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A Double-blind, Placebo-controlled Investigation of the Effects of *Passiflora incarnata* (Passionflower) Herbal Tea on Subjective Sleep Quality

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***Passiflora incarnata* is a traditional herbal sedative, anxiolytic and a popular sleep aid used for the treatment of sleep disturbance. Several controlled experiments have demonstrated enhanced sleep in laboratory animals, but clinical trials in humans are lacking. The aim of the present study was to investigate the efficacy of *Passiflora incarnata* herbal tea on human sleep, as measured using sleep diaries validated by polysomnography (PSG). This study featured a double-blind, placebo-controlled, repeated-measures design with a counterbalanced order of treatments (passionflower vs placebo tea), separated by a 1 week 'washout' period. Forty-one participants (18–35 years) were exposed to each treatment for a week, whereby they consumed a cup of the tea and filled out a sleep diary for 7 days, and completed Spielberger's state-trait anxiety inventory on the seventh morning. Ten participants also underwent overnight PSG on the last night of each treatment period. Of six sleep-diary measures analysed, sleep quality showed a significantly better rating for passionflower compared with placebo ($t(40) = 2.70$, $p < 0.01$). These initial findings suggest that the consumption of a low dose of *Passiflora incarnata*, in the form of tea, yields short-term subjective sleep benefits for healthy adults with mild fluctuations in sleep quality.**

Keywords: Passiflora; *Passiflora incarnata*; passionflower; sleep; polysomnography; herbal tea.

INTRODUCTION

Epidemiological studies have estimated that about one-third of the general population worldwide suffers from varying degrees of insomnia (Ohayon, 2002). The use of herbal medicines as an alternative treatment for insomnia symptoms has been increasing, because herbal products are readily accessible over the counter and are generally perceived to be safe (Gyllenhaal *et al*., 2000). However, many traditional sedative herbs, such as *Passiflora incarnata*, are employed to aid sleep without scientific support for their efficacy and safety for human consumption (Meoli *et al*., 2005).

Passiflora incarnata, commonly known as passionflower, is a climbing vine with white purple-tinged flowers (Cronin, 2003). It is a folk anxiolytic and sedative used for the treatment of anxiety and insomnia symptoms, and has a history of use as a sedative in Brazil, Iraq, Turkey and North America (Dhawan *et al*., 2001a, 2004). To date, there is little scientifically validated evidence regarding either the constituents of *Passiflora incarnata* that are responsible for the speculated sedative and anxiolytic effects, or the plant's mechanism of action on sleep (Cronin, 2003; Dhawan *et al*., 2004).

The possible therapeutic use of *Passiflora incarnata* in the treatment of anxiety has been studied mainly in animals. There is consistent evidence supporting an anxiolytic effect of *Passiflora incarnata* in mice, as a significant anxiolytic effect was observed in the elevated plus-maze apparatus of anxiety at doses ranging from 75 to 300 mg/kg, with a peak effect at 125 mg/kg (Dhawan *et al*., 2001a, 2001b, 2001c, 2003). After finding no anxiolytic effect at the highest dose of 300 mg/kg, Dhawan *et al*. (2001c) suggested that the diminishing anxiolytic effect found at the higher doses could be masked by the sedative property of *Passiflora incarnata*.

Although the effects of *Passiflora incarnata* have rarely been studied in humans, two clinical trials have demonstrated its efficacy in the treatment of anxiety (Akhondzadeh *et al*., 2001b; Movafegh *et al*., 2008). Two further studies using the plant in the treatment of opiate withdrawal (Akhondzadeh *et al*., 2001a) and attention-deficit hyperactivity disorder (Akhondzadeh *et al*., 2005) have attributed treatment effects to anxiolytic and sedative action of the passionflower extract. In Akhondzadeh *et al*.'s (2001b) study, the Hamilton anxiety rating scale was employed to assess the anxiety levels of 36 outpatients diagnosed with generalized anxiety disorder. The anxiety scores indicated that passionflower (45 drops of *Passiflora incarnata* extract per day) was as effective as the positive control condition (30 mg of oxazepam per day) in reducing anxiety levels at the end of the 28 day treatment. Similarly, Movafegh *et al*. (2008) used a numerical rating scale to evaluate the anxiety levels of 60 ambulatory surgery patients during the 90 min period between premedication (placebo or 500 mg passionflower tablets) and surgery. They found that the passionflower group had significantly lower anxiety ratings than the placebo group after premedication. These clinical findings indicate that *Passiflora incarnata* may be effective

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in reducing short-term and long-term heightened anxiety levels, though Akhondzadeh *et al.*'s (2001a, 2001b) findings could be attributed to expectancy effects because no placebo-controlled conditions were employed in these studies.

Since anxiety has been shown to be correlated positively with sleep disturbance (Spira *et al.*, 2008; Spoormaker and van den Bout, 2005), *Passiflora incarnata* may enhance sleep in humans as a secondary consequence of its anxiolytic effects. The sedative effects of *Passiflora incarnata* have been examined in mice and rats, whereby the animals were injected with either a passionflower preparation or vehicle liquid, followed by pentobarbital to induce sleep. Sleep initiation and duration were measured based on the absence of rolling back when turned over, and the time elapsed between the loss and the regaining of the righting reflex. It was found that passionflower extracts significantly prolonged the pentobarbital-induced sleep time in mice at doses ranging from 60 to 400 mg/kg (Capasso and Sorrentino, 2005; Dhawan *et al.*, 2003; Speroni and Minghetti, 1988; Speroni *et al.*, 1996a, 1996b). Soulimani *et al.* (1997) reported that an aqueous passionflower extract, but not a hydroalcohol extract, potentiated sleep initiation in mice at 200, 400 and 800 mg/kg doses, with a significant effect at 800 mg/kg. Thus, the sedative effects seemed to be dose-dependent, but were reportedly influenced by the solvent used to prepare the extract.

Contrary to the findings in mice, rat studies have failed to find that *Passiflora incarnata* has any significant influence on various sleep parameters, such as sleep duration (Zanoli *et al.*, 2000), and also sleep-onset latency, number of awakenings, duration of rapid eye movement (REM) and non-REM sleep measured via electroencephalography (Shinomiya *et al.*, 2005). The inconsistent findings might be due to the species variation, or the sample size of 8–12 rats being too small to observe statistically significant differences between treatment conditions. Despite these initial animal experiments, there appear to be no studies that have examined the possible sedative effects of *Passiflora incarnata* on human sleep.

In human sleep research, sleep is assessed by reference to a selection of sleep parameters, which can be measured subjectively via sleep diaries and objectively via polysomnography (PSG; Lockley *et al.*, 1999). Although subjective and PSG measures of sleep have been found to be positively correlated (Argyropoulos *et al.*, 2003; Bastien *et al.*, 2003), discrepancies between these sleep measures have also been acknowledged (Bastien *et al.*, 2003; Lockley *et al.*, 1999). Therefore, sleep research should incorporate the use of both sleep diaries and PSG and their relationship to one another examined.

The aim of this study was to investigate whether *Passiflora incarnata* tea has a positive impact on aspects of human sleep relative to a placebo condition. It was hypothesized that this would be evident from better subjective sleep reports and PSG records. It was further hypothesized that there would be significant positive correlations between subjective and PSG measures of sleep.

MEASURES AND METHODS

Participants. Forty-one healthy volunteers (14 males and 27 females), aged 18–35 years ($M = 22.73$ years, $SD = 6.22$), were recruited through advertisements placed around the university campus. Of this sample, three males and seven females ($M = 23.20$ years, $SD = 6.22$) also participated in an optional PSG study at the university sleep laboratory, and were reimbursed with a sum of $40 for travel expenses. All participants provided their written informed consent prior to commencing the experiment, which was approved by the University Human Ethics Committee (project number: CF07/2803 – 2007001721).

Screening questionnaire. Volunteers were required to answer questions concerning their health and sleeping patterns. Without the availability of comprehensive polysomnographic assessment of participants, it was decided to exclude volunteers with health problems and extreme sleep difficulties. This was primarily related to the multifaceted etiology of sleep disruption, as many people with extreme sleep difficulties will typically have sleep fragmentation syndromes such as sleep apnea, periodic limb movements or bruxism, rather than primary insomnia *per se*. The criteria for exclusion from participation were as follows: (a) a habitual sleep duration of less than 4 h or more than 10 h; (b) presence/history of a sleep disorder; (c) presence of a substance dependency (alcohol or drugs); (d) presence of a heart or blood vessel disease; (e) presence of a medical condition or mental illness that is known to affect sleep; (f) current use of drugs, melatonin products, remedies or medications other than contraceptives; (g) pregnancy or lactation; and (h) three or more naps a week.

Passionflower and parsley teabags

Passionflower teabags (each containing 2 g of dried *Passiflora incarnata* leaves, stems, seeds and flowers) and parsley teabags (each containing 2 g of dried *Petroselinum crispum*) were manufactured by Hilde Hemmes' Herbal Supplies Pty Ltd (SA, Australia) specifically for the present study. Passionflower was the experimental treatment, whereas parsley was employed as the placebo. The packaging of passionflower and placebo teabags was identical, with teabags sealed in a foil bag and placed inside a carton box. All boxes were identified by a letter 'A' (placebo) or 'B' (passionflower). This identification was known only by the senior investigator who did not engage in data collection or analyses.

Preparations of herbal teas. Aqueous delivery of the dried herbs in the form of tea preparations was used, as previous animal experiments had shown distilled water preparations of *Passiflora incarnata* to be successful (Dhawan *et al.*, 2003; Soulimani *et al.*, 1997), and this was also thought best to represent ecologically the current ingestion of such commercial preparations in the general population. To ensure consistent delivery of the tea preparations, participants were given standard styrofoam cups with lids and were instructed to infuse the relevant teabag with boiling water in the full covered cup provided (equivalent to 250 mL) for 10 min before removing the teabag.

Sleep diary (for subjective sleep measures). The diary, consisting of two sections, was a measure of the

participants' subjective perception of their sleep during the two treatment periods. For the evening section, participants were required to record the number and duration of naps, types and amount of caffeine/alcohol consumption, and bedtime. For the morning section, participants were required to record the time taken to fall asleep, number and duration of awakenings, wake time before rising, rising time, feelings upon rising (on a five-point scale, ranging from [1] fatigued to [5] very refreshed), and sleep quality (on a five-point scale, ranging from [1] poor to [5] excellent).

PSG recording (for objective PSG sleep measures). Sleep was monitored using a Compumedics S-Series 16 channel polygraph. The recording montage consisted of standard electroencephalogram (EEG), electrooculogram (EOG) and electromyogram (EMG) channels (Rechtschaffen and Kales, 1968). For EEG recording, grass gold cup disk electrodes were affixed to the scalp at C4/A1 and C3/A2 according to the international 10–20 placements system (Jasper, 1958). For EOG recording, electrodes were placed at the inner canthi of each eye and each referenced to Fpz. For EMG recording, electrodes were placed at the mentalis musculature of the chin. Prior to electrode attachment, each site was prepared using 70% v/v isopropyl alcohol swabs to remove any surface oil. EEG sites were abraded using trace preparation tape to reduce impedance. Electrodes were attached to the head using electrode paste and gauze, and attached to the face using electrode paste and surgical tape. Recording impedance was maintained below 5 Kohms.

State-trait anxiety inventory, state version, form-Y (STAI-S). This 20-item state anxiety scale was designed to measure the extent to which respondents are experiencing anxiety symptoms as they complete the scale (Spielberger, 1983). Responses were made on a four-point Likert scale. Total anxiety scores could vary from 20 to 80 with higher scores indicating higher levels of state anxiety.

Design. The present study featured a double-blind, placebo-controlled, repeated-measures design. The independent variable was the treatment condition (passionflower vs placebo). Both the experimenter and participants were blind to the treatment conditions. Participants received each treatment for a week during which their subjective and objective PSG sleep and STAI-S score were recorded, with a 1 week 'washout' period in between to remove any residual effect from the first treatment. The order of the treatments was counterbalanced. The dependent variables consisted of four quantitative sleep parameters (sleep efficiency, total sleep time, sleep onset-latency, and number of nocturnal awakenings), two qualitative sleep parameters (sleep quality and feelings of refreshment upon rising) and STAI-S score. The PSG and subjective sleep parameters measured during the placebo treatment were employed as a baseline comparison with those measured during the passionflower treatment. Moreover, PSG measurements were used to evaluate the validity of the subjective quantitative sleep measurements.

Procedure. Interested volunteers were invited to attend a 10–30 min briefing session and to complete the screening questionnaire to determine their eligibility to participate in this study. Those not eligible for the study were debriefed at the session. Eligible volunteers were given the sleep diary together with the STAI-S (with a unique code number for identification), a packet of each of the passionflower and parsley teabags, and an outline of the experimental procedures which is illustrated in Fig. 1.

All participants underwent the passionflower or placebo treatment first for a week, followed by a 1 week break, then the remaining treatment for another week. From day 1 to day 7, participants prepared a cup of tea according to the instructions provided to them, consumed the tea approximately an hour before bedtime, and filled out the sleep diary preceding sleep. From day 2 to day 8, the participants filled out the sleep diary upon rising. On day 7, participants completed the STAI-S in the morning; those who participated in the PSG study arrived at the university sleep laboratory at least an hour before their usual bedtime and slept there overnight after being connected for PSG recording.

RESULTS

All 41 participants returned the sleep diary and STAI-S; 10 of them completed the PSG study. Six subjective sleep parameters were selected for statistical analysis. Sleep-onset latency (SOL), sleep quality (SQ), number of nocturnal awakenings (NNA) and feelings of refreshment upon rising (FR), were drawn directly from the sleep diaries. Total sleep time (TST) and sleep efficiency (SE) were derived from information implicit

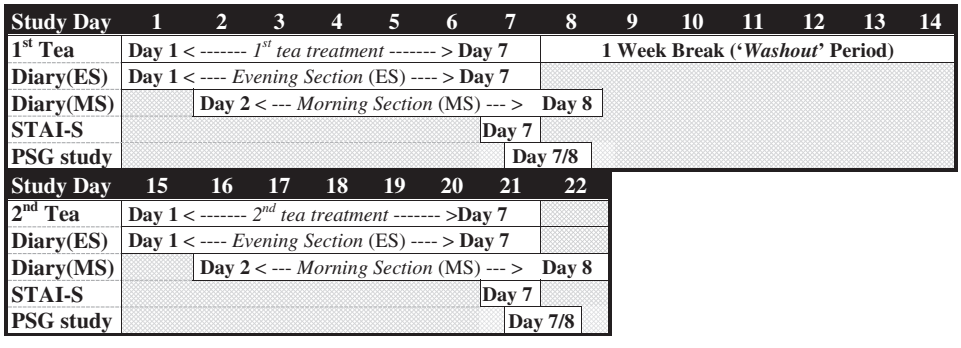

Figure 1. The protocol for the 22 day study. The experimental tasks are shown in the first column below the heading 'Study Day'. The shaded areas indicate the days on which each of the tasks occurred.

in the sleep diaries. Each subjective sleep parameter was averaged across the 7 day records of each treatment period. Furthermore, 20 PSG recordings were scored by an experienced sleep technician blind to the treatment conditions. A PSG report for each recording was generated to provide the data for quantitative sleep parameters, including NNA, SE, SOL and TST.

All statistical analyses were performed using the 'Statistical Package for Social Scientists' (SPSS for windows, standard version 15.0.1.1). Due to the small sample size, no outliers were excluded from any of the data analyses (Tabachnick and Fidell, 2007). Since one participant failed to consume the passionflower tea on day 6 evening, the participant's STAI-S scores and sleep diary data recorded on day 6 evening and day 7 morning were excluded from the pooled data. Another participant failed to report SOL. Therefore, when analysing the data for subjective SOL and state anxiety, n was reduced to 40.

Treatment effects on the sleep parameters

Preliminary analyses were performed on the sleep parameters to determine any violations of the assumption of normality underlying t-tests. Violations were detected for subjective NNA, and subjective and PSG SOL, as they differed significantly from a normal distribution according to the Shapiro-Wilk W statistic ($p < 0.05$). Thus, the median and interquartile range, along with non-parametric Wilcoxon signed-rank tests, were used when comparing these variables. For the remaining comparisons, mean, standard deviation and paired-samples t-tests were used. To account for multiple comparisons of related measures of sleep, the type I error rate was set at $\alpha = 0.01$, which is approximately consistent with the Bonferroni adjustment method ($\alpha = 0.05/6$; Tabachnick and Fidell, 2007).

Comparisons of the subjective sleep parameters between conditions revealed no significant differences in subjective SOL (Wilcoxon $Z = 0.61$, $p > 0.01$), NNA (Wilcoxon $Z = 0.65$, $p > 0.01$), SE, TST and FR as shown in Table 1, but the mean rated SQ was found to be significantly higher in the passionflower condition than the placebo.

The PSG measures of quantitative sleep parameters paralleled the results for the corresponding subjective measures. No significant differences were observed in the objective SOL between the passionflower ($Md = 15$, interquartile range = 18) and placebo ($Md = 8$, interquartile range = 26) conditions (Wilcoxon $Z = 0.61$, $p > 0.01$), the mean objective SE between the passionflower ($M = 87.73$, $SD = 9$) and placebo ($M = 85.72$, $SD = 11.85$) conditions ($t(8) = -1.37$, $p > 0.01$), the mean objective TST between the passionflower ($M = 411.89$, $SD = 37.65$) and placebo ($M = 398.33$, $SD = 48.35$) conditions ($t(8) = -1.29$, $p > 0.01$), and the mean objective total NNA between the passionflower ($M = 28.11$, $SD = 11.37$) and placebo ($M = 26.44$, $SD = 13.82$) conditions ($t(8) = -0.40$, $p > 0.01$). Also, paired samples t-tests revealed no significant differences in the duration of slow-wave sleep (SWS; $t(8) = -0.61$, $p > 0.01$) and REM sleep ($t(8) = -1.48$, $p > 0.01$) between conditions.

Correlations between subjective sleep and PSG measurements

The scatterplots of the subjective and PSG data for the quantitative sleep parameters are presented in Fig. 2. On inspection of the SE and NNA scatterplot, the residuals showed considerable variation across the range and therefore appeared to have violated the assumption of homogeneity of variance. Violations of the normality assumption were also detected for SOL and SE according to the Shapiro-Wilk W statistic ($p < 0.05$). Therefore, in order to test the relationship between the subjective and objective measures of these variables, Spearman's rank correlation coefficient (r_s) was used rather than Pearson product-moment correlation coefficient (r).

Spearman's correlations showed significant strong positive relationships between the subjective and objective measures of SE ($r_s = 0.69$, $n = 10$, $p < 0.05$) and SOL ($r_s = 0.92$, $n = 10$, $p < 0.001$), but no significant relationship between subjective and objective NNA ($r_s = 0.41$, $n = 10$, $p > 0.05$). Pearson's correlation revealed no significant relationship for TST between the sleep measures ($r = 0.61$, $n = 10$, $p > 0.05$). Paired-samples t-tests were calculated to examine whether the participants' estimations of TST and NNA differed significantly from the corresponding PSG data. A significant difference was found between subjective ($M = 440.30$, $SD = 60.35$) and objective ($M = 401.70$, $SD = 46.81$) TST ($t(9) = -2.49$, $p < 0.05$), and between subjective ($M = 0.80$, $SD = 0.79$) and objective ($M = 25.20$, $SD = 13.61$) NNA ($t(9) = 5.75$, $p < 0.001$), suggesting that the participants significantly underestimated their NNA and overestimated their TST.

Treatment effects on anxiety levels

Since the total STAI-S scores differed significantly from a normal distribution according to the Shapiro-Wilk W statistic ($p < 0.05$), the non-parametric test was calculated

Table 1. Mean value (standard deviation) of the subjective sleep parameters as recorded in sleep diaries during the passionflower and placebo conditions

Subjective sleep parameter	n	Placebo *M (SD)*	Passionflower *M (SD)*	t statistic
Sleep efficiency (SE, %)	41	93.17 (3.15)	93.17 (3.48)	0.002
Total sleep time (TST, min)	41	481.34 (56.57)	479.76 (50.69)	0.32
Feelings of refreshment (FR)	41	3.37 (0.64)	3.49 (0.62)	−1.24
Sleep quality (SQ)	41	3.57 (0.56)	3.83 (0.61)	−2.70[a]

[a] $p \leq 0.01$.

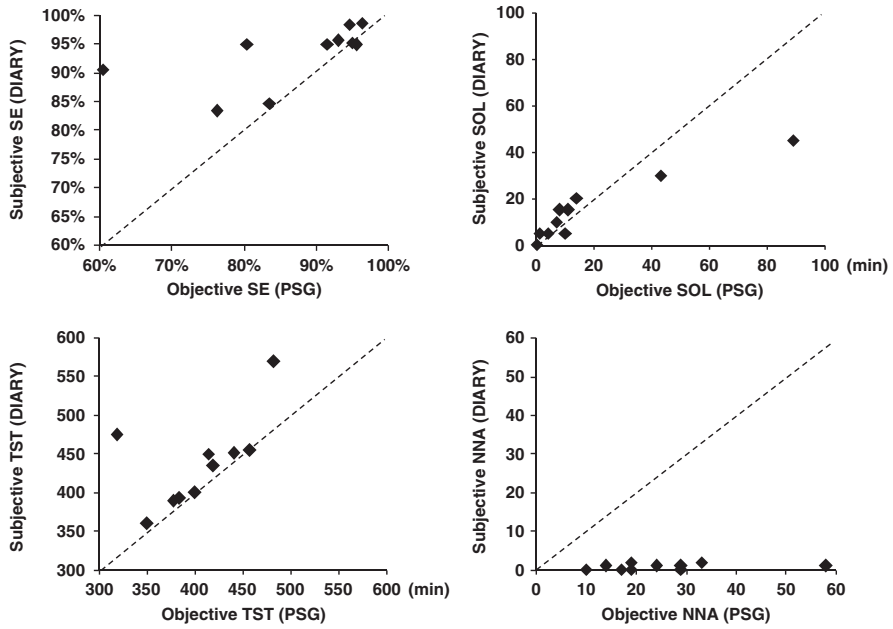

Figure 2. Correlations between subjective sleep and objective PSG parameters measured during the placebo condition. Each dot represents a participant's subjective and objective mean values of the specified sleep parameter. The dotted line indicates the points at which the subjective sleep data perfectly match the PSG data. Dots above the line reflect overestimation and below reflect underestimation of the physiological sleep measured via PSG.

and showed no significant difference in state anxiety between the passionflower ($Md = 36$, interquartile range = 8) and placebo ($Md = 37$, interquartile range = 14) conditions, Wilcoxon $Z = -0.75$, $p > 0.05$.

The likelihood of identifying the passionflower tea

The effectiveness of blinding participants with regards to the passionflower condition was investigated. On day 2 of each treatment, the participants were asked to guess which condition they were experiencing. During the passionflower treatment, 25 participants made a guess, whereas the remaining 16 participants indicated that they could not decide. A Chi-squared test revealed that the frequency of correct guesses (64%) was not significantly higher than that would have been expected by chance (50%), χ^2 (1, $N = 25$) = 0.16, $p > 0.05$.

DISCUSSION

Amongst the PSG and subjective sleep parameters analysed, only subjective SQ was found to be significantly better in the passionflower condition compared with the placebo. Similar to Shinomiya *et al.*'s findings (2005) in the rat, *Passiflora incarnata* produced no significant changes in any of the PSG parameters. It is possible that the small sample size in both studies had limited the power of the statistical analyses used to detect significant differences. Moreover, any effects of *Passiflora incarnata* could have been masked by the experimental noise from a first-night effect in the sleep laboratory (Bastien *et al.*, 2003). In other words, the poor sleep of participants not adapted to sleeping in a laboratory environment was counterbalanced across the two conditions, possibly masking any small treatment effects that may have existed. Due to these limitations, the PSG findings in just ten participants should be interpreted with caution.

In the present study, the passionflower tea preparation was three times less than the recommended dosage (3 cups of tea per day). For ethical reasons, the tea could only be consumed once a day, at night time, to avoid daytime sedation. Given that the sedative effects of *Passiflora incarnata* could be dose-dependent (Soulimani *et al.*, 1997), the reduced dosage might have been insufficient to produce changes in quantitative sleep structure. This is particularly the case for the PSG measures of sleep because PSG recordings might not be sensitive enough to detect short-term changes with a mild treatment dose (Morin *et al.*, 2005). Furthermore, the efficacy of *Passiflora incarnata* could be influenced by the solvent used to form the herbal preparation (Soulimani *et al.*, 1997), so administering *Passiflora incarnata* in the form of tea might not be maximally effective: the essential sedative properties of the herb might not have been extracted at all, or might have only diffused partially from a teabag. This might have rendered any sedative properties of *Passiflora incarnata* ineffective in enhancing sleep quantity.

Significant positive correlations between the subjective and PSG measures of quantitative sleep were found for SOL and SE, but not for TST and NNA. The results for SOL and SE are consistent with the previous findings (Bastien *et al.*, 2003; Lockley *et al.*, 1999); they indicated that the sleep diary used was a valid measure for assessing the treatment effects on SOL and SE. However, the results for subjective TST and NNA are questionable. The considerable variation between sleep diary and PSG measurements could have been attributed to the participants' inability to perceive or recall their wakefulness after sleep onset (Argyropoulos *et al.*, 2003; Lockley *et al.*, 1999), as the participants tended to overestimate their sleep duration and underestimate their NNA. This is in line with the notion that memory

is poor throughout the sleep period due to the transitions between sleep–wake states (Lockley *et al*., 1999). Hence, the effects of *Passiflora incarnata* on TST and NNA may need to be re-examined using PSG with a larger sample of participants.

Of the subjective qualitative sleep parameters, there was a significant improvement in the reported SQ in the passionflower treatment, with a mean increase of 5.2% relative to the placebo. One possible explanation for this result could be that the participants held preconceived expectancies regarding the effects of *Passiflora incarnata*, that means they were able to recognize passionflower as the true condition and reported an improvement in their SQ. However, the number of participants who correctly identified the passionflower condition was not significantly greater than chance, and only 56% of those who guessed passionflower correctly also reported an increase in perceived SQ. Therefore, an expectancy effect alone does not provide a likely explanation for the results observed. Another possible explanation is that *Passiflora incarnata* alters underlying sleep quality which is not recorded using traditional PSG measures. However, it is also possible that the lack of significant differences in PSG measures of TST and SE between conditions in the small subset of ten participants might be due to low statistical power. Based on the effect size of the group differences calculated from the PSG data (Cohen's $d = 0.36$ and 0.34, respectively), it is estimated that a sample size of at least 100 participants would be needed to observe statistically significant TST and SE effects of this *Passiflora incarnata* preparation in a very large scale PSG study (Faul *et al*., 2007).

The results indicated that the STAI-S scores did not differ significantly between conditions, suggesting that *Passiflora incarnata* does not modulate state anxiety levels in humans. Such a finding is inconsistent with those of Akhondzadeh *et al*. (2001b) and Movafegh *et al*. (2008), where *Passiflora incarnata* was found to be effective in reducing state anxiety. However, the present sample appeared to be a low anxiety group within the normal population as indicated by the low mean STAI-S scores ($M = 38.25$ and 37.32), both were lower than that reported for healthy adults not using psychoactive medications ($M = 39.6$; Lane *et al*., 2007). Therefore, *Passiflora incarnata* might not be effective for individuals with already low anxiety levels. Another possible reason for the inconsistency could have been the long interval between the administration of passionflower and the measurement of anxiety. Unlike Movafegh *et al*.'s study where anxiety was assessed within 90 min after premedication with passionflower, the passionflower tea was administered at night, so measuring anxiety the next morning might have been too late to capture any immediate anxiolytic effects that could potentially aid sleep onset or initial sleep maintenance.

There were some other limitations of the study that should be considered. First, any sedative effects of *Passiflora incarnata* might have been masked by ceiling effects (Morin *et al*., 2005). This is possibly because this study excluded individuals with sleep disorders and extreme sleep difficulties, and so the participants as a group reported high SE ($M = 93.17\%$), leaving little room for improvement in sleep to occur. The results of this study therefore suggest that the sedative effects of *Passiflora incarnata* should now be investigated in a sample of clinically diagnosed primary insomnia patients. Second, a week of passionflower treatment might have been inadequate to observe significant improvements in sleep or anxiety, as Akhondzadeh *et al*.'s (2001b) 28-day trial indicated that *Passiflora incarnata* might have a slow onset of action. Despite some limitations of this study, the finding that *Passiflora incarnata* improved perceived SQ appears to be the first evidence for the efficacy of the herb on subjective SQ in humans. This suggests that *Passiflora incarnata* may be a viable alternative for managing mild SQ complaints.

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Conflict of Interest

No conflicts of interest exist for the authors.

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