

## **Nutritional Supplementation with Modera XL to Support Normal Metabolic Response to Stopping Addiction Behavior**

### **Problem Statement**

Sufferers of addiction and chemical dependence (with regard to alcohol, tobacco, street drugs, and prescription drugs) commonly have extremely severe and potentially debilitating experiences when they quit or reduce the intake of their drug of choice (DOC). These experiences can include anxiety, depression, fatigue, cognitive impairment, sleep disturbances, pain, nausea, vomiting, tremor, craving, and other physical and psychological manifestations. These experiences can contribute significantly to a failure in the sufferers' attempt to reduce or quit the DOC.

### **Hypothesis**

Modera XL (a nutritional supplement containing vitamins, minerals, amino acids, and a proprietary blend of natural adaptogens) taken orally between 2 and 5 times per day (as directed, per effervescent packet instructions), can regulate the experiences typically encountered by sufferers of addiction and chemical dependence when they reduce or quit consumption of an addictive substance (or DOC).

### **Methods**

Voluntary subjects (or participants) started and maintained use of Modera XL ("the product") for a two-week period. There was no monetary incentive for participation. However, the product was provided to the subjects free-of-charge. Also, participants were informed in writing that the results of this study may be used in the future for marketing and that the scientific results could be submitted for publication. Subjects signed written consent documents to release their data and likenesses for use as stated above. Confidentiality of the participants' personal information (identity, medical history, etc.) was maintained unless a participant explicitly gave written permission to divulge such information.

Each subject filled out a questionnaire on the intake day to document characteristics of drug use (including tobacco, alcohol, street drugs, and prescription controlled substances). The questionnaire was two pages in length (or one page, front and back). The data collected covered symptoms of withdrawal as well as basic demographics (e.g. name, age, and pertinent medical and/or psychiatric history).

Midway through the study, each subject was contacted via telephone to complete another questionnaire. The one-week (midpoint) questionnaire included the data from the intake questionnaire which was capable of changing (i.e. the demographic data was not re-recorded). This data described both actual use and psychological craving for the DOC in addition to experiences such as anxiety, sleep disturbances, nausea, etc. (see Tables on pp. 5-13).

At the completion of the two-week period, each subject filled out another questionnaire documenting the same data. This data was then analyzed to assess the changes achieved through the use of the product. The variable data was therefore collected on three different dates, with approximately one week intervals. The initial and final questionnaires also included a written section for the subjects' personal characterization of their experiences.

## Materials

In addition to paper questionnaires and other paper documentation, the subjects were interviewed in person by an expert bio-pharmacologist and/or a physician with expertise in clinical nutrition. Additionally, video recordings and still photographs of many of the subjects were obtained for possible use at a later date as marketing tools for this new product (Modera XL). Telephonic communication was utilized for the midpoint data collection. The intake and exit questionnaires were obtained in person.

Modera XL (“the product”) contains  $\gamma$ -Aminobutyric acid (GABA), Ascorbic acid (vitamin C), Biotin (vitamin B<sub>7</sub>), Calcium, Calcium pantothenate (vitamin B<sub>5</sub>), Centella asiatica (Gotu kola) leaf extract, Chromium dinicotinate glycinate, Cyanocobalamin (vitamin B<sub>12</sub>), Dimethylaminoethanol (DMAE) bitartrate, Eleutherococcus senticosus root extract, Folate (vitamin B<sub>9</sub>), L-Glutamine, Griffonia simplicifolia seed extract (source of 5-Hydroxytryptophan), Magnesium, Manganese, DL-Methionine, Mucuna pruriens seed extract, DL-Phenylalanine, Potassium, Pyridoxine (vitamin B<sub>6</sub>), Rhodiola rosea root extract, Sodium bicarbonate, Thiamin (vitamin B<sub>1</sub>), L-Tyrosine, and Zinc.

## Results

At the initiation of this study, 37 subjects had volunteered for participation. Twenty-one subjects successfully completed the study. Of the 16 dropouts, 5 were lost to follow-up (LTF) and the reason for their drop-out remains unknown. Of those 5, 1 subject was LTF prior to the midpoint data collection. Eleven subjects dropped out but maintained communication adequate to ascertain the reason for their dropout. Of these 11, six dropped out prior to the midpoint (and after the intake interview).

Of the 11 subjects who dropped out for known reasons, two of them had experiences that may have been minor adverse events. These two drop-outs did not make it to the midpoint. One [D6S] experienced vivid dreams and the other [D7S] had stomach discomfort. Neither of these experiences meet the criteria of “serious adverse event” requiring a report to the FDA.<sup>1</sup>

One of the subjects [D5CP] was removed from the study because he/she had several changes in his/her non-Modera XL related treatment products. With his/her copious adjustments to other treatment agents during the study period, we felt that we could not extrapolate meaningful conclusions from his/her results. Another subject [D8SP] began having subjective experiences similar to the early use of prescription varenicline. He/she reported that later on, during varenicline use, he/she had a negative experience and he/she therefore discontinued the Modera XL because he/she was not willing to risk the possibility of having adverse events (as he/she did have later in varenicline treatment). An elaborate description of his/her subjective experience with Modera XL was not clearly documented; but, he/she did deny that his/her Modera XL experience was “negative” per se.

Two other drop-outs did complain of health issues but were not deemed to have had adverse events. One [D2] had flu-like symptoms which had been present prior to taking the product; however, he/she

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<sup>1</sup> The Statute provides: “The term “serious adverse event” is an adverse event that-- (A) results in-- (i) death; (ii) a life-threatening experience; (iii) inpatient hospitalization; (iv) a persistent or significant disability or incapacity; or (v) a congenital anomaly or birth defect; or (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).”

believed he/she felt worse with regards to the viral symptoms and discontinued use of the product prior to the midpoint. He/she did not report any correlation of his/her flu-like symptoms with use of the product. Another subject [P3], who dropped out after the midpoint, reported only that he/she was “sick.” He/she did not provide a third set of data, but did not report any adverse experiences from the product.

One participant [D1] dropped out of the study soon after intake because he/she is a local professional and had concerns about his/her reputation. He/she did elect to continue taking the product, but declined to participate through data collection. Another subject [D4] dropped out because of an inter-personal conflict with another one of the participants (subjects). One subject [DL9] dropped out prior to taking any Modera XL due to legal complications. He/she showed up for the intake interview; then he/she had to depart for a scheduled court appearance, at which he/she was detained.

One subject [19P] had a personal emergency calling him/her out of the state for several weeks and had to withdraw from the study after the second set of data points was collected. He/she denied any adverse effects. Another participant [P5] did not show up for the exit interview and when contacted reported only that he/she could not participate due to a “family crisis.”

From the 21 participants who completed the study, data was compiled into nine pertinent tables. The variable data were grouped into three main categories: Drug Use, Cravings (for the drugs), and Indications. Each category has three sets of data points—Intake, Midpoint, and Exit—occurring at one-week intervals. A guide to the tables (which appear on pp. 5-13) is as follows:

	Intake	Midpoint	Exit
Drug Use	See Table 1A	See Table 1B	See Table 1C
Cravings	See Table 2A	See Table 2B	See Table 2C
Indications	See Table 3A	See Table 3B	See Table 3C

The subjects were given a range from 1 to 10 in each category listed in the tables. A larger number indicated a higher intake of the substance, higher craving, or worse indications. The final column in each of the tables shows an average for the data in the corresponding row (an average quantification of all 21 subjects’ reported drug use, cravings, or symptoms).

These averages were then cumulated into three tables (see p. 14) comparing the results of one week and two weeks of use of Modera XL. See Table 1X and Chart 1X for comparison of the average reported Drug Use across the three data collections. See Table 2X and Chart 2X for a comparison of the average reported Cravings across the three data collections. See Table 3X and Charts 3X<sub>I</sub> and 3X<sub>II</sub> for comparison of the average reported Indications across the three data collections. (Charts 1X, 2X, 3X<sub>I</sub>, and 3X<sub>II</sub> can be found on pp. 15-18.)

The average drug use and cravings decreased for all substance types between intake and exit. For alcohol and marijuana, the average use was slightly lower at the midpoint than at the exit of the study (however, the exit values *were lower* than the intake values). All other substance types showed a continuous decrease from week to week; the midpoint for all substances except alcohol and marijuana were lower than the intake data points, and the exit data points were lower than the midpoints.

Indications decreased consistently across all metrics. Each of the interrogated indications showed a lower average midpoint than the corresponding average intake data point. Likewise, the average exit data points were all lower than the corresponding average midpoints.

### **Discussion**

This study was open and not placebo controlled. Therefore, it is not possible to rule out some degree of placebo effect. Nonetheless, the results were ubiquitously favorable for all 21 subjects who finished the study. There was a decrease in drug use, cravings, and indications for all participants. A placebo controlled follow-up study is warranted.

Of 37 initial volunteers, 21 completed the study (57% completion). Of the 11 dropouts, only two were due to possible minor events. This represents a rate between 5 and 8% (2 out of 36 initial subjects who took the product vs. 2 out of 23 [21 subjects who completed the entire study + 2 who reported possible adverse events and dropped out]). These events might have been mitigated if more time had been allotted to taper up to a therapeutic serving of the product or/and if more resources had been available to work more closely with each individual to explore an optimum regimen of Modera XL use for these subjects.

The slight dip in alcohol and marijuana use at the midpoint compared to the exit of the study is not clearly understood. A longer duration of a follow-up study, and smaller intervals for data collections would help delineate this.

### **Conclusion**

The use of Modera XL effervescent packets between two and five times per day corresponded to a decrease in drug use, craving, and indications over a two week trial period for all of the participants who completed the study. Modera XL was safe and well tolerated. Although there was excellent success for the participants during their use of this product, this was an open, non-placebo-controlled study and placebo phenomenon cannot be ruled out. This study provides evidence of safety and efficacy for the use of Modera XL (a product containing constituents which have been used individually for many years which have a plethora of published data and research in the scientific literature indicating the safety and efficacy of the individual constituents) to support normal structure and function where subjects seek to reduce or quit the use of addictive substances. Further studies to scientifically quantify the efficacy of this product are warranted (i.e. blinded, placebo controlled) and will help to quantify the potential therapeutic benefits of this unique combination of nutritional supplements and nutrient adaptogens.