

### An N-of-1 Placebo-Controlled Trial in Clinical Practice

Many articles in this journal explain how patients can restore their health using healing doses of vitamins and other supplements, optimized to suit their diagnoses. Jonathan Prousky's N-of-1 paper (*J Orthomol Med*, 2010; 25: 195-213) reported a case where niacinamide did not appear to help one patient reduce anxiety, although the patient did lessen her anxiety during the research trial. Prousky reported that the anxious patient had a mildly negative response when taking niacinamide.

Prousky's book *Anxiety-Orthomolecular Diagnosis and Treatment* (Toronto, ON. CCNM Press Inc. 2006; 39-63) reported four cases where other patients responded positively to niacinamide for anxiety. His book identified pellagra, NAD deficiency and hypoglycemia as three metabolic conditions which might cause or contribute to anxiety and which might improve if patients took niacinamide.

#### Anecdote of 1

When I first took vitamin B<sub>3</sub>, it seemed to make me worse. Carl Pfeiffer mentions this possibility in *Nutrition and Mental Illness* (Rochester, VT. Healing Arts Press. 1987; 26-32), especially if patients have high histamine. For several years I avoided taking niacin or niacinamide but took other vitamins, minerals and amino acids for a bipolar II mood disorder, migraines and anxiety. I continued to read about B<sub>3</sub> and wondering how to get its healing benefits, without making myself worse.

I wrote to Abram Hoffer, PhD, MD. He was not surprised by my anecdote and referred to the principle of biochemical individuality which Roger Williams, PhD, conceptualized in his book *Biochemical Individuality* (New York, NY. John Wiley & Sons. 1956).

Eventually, medical tests showed elevated cholesterol. Not wanting to take a sta-

tin drug, I decided to try niacin again. Even 100 mg of niacin triggered a pronounced but brief flush; however, niacin soon lowered my cholesterol into the normal range. That surprised my doctor.

I wondered about taking methyl sources with niacin. Pfeiffer's book explains that methionine can lower histamine. Hoffer wrote that methionine could make schizophrenics worse but since I don't have that diagnosis, I was not worried about taking a small dose of methionine with niacin. Later I added TMG (trimethylglycine). Now I take 1,000 mg of niacin and 1,000 mg of niacinamide in daily divided doses, with methionine and TMG.

Perhaps Dr. Prousky's paper could have mentioned that some patients may be good responders to niacinamide, while others may not respond and a few may respond unfavourably. The range of response to nutritional supplements by individual patients and the possible use of methyl sources with methyl acceptors might interest orthomolecular health professionals.

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#### Author Responds

I read Mr. Sealey's letter with great interest. I agree that niacin and niacinamide function as methyl acceptors and might not help all patients. I also agree that individual therapeutic responses to niacin and niacinamide vary and depend on numerous individual biochemical factors that are not well established and not easy to sort out clinically. Combining methyl sources with methyl acceptors is something that many orthomolecular practitioners do empirically. Clinical trials evaluating how specific orthomolecular combinations influence methylation in neuropsychiatric disorders are desperately needed.

While I agree with many of the points

he makes, the references to my recently published N-of-1 study require further comment. Sealey mentions that I should have been more explicit in how patients might respond to niacinamide. This was never the intention of my N-of-1 study. Prior to this study, I reported some of my successes when using niacinamide for anxiety; these anecdotes lacked scientific rigor. The patient in the N-of-1 study was blinded, as was I, which made the results more scientifically useful. Many confounding variables could have influenced the favourable effects I observed in my previously-published anecdotes. In my N-of-1 study, many confounding variables were removed and it was clear that the niacinamide did not help this patient but rather mildly increased (i.e., worsened) her anxiety. I also mentioned that this outcome cannot be generalized to other individuals seeking help for their anxiety, which does not discount niacinamide's potential usefulness for other patients. While I concluded that there are more questions than answers about the effectiveness or lack of effectiveness of niacinamide for anxiety, I also stated that further study is certainly needed.

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### A Return to Healing - Revisited

I am moved to respond to Dr. Richard P. Huemer's review in JOM (Vol. 25, No. 2) of Dr. Len Saputo's new book *A Return to Healing: Radical Health Care Reform and the Future of Medicine*. Although he generally

likes the health proposals of the book and is roused to see them stated so incisively by Dr. Saputo, as any of us would be, the reviewer is riding a hobbyhorse and someone has to try to knock him off it. For he really is serious about what he calls "free market" health care. His one big problem with the book, he says, is that Dr. Saputo supports a government-run, single-payer system; he scorns this as a "collectivist solution." He frowns on "the author's disdain of free markets," and believes it must be because Dr. Saputo does not "understand the definition of free market": "which is simply one in which prices for goods and services are set by mutual agreement of seller and buyer."

Well, then, let us do our best to understand. I think it is fair to say without distortion that in a free market the seller tries for as high a price as possible and the buyer looks for the bargain; and if mutual agreement is not achieved either party can break off the negotiation at any point and seek sales or purchases elsewhere.

I doubt if the reviewer will assent to the above spelling out of his "simple" definition of free market. But if he doesn't mean this, what does he mean when he says that the free market solution "should be seriously given a try before being dismissed out of hand"?

One must reiterate that the reviewer does appreciate Dr. Saputo's book and seems to be a good friend; but then he unexpectedly turns on him on the question of the single-payer system, which most of us in Canada (according to all polls) don't want to lose. After referring to Paul Krugman's support for government-run health insurance as "collectivist twaddle," the reviewer takes up a couple of "functional" cases that Dr. Saputo mentions: "One is the Canadian system, the infelicitous inclusion of which may reflect the author's unfamiliarity with its shortcomings." One doesn't know whether to laugh or cry over this curt dismissal. But we must not toss the review aside, for a second example gets very interesting, because it clearly stands as a refutation of the reviewer's whole point: "Another [example of a single-payer system] is the French, which really does seem to work

well according to first-hand accounts I have received.” To which the reviewer adds, to our further astonishment: “But then, the French can afford it.” It’s what many of us say about the Canadian system: that the only trouble is that governments seem always to be starving it of the money that would enable it to work at its best.

One must then go on to hear the review out on why the French can afford a good single-payer health care system. It is quite a remarkable and surprisingly moving passage: “They [the French] have no far-flung military establishments across the globe, are not fighting wars on two fronts, and do not struggle to maintain hegemony over the rest of the world...Loosening the tentacle-grip of imperialist ambition and renouncing bellicosity must be part of the cultural and social healing necessary to reforming health care.” Here the reviewer, no longer on his hobbyhorse, is raising a very different flag, one that we can rally under. He actually is pushing Dr. Saputo’s argument to its logical conclusion: that the change of medical paradigm we so much are looking forward to is probably going to be one part of a change in the wider political system, when the military-industrial-pharmaceutical complex is cast off and there is a chance for attention to all the good things Dr. Saputo talks about and the reviewer mainly agrees with.

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