The effects of chamomile extract on sleep quality among elderly people: A clinical trial

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ABSTRACT

Background: The prevalence of insomnia increases with age. Chamomile is among the medicinal plants which are used as tranquilizer. Yet, there is inadequate experimental and clinical evidence regarding its hypnotic effects. This study sought to evaluate the effects of chamomile extract on sleep quality among elderly people.

Design: A single-blind randomized controlled trial was performed.

Setting: A convenient sample of sixty elderly people who aged sixty or more and lived in Kahrizak day care nursing home, Karaj, Iran, were randomly allocated to a control and a treatment group. The treatment group received chamomile extract capsules (200 mg) twice a day for 28 consecutive days while the control group received wheat flour capsules (200 mg) in the same manner. Using the Pittsburgh Sleep Quality Index, sleep quality was assessed immediately before, two weeks after beginning, immediately after the completion, and two weeks after the completion of the intervention. The data were analyzed via the independent-sample t, Chi-square, and Fisher’s exact tests as well as the repeated measures analysis of variance.

Results: The means of age in the control and the treatment groups were 70.73 ± 6.44 and 69.36 ± 4.99, respectively. Except for the habitual sleep efficiency component of the Sleep Quality Index, the study groups did not differ significantly from each other at baseline regarding the scores of the other components of the index. Moreover, at baseline, sleep quality in both groups was low, with no statistically significant between-group difference (P = 0.639). However, after the intervention, sleep quality in the treatment group was significantly better than the control group (P < 0.05).

Conclusion: The use of chamomile extract can significantly improve sleep quality among elderly people. Thus, it can be used as a safe modality for promoting elderly people’s sleep.

1. Introduction

Poor sleep quality is one of the main characteristics of chronic insomnia and a common health problem among elderly people. Any sleep pattern disturbances can directly or indirectly affect physical and psychological health. Thus, sleep assessment and sleep quality improvement, particularly among elderly people, are among the most important care measures.

Studies show that the prevalence of sleep disturbances increases with age so that 50% of elderly people who live in private homes and 70% of nursing home residents suffer from sleep disturbances. A recent study reported that sleep disturbances affect 88.4% of the residents of Kahrizak nursing home, Tehran, Iran. The most common sleep disturbances that affect elderly people are dyssomnia and insomnia.

Sleep disturbances are managed by different modalities including, but not limited to, behavioral therapy, cognitive therapy, sleep hygiene practices, and medication therapy. Most elderly people manage their sleep disturbances by hypnotic agents. However, a study revealed that anxiolytic agents and barbiturates increase insomnia among elderly people by 50%. Moreover, long-term use of some hypnotic agents may result in dependence and tolerance so that their discontinuation can cause the symptoms of withdrawal syndrome which are in turn more severe than the symptoms of sleep disturbances.

Due to the side effects of sleep medications, special attention has been given to traditional and herbal therapies in recent years. Chamomile is one of the medicinal plants which are used in Iranian Traditional Medicine as hypnotic and tranquilizer. Traditionally, chamomile and its derivatives has been used as an anti-inflammatory, antioxidant, mild astringent and healing medicine. It is also used to treat mucous/skin and respiratory tract disorders, neuralgia, mastitis, and hemorrhoids. In addition, chamomile in the form of an aqueous extract has been frequently used as a mild agent to sedate agitation, anxiety, and sleep-related problems. Moreover, the
anticonvulsant and digestive system relaxing effect of the herb has been reported.\textsuperscript{15,16}

Approximately 120 bioactive constituents have been identified in chamomile, including 28 terpenoids and 36 flavonoids. Chamomile contains some terpenoids like α-bisabolol, chamazulene and acetylene derivatives, esters of angelic acid and ticlic acid, farnesene and α-pinen, nobilin and 3-epinobilin. Also, the bisabolol oxides and azulen, spiro-ether quiterpene lactones, glycosides, hydroxycoumarins, flavonoids (e.g. apigenin, luteolin, patuletin, and quercetin), coumarins (herniarin and umbelliferone), and mucilage are among the major ingredients of chamomile. Among the flavonoids, apigenin is the most promising compound.\textsuperscript{15,17}

Previous studies showed that chamomile improves sleep quality\textsuperscript{18} and alleviates depression and anxiety.\textsuperscript{19,20} Besides, review studies showed the effectiveness of chamomile in managing insomnia and producing tranquilizing effects and attributed its effects to its apigenin and flavonoid compounds which bind benzodiazepine receptors in the brain.\textsuperscript{21,22} Yet, a study assessed sixteen herbal medicines used to manage depression, anxiety, and insomnia and reported that although a wide variety of herbal medicines such as chamomile and valerian are known to have complex psychoactive effects, there is inadequate experimental and clinical evidence regarding their effectiveness in managing health problems among human beings.\textsuperscript{23} Similarly, Zick et al. also reported that a four-week therapy with oral chamomile extract had moderate effects on sleep problems and daytime functioning while had no significant effect on sleep latency and nighttime awakenings.\textsuperscript{24} Given the conflicting findings of previous studies respecting the effectiveness of chamomile in reducing sleep disturbances, the present study was undertaken to evaluate the effects of chamomile extract on sleep quality among elderly people.

2. Methods

This single-blind randomized controlled trial was made from April to May 2016. Study population comprised all 195 elderly people (86 males and 109 females) who aged sixty or more and lived in Kahrizak day care nursing home, Karaj, Iran. The results of a study on the effects of chamomile extract on elderly people’s sleep quality had shown that the means of sleep quality in the control and experimental groups were 8.24 ± 4.07 and 5.05 ± 3.7, respectively.\textsuperscript{18} These findings were used to calculate sample size in the present study with a type I and II errors of 0.05 and 0.2, respectively. Consequently, using the following formula \(n = \left(\frac{z_{1-\alpha} + z_{1-\beta/2}}{\sigma_i} \right)^2 \times \left(\frac{z_{1-\alpha} + z_{1-\beta/2}}{\sigma_i} \right)^2 / (\mu_i - \mu_j)^2\) the sample size was estimated to be 24 cases for each group. Yet, to compensate a possible withdrawal rate of 20%, thirty eligible elderly people were conveniently recruited to each group—sixty in total. The participants were allocated to a control and a treatment group through block randomization. The size of each block was 6 and thus, five blocks were considered for each group. Fig. 1 presents the study flow diagram.

Eligibility criteria were an age of sixty or more, a score of 5 or more in the Pittsburgh Sleep Quality Index (PSQI), membership in Kahrizak day care nursing home, no allergy to chamomile and its derivatives, no previous use of chamomile or its derivatives, full consciousness, ability to communicate verbally and respond study instruments, no use of anticoagulants (such as heparin, warfarin, aspirin, and plavix), no dependence on medications or drugs (including opioids, alcohol, analgescics, antidepressants, and hypnotics), and no affliction by known asthma, cancer, insulin-dependent diabetes mellitus, and systemic lupus erythematosus, cardiac failure, and mental, hepatic, or renal disorders (according to the participants’ medical records). Participants were excluded if they did not tolerate chamomile or showed sensitivity to it, used chamomile herb or its other derivatives during the study for three consecutive days, experienced death, became hospitalized in hospital settings, or were transferred to other nursing homes.

2.1. Data collection instruments

Two instruments were used for data collection namely a personal and clinical characteristics questionnaire as well as PSQI. PSQI is a standard eighteen-item index, the items of which are grouped into the following seven components: subjective sleep quality: item 9; sleep latency: item 2 and the part A of the item 5; sleep duration: item 4; habitual sleep efficiency: measured through dividing the total sleeping hours by the total hours in bed multiplied by 100; sleep disturbances: calculated by averaging the scores of the sub-items of the item 5; use of sleeping medications: item 6; and daytime dysfunction: calculated by averaging the scores of the items 7 and 8. The score of each item and each component ranges from 0 to 3. The sum score of these seven components is considered as the total PSQI score which is 0–21. Scores greater than 5 show low sleep quality. Solleimany et al. confirmed that the Persian PSQI has acceptable content validity and reported a test-retest correlation coefficient of 0.87% for the index.\textsuperscript{24} The instruments of the study were completed for each eligible participant through interviewing them. Baseline data collection was done immediately after recruitment to the study.

2.2. Intervention

Chamomile extract and wheat flour capsules were respectively used for participants in the experimental and the control groups. The capsules were produced and coded by Ahura Pharmaceutical Company, Shiraz, Iran. The capsules were provided to a physician who assisted us in doing the study. The physician prescribed participants in the treatment group with chamomile capsules (200 mg) and asked them to take two capsules per 24 h for 28 consecutive days. Moreover, he asked them to avoid the over-the-counter use of any chamomile or valerian derivatives during the study. Participants in the control group were treated similarly but with wheat flour capsules (200 mg). Sleep quality was assessed through interviewing the participants at four time points, namely immediately before the intervention (T1), two weeks after the beginning of the intervention (T2), immediately after the completion of the intervention (T3), and two weeks after the completion of the intervention (T4). Interviews were held personally in a quiet and comfortable room in the study setting. All interviews were conducted by the second researcher and were held during the daytime i.e. between 08:00 and 14:00.

Due to the significance of the research topic and the hygienic issues of the intervention for authorities in the research setting both physician and the nurse who assessed the sleep quality were not blind to the intervention in order to be able to assess the possible occurrence of adverse effects of the chamomile. However, the physician and nurse tried to keep their behavior consistent with the participants in both study groups. Moreover, all the participants were trained to report any adverse effect of the prescribed capsules to the physician to receive necessary recommendation. The physician has also been trained to document any adverse effect reported by the participants and finally report it to the research team.

2.3. Chamomile extract preparation

Chamomile extract was produced from \textit{Matricaria recutita} using the percolation method in the following steps. Primarily, the plant was ground and soaked in 70% ethanol. Then, extraction process was done during a whole week and the extract was concentrated in vacuum. After that, the concentrate was dried to chamomile extract powder using a drier spray. Finally, the dosage of the extract was determined and chamomile extract capsules (200 mg) were produced using a capsule filler machine. For the participants in the control group, capsules were filled with wheat flour (200 mg). To keep the study blind for the participants, the capsules of chamomile extract and wheat flour were prepared with similar shape, size and color but differed in their cods
(i.e. “a” or “b”).

2.4. Ethical considerations

The study was approved by the Institutional Review Board and the Ethics Committee of Koshan University of Medical Sciences, Koshan, Iran (approval code: IR.KAUMS.REC.1394.157), and was registered by the Iranian Registry of Clinical Trials (registration code: IRCT201609023618N5). At the beginning of the study, we provided the participants with explanations about the aims of the study and the types of the intervention in the study. Of course, they were blind to the type of capsules they were going to receive. Moreover, we ensured them about the facts that their participation in the study was voluntary and they could withdraw from the study at any time. We also assured them that their personal information would be handled confidentially. Participation in the study charged them no cost. The rights of the participants were protected according to the Declaration of Helsinki.

2.5. Data analysis

The data were described via the measures of descriptive statistics such as frequency tables, mean, and standard deviation. On the other hand, the groups were compared with each other regarding nominal and categorical variables (such as gender, educational and marital status, and history of chronic conditions) through the Chi-square and the Fisher’s exact tests while between-group comparisons regarding interval and ratio variables (such as age) were performed through the independent-sample t-test. Besides, comparisons of the variations of PSQI scores across the four measurement time points were done through the repeated measures analysis of variance (RM ANOVA). Moreover, Greenhouse-Geisser estimation was used for epsilon corrections and Bonferroni test for pairwise comparisons. All analyses were carried out using the SPSS software v. 13 (SPSSInc.Chicago, Illinois, USA).

3. Results

From the sixty participating elderly people 68.3% were female, 66.7% were married, and 60% were illiterate. The means of age in the control and the treatment groups were 70.73 ± 6.44 and 69.36 ± 4.99, respectively. The independent-sample t-test revealed no significant between-group difference respecting the mean of participants’ age (P = 0.363). In addition, the Chi-square and the Fisher’s exact tests showed that the groups did not differ significantly from each other with respect to the participants’ gender, educational and marital status, and history of chronic conditions (P < 0.05; Table 1).

At T1 and T2, between-group differences regarding the mean score of PSQI were not statistically significant (P = 0.639) while at T3 and T4, those differences were statistically significant (P = 0.007 and 0.002, respectively; Table 2). The RM ANOVA was done for comparing the variations of PSQI scores across the four measurement time points. The Mauchly’s test showed that sphericity was not assumed (χ² (5) = 94.066 and P = 0.001). Thus, the degrees of freedom were corrected through the Greenhouse-Geisser estimation. Accordingly, the results showed that chamomile extract significantly affected total sleep quality (F = 32.318, df = 1.472, and P = 0.001). Also, there was no significant interaction between time and group (F = 2.45, df = 1.47, P = 0.07) (Table 2 and Fig. 2). Moreover, the Tests of Between-Subjects Effects showed a significant difference between the PSQI scores of the two groups (P = 0.001).

Fig. 2 also shows that sleep quality in the control group did not change considerably across the four measurement time points. Pairwise comparisons also showed a significant difference only between the first and the third measurements in this group (P = 0.012). However, the trend of PSQI score variations in the treatment group was downward and significant. The pairwise comparisons also showed that all measurements in this group were significantly different from each other (P = 0.001) except for the third and the fourth times (P = 0.99). In other words, sleep quality in the treatment group improved significantly during the study. Moreover, except for the components of ‘sleep duration’ and ‘use of sleeping medications’, all components of
animal models.25 Chamomile extract includes di

Amsterdam et al. reported that oral intake of chamomile extract sig-

ni

omatherapy with chamomile and lavender essential oils could sig-

chamomile extract and sleep quality of elderly people.18 In addition, 

found a signi 

turbances and daytime functioning among patients who su 

sleep disturbances while the therapy had no signi 

tances.23 Cho et al. also reported that ar-

sleep quality were statistically signi 

However, after the intervention, between-group di 

fi 

ferences respecting the daytime functioning component of PSQI

was reported by the participants.

PSQI were significantly different among the two groups in all mea-

surement time points (Table 3).

During the study, no adverse effect related to chamomile extract use 

was reported by the participants.

4. Discussion

The findings of the present study showed poor sleep quality in both 

groups at baseline with no significant between-group difference. 

However, after the intervention, between-group differences respecting 

sleep quality were statistically significant.

In line with our findings, Zick et al. reported that a four-week 

therapy with oral chamomile extract moderately affected sleep dis-

turbances and daytime functioning among patients who suffered from 

sleep disturbances while the therapy had no significant effect on sleep 

latency and nighttime awakenings.25 Cho et al. also reported that ar-

omatherapy with chamomile and lavender essential oils could sig-

ificantly affect the sleep quality.20 Similarly, Abdollahzadeh and Naji 

found a significant correlation between a four-week oral intake of 

chamomile extract and sleep quality of elderly people.18 In addition, 

Amsterdam et al. reported that oral intake of chamomile extract sig-

ificantly alleviated depression and anxiety disorders.19 Another study 

also showed the tranquilizing and hypnotic effects of chamomile in 

animal models.26 Chamomile extract includes different components 

such as apigenin, apigetrin, chamazulene, bisabolol, and faren ses, of 

which, apigenin (a water-soluble component) binds benzodiazepine 

sites and causes tranquilizing effects in the central nervous system.26 

Nonetheless, Avallone et al. reported that chamomile may not have 

decisive hypnotic effects and thus, recommended further investigations 

in this area.27

Our findings also revealed that the study intervention did not sign-

ificantly affect the sleep duration component of PSQI. This finding can 

be attributed to the short duration of the study intervention. Moreover, 

the study groups differed significantly from each other respecting the 

use of sleeping medications component of PSQI neither before nor after 

the intervention. This finding was probably due to the fact that we did 

not recommend or ask the participants to reduce the dose or dis-

continue the use of their hypnotic medications. Besides, the between-

group difference regarding the daytime functioning component of PSQI 

was not statistically significant probably due to prolonged sleep la-

tency, frequent nighttime awakenings, early morning awakening, and 

subsequent daytime tiredness and sleepiness.

Generally, chamomile is a safe herb and a relatively low percentage 

of people are sensitive to it. Some people may develop contact allergies 

to chamomile, especially if they take other drugs that help to trigger the 
sensitization.15 In a large-scale clinical trial only 3.1% of 3851 in-

dividuals experienced an allergic reaction to chamomile.28 Contact al-

ergy to chamomile may also present if the people have skin contact 

with it.16 During the study, no adverse effect related to chamomile 

extract use was reported by the participants.

5. Study limitations

This study has several limitations that might be sources of potential 
bias and imprecision. First, our study was single-blinded. Therefore, it 
is recommended to repeat a larger, double-blinded study with longer 
period of follow-up. The individual differences of the participants, such

Table 1
Between-group comparisons with respect to participants’ demographic and clinical characteristics.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment, N (%)</td>
<td>Control, N (%)</td>
</tr>
<tr>
<td>Age (Mean ± SD)</td>
<td>69.36 ± 4.99</td>
<td>70.73 ± 6.44</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>9 (30)</td>
<td>10 (33.3)</td>
</tr>
<tr>
<td>Female</td>
<td>21 (70)</td>
<td>20 (66.7)</td>
</tr>
<tr>
<td>Educational status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>16 (53.3)</td>
<td>20 (66.7)</td>
</tr>
<tr>
<td>Primary</td>
<td>12 (40)</td>
<td>8 (26.7)</td>
</tr>
<tr>
<td>Secondary and higher</td>
<td>2 (6.7)</td>
<td>2 (3.33)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>17 (56.7)</td>
<td>23 (76.7)</td>
</tr>
<tr>
<td>Widowed</td>
<td>13 (43.3)</td>
<td>7 (23.3)</td>
</tr>
<tr>
<td>History of chronic conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>21 (70)</td>
<td>25 (83.3)</td>
</tr>
<tr>
<td>No</td>
<td>9 (30)</td>
<td>5 (16.7)</td>
</tr>
<tr>
<td>Type of co-morbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastritis</td>
<td>5 (12.5)</td>
<td>4 (10.5)</td>
</tr>
<tr>
<td>Arthritis</td>
<td>16 (40)</td>
<td>19 (50)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>11 (27.5)</td>
<td>12 (31.6)</td>
</tr>
<tr>
<td>Type II diabetes</td>
<td>8 (20)</td>
<td>3 (7.9)</td>
</tr>
<tr>
<td>Hypnotic dugs use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6 (20)</td>
<td>4 (13.3)</td>
</tr>
<tr>
<td>No</td>
<td>24 (80)</td>
<td>26 (86.7)</td>
</tr>
</tbody>
</table>

a Some of the people had several co-morbidities.

Table 2
The comparisons of the mean PSQI scores at four measurement time points.

<table>
<thead>
<tr>
<th>Total PSQI score*</th>
<th>Time</th>
<th>Treatment group</th>
<th>Control group</th>
<th>P value, (RM ANOVA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1</td>
<td>T2</td>
<td>T3</td>
<td>T4</td>
</tr>
<tr>
<td></td>
<td>11.80 ± 3.68</td>
<td>10.90 ± 3.07</td>
<td>9.20 ± 2.68</td>
<td>9.13 ± 2.44</td>
</tr>
<tr>
<td></td>
<td>12.20 ± 2.82</td>
<td>12.00 ± 2.62</td>
<td>11.20 ± 2.84</td>
<td>11.40 ± 2.94</td>
</tr>
</tbody>
</table>

* Data were presented as mean ± standard deviation.
** t-test.
Table 3
The comparisons of the mean scores of PSQI components at four measurement time points.

<table>
<thead>
<tr>
<th>PSQI component scores</th>
<th>Time</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1</td>
<td>T2</td>
</tr>
<tr>
<td>Sleep duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>2.86 ± 0.50</td>
<td>2.83 ± 0.53</td>
</tr>
<tr>
<td>Control group</td>
<td>3.00 ± 0.00</td>
<td>3.0 ± 0.00</td>
</tr>
<tr>
<td>Use of sleeping medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>0.43 ± 0.93</td>
<td>0.43 ± 0.93</td>
</tr>
<tr>
<td>Control group</td>
<td>0.46 ± 1.008</td>
<td>0.46 ± 1.008</td>
</tr>
<tr>
<td>Subjective sleep quality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>1.70 ± 0.91</td>
<td>1.20 ± 0.55</td>
</tr>
<tr>
<td>Control group</td>
<td>1.43 ± 0.89</td>
<td>1.36 ± 0.80</td>
</tr>
<tr>
<td>Sleep disturbances</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>1.60 ± 0.49</td>
<td>1.50 ± 0.50</td>
</tr>
<tr>
<td>Control group</td>
<td>1.60 ± 0.49</td>
<td>1.60 ± 0.49</td>
</tr>
<tr>
<td>Daytime dysfunction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>0.60 ± 0.85</td>
<td>0.50 ± 0.68</td>
</tr>
<tr>
<td>Control group</td>
<td>0.36 ± 0.55</td>
<td>0.40 ± 0.56</td>
</tr>
<tr>
<td>Habitual sleep efficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>2.20 ± 0.92</td>
<td>2.10 ± 0.95</td>
</tr>
<tr>
<td>Control group</td>
<td>2.93 ± 0.36</td>
<td>2.93 ± 0.36</td>
</tr>
<tr>
<td>Sleep latency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment group</td>
<td>2.20 ± 0.88</td>
<td>2.16 ± 0.91</td>
</tr>
<tr>
<td>Control group</td>
<td>2.26 ± 0.73</td>
<td>2.26 ± 0.73</td>
</tr>
</tbody>
</table>

* All data are presented as mean ± standard deviation.
** Repeated measures analysis of variance.

as their gender, age and psychological condition might also influence the pattern and quality of sleep but these variables were out of the researchers’ control. Moreover, we did not investigate the individual differences in sleep habits and usual patterns of activity and rest of the participants. Furthermore, although we questioned the participants about the hypnotic drugs use, we did not assess the actual amount of sleep medications used by them and other issues related to insomnia. The use of sleep medications was also assessed based on the participants self-report. Hence, further studies are suggested to consider the effects of these variables.

Besides, although the study was done in a day care nursing home, the findings may not be generalizable to all nursing home residents. In addition, this study was carried out in a single center and on a small sample of elderly people. Multi-center studies with large sample sizes are needed for producing decisive evidence regarding the effectiveness of chamomile oral intake in improving sleep quality.

6. Conclusion
The findings of this study show that the use of chamomile extract can significantly improve sleep quality among elderly people. Given the high prevalence of sleep disturbances among elderly people and the adverse effects of hypnotic medications, chamomile extract can be used as a safe modality for promoting elderly people’s sleep.

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