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Complimentary and Alternative Medicine for Sleep Disturbances in Older Adults

Nalaka S. Gooneratne, MDMSc [Assistant Professor]

Division of Geriatric Medicine, Center for Sleep and Respiratory Neurobiology, University of Pennsylvania School of Medicine, 3615 Chestnut St, Philadelphia, PA 19104, O: 215 349 5938, F: 215 573 8684, e-mail: ngoonera@mail.med.upenn.edu

Synopsis

Complimentary and alternative medicines (CAM) are frequently used for the treatment of sleep disorders, but in many cases, patients do not discuss these therapies directly with their health care provider. There is a growing body of well-designed clinical trials using CAM that have shown the following: 1) Melatonin is an effective agent for the treatment of circadian phase disorders that affect sleep, however, the role of melatonin in the treatment of primary or secondary insomnia is less well established. 2) Valerian has shown a benefit in some, but not all clinical trials. 3) Several other modalities, such as Tai Chi, acupuncture, acupressure, yoga and meditation have improved sleep parameters in a limited number of early trials. Future work examining CAM has the potential to significantly add to our treatment options for sleep disorders in older adults.

Keywords

Complementary and alternative medicine; insomnia; aged; melatonin; valerian

Introduction

Complimentary and alternative medicines (CAM) have a long history of use for the treatment of sleep disorders. In the 2nd century AD, for example, the prominent ancient Greek physician Galen (Claudius Galenus) prescribed valerian for insomnia.¹ CAM therapies are defined by the National Center for Complimentary and Alternative Medicine (NCCAM) as "a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine." ² While the terms are often used synonymously, a more accurate statement is that complementary medicines are "used **together with** conventional medicine", while alternative medicines are "used **in place of** conventional medicine (Figure 1).² Inherent in this definition of CAM is a concept of change: what is considered to be a CAM therapy today may become a conventional form of treatment in the future. An example of this would be the growth of clinical patient support groups, or the use of some forms of cognitive-behavioral therapy as mainstream medical treatments.²

There exist several hundred different forms of CAM therapy (Figure 1). The classification method used by NCCAM consists of five broad domains: 1) Alternative medical systems that are based on a set of theories and practices that have generally developed apart from conventional medicine. These include acupuncture, ayurveda, or homeopathy. 2) Biologically

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based practices that consist of compounds often found in nature, such as herbal products. 3) Mind-body medicine which uses systems of thought that can affect bodily functions. This is a broad category that can include meditation, tai chi, yoga and biofeedback. 4) Manipulative and body-based practices which rely on movement of select parts of the body. An example would be massage-based therapies. 5) Energy medicine that emphasizes the use of energy fields including bio-electromagnetic based therapies.²

It is also important to note that many CAM therapies, in particular the biologically based practices and some forms of alternative medical systems, are regulated under the Dietary Supplemental and Education Act of 1994. According to these guidelines, these compounds are not required to undergo purity, safety or efficacy testing. Standardization of compounds across different research studies is thus not always consistent, and some products may not contain the ingredients they advertise. Furthermore, under these guidelines, these products cannot claim treatment effects for specific disease processes in their marketing or advertising.

This review will focus on CAM therapies for sleep disorders in older adults. Since there are a large number of CAM therapies, we will limit our discussion to the therapies that are most widely used and for which an adequate body of scientific data exists upon which to base conclusions. Due to the relative paucity of literature for certain modalities, we will also review studies on sleep treatment in younger subjects where appropriate. Several reviews exist of CAM therapy to which the reader is referred for more information about specific modalities. $^{3-14}$ The major categories that will be discussed in this review include the following (Figure 2): 1) Alternative medical systems—acupuncture, ayurveda; 2) Biological—melatonin, valerian; 3) Mind-body—meditation, yoga, Tai Chi; and 4) Manipulation—massage.

CAM usage by older adults

A recent telephone survey of 1,559 people over the age of 50 conducted by the American Association of Retired Persons (AARP) and the National Center for Complementary and Alternative Medicine (NCCAM) noted that 54% of persons aged 65 or older had used a CAM therapy or practice.¹⁵ The 30% response rate, fairly typical for telephone surveys that do not offer financial compensation, may have overestimated CAM use since users may be more likely to respond than non-users. Nevertheless, the overall prevalence of use is quite high.

When considering factors that influenced CAM use, individuals with a higher income or more years of college education were more likely to use CAM.¹⁵ Much of the information obtained by older adults regarding CAM therapies came from family or friends (22%), publications (14%) or radio/TV/internet (20%). Only 31% of CAM users had discussed CAM with their physician¹⁵ and only 12% obtained information about CAM from their physicians.¹⁵ This highlights the need for physicians to inquire about CAM and help educate their patients regarding CAM. Furthermore, asking about CAM use can help a physician to minimize the risk of polypharmacy: 75% of those who had taken an herbal or dietary product during their lifetime were also taking one or more prescription medications.¹⁵

The majority of patients with insomnia also have comorbidities: only 4.1% of patients with insomnia did not have a comorbidity.¹⁶ In older adults, many of whom are taking multiple medications, the potential interactions between CAM products and conventional medicine are important to consider. Unfortunately, there is a relative paucity of literature dealing with this topic (see Figure 3).

When considering the use of CAM for insomnia in particular, a recent analysis of the National Health Interview Survey (NHIS) dataset (74.3% response rate) by Pearson et al. revealed that 4.5% adults (over age 18, noninstitutionalized) used some form of CAM for their insomnia or trouble sleeping in the past year.¹⁶ This extrapolates to 1,615,699 adults over age 18 in the

United States, with 113,000 adults over the age of 65 using CAM. Other sedative prescription drugs, by comparison, are used by approximately 5–10% of adults (age over 16–18 years) with insomnia.^{17, 18} Another interesting observation was that the prevalence of CAM use in those with insomnia tended to decrease with age (Figure 4). The most commonly used CAM modalities in adults were biologically based therapies (64.8% of adult CAM users) and mindbody therapies (39.1% of adult CAM users); those with comorbidities tended to prefer biologically based therapies ¹⁶.

Melatonin

Melatonin is one of the most thoroughly studied CAM biologic compounds used for sleep. It is a hormone produced by the pineal gland that is postulated to play a significant role in regulating the sleep-wake cycle ¹⁹. It has low daytime circulating levels and elevated nocturnal levels that coincide with the sleep phase ²⁰. Melatonin has the ability to influence the timing of the circadian sleep-wake cycle, as has been demonstrated by work in subjects with a free-running circadian rhythm ²¹. It may also have sedative effects possibly via direct inhibition of the suprachiasmatic nucleus via a feedback loop ²², ²³. Melatonin injected into other brain regions, such as the medial preoptic area, can induce sleep as well ²⁴.

Numerous studies have shown decreased melatonin levels in the elderly relative to subjects under age 30 ^{25–27}. This may in part be due to declines in the number of pinealocytes ²⁸, or neuronal degeneration of the SCN and resultant circadian desynchrony ²⁹. The presence of insomnia itself is also independently associated with serum melatonin deficiency in some studies ^{30, 31} but not in others ^{29, 32–34}. Melatonin deficiency is due to three potential factors: medications, age-related changes, and melatonin suppression from comorbid medical condition. Melatonin is profoundly decreased by a variety of medications commonly used by the elderly, including beta-blockers ³⁵ and non-steroidal anti-inflammatory drugs (NSAIDs) ³⁶ and the extent of melatonin suppression may be more profound in the elderly than in younger subjects ³⁷. In addition to medications, a variety of primary conditions, such as chronic pain ³⁸, myocardial infarction ³⁹, and ischemic stroke ⁴⁰ are strongly associated with decreased melatonin levels. This melatonin deficiency is particularly problematic in the elderly as animal studies have shown decreased levels of the Mel1a receptor with aging ⁴¹.

These findings have led to a strong interest in using exogenous melatonin to treat chronic primary insomnia in older adults. Doses have ranged from 0.1–0.3 mg (which results in physiologic melatonin levels) to 5–10 mg (pharmacologic melatonin levels). Initial studies showed evidence of a benefit 42 including reduced sleep latency in patients with cognitive impairment 43 , however these studies relied on wrist-activity assessment of sleep-wake. Other wrist-activity studies have been negative, however 44 . In the largest study to date that uses objective measures, Singer et al. studied 157 older adults with Alzheimer's Disease and randomized them into three groups: placebo, melatonin 2.5 mg sustained release, and melatonin 10 mg 45 . There was no statistically significant benefit on objective parameters (wrist-activity monitoring) with melatonin therapy; this was the primary study measure. Caregivers did note improvement in sleep (as assessed using a sleep diary) for patients using the 2.5 mg sustained release formulation; however there was no significant difference in the subjective Sleep Disturbance Index scores amongst the study arms.

More rigorous studies relying on polysomnography (which is often required by the FDA-for sedative-hypnotics to show efficacy) have also been conducted. Some studies have shown a benefit 46 , 47 , while others did not demonstrate significant improvements in sleep patterns 48 , 49 .

Recently, a large meta-analysis was conducted of melatonin therapy for sleep ⁵⁰. The metaanalysis suggested that melatonin had a clinically insignificant benefit for primary insomnia in older adults: there was a 7.8 min improvement in sleep latency, but no overall improvement in sleep efficiency. Patients with delayed sleep phase syndrome did show a larger, clinically significant benefit of 38.8 min. No benefit was noted for secondary insomnia.

Attempts have also been made to target specific subgroups of patients by their melatonin profile. For example, one study by Hughes et al. found no overall benefit, but noted that the most prominent improvement occurred in patients who had a short duration of endogenous melatonin secretion ⁴⁸. Of note, this study had an unusual treatment regimen in which all subjects were awoken 4.5 hours after the initial melatonin dose to take a middle-of-the-night dose. One actigraphy based study in patients with low melatonin levels noted improved sleep ⁵¹, however only the first six hours of sleep were analyzed in this study. Another self-report study found evidence of benefit ⁵² however the interpretation of these results is limited by the study design which consisted of a non-randomized placebo/melatonin paradigm. Alternative forms of melatonin have also been tested, including transbuccal melatonin, with no significant benefit in elderly subjects with insomnia ⁴⁹.

In general, melatonin is well tolerated in the dose range of 0.1 mg to 10 mg with few reported adverse events $^{53-55}$. One particular concern in the elderly, however, is that of daytime sleepiness 56 . No clinical trials of melatonin in the elderly have measured objective markers of daytime sleepiness. However, one study in younger subjects using objective measures of performance suggests that the sedative effects of melatonin persist even up to seven hours after ingestion 57 and another study noted "tiredness at rising" in four (out of eleven) subjects treated with melatonin 58 . Thus while melatonin has the potential to improve sleep efficiency and thereby result in decreased daytime sleepiness, its use may directly lead to daytime sleepiness. It is also possible that melatonin doses of 3-5 mg may lead to increased sleep disruption as has been noted in 4 of 16 younger subjects given melatonin in a temporal isolation study 59 . Despite these concerns, Jean-Louis et al., in their previously mentioned study of melatonin 6 mg in cognitively-impaired subjects, noted improved memory recall and concentration, and no increased subjective fatigue 43 . In addition, melatonin is less likely to lead to dependence and abuse as can occur with other sedative-hypnotics as it does not cause euphoria 60 .

A large body of work has been done examining melatonin's effects on other organ systems in regards to its safety profile. These findings are summarized below.

Cardiovascular Effects

Human studies using doses such as melatonin 5 mg have observed that melatonin may impair the antihypertensive efficacy of calcium channel blockers to a mild degree. In subjects on nifedipine who were treated with melatonin, there was a mean increase in systolic blood pressure of 6.5 mmHg and in diastolic blood pressure of 4.9 mmHg ⁶¹. Human studies show mild reduction in blood pressure with physiologic doses of melatonin ⁶².

Immune System Effects

Melatonin may have immunomodulatory effects, although no clear consensus exists in this regard as to overall safety ⁶³. Some studies have suggested a pro-inflammatory role in conditions such as autoimmune arthritis ⁶⁴, ⁶⁵, while others have found melatonin to be protective against the development of autoimmune disorders such as Type I Diabetes Mellitus ⁶⁶ and experimental models of inflammation such as carrageenan ⁶⁷. There has also been one case report regarding the development of auto-immune hepatitis in a patient taking melatonin ⁶⁸. Of note, the melatonin formulation taken by the patient may have contained unknown additives ⁶⁹.

Other Effects

The use of melatonin 10 mg for three months has been associated with suppression of endogenous melatonin and the development of an unentrained (free-running) sleep-wake cycle after melatonin withdrawal in two of five subjects in one study of bipolar disorder ⁷⁰; research in non-bipolar disorder subjects has shown no suppression of endogenous melatonin, however (A. Lewy, personal communication). Melatonin may increase the severity of sleep apnea as noted in one study which documented mild-moderate increases in sleep apnea in some subjects taking melatonin ⁷¹. Melatonin may affect follicle stimulating hormone (FSH), luteotropic hormone (LH) and thyroid hormones, however this has not been found to have significant clinical effects in older adults ^{72, 73}. Other side effects noted with melatonin include headache and pruritis in less than 10% of subjects ⁷⁴.

To study these concerns, several studies have evaluated the safety of melatonin. One study using 10.0 mg over a one month period documented no evidence of adverse events in younger subjects ⁵⁴. An open-label study of 22 older patients (mean age 60.1 years) with 3 mg of melatonin for six months found no significant changes in endocrine and routine chemistry/liver function analysis, including FSH, LH and thyroid stimulating hormone ⁵³. Another study administered 1.0 mg for 2 months in elderly subjects with no reported side effects ⁵¹. In an extended open-label study of 2 mg of melatonin nightly for six months, elderly subjects had decreased estradiol levels, and increased IGD-I and DHEAS levels, but no adverse clinical events occurred ⁷⁵.

There have also been two large reviews of melatonin that have been published recently (2004). The first review was conducted by the Institute of Medicine/National Academies (Dietary Supplements: A Framework for Evaluation Safety, Prototype Monograph on Melatonin)⁷⁶. This 70 page review observed that the only cardiovascular adverse events noted with melatonin from approximately 60 clinical studies (including both young, middle aged and elderly subjects) were an increase in blood pressure of approximately 6.5 mmHg in hypertensive patients on calcium channel blockers as mentioned earlier. A second large review of melatonin was recently published by the Agency for Healthcare Research and Quality (AHRQ), titled: Evidence Report/Technology Assessment: Number 108, Melatonin for Treatment of Sleep Disorders.⁵⁰. The review concluded that adverse "effects were not significant compared to placebo". They also concluded that melatonin is a "relatively safe substance" in the short term.

Overall, the current evidence suggests that melatonin has a clear role in the management of circadian sleep disorders, such as delayed sleep phase syndrome. The evidence is more equivocal for primary or secondary insomnia, or for the treatment of insomnia in patients with cognitive impairment. It may be that in certain subgroups, such as patients with low melatonin levels or abnormal timing of their melatonin cycle, exogenous melatonin may have a beneficial role; however more work is needed in this area. Fortunately, melatonin appears to have a relatively benign side effect profile.

Valerian

The plant species Valeriana, in particular *Valeriana officinalis* and to a lesser extent *Valeriana edulis*, is the source of the ingredients in valerian. These ingredients can be divided into the following categories: valepotriates, sesquiterpenes (volatile oil components which account for valerian's unpleasant odor), and amino acids (such as GABA and glutamine)⁷⁷. Putative sites of action of valerian include the GABA receptor ⁷⁸, binding at A(1) adenosine receptors ⁷⁹ or, as more recently noted, the 5-HT-5a receptor ⁸⁰.

The extraction and preparation method can influence the relative concentrations of each of the valerian components in a given formulation, thus one issue with clinical studies of valerian

compounds is while each study may use "valerian", the specific components may differ. As noted earlier, standardization and purity of biologically based compounds can be a concern, and this applies also to valerian compounds. A recent report by ConsumerLab.com noted that 4 of 17 valerian products had no detectable valerian content, 4 had half the amount listed, two had lead contamination, and one had cadmium contamination ⁸¹.

Valerian has been studied in several randomized, placebo-controlled studies, in doses ranging from 400–900 mg ⁵, ⁶ One study using both subjective and objective (polysomnography and actigraphy) measures in 18 subjects without sleep problems noted that while subjective measures improved, objective measures showed small, clinical and statistically insignificant improvements ⁸². Another actigraphy-based study observed a statistically significant improvement in sleep latency (from $15.8 \pm - 5.8 \min \text{ to } 9.0 \pm - 3.9 \min, p < 0.01$) in patients with insomnia, however, higher doses of 900 mg were associated with morning sleepiness 83 . Polysomnography-based research has also shown that a prolonged (2 week) course of treatment was associated with reductions in sleep latency, but no overall change in sleep efficiency ⁸⁴. Leathwood et al conducted a study in which subgroup analysis included older adult poor sleepers ⁸⁵. They noted that 63% reported subjective improvement with valerian; however, 43% also noted improvement with placebo and there was thus no statistically significant difference. Valerian has also been used as a tool to assist with weaning patients from benzodiazepines with some limited success. Sleep quality improved and wakefulness after sleep onset decreased, however, there was an increased sleep latency ⁸⁶. Comparisons with benzodiazepines, such as oxazepam have also been performed and have found that valerian was as effective as oxazepam in improving sleep; however, it was not a placebo controlled study and relied on subjective self-report ⁸⁷. Valerian has also been used in combination with other agents, such as hops. This valerian-hops combination resulted in a reduced self-reported sleep latency of 5.6 min (p=0.079) relative to placebo, and all other subjective and polysomnographic measures were similar.

Studies specifically targeting older adults with insomnia have also been conducted using objective measures. A randomized, placebo-controlled study of 14 subjects noted that total sleep time and slow-wave sleep improved with valerian ⁸⁸. The valerian group, however, had significantly worse baseline sleep parameters, thus making it difficult to determine if these results represent a true effect of valerian or a regression towards the mean phenomenon. A later study using a one night dosing paradigm found no significant benefit of valerian relative to placebo ⁸⁹.

In general, valerian has been found to be safe with minimal side effects in the published literature. Rare side effects that have been reported include gastrointestinal upset, contact allergies, headache, restless sleep, and mydriasis ⁹⁰. In comparison to placebo, adverse events occurred at a similar rate, and there was no rebound insomnia or withdrawal effects with valerian ⁹¹. Valerian has been considered as a possible treatment for sleep disruption in comorbid medical states, such as cancer ⁹² and rheumatoid arthritis ⁹³, however due to uncertainty regarding polypharmacy and metabolism, it is not recommended for use in critically ill patients ⁹⁴. Valepotriates may also alkylate DNA, and can thus have theoretical cytotoxic and carcinogenic potential ⁷⁷. Since valerian may act on GABA receptors, valerian may potentiate the sedative effects of other central nervous system depressants ⁹⁵. Research examining the daytime "hangover" cognitive effects found no difference between placebo and valerian ^{91, 96}. There is also a case report of valerian withdrawal symptoms which were characterized by delirium in a patient who had been using one-half to two grams per dose up to five times daily for several years; symptoms improved with benzodiazepine therapy ⁹⁷.

In summary, valerian has been studied in several randomized, placebo-controlled trials, including several studies in older adults. There appears to be evidence of a mild subjective

improvement in sleep with valerian, especially when used for two weeks or more. However, the objective testing has had less consistent results with little or no improvement noted. Some, but not all, studies have observed increased slow wave sleep, which could be an important finding if validated in additional work. Methodological limitations, non-standardized formulations and the small sample size of the existing literature (which creates a higher likelihood of type 2 errors), suggests that future larger studies are needed once a well-characterized and standardized form of valerian is developed.

Manipulative and Body-Based Practices

The manipulative and body-based practices encompass a broad range of therapies that involve hands-on interventions. The majority of the published literature on massage therapy are for sleep disorders in infants and children. Studies in adult populations are limited and tend to focus on patients with comorbid medical conditions. One study examined the use of aromatherapy massage for hospice patients using self-report measures of sleep. This randomized, placebo-controlled study noted no benefits in quality of life or pain control; however, there were statistically significant improvements in sleep and depression 98 . Another randomized study comparing therapeutic massage and relaxation tapes in the management of stress noted that while patients expressed a preference for massage, both modalities showed improvements in sleep, with no significant benefit of one over the other ⁹⁹. Combination therapies using massage have also suggested a benefit, although these often have not included a placebo arm ¹⁰⁰. Polysomnography studies of massage have also been conducted: Richards et al. conducted a randomized trial of a massage intervention compared to placebo and observed a one hour increase in sleep time for the massage therapy group 101. Massage therapy has also been used for fibromyalgia, where it has been found to increase sleep time and reduce pain levels 102, 103.

Another form of manipulative therapy is acupressure, which is a non-invasive technique that involves stimulation of meridian or acupoints on the body using finger pressing movements. It can be administered by nursing staff, or by family members of a patient. Acupressure has been studied in a randomized design in institutionalized older adults ¹⁰⁴. This study noted statistically significant improvements in both the Pittsburgh Sleep Quality Index (primary outcome measure) and number of nocturnal awakenings in the acupressure group relative to the two placebo arms (sham acupressure and conversation). This group has also studied acupressure in end-stage renal patients using a similar design, and also observed evidence of statistically significant improvements in self-reported sleep quality, sleep latency and sleep efficiency ¹⁰⁵. Another study has replicated these findings ¹⁰⁶. Agitated behavior in patients with dementia has also been treated with acupressure, with one study noting reductions in the Cohen-Mansfield Agitation Inventory score, and other metrics of agitation in patients during the acupressure arm relative to the control arm ¹⁰⁷.

Another form of acupressure is auricular therapy, which involves applying pressure to acupoints either via the fingertips, medicinal seeds, or magnets ¹⁰⁸, ¹⁰⁹. Suen et al. conducted a 3 week randomized, single-blind placebo-controlled study using wrist-activity monitoring to provide an objective assessment of sleep parameters between magnetic auricular acupressure and two controls ¹⁰⁹. They observed statistically significant improvements in sleep latency, and sleep efficiency, with an overall increase of approximately 35 min in the total sleep time. Adverse effects were not discussed in their manuscript; however, auricular therapy is generally considered safe. A six month follow-up of this cohort was also conducted and found that insomnia symptoms remained ameliorated in the treatment group relative to the control groups 108.

The results of these studies are very intriguing. However, this work needs to be replicated in additional studies amongst more diverse cohorts before it can be routinely recommended for the management of insomnia.

Acupuncture

Acupuncture, which is considered in the category of alternative medical systems, also acts on meridian points to influence health ⁹. The majority of studies utilizing acupuncture have relied on subjective measures or have not had a placebo control, thus making interpretation of study findings difficult ⁹. Few studies have examined the effects of acupuncture in insomnia using polysomnography ¹¹⁰, ¹¹¹. While both demonstrated evidence of improved sleep, one was a pilot study that was not placebo-controlled ¹¹⁰. This study also demonstrated increases in nocturnal melatonin secretion and reductions in stress/anxiety scores compared to pre-treatment levels.

Acupuncture has also been examined as a treatment modality for sleep disruption due to other conditions, including insomnia post stroke ¹¹² and post menopausal symptoms ¹¹³, ¹¹⁴. Other sleep disorders that have been treated with acupuncture include fibromyalgia ¹¹⁵, ¹¹⁶ and sleep apnea ¹¹⁷, ¹¹⁸.

Meditation

While there are several forms of meditation, one of the most commonly studied for insomnia is mindfulness meditation. Stress reduction may be one of the mechanisms by which meditation can exert a beneficial effect on sleep and most of the studies that have demonstrated improved sleep during meditation therapy have been conducted as stress reduction studies. In this regard, it can be used as part of a cognitive therapy approach. In addition to stress reduction, there may also be differences in slow-wave sleep as a result of meditation ¹¹⁹. Meditation therapy has also been used in cancer patients and found to help improve sleep in two studies ¹²⁰, ¹²¹.

Yoga

Yoga is a multicomponent practice that consists of physical activity associated with specific postures, breathing exercises, and a specific philosophical attitude towards life. It has been shown to reduce anxiety levels and physiologic arousal. A randomized, parallel group study conducted over a six month treatment period compared yoga (60 minute session six days a week, with a 15 minute evening session), Ayurvedic therapy, and wait-list control in 69 older adults ¹²². Self-reported sleep measures were assessed and demonstrated a one-hour increase in total sleep time relative to pre-treatment that was significantly higher than changes in the wait-list or Ayurveda groups. When studied in other populations, such as lymphoma patients, yoga was found to improve subjective sleep parameters when compared to a wait-list control group ¹²³, 124.

Tai Chi

Tai Chi is a low- to moderate-intensity Chinese exercise that includes a meditational component. A study of the effects of Tai Chi (consisting of three 60 minutes sessions for 24 weeks) in 118 older adults in comparison to low-impact exercise noted that Tai Chi improved self-reported sleep duration by 48 min ¹²⁵. General health-related quality of life and daytime sleepiness levels also improved. No injuries were reported in either group. Of note, 33% of subjects withdrew from the study (no significant difference between the Tai Chi and exercise groups). These findings are very interesting and if replicated by additional research using objective measures, could add to the CAM treatment options for insomnia.

Conclusion

This review presents the main CAM therapies for sleep disorders in older adults on which adequate published evidence exists. By far, the largest body of work has been done with melatonin, which has been found to have a benefit in the treatment of circadian sleep disorders, with more equivocal results for primary or secondary insomnia. Valerian has also been found to improve sleep in some studies, but variability in extraction and formulation remains an issue. Other therapies that have shown promise in a limited number of studies need to be replicated in additional work at different sites that would help to validate the early findings in more diverse patient groups. Most of the CAM therapies discussed have benign side effect profiles from the limited body of data currently available. Thus, they hold the potential to significantly benefit sleep in older adults, a population most at risk for polypharmacy and altered drug metabolism. Increased emphasis on objective measures, more rigorous study design (parallel arm placebocontrolled designs) and larger study sample sizes are crucial next steps for the field.

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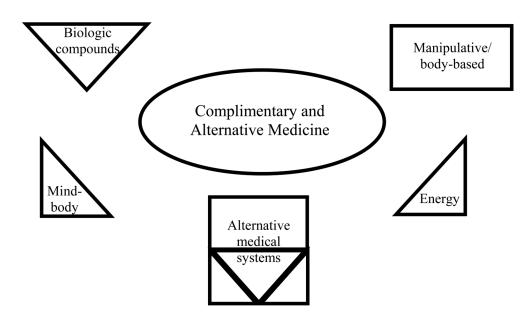
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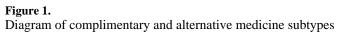
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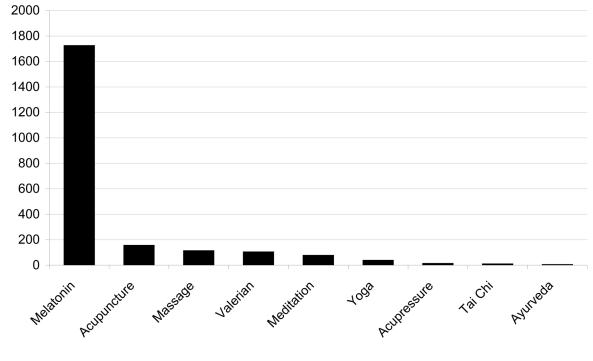
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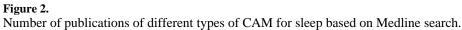
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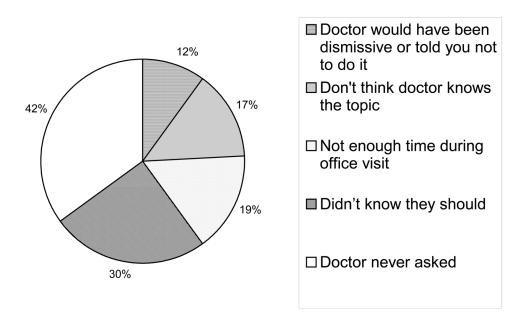


Figure 3.

Reasons cited for not having discussed CAM with their physician. Adapted from American Association of Retired Persons/National Center for Complementary and Alternative Medicine, "Complementary and Alternative Medicine: What People 50 and Over Are Using and Discussing with Their Physicians", 2007

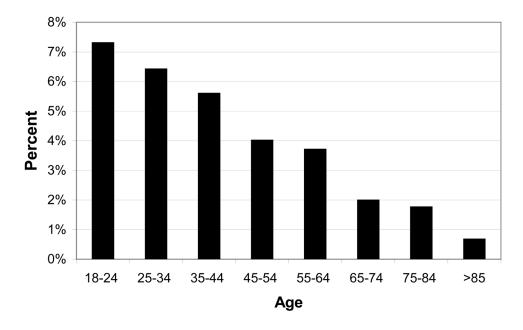


Figure 4.

Prevalence of CAM use by age group. Adapted from Pearson et al., "Insomnia, trouble sleeping, and complementary and alternative medicine: Analysis of the 2002 national health interview survey data", Arch Inter Med, 2006.