A clinical test of the effects of Valerian root on waking hours at night

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Introduction: Valerian root is a traditional plant primarily used medically to relieve insomnia and promote sleep [**?**]. Although a common traditional remedy, medical trials assessing the effectiveness of Valerian root are limited and have so far given mixed results [**?**]. Hence, this study seeks to join this body of literature and help clarify whether Valerian root is an effective at promoting sleep.

Methods: We conducted an experimental trial of $n = 62$ residents on *the Islands*. We tried to take roughly equal numbers of male and female islanders from a variety of cities across the islands and from many age brackets (20-70 years of age) to distinguish Valerian's effects from age-related, sex-related, and geographical factors which may affect sleep. Each test subject was randomly assigned to take either a 1g tablet of Valerian each night, or be given placebo sugar tablets (each with 50% probability). This gave sample sizes $n_C = 30$ for the control group and $n_V = 32$ Valerian takers.

To ensure the presence Valerian in the latter group's bodies during sleep [**?**], these were given between 0.5-2 hours before the islanders' 10:00PM bedtimes every night. This was done for 4 consecutive nights. We measured the effectiveness of Valerian in promoting sleep by examining hours of their sleep cycle each night that residents were awake. This was taken from a hypnogram of each test subject's sleep (to within ± 10 mins), both before beginning the trial, as well after 1-4 nights afterward. This limited number of nights (as opposed to a weeks-long trial) is used to prevent our result from being affected by the development of tolerances to Valerian's effects.

Our test subjects' sleep habits over the trial may be influenced by their Valerian consumption, and external factors such as their age, personal health, and environment. Assuming linearity in the number of nights t since trials began (not terrible over short timescales), the mean waking hours y^C for the control group and y^V for the Valerian takers will be:

$$y^C = \beta_0^C + \beta_1^C t, \qquad y^V = \beta_0^V + \beta_1^V t$$

For some parameters β_0^C, β_0^V representing baseline average waking hours before the trial began, and β_1^C, β_1^V representing the rate per day of sleeping change increases. If each test subject's waking time is independent of the others', and our data is normally distributed around our two lines with a variance independent of t, we can estimate these parameters and their standard deviations $\sigma_0^C, \sigma_1^C, \sigma_0^V, \sigma_1^V$ from a linear regression model.

If both the control and Valerian taker groups are representative of the islands' population, the nightly changes β_1^C, β_1^V should have no difference in each other besides those due to Valerian's effects. Hence, we test the hypotheses:

$$H_0 : \beta_1^C = \beta_1^V, \qquad H_1 : \beta_1^C > \beta_1^V$$

Where the null hypothesis H_0 corresponds to the Valerian having no effect on waking hours at night, and the alternative hypothesis H_1 corresponds to Valerian producing a statistically significant reduction in waking hours each night comoared to our control group. To evaluate these hypotheses, we note that our estimates of β_1^C, β_1^V should be T-distrubuted under our assumptions, with degrees of freedom $n_C - 1, n_V - 1$ respectively. Hence, assuming our null hypothesis, we expect the below to be t_{df}-distributed, with degrees of freedom df given by Welch's approximation:

$$T = \frac{\beta_1^C - \beta_1^V}{\sqrt{\frac{(\sigma_1^C)^2}{n_C} + \frac{(\sigma_1^V)^2}{n_V}}}$$

We then compute the probability of our data being more extreme than predicted from our T value assuming H_0 as $p = \mathbb{P}(t_{df} \geq T)$ and evaluate our hypotheses against a standard 95% confidence criterion.

Ethics: Consent was obtained from all islanders we tested on. Since Valerian root may be a sedative (and hence interact negatively with alcohol [**?**]), all test subjects were told to reduce alcohol consumption during the trial. Moreover, pregnant women were excluded from our study, as little is known of valerian's effects on pregnancies [**?**].

Notes for discussion: Here are some things which are worth noting (I'm just not sure if this is best to put in method or conclusion). This is NOT a section of the report, and should be edited out and incorporated into the report properly later

- Just looking at waking hours gives an incomplete characterisation of sedative-hypnotic drugs, as this does not analyse the quality of the persons' sleep (for example, there is evidence hypnotic-sedative drugs increase the prevalence of the N1 and N2 phases of deep sleep (its 2 shallower phases) while lowering the time spent in REM sleep and N3 deep

sleep [**?**], disrupting the typical sleep cycle and giving lower quality sleep).

- My preliminary data analysis is actually suggesting that Valerian is a stimulant, with Valerian takers experiencing a lower rate of decrease in waking hours compared to the placebo takers. This is fine – we'll just need to p-test for Valerian being a stimulant (i.e. for null hypothesis $\beta_1^{\text{Valerian}} = \beta_1^{\text{Control}}$ and alternative hypothesis $\beta_1^{\text{Valerian}} > \beta_1^{\text{Control}}$). There may even be some historical precedent for Valerian being used as a stimulant in the 19th century [**?**], so this would be an interesting thing to talk about.

- One person dropped out of my study, but he did so before I could do any proper measurements on him (I gave islanders about 24 hours to reduce their alcohol consumption before beginning trials). This may be worth mentioning in the report, but since no data ended being collected from him, I do not think it is the end of the world.

- Using hypnograms instead of a survey helped prevent errors in the study from the islanders poorly estimating and/or lying about the hours of sleep they got, but it introduced the issue of me having to read the hypnograms in order to assign a sleeping time to them, which could not be done with perfect accuracy. I'd say sleep times are only really know to ± 10 minutes, and is only given to a fidelity of 5 minutes.

- I did not specifically select for islanders who were getting low amounts of sleep each night (I TRIED to with the islands' newspaper feature, but it would not work for any questions I wanted to ask about sleep schedules or anxiety/stress). This may make the effects of Valerain less pronounced here (if someone is already getting a healthy amount of sleep each night, the drug may not necessarily increase those hours). This could be worth discussing.

Results: Linear regression models were fitted to both the control and valerian groups' data to estimate the baseline waking hours per night (β_0^C, β_0^V) and the average rate of change in waking hours per night (β_1^C, β_1^V). For the conrol group the model was determined by:

$$y^c = 133.9 - 2.92t$$

with the slope estimate: $beta_1^c = -2.92$ having a standard error of The model for the valerian data was given by:

$$y^V = 118.1 + 3.56t$$

with the slope estimate: $beta_1^v = -3.56$ having a standard error of

Both slope estimates were slightly negative (discussion) indicating a minor decrease in waking minutes per night over the course of the trial for both groups. The valerian group indicated a steeper decline in waking minutes per night, however using a welch test this difference in slope was found to be statistically insignificant. using these slope estimates and their standard errors, we computed the test statistic T and degrees of freedom df using Welch's approximation, giving: