

## CASE REPORT

### **The Successful Management of Ulcerative Colitis with A Nutritional Intervention: A Case Report**

Scheller B, Winter C, Zamyad J, Felmlee K, Heard D

**Case Description:** A 23-year-old Caucasian female was diagnosed with Ulcerative Colitis (UC) and symptoms were successfully managed with the 5-Rs (remove, replace, re-inoculate, repair and rebalance) gut restoration program. Diagnostic laboratory testing was initially utilized, which identified microbial imbalances, vitamin D deficiency and vitamin B12 deficiency. Nutrition therapy was then implemented over the course of 7 months, which included a whole foods elimination diet that was low in FODMAPs and avoided leading allergens such as cow dairy, soy, gluten, and corn. Nutritional supplements were implemented in phases to aid in rebalancing gut bacteria, repair the mucosal lining and correct nutritional deficiencies. After dietary adherence and the 5-Rs program, the patient became 100% asymptomatic with no use of mesalamine suppositories for more than 6 weeks.

**Conclusion:** This case report suggests the effectiveness of the 5-Rs program approach for the successful management of UC. Long-term resolution was supported by the elimination of specific foods, nutrition supplementation, and stress management.

## STUDY DESIGN

Supplementation of Carnosine for Glycemic Control in a Diabetic Population of 25-29 Obese Women: A Prospective Case Series

Martin E, Bawazir A, Coetzee O

**BACKGROUND:** Diabetes is a global pandemic, causing approximately 4 million deaths in 2017. Carnosine, an endogenously-produced substance, ameliorates diabetic complications and inhibits the formation of advanced glycation end-products (AGEs). Through increasing the activity of H3 receptors, the breakdown products of carnosine reduce food intake and body weight, while increasing beta cell activity. Men have a 22-82% higher level of carnosine than women. Proven to improve secondary complications of diabetes and provide glycemic control when used in combination with other agents, there are no human trials to demonstrate carnosine's blood-glucose lowering ability for diabetics when used alone.

**Objectives:** This prospective case series evaluates the effect of supplementing carnosine in type 2 diabetic patients on reducing fasting blood glucose (FBS) levels and HBA1c.

**Methods:** 25-29 women diagnosed with T2DM  $\geq 12$  months, HbA1c  $\geq 6.5\%$ , and BMI  $\geq 30$  kg/m<sup>2</sup> will be recruited. Carnosine has been shown to reduce high blood pressure; therefore, we will exclude anyone taking antihypertensive medications, as well as medications that increase insulin secretion, insulin injections, and/or anti-glycemic supplements. Participants will be recruited from two primary care medical practices in Boston, MA. The consent to be studied and for multiple blood draws will be obtained. A hyperglycemia diagnosis and baseline anthropometrics will be confirmed at the initial assessment. FBS and HbA1c will be tested initially, and at 90 and 180 days after the beginning of the intervention. Participants will maintain their normal lifestyle and diet throughout. Blood testing will occur after a 10-hour overnight fast. The average washout period for carnosine is 9 weeks; thus, we will assess the degree of change in FBS and HbA1c after intervention and post-supplementation. To reduce risk of investigator bias, blood test results will be collected by a health care practitioner not involved in the study.

**Discussion:** There have been few studies to show the beneficial use of carnosine supplementation in the treatment of diabetes. Specifically, while carnosine been shown to improve some secondary complications of diabetes and has demonstrated beneficial effect when used in combination with cinnamon and chromium, there is apparently no human trials to demonstrate its blood-glucose lowering ability for diabetics when used alone.

## **Scutellaria Lateriflora (American Skullcap) For Anxiety in Adult Patients: A Multiple Baseline Research Study**

Scheller B, Heard, D

**Background:** Many US adults experience some type of anxiety disorder. Benzodiazepines (BDZs) are medications that are commonly prescribed for psychological disorders involving anxiety and mood, but these medications have many negative side effects. There has been a great interest and need to discover safe alternative options.

**Objectives:** This research study is designed to investigate whether *Scutellaria lateriflora* (*S. lateriflora*), also known as American Skullcap, has anxiolytic effects that can improve levels of anxiety, stress, fatigue and sleep.

**Methods:** Participants (Adults age 18+, with a history of moderate anxiety) will be screened for current use of conflicting medications, supplementation, chronic health issues as well as addictions (e.g.: drugs, caffeine, tobacco) that can impact the central nervous system and effect levels of anxiety. An experimental multiple baseline study with a classical AB-design will be used. Patient reported outcome (PRO) measures, including the Beck's Anxiety Inventory [BAI] and the Beck's Depression Inventory II [BDI-II], will be used as a screener to confirm anxiety at baseline and for final outcome assessment. The Daily Assessment of Symptoms-Anxiety [DAS-A] will be used to track changes in anxiety symptoms each day the participants are in the study. The study period for each participant will be 21 days. The intervention will include 350 mg of freeze-dried *S. lateriflora* (aerial parts) administered three times per day. Participants will also take a placebo containing spinach prior to starting their intervention of *S. lateriflora*. Participant intervention start times will be randomized and researchers will be blinded to timing.

**Discussion:** There have been some research studies conducted on *S. lateriflora*, but previous research study flaws open several areas of opportunity. For example: improved study design, elimination of confounding factors and biases, as well as expansion of symptoms assessed to include stress, sleep, and fatigue to determine the efficacy of *S. lateriflora* for anxiety symptoms.

## PRIMARY RESEARCH

### **Phase II Clinical Drug Trial to Assess the Safety and Feasibility of High Dose Vitamin D3 In Pediatric Patients with Cystic Fibrosis**

Carr V, Fernandez Hodge D, Green D

**Background:** Children with Cystic fibrosis (CF), due to intestinal malabsorption and pancreatic insufficiency, are at risk of developing a vitamin D (Vit D) insufficiency. In this population, Vit D insufficiency has been linked to increased inflammatory markers, poor bone health, and increased frequency of lung infections. Treatment guidelines (to correct a Vit D insufficiency in CF) were published by the CF Foundation in 2012. Since that time, our clinic has continued to observe poor Vit D levels despite additional supplementation per these guidelines.

**Objectives:** To assess if a single oral high dose (250,000 International Units (IU)) of Vit D3 is safe and feasible.

**Methods:** This study is a one-arm phase II clinical drug trial in pediatric patients with CF aged 3 to 18 years followed in the John's Hopkins All Children's Pediatric CF center. Inclusion criteria were met by patients with 25OHD <30 ng/mL (Vit D insufficiency). Exclusion criteria included any history of kidney disease/stones, hypercalcemia/hypercalciuria, abnormal creatinine levels 2 times the upper limit of normal (ULN), CF liver disease/cirrhosis, elevated liver transaminases 5 times ULN, parathyroid disorder or pregnancy. Subjects were provided a single dose during CF clinic. Safety was assessed with a serum calcium (Ca) level and a serum phosphorus (Phos) level measured at 1 week and 3 months following the dosage based on the half-life of Vit D and based on CF standard treatment guidelines. If Ca or Phos were elevated, a parathyroid hormone level (PTH) and spot urine Ca to creatinine ratio was obtained. To assess feasibility, participants answered a 10-item questionnaire on gastrointestinal symptoms experienced and overall ease of the regimen. Based on power analysis using another similar study, a total of 27 patients were enrolled.

**Results:** Only three patients had safety labs that required additional investigation. All levels resolved without additional treatment and were not clinically significant or harmful to any of the patients. One patient had hypercalcemia and three patients had hyperphosphatemia where two patients in total required PTH levels. The feasibility questionnaire indicated that this regimen was feasible as all 27 participants indicated that they preferred taking a one-time high dose over daily vitamin D and indicated that they would do this regimen again. Additionally, only 5 participants reported complaints of stomach upset after treatment, but this subsided shortly after. Although statistical analysis is still being completed, at baseline, mean Vit D levels were at 22.7 ng/mL and went up to a mean level of 29.1 ng/mL at 3 months. It is also unclear at this time if this increase in Vit D levels from baseline to 3 months is significant.

**Conclusion:** Based on these findings, where none of the participants required treatment for hypercalcemia or hyperphosphatemia, oral, high-dose Vit D3 can be safely administered to pediatric patients with CF. This regimen may also be a feasible option for pediatric patients with CF, based on the feasibility questionnaire.

## **Obese Patients' Perspectives on Ideal Nutritionist Care**

Youngblood S, Moore A, Felmlee K

**Background:** It is recognized that primary care physicians have difficulty providing weight loss counseling, and nutritionists may be best suited to administer weight management care. However, research is currently lacking on what patients themselves consider to be an effective patient-nutritionist relationship.

**Objectives:** The objective of this pilot study is to fill a gap in the literature by investigating the nutrition-related experiences and perceptions of people who are considered clinically obese according to CDC standards.

**Methods:** Semi-structured interviews were conducted with 9 obese individuals who were over the age of 18 and had seen a nutritionist at least once in the past. Data was gathered in three components: a structured, self-administered demographic questionnaire; a 36-item validated Quality-of-Life (QoL) questionnaire; and a semi-structured personal interview with the individual researchers. Qualitative data were analyzed inductively using constant comparison.

**Results:** In spite of the small (n = 9) sample size and pilot nature of the study, a wider range of opinions about what would make for an ideal patient-nutritionist relationship was expected. However, although the group of participants was characterized by a diverse range in age, race, educational background, income, and individual level of skill in the kitchen, several commonalities emerged when discussing what the patients themselves believe would result in a more effective relationship between patient and nutrition professional. Most notably patients expressed: (1) desire for open and accessible communication, (2) a propensity to feel more comfortable in a same-sex patient-nutritionist setting, (3) an interest in knowing the rationale behind a recommended protocol, and (4) an interest in transparent business practices.

**Conclusion:** Nutritionists are generally considered to be the first line of defense in weight management care which is a growing need in United States. It is therefore useful to find new solutions for the facilitation of relationships between obese individuals and nutrition professionals. Further studies are needed to systematically address questions such as whether the study findings would emerge as stable patterns with the addition of further interviews; whether additional themes would surface; and how patient preferences should be considered in the day-to-day operation of the nutritionists themselves. There is also a need to develop guidelines for private weight management care that consider not only nutritional aspects but also the best way to give weight management support in order to optimize QoL and increase compliance of the patient.

## **A Survey of Telenutrition in the CNS Community**

Tiffany Haugh, Jami Zamyad, Heather Carerra

**Background:** The following survey investigates the use of telehealth for nutrition counseling among Certified Nutrition Specialists (CNS) living in the United States. The fields of clinical nutrition and telehealth are both rapidly growing to meet the demands of patients living in remote areas who wish to partner with nutrition practitioners to address their health concerns. Telehealth has opened a new avenue for practitioners to reach clients in different parts of the country, and in some cases in different parts of the world.

**Objectives:** The main purpose of the survey is to elucidate the attitudes, beliefs, challenges, and actual use of telehealth/telenutrition practices among nutrition professionals with the CNS designation.

**Methods:** A modified version of the “Academy of Nutrition and Dietetics Telehealth Practice Survey 2015” was used as a template for the survey’s development. Participants were reached via social media, various university faculty and alumni, and the BCNS Conferences from November 7-10, 2018 in Seattle, Washington. CNS at the conference could complete the survey on portable devices at the project booth and we also given instructions on how to complete the survey later. In addition, the snowball sampling technique was used to spread the survey throughout the CNS community. Quantitative and qualitative data was gathered via Survey Monkey. The survey used categorical multiple-choice questions or Likert scales.

**Results:** A total of 58 CNS professionals completed this survey. Participants were mostly female (90%), white (88%), and between 30-49 years old (60%). A majority of participants have been practicing for less than 5 years (59%) with concentration in the northeast region of the United States. A third of CNS participants practice primarily via telenutrition, and a majority (71%) also maintain a private practice. Among these practitioners, 26% see clients outside of their home state. Overall, the majority (62%) agree or somewhat agree that state licensure laws play a role in their willingness to work with clients outside of their home state.

**Conclusions:** The results of this survey can be used to inform lawmakers, advocates, insurers, and educators about the use of telehealth in the nutrition profession, so that they can provide laws, materials, and resources to make the public aware of its availability, and make the guidelines for use clearer for practitioners who use it.

## **Experimental Study of The Effects of Immunothrive, A Proprietary Herbal Blend on Th1/Th2 Biomarkers**

Clayton G, Farris MJ, Romig W, Winter C

**Background:** A wide range of chronic conditions are mediated through inflammation. The ability to regulate this process is an important focus in functional medicine. Proinflammatory cytokines (Interleukins (IL-4, IL-6, and IL-10) and Tumor Necrosis Factor-alpha (TNF- $\alpha$ ) have been shown to promote or inhibit Th1/Th2 differentiation and are therefore biomarkers of interest in studying inflammation. The results of animal and human studies have shown that some herbs in isolation can promote a beneficial immune response. Polyphenols in flowers, leaves, and bark have been attributed to their anti-inflammatory activities as well. Collectively, these therapeutic effects may impact both innate and adaptive immunity.

**Objectives:** This feasibility study tests a proprietary blend of *Moringa olifera*, *Murraya koenigii*, Curcumin longa, Pine bark, and Spirulina extracts on proinflammatory cytokines (Interleukins (IL-4, IL-6, and IL-10) and Tumor Necrosis Factor-alpha (TNF- $\alpha$ ). This research was conducted on individuals with metabolic syndrome to determine safety, feasibility for larger trials, and the immunomodulatory effect of an herbal formulation.

**Methods:** Study participants were instructed to ingest three capsules of the herbal formula daily for a total of 30 days. Blood was drawn at baseline and post-intervention to measure the levels of specific cytokine biomarkers. A Medical Symptoms Questionnaire (MSQ) was also administered to assess change in symptoms reported by the participants.

**Results:** Results of the cytokine assays were assessed to determine the net effect of the herbal intervention on inflammatory markers. The laboratory findings were inconclusive due to laboratory limitations and confounding factors. Considerable improvement was seen in the MSQ scores. Subjects, 1, 2 and 3 showed a 59% improvement (a decrease from 109 to 45), an 81% improvement (a decrease from 75 to 14) and a 62% improvement (a decrease from 8 to 3) respectively. All three reported overall improvements in their health.

**Conclusion:** Results of this feasibility study suggest that the herbs in this supplement are safe for human use, however additional studies should be conducted on a larger population to gain additional data. The cytokine panels used for this study offered limited insights into the effects on the immune system. Future studies should therefore consider using the T regulatory markers: CD3, CD4, CD25, CD127, FoxP3, Ki67, and CD45RA.

## LITERATURE REVIEWS

The Anxiolytic Effect of *Scutellaria Lateriflora* (American Skullcap): A Literature Review.

Martin E, Bawazir A, Coetzee O

**BACKGROUND:** Anxiety disorders are the most prevalent psychiatric disorders, affecting 18.1% of the American population. Medications are the most common treatments for anxiety disorders; however, pharmaceutical drugs have potentially harmful side effects. Accordingly, individuals have sought perceived safe alternatives, such as herbal medicines, for treating various psychiatric disorders and ailments, including anxiety and depression. *Scutellaria lateriflora* (*S. lateriflora*), also known as American skullcap, has been used in traditional medicine as a sedative/nerve tonic and anticonvulsant to treat epilepsy, insomnia, anxiety, nervous tension, neuralgia, and gastrointestinal problems.

**RESEARCH OBJECTIVE:** *S. lateriflora* has been studied less rigorously than other more widely-known anxiolytic medicinal herbs. The objective of this review is to investigate the anxiolytic effects of *S. lateriflora* based on the present literature.

**METHOD:** Databases of PubMed, MEDLINE (OVID), Embase, and Web of Science were searched using the search terms *Scutellaria lateriflora*, *S. lateriflora*, and American skullcap. We selected articles that have general review of *S. lateriflora* and/or any paper related to anxiety, depression and psychiatric disorders.

**RESULTS:** The review of the literature showed that the therapeutic use of *S. lateriflora* has demonstrated anti-anxiety effects without noticeable adverse effects. We found four studies related to the anxiolytic effects of the *S. lateriflora*; two double-blind, placebo-controlled trials, one pilot survey, and one in-vivo study. However, these studies were either of low-quality and/or had some design flaws.

**CONCLUSION:** There has been extensive use of *S. lateriflora* for the reduction of symptoms of anxiety; however, conclusive evidence is lacking. Well-designed clinical trials are needed to overcome the flaws in previous studies.

A Literature Review of Nutrition and Integrative Interventions for Erectile Dysfunction

Weingard T



