, average waking time in the morning, and sleep duration were decreased by 14 minutes per year, and no major side effects were reported.

In the current study, only one case of headache was observed, in which melatonin was discontinued and the child was excluded from the study. Exogenous melatonin can be administered through different routes and in variable doses. Melatonin has a significant effect on total sleep time and quality during pre- and post-assessment of children with neurodevelopmental and sleep disorders. Naturally, melatonin secretion follows a

daily rhythm with minimal secretion during the day, and the number of secretions increases with the arrival of night and after midnight between 2 and 4 am. In response to the release of norepinephrine from retinal light receptors, melatonin is released from the pineal gland, which activates the retinohypothalamic-pineal system in response to low light, thereby improving sleep (12). In 2019, Esposito et al. reported the efficacy and safety of melatonin in the treatment of insomnia and sleep disorders in children. Melatonin can be safe and effective not only for early sleep disorders but also for sleep disorders related to various neurological conditions. However, there is still uncertainty about dosage regimens due to the lack of adequate data. Therefore, the dose of melatonin should be individualized based on several factors including the severity and type of sleep problem and the related neuropathology. Appropriate doses should be determined based on the severity and type of disorder to minimize side effects (11). On the other hand, behavioral therapy in the present study had positive effects on children's sleep in both groups. In infants and young children, problems before going to bed and waking up at night are common and the main manifestation is insomnia. Poor sleep can severely affect the performance and mood of the children and their caregivers throughout the day. Keeping a comprehensive sleep history and a sleep diary that records sleep time problems, excessive daytime sleepiness, number of waking up at night, regular sleep, duration of sleep, and respiratory distress is beneficial in the diagnosis of sleep problems in young children. Behavioral therapies for insomnia in children include blackout, sleeping in bed with positive routines, and planning to awaken. Previous studies on behavioral interventions for young children have shown significant improvements in sleep onset delay, frequency of night awakenings, and

duration of night awakenings. Educating parents about their child's sleep, bedtime routine, and sleep hygiene is essential for this treatment (10). Behavior therapy in the present study showed that in both groups, there was a significant difference between children sleeping in the parent's bed and the parents staying after the lights were switched off. In the behavior therapy/non-melatonin-treated group, 77.70 % never slept with their parents after treatment, which is an improvement from 7.40 % assessed before the treatment. In the behavior therapy/melatonin-treated group, 41.40 % of the children were willing to sleep with their parents every night after the treatment, compared to 44.80 % assessed before the treatment. In a study conducted by El Rafihi-Ferreira et al. in 2019, sleep problems were reported to be common in children and they could affect behavioral and emotional functioning. In this study, 62 children aged one to five years underwent behavioral therapy. The intervention consisted of five two-month sessions, during which the parents were trained on their child's sleep and received guidance on creating sleep patterns and routines and using blackout techniques. Sleep patterns and behavioral problems were assessed by parental reporting criteria. In this study, the children who were subject to the intervention had a greater improvement than the control group in terms of sleep delay, waking up at night, behaviors such as resistance to going to bed, the tendency to sleep with their parents, and behavior during the day after treatment. Parent-based behavioral interventions are effective in improving the quality of sleep and daily behavior of children (16).

In this study, insomnia was introduced as a very common problem in childhood that if left untreated, can last for years. In addition to hurting children, this problem can also hurt their families. Therefore, it is preferred to identify and treat it as soon as

possible, and using a drug such as melatonin can be very effective in this regard. In addition, interventions based on the principles of behavioral therapy are also very important and effective. Bedtime education focuses on helping children develop self-relaxation strategies for falling asleep and resuming sleep during the night. In the case of young children, these interventions are mostly based on educating and modifying parental behaviors (17-19).

Therefore, proper education of parents and proper implementation of this education by them is very important in this area. In cases where the parents are not well educated or the children are not properly educated, there will be no positive results. Relaxation and stress reduction techniques, modification of cognitive processes related to worry and anxiety, and positive imagery training are also effective in reducing the severity of children's sleep disorders (19).

4-1. Limitations of the study

The number of children and parents who were willing to cooperate was small and some parents might not have spent much time educating their children and thus did not get the desired result.

5- CONCLUSION

After the treatment, the mean number of night awakenings and the length of wakefulness of the children at night (minutes) were lower in the behavior therapy/melatonin-treated group. Moreover, in this group, children slept for more hours in the morning. The results can be used to treat children with sleep disorders and they will be available for researchers to continue related studies in this area. Considering the importance of sleep disorders in children, there is a need for more studies in this field, and the appropriate doses of treatment with melatonin should be determined based on the severity and type of disorder.

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7- CONFLICT OF INTERESTS

None.

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