



## 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  $70.73 \pm 6.44$  and  $69.36 \pm 4.99$ , 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 the main characteristics of chronic insomnia<sup>1</sup> and a common health problem among elderly people.<sup>2,3</sup> Any sleep pattern disturbances can directly or indirectly affect physical and psychological health.<sup>4</sup> 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.<sup>5–8</sup> A recent study reported that sleep disturbances affect 88.4% of the residents of Kahrizak nursing home, Tehran, Iran.<sup>9</sup> The most common sleep disturbances that affect elderly people are dyssomnia and insomnia.<sup>10</sup>

Sleep disturbances are managed by different modalities including, but not limited to, behavioral therapy, cognitive therapy, sleep hygiene

practices, and medication therapy.<sup>10</sup> 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%.<sup>11</sup> 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.<sup>12</sup>

Due to the side effects of sleep medications, special attention has been given to traditional and herbal therapies in recent years.<sup>13</sup> Chamomile is one of the medicinal plants which are used in Iranian Traditional Medicine as hypnotic and tranquilizer.<sup>14</sup>

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

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anticonvulsant and digestive system relaxing effect of the herb has been reported.<sup>15,16</sup>

Approximately 120 bioactive constituents have been identified in chamomile, including 28 terpenoids and 36 flavonoids. Chamomile contains some terpenoids like  $\alpha$ -bisabolol, chamazulene and acetylene derivatives, esters of angelic acid and tiglic acid, farnesene and  $\alpha$ -pinene, nobilin and 3-epinobilin. Also, the bisabolol oxides and azulene, spiro-ether quiterpene lactones, glycosides, hydroxycoumarins, flavanoids (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.<sup>15,17</sup>

Previous studies showed that chamomile improves sleep quality<sup>18</sup> and alleviates depression and anxiety.<sup>19,20</sup> 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.<sup>21,22</sup> 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.<sup>20</sup> 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.<sup>23</sup> 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  $8.24 \pm 4.07$  and  $5.05 \pm 3.7$ , respectively.<sup>18</sup> 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 ( $n = ((z_{1-\alpha/2} + z_{1-\beta/2})^2 \times (\sigma_1^2 + \sigma_2^2)) / (\mu_1 - \mu_2)^2$ ) 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, analgesics, 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.<sup>24</sup> 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 *Matricaria recutita* using the percolation method in the following steps. Primarily, the plant was grinded 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

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