

A Tale of Two Trials

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The charity, DIRECT-MS, was founded by my wife and I ten years ago, three years after our oldest child was diagnosed with MS. DIRECT-MS stands for **DI**et **RE**search into the **C**ause and **T**reatment of **M**ultiple **S**clerosis. To help our son, we reviewed the MS literature and it became clear that there was a very good chance that nutritional factors were involved in the onset and progression of multiple sclerosis. We were overjoyed when our son improved dramatically following the use of various nutritional strategies which came from our literature research.

To share this information with other families affected by MS, we decided to try to work through the MS Society of Canada. However, after three years of letter writing, phone calls and personal visits to the local and national offices of the MSSOC, it became very apparent that diet was a four letter word to the Society. They refused our offer to supply science-based information on nutrition and MS to local Society offices and the Society had no interest in supporting any research into the possible role various nutritional factors may play in MS.

Thus DIRECT-MS was born out of the desire to fill the major gaps in the MS Society's myopic program. The goals of the fledgling charity were simple – 1) to provide persons with multiple sclerosis with reliable, scientific information on nutrition and MS so as to allow them to make an informed decision on whether or not to use nutritional strategies to combat MS and 2) to fund research into the role of nutritional factors in the onset and progression of MS.

Thanks to the advent of the World Wide Web and the Internet in the 1990s, we were able to meet our first goal mainly through the creation of a website which contained the relevant scientific information on nutrition and MS. Other communication strategies have included producing hard copies booklets on various topics on nutrition and MS, giving public lectures and bringing in experts in relevant fields to speak, producing webcasts of talks, and writing essays and magazine columns such as this one in New Pathways.

Fulfilling the second goal of supporting research proved to be much more challenging. Thanks to the generosity of many people and organizations, we

were able to raise enough money by 2003 to support one or two small clinical trials. Our main aspiration was to fund a controlled trial which tested the effectiveness of the recommended nutritional strategies for affecting the MS disease process. We contacted every MS researcher in Canada and had one show of interest. However, by the time we were ready to go ahead, the researcher found every excuse in the book to beg off. It was painfully clear that nutrition and MS research was not of any interest to the MS researchers of Canada despite a major interest in such research by those with MS.

In 2004, I was fortunate to be able to go on an MSRC-sponsored speaking tour in England and Scotland. The tour was primarily funded by Alan Caldwell who had benefited from the use of nutritional changes and who had raised money by biking from Seattle to the Golden Gate Bridge. My talk on Nutritional Strategies for Multiple Sclerosis at the University of Dundee was attended by Allan's neurologist, Dr Jonathan O'Riordan, and he saw the potential for the use of nutrition in MS. Within a year, Dr O'Riordan and his associate, Dr Pushkar Shah, had put together a plan for a controlled clinical trial to test the nutritional strategies for MS.

Recruitment for the trial began in 2006 and for the last two years the researchers have overseen its completion. Recently, preliminary results were presented at the MS World Congress in Montreal. Twenty-two patients completed the trial with 11 on the diet and 11 acting as controls (on MS Society dietary recommendations). It was found that, after one year, those on the recommended nutritional strategies had a lower rate of brain shrinkage and less change in disability scores as well as significantly better scores in MS Function Composite and Vision tests. The researchers concluded that dietary factors may be important in MS pathology and that the recommended nutritional strategies may have a role in slowing disease progression. Data on changes in MRI parameters for both groups will be available by year end.

In 1999, after reading a watershed paper by Dr Reinhold Vieth, Canada's leading researcher in vitamin D nutrition, it became very clear that vitamin D deficiency likely played a major role in MS. By 2005, the evidence linking vitamin D to MS and other serious diseases including other autoimmune diseases, cancer and cardio-vascular disease, was literally overwhelming. However, such information was not being given to the public. Consequently, DIRECT-MS sponsored Dr Vieth to give lectures to both health professionals and to the public on vitamin D and health. A casual conversation with Dr Vieth during that visit led to a verbal commitment that DIRECT-MS would

fund a dose/safety trial of vitamin D for MS to be done at the University of Toronto under the direction of Dr Vieth and Dr Paul O'Connor, one of Canada's leading MS clinical researchers.

The proposed trial had lost its sponsor and the MS Society of Canada was not interested in such research. We leapt at the chance to ensure such important research was done by these top researchers. The main goal of the trial was to determine the safety of high dose vitamin D and, by high dose, they meant 40,000 IU a day (100X the recommended dosage). Such information is essential for an eventual clinical trial which will test the effectiveness of vitamin D for MS. Furthermore, we saw such information as very important for all persons with MS to help establish how much vitamin D intake is safe. Secondary objectives of the trial included seeing if vitamin D was of value for MS through the measurement of disability changes and relapse rate and through laboratory studies of immunological markers.

The results of this trial were also presented at the MS World Congress and they were also very positive. The trial included 25 treated patients and 24 controls and it was found that the escalating doses of vitamin D, which resulted in 25D levels of over 400 nmol/l, had no adverse effects whatsoever. Everyone's serum calcium level stayed within the normal range and there was no difference between the control and treated groups. The researchers also found that "A greater proportion of treatment patients had stable/improved disability scores vs. control patients ($p=0.018$). Treatment patients had fewer relapses and a greater reduction in relapse rate vs. controls."

The immunological data are also proving to be of interest. The laboratory studies demonstrated that high dose vitamin D resulted in much lower levels of immune cell expansion and that immune responses to myelin proteins as well as milk proteins were significantly reduced. Thus high dose vitamin D appears to be an important suppressant of autoimmune reactions.

It has been gratifying for us to be able to support such important research and to see the positive results which have been achieved. The results demonstrate the benefits that the recommended nutritional strategies can have for persons with MS. We are now looking at future research projects which will help to clarify the roles and benefits of nutritional change for MS.