



## Clinical Abstract

### ***“Sleep Disorders: An observational Clinical Study shows the benefits of the Well-Being Dietary Supplements”***

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#### **Introduction and Purpose**

Sleep disorders disrupt and disturb the overall quality of life of more than 70 million people in the U.S. It can affect a child, teen, single adult, parent or senior citizen. In fact, most of those who have sleep disorders are completely unaware of it. Many of those who are aware of it never choose to seek the help that they need<sup>1</sup>.

Due to advances in the science of Sleep Medicine, help can be found for those who suffer from bad sleep. *The International Classification of Sleep Disorders, Second Edition* documents 81 official sleep disorders! Indeed, there are many possible reasons for sleeping poorly.

The right sleep disorder treatment depends on the cause. Following sleep hygienic principles may solve problems of physical or emotional discomfort<sup>2</sup>. When pain, illness, drugs or stresses are the culprit, the cause must be treated. Sleep disorders, including the sleep apneas, narcolepsy, primary insomnia, periodic limb movement disorder (PLMD), restless leg syndrome (RLS) and the circadian rhythm sleep disorders, are treatable.

There are numerous strategies and methods to cope with this physical or emotional discomfort, ranging from improved time and relationship management to daily life hygiene (nutrition, exercise, sleep).

The objective of this observational study is to show the impact of a daily intake of ACTIVA's Vitality Well Being Dietary supplement on the outcome scores related to sleep disorders.

## Methods

This observational study has been made on 10 voluntary patients complaining from Sleep Disorders for more than three months, in an open practice set up. These patients were not exhibiting psychological issues and were not under anti-depression or neuroleptic treatments that could bias the result of the study.

Simple outcome related scores (Table1) were utilized to evaluate the amount of sleep hours, the occurrence (frequency) of daytime fatigue states and the amount of nighttime awakenings.

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**Number of hours slept**

H0 : 6 hours or more

H1 : 5 hours

H2 : 4 hours

H3 : 3 hours

H4 : 2 hours or less

**Frequency of Daytime Fatigue State**

D0 : Normal

D1 : Frequent

D2 : Very Frequent

**Amount of nocturne awakenings**

F2 : 2 per night

F3 : 3 per night

F4 : 4 per night

F5 : 5 per night

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Table 1 : Outcome Related Scores Survey

All the patients have been following a daily intake of one or two capsules of Well-Being Sleep in the morning, for two months.

Well-Being Sleep is part of a full product line of 12 health condition formulated dietary supplements, based on carefully engineered blends of herbal extracts. A patented and innovative encapsulated process offers an effective gastro-protection of the active ingredients for an optimal release and absorption (do you want to utilize the word absorption?) directly into the intestines. This controlled release mechanism allows an increased response to the active compounds, with a reduction in the dosing (one pill a day or infant formulations).

Patients have been monitored during three months, every 15 days, to measure the outcome score and ensure compliance to the protocol.

## Results

**Total Amount of Hours Slept:** as shown in Table 2, the overall effect of the Well Being protocol is to shift the outcome scores from a profile where patients report a few hours of sleep to a distribution where the total hours slept has doubled, in less than 60 days. In fact, the trend is visible as soon as 30 days for some patients. In particular, by comparing the cumulative scores of patient reporting to sleep four hours or less, one could derive that more than 75% of the patients treated with Well-Being Sleep recover more than two hours of sleep per night (now reporting six and more hours of slept) in less than 60 days.

### Trend of the Total Amount of Hours Slept

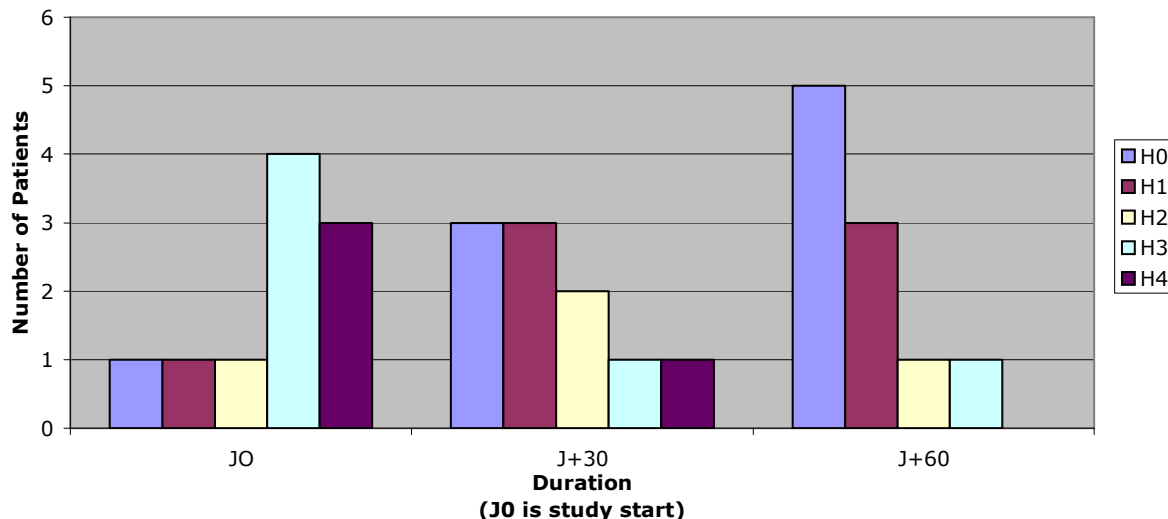


Table 2: Trend of the Total Hours Slept during the protocol. J0 is at the beginning of the study. The other data points are plotted at 30 day intervals. As a reminder, H0: 6 hours or more, H1: 5 hours, H2: 4 hours, H3: 3 hours, H4: 2 hours or less

**Frequency of Daytime Fatigue State:** Patients have been surveyed to comment on the occurrence of their daytime fatigue state, or in other words, to report how often they feel “tired” during the day. A three tiered scale was selected to force discrimination for this outcome scoring, that is rather subjective. As displayed on Table 3, one can first observe that the effects are reported very quickly, in less than 30 days, for most of the patients. In particular, by measuring the cumulative scores to the right and to the left of the “Normal State”, one could derive that 90% of the patients treated with Well-Being Sleep will report the elimination of their daytime “sleepiness” in less than 60 days.

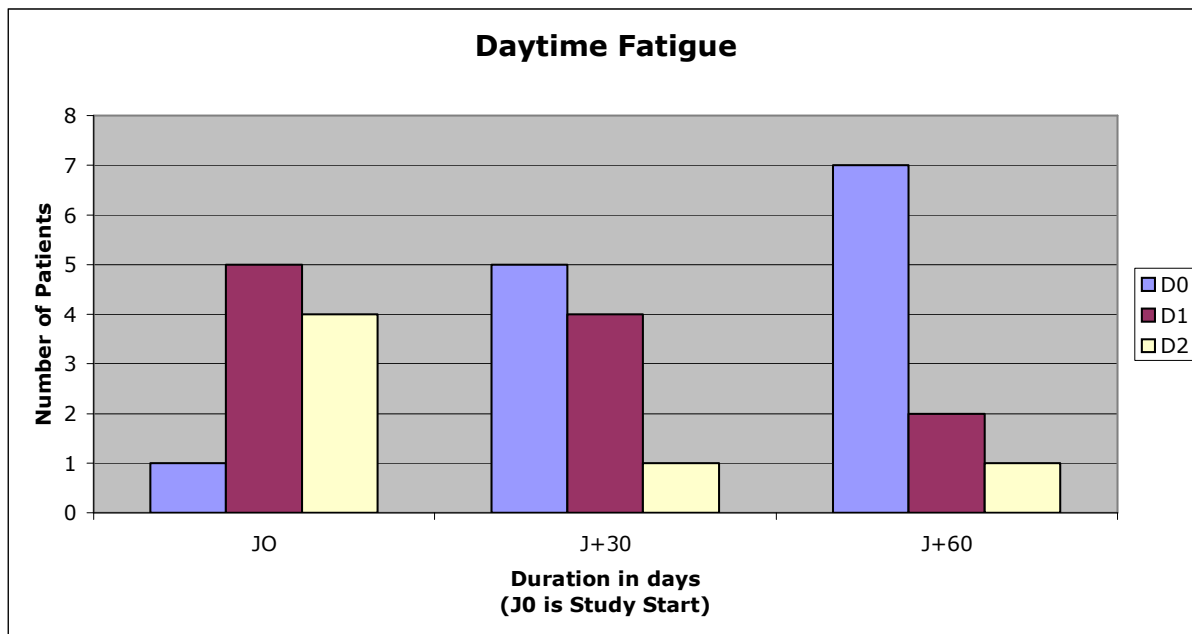


Table 3: Trend of the daytime Fatigue Frequency Scores during the protocol. J0 is at the beginning of the study. The other data points are plotted at 30 day intervals. As a reminder D0: Normal, D1: Frequent, D2: Very Frequent

**Nocturne awakenings:** In addition to the total hours slept, the number of nocturne awakenings has been surveyed, as a way to monitor the quality of sleep. As seen on Table 4, a substantial

improvement is visible as soon as 30 days into the protocol. In 60 day, the number of patients reporting less than three nocturne awakenings has doubled and more than 60% of patients reporting severe and frequent awakenings (four or more) has seen their condition improve.

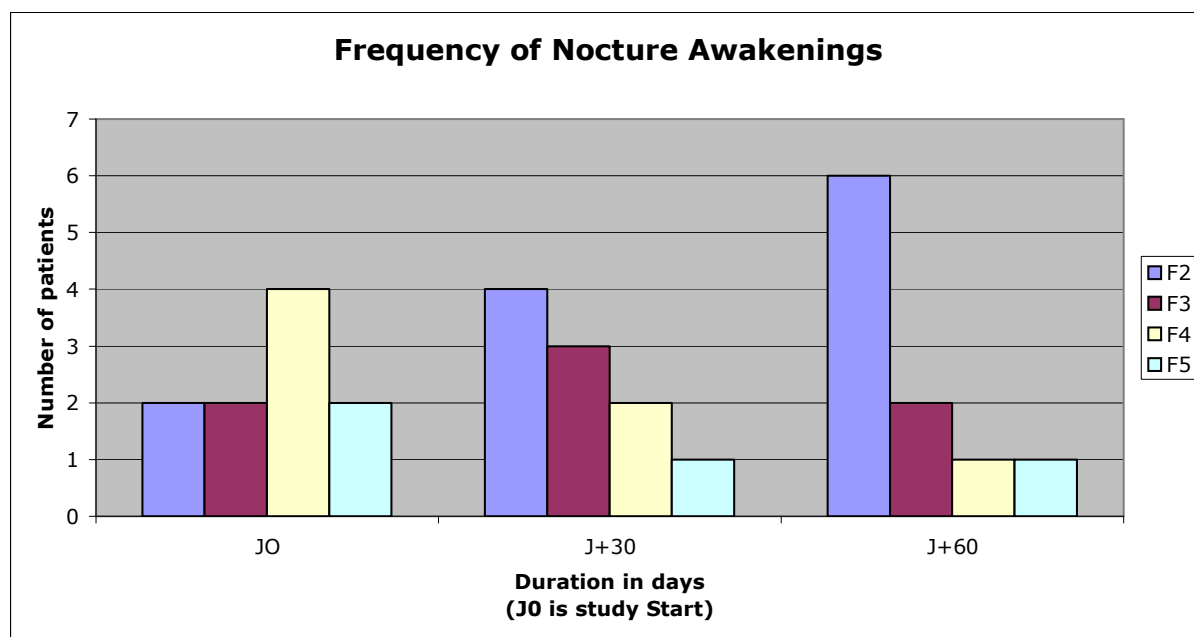


Table 4: Trend of the Total Nocturne Awakenings during the protocol. J0 is at the beginning of the study. The other data points are plotted at 30 day intervals. As a reminder: F2: 2 per night, F3: 3 per night, F4: 4 per night, F5: 5 per night

**Discussion and limitations:** The efficacies of selected herbal extracts to improve health conditions have been documented in numerous studies and are increasingly becoming accepted by the consumer and the healthcare communities<sup>3</sup>. By using selected blends of well known and standard herbal extracts, the Well-Being product line leverages the knowledge already established around these compounds<sup>4</sup>, and it is not surprising to verify these results in this observational study.

In fact, one could make an argument that the micro-pellets formulation and related intestinal release process are directly responsible for the very fast results observed in most of the patients in less than 30 days. This rationale is well established in the pharmaceutical world, comparative and kinetic studies in the herbal extract/dietary supplement could be carried out to further validate these initial results.

One could also make a case that the “one a day” intake of the Well-Being ?????would be a huge factor to drive long term compliance for protocols treating chronic states. Indeed, the tasteless, odor less, easy to swallow, multi ingredient/extract and single daily intake formulation/pill seems extremely competitive if compared to existing herbal formulations, even in liquid form.

Last, the promising results observed during these observational studies would benefit to be validated on a larger scale, for which relevant statistical analysis could be performed.

## Conclusion

A three month observational clinical study on 10 patients complaining from Sleep Disorders has been performed in an open practice set up. The screened patients have followed a two month protocol based on a daily intake of 1-2 Well Being Sleep pills. The patients have been monitored every 15 days to respond to outcome based score surveys and to ensure their compliance to the protocol for three months.

In less than 60 days, 60% to 75% of the patients complaining from severe Sleep Disorders such as four hours or less of sleep per night or more than four nocturne awakenings, reported significant improvements, gaining three to four hours of sleep per night or reducing their nighttime awakenings by half. Improvements have been observed for more than half of the patients sampled in less than 30 days.

Both the selection of the herbal extracts blends and the innovative controlled release mechanism (micro-granules) of the Well-Being??????? are accountable for these results.

A more powerful study and statistical analysis, as well as, a direct comparison with alternative formulations (bulk pellets or liquids) would be welcomed to further validate these initial observations.

**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

## References:

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<sup>1</sup> American Academy of Sleep. Sleep disorders : <http://www.sleepeducation.com/Disorders.aspx>

<sup>2</sup> Little, Nan (2007-01-01). "[What Causes Sleep Difficulty?](#)". Insight Journal. Retrieved on [2008-01-25](#).

<sup>3</sup> Medline all Herbs and supplements : [http://www.nlm.nih.gov/medlineplus/druginfo/herb\\_All.html#N](http://www.nlm.nih.gov/medlineplus/druginfo/herb_All.html#N)

<sup>4</sup> National Institutes of Health: <http://health.nih.gov/result.asp/324>