



## Clinical Abstract

### ***“An observational Clinical Study shows the improvement of vitality related outcomes scores with Well-Being Dietary Supplements”***

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#### **Introduction and Purposes**

Emotional exhaustion is a chronic state of physical and emotional depletion that results from excessive job demands and continuous hassles<sup>1</sup>. It describes feelings of being emotionally overextended and exhausted by one's work and is manifested by both physical fatigue and a sense of feeling psychologically and emotionally “drained”.<sup>2</sup>

Most emotional exhaustion research has been guided by Maslach's and Jackson's: *The Burnout: the Cost of Caring*, which suggests, burnout consists of three interrelated parts: emotional exhaustion, depersonalization, and diminished personal accomplishment. Depersonalization refers to a set of callous and insensitive behaviors displayed in a socially or professional interactive context (i.e. A worker toward a client). Diminished personal accomplishment refers to negative evaluations of the self.<sup>3</sup>

There is a lot of variability of perception and social tolerance to the state of Emotional Exhaustion: for instance regional and national cultures have been shown to have different norms for emotional expressions<sup>4</sup>, and vary in their expectations for regulating and expressing emotions in the workplace<sup>5</sup>. For example, some cultures are more institutionally-oriented, with strong norms about regulating emotions to fulfill institutional roles and standards, whereas other cultures are more impulsively-oriented that value expressing unregulated emotions.<sup>6</sup>

An example of a culture with a strong institutional-orientation toward emotions is the United States, due to the strong American norm to act positively and hide negative feelings<sup>7</sup>. Whereas, France can be used as an example of a country with a more impulsive-orientation toward emotions.<sup>8</sup>

There are numerous strategies and methods to cope with this chronic state, ranging from improved Manager-Employee relationships 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 Emotional Exhaustion.

## Methods

This observational study has been made on 10 voluntary patients complaining from Emotional Exhaustion for more than two 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 frequency and the intensity of their Emotional Exhaustion state. In the same survey, Mood Troubles have been looked at as well.

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### Frequency of the Emotional Exhaustion State

P0 : No Exhaustion  
P1 : Normal Exhaustion  
P2 : Temporary Exhaustion  
P3 : Frequent Exhaustion  
P4 : Recurrent / Chronic Exhaustion

### Intensity of the Emotional Exhaustion State

S0 : No Emotional Exhaustion  
S1 : Normal State  
S2 : Intense Emotional Exhaustion

### Frequency of the Troubles of the Mood

H0 : No Troubles  
H1 : Normal  
H2 : Temporary Troubles  
H3 : Frequent Troubles  
H4 : Recurrent / Chronic Troubles

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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 Vitality in the morning, for two months.

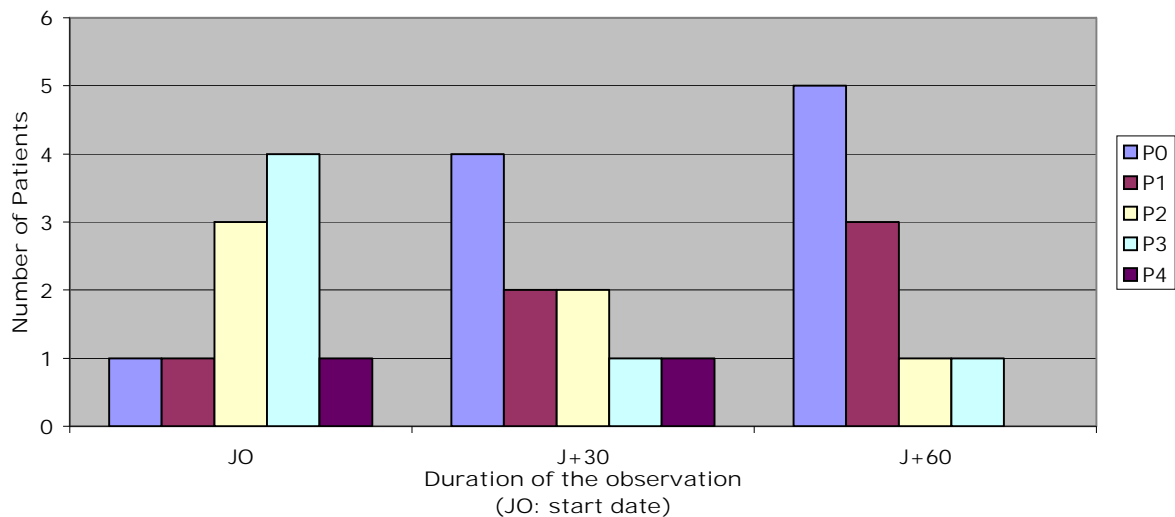
Well-Being Vitality is part of a full product line of 12 health condition formulated dietary supplements, based on carefully engineered blends of herbal extracts. A patented and innovative encapsulated process offers an effective gastro-protection of the active ingredients for an optimal release and absorption directly into the intestines. This controlled release mechanism allows an increased response to the active compounds. The result is a reduction in the dosage (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

**Emotional Exhaustion Frequency:** as shown in Table 2, the overall effect of the Well Being protocol is to shift the outcome scores from a profile where patients complain from “Frequent” state of Emotional Exhaustion to a profile where “No” or “Normal” mental exhaustion is dominant in less than 60 days. In fact, the trend is visible as soon as 30 days for some patients. In particular, by measuring the cumulative scores to the right and to the left of the “Normal” state, one could derive that there is a significant overall improvement in 75% of the patients treated with Well-Being Vitality in less than 60 days.

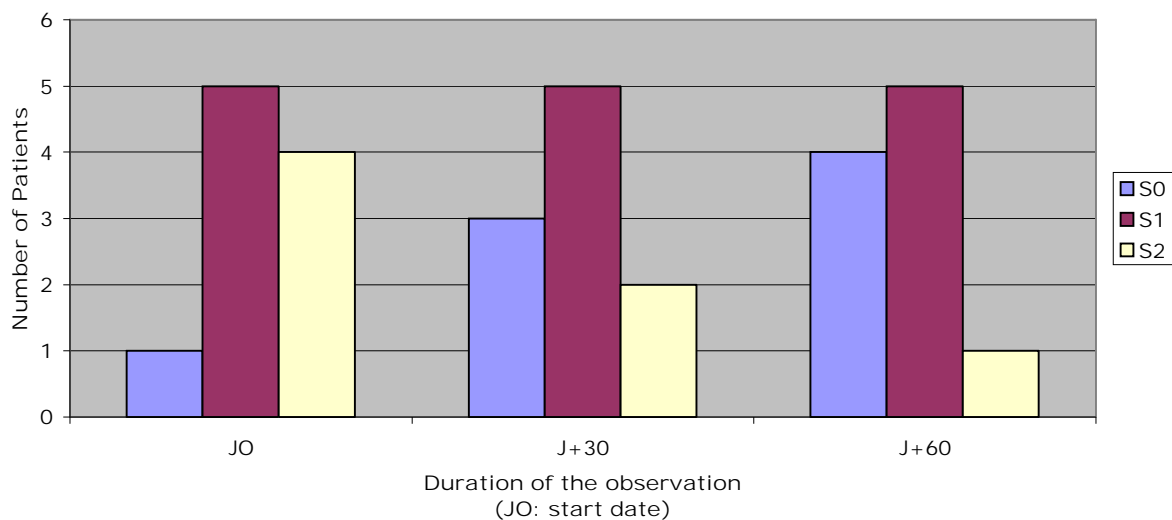
### Emotional Exhaustion Trending (Frequency)



**Table 2:** Trend of the Emotional Exhaustion Frequency Outcome Scores during the protocol. JO is at the beginning of the study. The other data points are plotted at 30 day intervals. As a reminder, P0 : No Exhaustion - P1 : Normal Exhaustion - P2 : Temporary Exhaustion - P3 : Frequent Exhaustion - P4 : Recurrent / Chronic Exhaustion

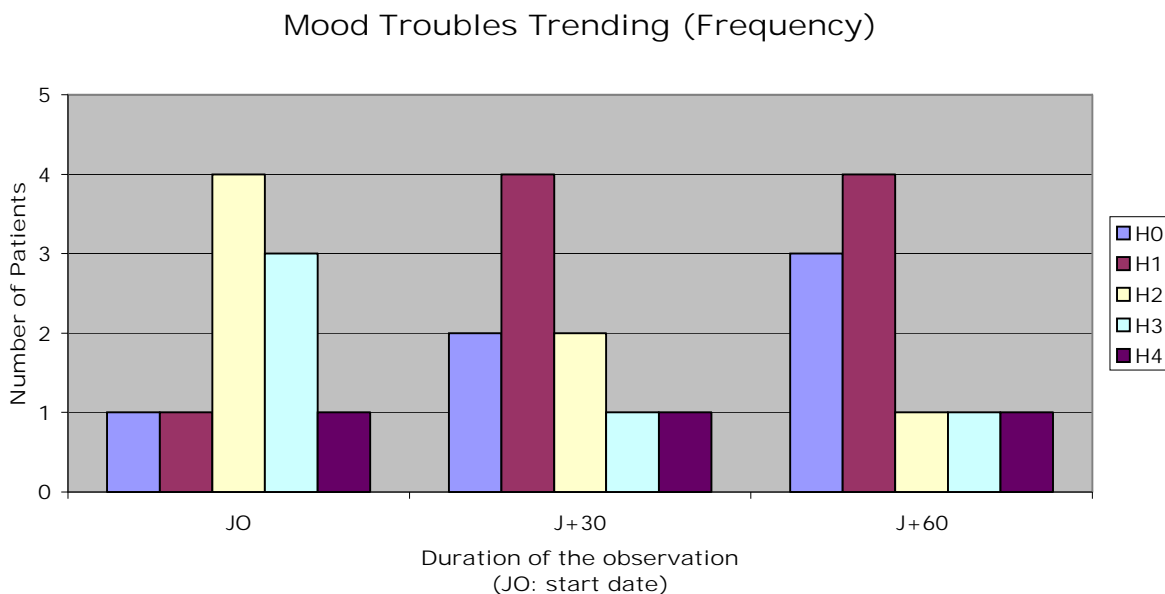
**Emotional Exhaustion Intensity:** Patients have been surveyed to comment on the intensity of their Emotional Exhaustion, and the three-level scores that have been chosen force a somewhat clear-cut segregation between the “Normal” and the “Intense” states. As one would naturally expect, the “Intense” score translates quite a bothering state. Having said that, the results shown in Table 3 highlight that the Well-Being Vitality protocol helps turnaround the situation and significantly shift the perceived level of intensity to either “Normal or No” state. In particular, by measuring the cumulative scores to the right and to the left of the “Normal” state, one could derive that there is a significant overall improvement in 75% of the patients treated with Well-Being Vitality in less than 60 days.

### Emotional Exhaustion Trending (Intensity)



**Table 3 :** Trend of the Emotional Exhaustion Intensity Outcome Scores during the protocol. JO is at the beginning of the study. The other data points are plotted at 30 day intervals. As a reminder: S0: No Emotional Exhaustion, S1: Normal State, S2 : Intense Emotional Exhaustion

**Mood Troubles:** In addition to the Emotional Exhaustion outcome scores, Mood Trouble frequency have been evaluated, as a proxy way to gage Emotional Exhaustion and verify the results directly measured on this parameter and discussed above. As shown on Table 4, the distribution of the Mood Trouble scores are following an identical pattern to the one displayed on Table 2 (Emotional Exhaustion). Again, we can observe a general shift of the score distribution to the left (“No Troubles” or “Normal” states) while “Temporary” and “Frequent” scores are drastically reduced, even as soon as in 30 days. Again, by measuring the cumulative scores to the right and to the left of the “Normal” state, one could derive that there is a overall improvement of mood troubles in 60% of the patients treated with Well-Being Vitality in less than 60 days.



**Table 4 :** Trend of the Mood Troubles Frequency Outcome 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: H0 : No Troubles, H1 : Normal, H2 : Temporary Troubles, H3 : Frequent Troubles, H4 : Recurrent / Chronic Troubles

**Discussion and limitations:** the efficacy of selected herbal extracts to improve health conditions has been documented in numerous studies and is increasingly become accepted by the consumer and the healthcare communities <sup>9</sup>. By using selected blends of well known and standard herbal extracts, the Well-Being product line leverages all the knowledge already established around these compounds <sup>10</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. Even though 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 of the formulated/pill seems extremely competitive if compared to existing herbal formulations, even those 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 Emotional Exhaustion has been performed in an open practice set up. The screened patients have followed a two month protocol based on a daily intake of one to two Well Being Vitality 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, Emotional Exhaustion frequency, intensity and Mood Troubles frequency have been driven back to normal (or total disappearance) for 75% of the patients treated with Well-Being Vitality. Improvements have been observed for more than half of the patients sampled in less than 30 days. Both the selection of the herbal extract 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>2</sup> Zohar, D. (1997). Predicting burnout with a hassle-based measure of role demands. *Journal of Organizational Behavior*, 18(2), 101-115

<sup>3</sup> Maslach, C. (1982). *The Burnout: The Cost of Caring*. Englewood Cliffs: Prentice Hall.  
Maslach, C., Jackson, S. E. (1986). *The Maslach Burnout Inventory* (2nd ed.). Palo Alto, CA: Consulting Psychologists Press. Maslach, C., & Leiter, M. P. (1997). *The truth about burnout: How organizations cause personal stress and what to do about it*. San Francisco, CA: Jossey-Bass.  
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<sup>4</sup> Ekman, P. (1972). Universals and cultural differences in facial expressions of emotions. In J. Cole (Ed.), *Nebraska symposium on motivation 1971* (pp. 207-283). Lincoln: University of Nebraska Press.

<sup>5</sup> Cooper, D., Doucet, L., & Pratt, M. (2003, August). I'm not smiling because I like you: Cultural differences in emotional displays at work. Paper presented at the Academy of Management, Seattle, WA.

<sup>6</sup> Gordon, S. L. (1989). Institutional and impulsive orientations in selective appropriating emotions to self. In D. D. Franks & D. McCarthy (Eds.), *The sociology of emotions: Original essays and research papers* (pp. 115-136). Greenwich, CT: JAI Press.

<sup>7</sup> Schneider, D.J. (1981). Tactical self-presentations: Toward a broader conception. In J.T. Tedeschi (Ed.), *Impression management theory and social psychological research* (pp. 23-40). New York: Academic Press.

<sup>8</sup> Hallowell, R., Bowen, D. E., & Knoop, C. I. (2002). Four seasons goes ?? to Paris. *Academy of Management Executive*, 16(4), 7-24.

<sup>9</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>10</sup> National Institutes of Health: <http://health.nih.gov/result.asp/324>