Neurogenesis, Inc.

Symptom Reduction In Persons Withdrawing from Benzodiazepines

DRAFT DOCUMENT

Study Report

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ABSTRACT

An amino acid, vitamin and mineral formulation was designed to restore GABAergic, opioidergic, and serotonergic deficits observed in persons suffering acute and protracted withdrawal symptoms associated with reduced use of benzodiazepines. In addition amino acids, vitamins and minerals were added which have been shown to further reduce anxiety provoked responses of striated and cardiac musculature. Seventeen adult male and eighteen adult female subjects who had been prescribed benzodiazepines for periods of time ranging from one to fifteen years, and who were all experiencing withdrawal symptoms as a result of attempting to reduce and stop the drugs, volunteered for the study. Twenty seven of the participants were following an individual tapering regimen. This approach is strongly supported by the author of this study.
Each respondent understood they would not know whether they were receiving placebo or experimental product. Each was given a 30 day supply of either placebo or experimental. At the end of 30 days the products were switched and those having received placebo received experimental and visa versa. Symptoms were described and noted for each participant prior to beginning the study and during the study. Symptoms varied from extreme to moderate withdrawal depending on the benzodiazepine being used. Those persons attempting to taper Klonopin, Xanax or Ativan had a more difficult time due to rapid cycling of highs and lows of Norepinepherine activity. Those persons on long acting benzodiazepines such as Valium were more successful in the tapering process and experienced lower levels of anxiety and associated symptoms. Regardless of the drug being used, however, all respondents but two expressed that they were better able to function and were more clear headed when using the supplement as part of their tapering. The time period for this study was relatively short and further results will be documented over the coming months. At this time the product is scheduled to be tested in Europe as well as the United States.

INTRODUCTION

Since 1964 the use of benzodiazepines in this country has exploded to epidemic proportions. Librium, the first discovered, became known as “mothers little helper” and prescriptions for these “tranquilizers” were soon in the millions per year. People began to expect a pill to solve their problems of worry and anxiety and we soon stopped “solving” our problems and took drugs to change the way we felt. No one knew or expected that the use of these pharmaceuticals would one day create a monster of a problem linked to their use.
As patients took these drugs for longer periods of time and then attempted to stop they were confronted with terrible psychological and physiological withdrawal symptoms which incapacitated them. People in withdrawal have lost jobs, families, their very lives as the extreme anxiety,

sleeplessness, confusion, heart problems and other extreme withdrawal factors prevented them from interacting in society in any meaningful manner.
Even patients who attempted to very slowly taper their dosages and gradually withdraw from this dependency experienced some degree of discomfort and the difficulty remained for months and years after use. While these people were no longer “dependent” on the benzodiazepine they continued to suffer protracted withdrawal and a significant degree of disability.

Over the years even more potent benzodiazepines have been developed with the result that even more debilitating withdrawal is now evident. Recently, persons who were familiar with NeuroGenesis products and successes with nutritional supplements ask that we look at the “benzo” problem and determine if we could help those suffering with this dependency with a nutritional supplement.

Upon reviewing testimonies of people withdrawing from benzodiazepines and talking with numbers of people in this predicament it soon became clear that each person’s experience of withdrawal is unique. Although there are many features in common, every individual has his/her own personal pattern of withdrawal symptoms. These differ in type, quality, severity, time-course, duration, and many other features. Such variety is not surprising since the course of withdrawal depends on many factors: the dose, type, potency, duration of action and length of use of a particular benzodiazepine, the reason it was prescribed, the personality and individual vulnerability of the patient, his or her lifestyle, personal stressors and past experiences, the rate of withdrawal, and the degree of support available during and after withdrawal, to name but a few.

SUBJECTS AND METHOD

Eighteen adult female and seventeen adult male subjects from all areas of the United States made it known they would be willing to participate in a study related to benzodiazepine withdrawal. All but three of the subjects were currently taking benzodiazepines and the others had been off the drugs for periods of time up to 12 months. Of those on the drugs all but two were following some kind of a tapering regimen for gradual withdrawal. Ten of the subjects were taking Klonopin, eight were taking Xanax, two were taking Ativan and twelve were taking Valium.
Each person was interviewed by telephone and asked to describe the dose they were taking, any other medications, any other supplements and the symptoms they experienced on a daily basis. As expected the symptoms varied greatly but all described a torment that prevented the person from interacting in family and society successfully. (Persons taking antidepressants at the same time as benzodiazepines were excluded from the study). Each was then sent either placebo or experimental product sufficient to last 30 days and asked to take six capsules per day in divided doses. Each person was reinterviewed at periods between two and four weeks of the study and asked to again describe symptoms present at that time.
Not surprising those on placebo expressed little relief from the previous symptoms. Those on experimental product, however, indicated an awareness that some of their symptoms had diminished, and this added hope to their process. Interestingly, when the original experimental group was sent placebo for their second 30 day period they all stated they could tell the original discomfort was returning by the third week. They all requested that the previous “product” be sent to them when reinterviewed at the second and fourth week of the second month.
Eighteen of the original participants have remained in contact at the four month mark and all are still taking “experimental product”. They all report that the symptoms of withdrawal continue to wane as they taper their use of the tranquilizer. Several have stopped the benzodiazepine and are continuing on NeuRecover BZ and are expected to do so for an unknown period of time.
One factor that stood out as each reported their progress/lack thereof was that those persons taking Valium were much more able to taper their use and experienced improved functionality sooner than those on the other benzodiazepines. Klonopin was the most difficult to taper and assist with symptom reduction via nutritional supplementation. All Klonopin users described extreme mood swings and difficulty functioning when attempting to taper the drug. Xanax users reported the same phenomenom

and Ativan appeared to be almost as difficult. As Ashton points out in her manual, it much more simple to taper the long acting Valium and this was born out in our study.

RATIONALE FOR FORMULA

The Gamma Amino Butyric Acid (GABA) receptor is an extremely complex receptor system. GABA accounts for almost 40% of all neurotransmitters in the brain and this fact indicates it's importance in maintaining calm and logical thinking. Located on the GABA receptor are several other sites that become occupied by other various neurotransmitter chemicals. Principal among these auxiliary receptors are those that receive benzodiazepines. When a benzo occupies a receptor site it assists GABA in opening a channel into the neuron on which it is located and chloride (from NaCl, salt, for instance) passes through this channel into the neuron. This then reduces the firing rate of that neuron and "calms" down activity. While it is obvious that we were not born with a receptor for benzodiazepines, which were not known until 1964, it is obvious that we have a normal and natural neurotransmitter to act at these sites. These natural transmitters act very quickly and are so quickly degraded that they have not been positively identified and named at this time.
The issue that is most important and the issue that causes all the problems of dependency is this: when the auxiliary receptors are occupied for longer than normal periods of time by drugs such as benzo's the result is that the brain begins to reduce the supply of GABA. The brain works to maintain balance, homeostasis, and will not do what it doesn't need to do. If auxiliary receptors are busy doing most of the work it does not need to make GABA, and it does not. The problem comes when the person attempts to stop the use of the drug which is assisting GABA and now there is not enough GABA to do the job on its own. Also, since "artificial" neurotransmitters in the form of a benzo were being introduced the brain makes less of its' own auxiliary transmitter and the problem is compounded. Dependency now exists for the benzodiazepine to open channels to allow chloride to calm activity. If the channels are not opened then adrenalin and noradrenalin run rampant and continually fuel the fight or flight response. Heart rate increases, sleep decreases, appetite decreases, all the states that are required for an alert are constantly present. Normal everyday human activity is not possible when the brain and body are engaged in the process of fighting or fleeing.

FORMULA	PER CAPSULE
d-phenylalanine	5 mg
5-HTP	10 mg
Glycine	50 mg
Taurine	50 mg
L-Glutamine	50 mg
Metabolic Co-factors	Vitamins B_6 & C
Calcium as citrate	
Magnisium	
Zinc	
Folic Acid	

CONCLUSION

The depletion of brain chemistry required to maintain calm can be brought about by prolonged use of drugs such as benzodiazepines. The symptoms associated with this depletion become obvious when the drug is discontinued. The result is that the person is so incapacitated by these overwhelming negative states that they are virtually unable to function in society. In the past the medical community

has simply told the patient to take the benzodiazepine all the time. This leads to distinct problems with blunting of affect and reduced ability to think and act as required for job and family.
The solution is not more drug use. The solution has to involve rebuilding the normal brain chemistry needed to think and act calmly and rationally. This can be accomplished by a combined effort to gradually reduce the drug use and at the same time provide the building blocks for normal brain function which can only be gained from nutritional sources. In this case the precursor loading of the selective building blocks allows brain function to eventually resume normal function.