**A STUDY OF NUTRITION THERAPY FOR ATTENTION DEFICIT HYPERACTIVE DISORDER**

By Kevin A. Horvath, M.D. Upper Valley Pediatric Care Tipp City, Ohio

This is a study involving 40 children with attention deficit hyperactive disorder/attention deficit disorder (ADHD/ADD) who were stable and performing reasonably well on an appropriate dose of Ritalin. Due to the success of the author with the Reliv Now and Innergize Nutritional supplements in the management of ADHD, a double blind placebo controlled study was performed over a four week time period. The children were assessed at baseline, two and four weeks into the study by a reputable questionnaire. At two weeks each child's daily Ritalin dosage was decreased by 25 to 30%, so that an accurate assessment could be made as to the impact of the nutritional therapy for the treatment of ADHD. Overall, the children on placebo and Ritalin demonstrated the typical unpredictable, at times labile behavior characteristic of this disorder. The children on the Reliv product and Ritalin not only demonstrated a measurable improvement in behavior throughout the entire study, but also were far more predictable and consistent in their day to day living.

**INTRODUCTION**

The study was initiated with the careful selection of 40 children previously diagnosed with ADHD/ADD who were presently stable and demonstrating an overall favorable response to an appropriate dose of Ritalin. These children demonstrated Edelbrock scores using the Child Attention Profile test pre-Ritalin that were indicative of a diagnosis of ADHD/ADD, and all demonstrated statistically significant improvement on dosages of Ritalin ranging from 0.3 milligrams per kilogram per day to 1.0 milligrams per kilogram per day in appropriately divided dosages.

Upon an in depth explanation to the child's parents as to the parameters of this study and after obtaining an appropriate consent, each child was scored using the Child Attention Profile by both parent(s) and teacher(s) as a baseline for assessing their overall behavior prior to initiating the study.

Each child was then started on a combination of either Reliv Now and Innergize or a placebo of these true product, as well as continuing their routine Ritalin dosages. The Reliv Now and Innergize, as well as placebo was provided to the child's parents or guardian in numbered, but unlabeled containers and all product provided appeared and tasted similarly. Each family received randomly an amount sufficient for approximately one month of use, the dosage adjusted for body weight. All participants in the study were unaware of whether placebo or true product were being provided.

Reliv International was then asked to provide the master key of which numbered units were real or placebo to a third party of sound legal reputation who was specifically instructed to release the key only after the study was completed and all raw data was sent to this party. The purpose of this was to reassure that no attempts could be made to alter the data once the master key was obtained.

All children were to be on a twice daily regimen of Reliv Now/Innergize or placebo for approximately four weeks. After two weeks of being on either true product of placebo, all children had Edelbrock Child Attention Profile scores repeated both by parent(s) and teacher(s). Each child's Ritalin dosage was decreased by 25 to 30%. If a child at that time was receiving several dosages of Ritalin per day, every effort was made to decrease the dosage in as even of a manner as possible.

The decreased dosage of Ritalin was continued for two weeks upon which a third Child Attention Profile score was obtained from both parent(s) and teacher(s). At that point, the product was discontinued and the child resumed his/her previous does of Ritalin. If during the latter two weeks, a given child demonstrated a less than manageable behavior judged by either parent(s) or teacher(s), then the third series of Child Attention Profile scores were immediately obtained and the child then resumed his/her previous dose of Ritalin and the product discontinued.

Upon completion of this study, all scores were compiled. If multiple teachers were involved in scoring, then an average teacher score was used insuring that the same teachers observed that particular child at each of the three testing intervals. The data was then analyzed as to whether each child demonstrated behavior that improved or deteriorated while on true Reliv product versus placebo and what effect a modest drop in Ritalin had while the children remained on true product versus placebo.

**MATERIALS AND METHODS**

During the selection of 40 patients for this study, as well as during the introduction of the study to all of the involved parents, every attempt was made to reinforce objectiveness, open mindedness, and consistency during administration of this product in assessment of the child's behavior. It was stressed that without these points taken quite seriously throughout the study, its reliability would be minimal at best.

The dosage of true product and placebo were structured in this manner: for children 45 to 60 pounds, 1 to 1½ tablespoons of true or placebo Now and 1 tablespoon of true or placebo Innergize dissolved in 3 to 6 ounces of water twice daily were recommended. For children over 60 pounds, 1½ to 2 tablespoons of true or placebo Now and 1 to 1½ tablespoons of Innergize twice daily were recommended. The dosage range was established due to variations in compliance and overall acceptance of taste. For the first week, each child was started on a somewhat lower dose of true or placebo Now and Innergize, and then increased to this higher dosage. This dosage was arrived at mostly due to experimentation with a fairly large number of ADHD children prior to this study in terms of finding what safe threshold dose was needed to provide consistent overall improved behavior.

Each family was contacted every two to four days by a staff member who answered questions, offered advice in terms of various preparation techniques when compliance proved to be a problem, and generally was available to troubleshoot any difficulty the family encountered.

After two weeks into the study, each family was asked to rescore their child, as well as to obtain a similar score for the child's teacher(s). The family was asked to discuss the generalities of the study with the child's teacher(s) prior to initiating the study and to ask their teacher(s) to be as objectively aware as possible during the four week study, as well as with all testing assessment.

At the two week time period, each child's Ritalin dosage was decreased by 25 to 30%, as a stressor to study how children's behavior on true Reliv versus placebo. The dosage changes were individualized, for instance, a child on 10 milligrams every a.m. and 5 milligrams at noon and 4 p.m. for a total of 20 milligrams of Ritalin daily would be decreased to 7.5 milligrams every a.m., 5 milligrams at noon, and 2.5 milligrams at 4 p.m., for a total of 15 milligrams of Ritalin daily. At the two week mark, two patients were taken out of the study due to parental or patient noncompliance, both of whom were later determined to have randomly received true product.

Over the following three to seven days after decreasing the Ritalin dosage, approximately 15 to 18 children demonstrated markedly adverse behavior that required early rescoring by both parent(s) and teacher(s), and were then restarted on their previous dose of Ritalin and the product discontinued. This was felt to be quite satisfactory in view of the fact that 20 children received placebo and to the author it indicated the child chosen baseline dose of Ritalin was the true minimum that they needed to generate appropriately improved behavior.

The remaining children were than rescored by both parent(s) and teacher(s) at the four week interval. The product was discontinued and the previous dosage of Ritalin was resumed. As an aside, all of the children with the exception of two were receiving nongeneric Ritalin throughout the study, as well as routinely.

**RESULTS**

Enclosed are tables 1 and 2, which demonstrates the raw Edelbrock's Child Attention Profile scores for true product and the placebo respectfully. It was the author's firm impression that to appropriately evaluate this data, what was essential is how each child's behavior changed from baseline to the two and four week intervals. therefore, the data was evaluated by looking at each child's deviation in score and plotting the difference between tow two and four week scores from baseline.

For instance, the Edelbrock Child Attention Profile has 12 question of which a 0, 1, or 2 can be assigned with a high score of 24. Behavior commensurate with deteriorating attention span and impulsivity would generate a higher score. If a child had a baseline score of 10 and fter two weeks was scored at 13, and at four weeks scored at 17; then an appropriate behavior curve would start from baseline to a 3 point rise in score at two weeks and to a 7 point rise from baseline at four weeks. In other words, if behavior curves were plotted for each child in this manner, curves that rise from baseline showed deteriorating behavior, a flat line would indicate no change in behavior, and a drop in the curve would demonstrate improved behavior.

All data was plotted in this manner with separate graphs constructed for teacher and parental assessment on true product, as well as two graphs for placebo. In looking carefully at the behavioral curves, it became quite obvious that six children on true product and four children on placebo consistently reacted adversely to the product from the outset. This was clearly apparent by both parental and teacher assessments. These cases were picked purely on the basis of their behavioral curves, which rose sharply at two weeks and remained that way at four weeks. It was reasoned that certainly another factor was involved in effecting these children's behavior for why would a child on a vitamin product or placebo demonstrate significantly less optimal behavior prior to even changing their dosage of Ritalin?

The answer to this question became evident after reflecting on the ADHD patients that were tried on Reliv Now and Innergize prior to the study. Briefly put, most of these ADHD children the author had trialed on Reliv demonstrated remarkably improved behavior. However, a small handful became obviously worse. It was reasoned at that time, that the most likely cause of such an adverse reaction would be an allergic response and the most likely allergen in Reliv Now or Innergize would clearly be the whey protein in Now. Milk is undoubtedly the most common dietary allergen and a great deal has been written as to the overall increased allergicity these ADHD children demonstrate. Interestingly, every child who reacted adversely to Now/Innergize prior to this study went on to demonstrate a positive

allergy test (RAST) to milk, and all those children demonstrated remarkably improved behavior with a resultant decline in need for Ritalin once milk was eliminated from their diet.

Reviewing tables 1 and 2 will demonstrate a subset group at the bottom of the table corresponding to those who are felt to be milk allergic. Each patient was assigned a 3 digit number corresponding to the box number of the study product they received from Reliv. Bearing in mind that the only ingredient other than a neutral base in the placebo was whey protein, it stands to reason that a similar number of both placebo and true product children reacted in this manner. It is of significant interest that of these ten children that reacted adversely, three are RAST positive for milk, three are all brothers (two of whom received placebo and one true product) of which there is a significant family history of milk allergy, and of the remaining four patients, two of those were severely milk allergic as infants and the remaining two have RAST tests to milk pending at this time. Although the subject of milk allergy in ADHD children stirs considerable debate in the medical literature, it would stand to reason that the addition of Reliv now would trigger this minority of children in view of the relatively high dosages that the author felt were needed to properly manage their behavior.

It was the author's impression that the teacher assessment would reflect a more reliable score than the parental assessment, primarily because the children are fresh and well rested in the morning, school is fairly consistent and predicable from day to day, and the teacher may offer a more objective less biased assessment. Unfortunately, parents are faced with tired children and may have a highly variable routine from night to night. Parents many times are working a significant portion of the time and that the child is home and are faced with a considerably different disciplinary prospective than the teacher.

Factoring out the two children on true product who were noncompliant and the six on true product who were felt to be milk allergic, this left 12 remaining patients on true product whose behavioral curves are graphed on figure 1. What is of profound significance is the remarkably narrow deviation of behavioral change at the two and four week mark. At tow weeks, there was a 6 point spread in behavioral change and a 4 point spread at four weeks. The average child on true product improved by 1.85 points on the Child Attention Profile score at the two week mark and improved to a mean of 2.0 points at the four week mark despite a 25 to 30% drop in Ritalin two weeks prior.

Compare this cure to figure 2, which demonstrates teacher(s) assessment of 16 children on the placebo (please recall four patients were removed due to probable milk intolerance). It is obvious from figure 2 that the behavior of these children on placebo are chaotic and what appears to be random unexplainable behavior. Some children deteriorated at two weeks, then went on to improve or to continue to deteriorate at the four week mark. Other children improved at two weeks, then went on to deteriorate or to continue to improve at the four week mark. Although initially this curve may seem to be nothing more than totally random as previously stated, I believe it demonstrates the overall unpredictable, wildly variable behavior these ADHD children classically demonstrate. These children are very sensitive to their diet, as well as to the nearly infinite number of variables in their environment. Depending upon teacher or peer conflicts that week, whether there is an impending test or book report, or perhaps their routine at homes varies significantly from day to day, these children are very reactive to their environment. As a result, obviously, their attention span, level of impulsivity, and ability to stay on task will be effected. In brief summary of figure 2, there is a 17 point spread in behavioral change at the two week mark and a 20 point spread at the four week mark, which is obviously quite a contrast to the results depicted in figure 1.

**DISCUSSION**

In closely examining the data previously discussed, it is readily apparent that overall the children on true Reliv Now/Innergize improved after two weeks on the product and remains stable in their behavior after an additional two weeks despite a modest decline in their Ritalin dosage. This of course is in sharp contrast to placebo. What is of even greater significance is the much more predictable, stable behavior demonstrated by the children on true product. Contrasting both behavioral curves of figures 1 and 2 clearly points out that the amazing behavioral consistency of the children on true product versus an equal amazing lack of behavioral consistency on the children receiving placebo. This of course takes into account the elimination of the author's suspected milk allergic population. Also, an important point of mention are the very similar behavioral curves generated by parental assessment; although they were not included in the study graphically, the results demonstrated a similar yield with only slightly greater fluctuation in behavior on true product, as well as placebo. From a statistical prospective, the data was closely evaluated at a nearby university statistical center. Although statistical analysis clearly confirms the obvious disparity between placebo and true product by teacher(s) assessment, the shear fact that we were reduced to 12 patients on true product and 16 patients on placebo limited our level of statistical significance from a mathematical perspective.

Nonetheless, the results are clearly evident; it is apparent that given a greater number of patients a repeat study of a similar nature would be very useful to that a greater statistical margin could be demonstrated to the medical public.

In closing, it is the impression of this author that for children who are not milk allergic and who have been diagnosed with Attention Deficit Hyperactive Disorder or Attention Deficit Disorder, a combination of Reliv Now and Innergize appropriately dosed can be of tremendous benefit. To put it in a more clinical prospective, the author's patients who are mildly ADHD/ADD respond quite successfully in most cases to the Reliv Now and Innergize combination without the need for Ritalin. For those children who demonstrate a more prominent degree of ADHD/ADD, it is opinion of the author that there is still a need for Ritalin in conjunction with the Reliv products. However, their need for Ritalin is considerably less and the overall resultant behavioral changes appears to be much more positive than Ritalin alone at a greater dosage.