A Feasibility Study of Valerian Extract for Sleep Disturbance in Person With Arthritis

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Objectives: To present a pilot study of valerian to explore issues of feasibility and efficacy in studies of sedative herbs for arthritis-related sleep disturbance.

Methods: Fifteen persons with arthritis and mild sleep disturbance were randomized to receive 600 mg valerian (Valeriana officinalis, n = 7) or placebo (n = 8) for five nights.

Results: Protocol adherence (dosing and data collection) was high. Allocation concealment was successful using a novel approach for matching the placebo on the distinctive odor of valerian. Nonsignificant differences between the groups were found on all sleep outcomes, measured by daily diaries and wrist actigraphy.

Conclusion: The study methods were feasible, except for recruitment issues (addressed in the discussion), and may guide the testing of other sedative herbs for persons with arthritis. Although efficacy outcomes were inconclusive due to the small sample size of this study, recent evidence from larger trials of valerian also does not support its efficacy.

Keywords: valerian; arthritis; sleep; insomnia; phytotherapy

Sleep disturbances are becoming increasingly recognized as common symptoms in persons with chronic conditions, such as arthritis. Arthritis affects approximately 46 million persons in the United States (Hootman, Bolen, Helmick, & Langmaid, 2006) and is associated with difficulty falling asleep, frequent nocturnal awakenings, difficulty returning to sleep, and poor perceived sleep quality (SQ; Crosby, 1991; Drewes et al., 1998; Fiedlen et al., 2003; Hamilton, Catley, & Karlson, 2007; Hirsch et al., 1994; Jones, Koh, Steiner, Garrett, & Calin, 1996; Power, Perruccio, & Badley, 2005; Wolfe, Michaud, & Li, 2006; Zamarron, Maceiras, Mera, & Gomez-Reino, 2004; Zautra, Fasman, Parish, & Davis, 2007). Although conventional approaches such as sleep medications or cognitive-behavioral therapy may help, persons with arthritis and sleep disturbance appear particularly interested in complementary and alternative self-care approaches, such as herbal supplements (Jordan et al., 2000).

Valerian (Valeriana officinalis) is an herb with sedative properties that is commonly used as an over-the-counter sleep aid. In vitro and animal studies have shown effects of valerian and valerian constituents at neuroreceptors involved in sleep regulation, including gamma-aminobutyric acid (GABA) and adenosine receptors (Marder et al., 2003; Ortiz, Rassi, Maldonado, Gonzalez-Cabrera, & Ramos, 2006; Schumacher et al., 2002). Research on the efficacy of valerian in humans has produced mixed results and varied in quality. A systematic review published shortly before the implementation of this pilot study concluded that the overall evidence on valerian as a sleep aid was promising but inconclusive (Stevinson & Ernst, 2000). No previous studies have specifically tested valerian in persons with arthritis, but a few studies have tested valerian in older adults, the population in which arthritis is most common. Two...
early studies in older adults found improvement in self-reported ability to fall asleep and SQ with 14 to 30 nights of valerian (Jansen, 1977; Kamm Kohl, Jansen, & Brockmann, 1984).

Following implementation of the pilot study presented in this article, evidence emerged that does not support the general efficacy of valerian as a sleep aid. Three recent randomized, controlled trials tested valerian in older persons. These studies, which were of higher quality than previous evidence, found no significant differences between valerian and placebo on self-report or polysomnographic (PSG, sleep laboratory) sleep outcomes with interventions lasting 1 night (Diaper & Hindmarch, 2004); 14 nights (Donath et al., 2000), or 28 nights (Taibi, Landis, et al., 2007). Recently, one of the authors of this pilot study conducted a comprehensive systematic review (Taibi, Landis, Petry, & Vitiello, 2007) that included a number of trials completed after the previous, inconclusive systematic review (Stevinson & Ernst, 2000). Taibi, Vitiello, et al. (2007) concluded that the overall evidence did not support the efficacy of valerian because most studies, especially several recent, rigorous trials, did not find significant improvement in sleep outcomes with valerian compared to the placebo (Coxeter, Schluter, Eastwood, Nikles, & Glasziou, 2003; Diaper & Hindmarch, 2004; Donath et al., 2000; Jacobs, Bent, Tice, Blackwell, & Cummings, 2005; Kuhlmann, Berger, Podzuweit, & Schmidt, 1999; Vorbach, Gortelmeyer, & Bruning, 1996). Although another recent review using a different approach suggested that valerian may improve subjective sleep quality, this review also found inconsistent effects of valerian on other self-report and PSG sleep outcomes (Bent, Padula, Moore, Patterson, & Mehling, 2006). Therefore, the efficacy data presented here should be viewed in light of the current state of evidence on valerian.

The aims of this pilot study were to test the feasibility of the study design for future research on herbal sleep aids in persons with arthritis and to gather preliminary evidence on the efficacy of valerian to guide a larger trial of the herb. Feasibility outcomes included recruitment and retention, completeness of data collection, participants’ adherence to the data collection and intervention protocols, and effectiveness of allocation concealment. Efficacy outcomes were total sleep time (TST), sleep latency (SL), wake after sleep onset (WASO, calculated as percent of the sleep period), and sleep efficiency (SE) from self-report and actigraphy and sleep quality (SQ) ratings from self-report.

**Materials and Method**

**Sample**

Individuals with arthritis who reported difficulty sleeping were recruited primarily from a medical center rheumatology clinic where the physicians invited potential participants to speak with an onsite study recruiter or provided contact information if study staff were not onsite. Participants were also recruited from private rheumatology and medical practices and from the general community through newspaper and television advertisements, flyers, newsletters, and community events. Although statistical significance was not the primary goal of this feasibility study, a power analysis was done to establish a target sample size. Based on an estimated baseline mean sleep efficiency of 83.5% ± 7% (Leigh, Hindmarch, Bird, & Wright, 1988; Moldofsky, 1986) and a projected gain of 8% units (Donath et al., 2000), a target sample size of 34 (17 per intervention) would yield 80% power to detect group differences over time.

Inclusion criteria were (a) 18 to 70 years old; (b) diagnosed with arthritis (osteoarthritis, rheumatoid arthritis, inflammatory polyarthritis, ankylosing spondylitis, or psoriatic arthritis); (c) Pittsburgh Sleep Quality Index PSQI ≥ 5 to confirm sleep disturbance; (d) average pain ≥ 3 on a 0–10 numeric rating scale (NRS); and (e) use of adequate methods of birth control (women of reproductive age). Exclusion criteria were (a) diagnosis of fibromyalgia, lupus, chronic fatigue syndrome, or congestive heart failure; (b) shift work or travel across time zones; (c) treatment within the past year for depressive or bipolar disorder; (d) use of selected psychotropic medications or glucocorticoids; (e) diagnosis or symptoms of sleep apnea; (f) pregnancy or breastfeeding; (g) current or past history of liver disease or alcoholism; (h) plasma hepatic function tests outside the normal ranges; and (i) self-reported inflammatory flare of arthritis.

A computer-generated randomization schedule was kept by the University of Virginia (UVA) Investigational Pharmacy, which also assigned the valerian and placebo bottles code numbers and kept the record of group assignment. The investigators, study staff, and participants remained blind to assignment until after completion of the primary statistical analyses. The study protocol and consent form were reviewed and approved by the UVA General Clinical Research Center (GCRC) Protocol Review Committee and the Human Subjects Committee (Institutional Review Board).
Intervention
The product tested was Nature’s Resource valerian root extract (Valeriana officinalis extracted with 70% ethanol, 100-mg softgels, 0.8% valerenic acid by certificate of analysis, Pharmavite, LLC., San Fernando, CA). A 600-mg dose was given (6 softgels). The placebo softgels (Pharmavite) contained 100 mg soybean oil (without significant amounts of vitamin E or phytoestrogens), gelatin, glycerin, and water. Only one lot each of the valerian and placebo were used in the study. The valerian and placebo were identical in appearance and odor. To mask the placebo softgels, these were stored in plastic bottles that had previously contained 30 valerian softgels for at least one week, thus retaining the distinctive aroma of the volatile acids of valerian.

Baseline Measures
At baseline, participants completed the Health Assessment Questionnaire (HAQ) of functional status (scored 0–3, higher scores indicate greater limitation; Fries, Spitz, Kraines, & Holman, 1980) and the Rapid Assessment of Disease Activity in Rheumatology (RADAR) count of tender/painful joints (scored 0–48, higher scores indicate greater joint tenderness; Calvo et al., 1999; Mason et al., 1992). Average pain at baseline was rated on a numeric rating scale of 0 (no pain) to 10 (worst pain possible).

Feasibility Outcomes
Recruitment and retention were reported through descriptive summaries. Data collection was assessed by the percentage of the diaries completed by each individual. Protocol adherence was assessed by the number of dosing errors determined by pill counts (participants were given 33 softgels although only 30 were needed, and remaining softgels were counted at follow-up) and by participant reports of dosing time in the daily diaries. To check the effectiveness of allocation concealment at the end of the study, participants answered the question “Which intervention do you believe you received?” by responding: valerian, placebo, or uncertain.

Efficacy Outcomes
Daily sleep diaries. Participants completed daily sleep diaries each morning, reporting SQ ratings using a 0 (extremely poor) to 10 (extremely good) NRS, SL, WASO, and time in bed (TIB). Total sleep time was calculated (TIB – SL – WASO – time between awakening and arising) as was sleep efficiency (SE = TST/TIB × 100).

Wrist actigraphy. Sleep outcomes were assessed by Mini-Motionlogger wrist actigraphs (Ambulatory Monitoring Inc, AMI; Ardsley, NY). An actigraph is a small, watch-like accelerometer worn on the wrist to measure activity as a proxy measure of sleep given that activity levels are minimal during sleep (Sadeh & Acebo, 2002). Participants wore the actigraph for all eight study days. At bedtime and upon arising, participants pressed an event marker button on the device. The event markers were used to validate bed/rise times noted in the daily diaries when analyzing the actigraph data. The actigraphs were initialized to zero-crossings mode and to record activity counts over 1-min epochs. The stored data were scored using the Action-4 software package (AMI). Each epoch of activity was scored as sleep or wake using the Cole-Kripke algorithm, which has been well-validated in adult populations.

Adverse effects. To assess adverse effects, participants responded in the daily diaries to the question, “Did you experience any symptoms today that you do not normally experience? If so, please describe.” Liver function tests (LFTs) and serum high-sensitivity C-reactive protein (CRP, an inflammatory marker) were measured at both screening and follow-up to check for potential adverse effects on hepatic function or inflammation.

Procedure
After obtaining signed informed consent from participants and confirming arthritis diagnoses with participants’ physicians, a screening visit was completed (Visit 1) that included screening and baseline questionnaires (PSQI, demographics, HAQ, RADAR, pain NRS) and collection of a blood sample for LFTs and CRP. Eligible participants were then randomized to receive valerian or placebo. At Visit 2, participants received instructions, valerian or placebo softgels, daily diaries, and the wrist actigraph. The first 3 nights of measurement assessed baseline sleep; no softgels were taken. The next 5 nights, participants took 600 mg of valerian extract or placebo (6 softgels) 1 hour before bedtime. Within 48 hours of the last
Table 1. Characteristics of the Sample

<table>
<thead>
<tr>
<th></th>
<th>Placebo (n = 8)</th>
<th>Valerian (n = 7)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>53.13 ± 10.73</td>
<td>39.29 ± 18.67</td>
</tr>
<tr>
<td>Education (years)</td>
<td>16.38 ± 3.99</td>
<td>16.14 ± 3.67</td>
</tr>
<tr>
<td>HAQ (0-3 scale)</td>
<td>.25 ± .28</td>
<td>.15 ± .16</td>
</tr>
<tr>
<td>RADAR (0-48 scale)</td>
<td>5.87 ± 4.94</td>
<td>8.00 ± 5.63</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Marital status</td>
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</tr>
<tr>
<td>Married/partnered</td>
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<td>5</td>
</tr>
<tr>
<td>Not married</td>
<td>3</td>
<td>2</td>
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<tr>
<td>Employment</td>
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<tr>
<td>Working/homemaker/</td>
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<tr>
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<tr>
<td>Disabled</td>
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<td>1</td>
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<tr>
<td>Retired</td>
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<td>0</td>
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<tr>
<td>Arthritis diagnosis</td>
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<tr>
<td>Inflammatory arthritis</td>
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<td>4</td>
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<tr>
<td>Osteoarthritis</td>
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<td>1</td>
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<tr>
<td>Spondyloarthropathy</td>
<td>2</td>
<td>2</td>
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<tr>
<td>Medications</td>
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<tr>
<td>Analgesics</td>
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<td>2</td>
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<tr>
<td>Biologic response</td>
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<td>2</td>
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<tr>
<td>DMARDs</td>
<td>3</td>
<td>3</td>
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<td>NSAIDs</td>
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</table>

NOTE: Values provided are M ± SD or n. Analgesics included acetaminophen and tramadol. DMARD = disease-modifying anti-rheumatic drug; HAQ = Health Assessment Questionnaire; NSAID = nonsteroidal anti-inflammatory drug; RADAR = Rapid Assessment of Disease Activity in Rheumatology.

Results

Sample Characteristics

15 participants were enrolled in the trial (valerian group, n = 7; placebo group, n = 8), but actigraphy data were not available from one participant in the valerian group because of a device malfunction. Differences between the group characteristics were nonsignificant (Wilcoxon signed-ranks or chi-square tests, see Table 1). Mean scores on the HAQ and RADAR were low, indicating mild arthritis symptoms.

Feasibility

A total of 54 individuals contacted the research staff or spoke with the study recruiter at the clinic, 47 of whom were assessed for eligibility (7 could not be reached for screening). 32 participants were determined ineligible during the screening phase (Figure 1). 15 individuals qualified and were enrolled. Participants were recruited from the rheumatology clinic (n = 8), word-of-mouth (n = 4), classified advertisement (n = 1), a community arthritis clinic (n = 1), and advertisement in a large church newsletter (n = 1).

Once enrolled, all participants completed the intervention and all study visits. The diaries were returned with little missing data (mean missing = 0.7% missing, range = 0–3%). 7 participants were not missing any diary data.

Adherence to the intervention was high. Despite the strong odor of valerian and the matched placebo, no participants declined to take the study softgels. The pill counts to check for adherence to the dosing instructions revealed only two minor deviations: one valerian dose skipped due to late afternoon nausea and one extra pill remaining from a placebo-group participant. Dose timing was checked from the daily sleep diaries. Most nights, the participants reported taking the study softgels +30 min from the instructed time of 60 min before bedtime. 8 participants took the softgels more than 2 hr prior to bedtime on one night (n = 7) or two nights (n = 1). One
participant failed to note dosing time on two nights, but the pill count was correct. Overall, errors in either nightly administration or dose timing occurred on 12 of the 75 total dosing days (16%).

When asked whether they believed they received valerian, placebo, or were uncertain, the two groups were not significantly different in their responses ($\chi^2 = 0.80$, $p = .67$). All participants reported that they based their judgment on the perceived effectiveness of the intervention that they had received. None noted the appearance or aroma of the softgels, indicating that masking was successful.

Side Effects

During the intervention days, 5 participants in the valerian group reported a total of 7 unusual symptoms (10 occurrences, Table 3). The symptoms of musculoskeletal complaints, cold, sore throat, nausea, and headache were likely unrelated to the valerian, especially given that the latter two occurred late in the day and prior to ingestion of the valerian. The symptoms of dizziness and sleepiness (both in the same participant) were possibly related to the valerian. Plasma LFTs remained within normal limits in both groups. Serum CRP levels did not differ significantly between the groups.

Discussion

Feasibility

Recruitment and Retention. In this study, recruitment did not reach the targeted sample size ($N = 34$) despite extensive efforts, but retention of participants in the study was highly successful. Onsite recruitment at the rheumatology clinic was the most labor-intensive approach but also the most successful. Successful advertising strategies included announcements on public access television, the university clinical trials Web site, and a newsletter of a large local church as well as flyers on university buses. On the other hand, some of the extensive advertising efforts were relatively unsuccessful, including mailing flyers to over 500 health-oriented business, health care practices, and local churches; advertising in community newspapers; and posting flyers in community businesses. The low level of compensation ($30) and competition with recruitment for other arthritis studies in the area may have contributed to the recruitment difficulties.

The entire sample was of white ethnicity, which was surprising in light of our success recruiting African American participants through the rheumatology clinic in previous studies. The reasons for difficulty recruiting a racially diverse sample are unclear but may be related to the success in recruiting residents of rural areas where African Americans are less represented (10%) than in the city of Charlottesville (22%) (U.S. Census Bureau, 2000). Future recruitment efforts should take specific steps to address this problem, such as developing partnerships with community-based organizations and churches that represent African Americans and other racial/ethnic groups.
In addition to the issues discussed above, the stringent eligibility criteria also contributed to the recruitment difficulties. Five screened individuals were excluded due to medication restrictions and six due to the BMI restriction. Because the clinic rheumatologists did not note how many persons were not invited to participate based on their prescreening of the patient charts, it is unknown how many persons were actually disqualified by these criteria.

Persons with a BMI > 30 kg/m² were excluded because obstructive sleep apnea syndrome (OSAS) is associated with obesity (Young, Peppard, & Taheri, 2005). Persons with OSAS are commonly excluded from insomnia studies because OSAS-related sleep disturbance may obscure improvement in insomnia. OSAS is diagnosed by an overnight (PSG) sleep study (Kushida et al., 2005); thus future studies of herbal sleep aids may be able to use less strict BMI criteria by using PSG screening for OSAS. Because obesity is a risk factor for osteoarthritis as well as OSAS (Arden & Nevitt, 2006), greater inclusiveness would increase the representativeness of the study sample and the generalizability of the findings.

Another strict eligibility criterion was the exclusion of numerous medications due to reported potential for valerian to reduce the metabolism of these drugs, possibly resulting in increased blood levels. When we started the study, in vitro evidence showed that valerian inhibited intestinal and liver enzymes that metabolize over half of all marketed medications (Budzinski, Foster, Vandenhoek, & Arnason, 2000; Guengerich, 2003; Strandell, Neil, & Carlin, 2004). This exclusion was particularly problematic because individuals with arthritis often take numerous daily medications. More recent in vivo studies in humans showed that valerian did not significantly affect actual serum levels of drugs metabolized by these enzymes (Donovan et al., 2004; Gurley et al., 2005; Henderson, Miranda, Stevens, Deinzer, & Buhler, 2000). This exclusion was particularly problematic because individuals with arthritis often take numerous daily medications. More recent in vivo studies in humans showed that valerian did not significantly affect actual serum levels of drugs metabolized by these enzymes (Donovan et al., 2004; Gurley et al., 2005; Henderson, Miranda, Stevens, Deinzer, & Buhler, 2000).

Retention efforts were highly successful. Important retention strategies included follow-up by telephone and traveling to meet the participants. Approximately

<table>
<thead>
<tr>
<th>Table 2. Sleep Outcomes (M ± SD)</th>
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<tr>
<td><strong>Total Sleep Time (min)</strong></td>
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<tr>
<td>Placebo</td>
</tr>
<tr>
<td>Baseline</td>
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<tr>
<td>Intervention</td>
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<tr>
<td>Valerian</td>
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<tr>
<td>Baseline</td>
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<th>Table 3. Adverse Events Reported During the Intervention</th>
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<tr>
<td><strong>Placebo</strong></td>
</tr>
<tr>
<td>Group (n)</td>
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<tr>
<td>Participants reporting symptoms</td>
</tr>
<tr>
<td>Cold symptoms</td>
</tr>
<tr>
<td>Daytime dizziness</td>
</tr>
<tr>
<td>Daytime nausea</td>
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<tr>
<td>Daytime sleepiness</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Morning drowsiness</td>
</tr>
<tr>
<td>Musculoskeletal pain</td>
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<tr>
<td>Sore throat</td>
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</table>

NOTE: Baseline represents the mean of Nights 1 and 2, intervention represents the mean of Nights 7 and 8. No significant differences were found by analysis of covariance for self-report sleep latency (p > .05) or by RM-ANOVA for all other outcomes (time x group, p > .05). NA = not applicable. WASO = wake after sleep onset.
half \((n = 8)\) of the participants lived an hour or more from the study location. Willingness to meet these participants in their homes proved highly effective for recruitment and retention of participants in rural areas of the region.

**Protocol Adherence and Data Collection.** Participants reported adhering closely to the daily dosing of six softgels but deviated occasionally from the instructed dosing time of one hour before bedtime. Reasons for the timing errors were not apparent given that participants were instructed at the beginning of the study, called on the first day of dosing, and reminded in the daily diaries. This issue is particularly important in studies of herbs because therapeutic effects are believed to be more subtle than effects of conventional pharmaceuticals, and deviations from recommended dosing may obscure possible clinical effects in the study outcomes.

Adherence to the data collection protocol was high. Data collected from the sleep diaries and actigraphy contained a low proportion of missing data. The eight participants with incomplete diaries tended to omit the same question repeatedly, although the particular question omitted varied between participants. Careful review of dosing adherence and diary responses throughout long-term data collection may provide opportunities for additional instruction of participants who are repeatedly nonadherent to the protocol. Only one night of actigraphy data was lost due to a participant forgetting to wear the device. The most problematic issue causing the loss of actigraphic data was related to device malfunction (initiation to the wrong signal amplification setting) rather than participant error. This problem would not occur with the newer actigraph models.

**Effectiveness of Allocation Concealment.** This study used a novel approach to masking the placebo which was highly successful, given that none of the participants were able to differentiate the valerian from the placebo based on appearance or odor. The placebo bottles were “odorized” with the valerian product. Another recent trial of valerian used a slightly different, but equally successful, approach, odorizing the actual placebo capsules by storing them in proximity to, but not touching, a particularly odoriferous valerian preparation (Taibi, Vitiello, et al., 2007). Several herbs, in addition to valerian, have volatile constituents with strong, recognizable odors, and failure to address the aroma may allow for participants’ distinction between the verum treatment and the placebo. This issue has been a particular weakness of previous valerian research, with few studies reporting masking of the placebo.

**Efficacy**

This pilot study gathered preliminary evidence on the efficacy of valerian to reduce sleep disturbance in persons with mild arthritis and mildly fragmented sleep. The study did not find any significant differences between the valerian and placebo either in statistical comparisons or in graphical exploration of daily trends within individuals. These findings should be interpreted with caution because of the small sample size and the short treatment duration that was less than the 2 weeks’ use often recommended for valerian to be effective. However, placed in the broader context of current research on valerian as a sleep aid, this study is consistent with the null findings of larger, more rigorous studies of longer duration (Coxeter, et al., 2003; Diaper & Hindmarch, 2004; Donath et al., 2000; Jacobs, et al., 2005; Kuhlmann, et al., 1999; Vorbach, et al., 1996).

**Future Research**

The evidence on valerian and other herbal sedatives, including hops, lemon balm, passion flower, and chamomile, has not yet addressed certain relevant issues. First, no studies were found that tested these herbs for specific patterns of insomnia symptoms (i.e., difficulty falling asleep versus difficulty remaining asleep) that may respond differently depending on the pharmacokinetics of various herbs. Second, no studies have specifically tested liquid preparations (teas, tinctures) of herbal sleep aids, which may have different effects than dried extracts. This gap in the literature is significant given that the German Commission E monographs and the British Herbal Pharmacopeia, both highly-regarded resources, base many dosing recommendations on liquid preparations of herbal sedatives (Blumenthal, 1998; Schulz, Hansel, & Tyler, 2001).

Finally, little research exists on herbal combinations formulated specifically for an individual’s symptom patterns, which is common practice among herbalists. The field of acupuncture research may inform the design of such trials. Acupuncture study protocols often allow individualization of treatment by allowing selection of treatment options based on
assessment of symptom patterns according to traditional Eastern medical theory rather than Western medical diagnoses (Ahn & Kaptchuk, 2005). This approach maintains fidelity to the whole system of treatment being tested rather than imposing a Western paradigm upon a traditional practice. Similar research methods may be useful for herbal research by allowing for the use of certain combinations of herbs within a protocol based on traditionally assessment of insomnia symptoms.

In summary, sleep disturbance is a common symptom in chronic conditions, including arthritis, and treatment should include direct care of sleep disturbance. Persons with arthritis-related sleep disturbance show interest in using herbs, but little evidence exists on the efficacy of herbal products for improving sleep in this population. Although this pilot study lacked sufficient statistical power to arrive at definitive conclusions on the efficacy of valerian, the current research literature on the herb does not support its use as a sleep aid. Other herbs may be useful, but little evidence exists. The feasibility issues discussed in this report may guide future research on herbal sedatives in persons with chronic conditions such as arthritis.

References


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