Complementary Treatment of Chronic Digestive Disorders with Malabsorption Syndrome Using HSOs

by Peter R. Rothschild, MD, PhD
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Chronic Digestive Disorder with Malabsorption Syndrome is considered by some to be resistant to conventional clinical therapies. Until recently, only palliative methods had been developed, which proved toxic when administered over prolonged periods.

Studies revealed wide-ranging evidence that the amalgamation of manifold, precision-bred Homeostatic Soil Organisms™ (HSOs) offer a therapeutic tool that may assist physicians in treating conditions that in the past have been persistently resistant to therapies of any kind.

Though HSOs appear to be as old as the earth, only recently have scientists come to realize the effects of living too far removed from these beneficial bacteria. Society's separation from dirt and germs may well be the cause of the growing incidence of a wide range of maladies, says epidemiologist David Strachan, who first advanced the over-cleanliness theory in 1989 while at Britain's London School of Hygiene and Tropical Medicine.

Only a theory in 1989, Strachan's assertions have since been validated by scientific research. New Scientist magazine recently reported that researchers have discovered that microorganisms found in dirt influence maturation of the immune system so that it is either functional or dysfunctional. The organisms to which we are exposed "condition" our immune system so that it intuitively knows when to produce and activate T-helper (Th) cells.

When children are exposed to adequate amounts of viruses, bacteria and other microorganisms – when they are allowed to play in the dirt and put their fingers in their mouths – their Th cells mature in proper proportion into desirable Th1 cells. But without adequate internal exposure to soil microbes, their immune cells have a tendency to overreact and are more likely to mature into Th2 cells.

In the past fifty years, with the over-sterilization of nearly everything in our environment, far too many children have been denied this much needed exposure to microorganisms in the soil, and so their immune systems have not been properly educated.

Modern, high-tech farming and processing methods remove and/or destroy the most important life-giving nutrients in our foods before they ever reach the supermarket shelves. We sterilize our soil with pesticides and herbicides, destroying beneficial and harmful bacteria alike.

Pesticides and herbicides do to the soil what overuse of medical antibiotics have done to the human gastrointestinal tract – eliminate not only the harmful but also the beneficial bacteria. Yet, in spite of the plethora of evidence to that effect, many physicians consistently prescribe antibiotics to their patients; even where other options are available.

The HSO Formula

By utilizing current research data and doing considerable research of their own, Garden of Life® has developed a product that addresses the concerns of many regarding the treatment of conditions that are resistant to conventional therapies.

Primal Defense™, a natural whole food supplement, consists of 14 specifically bred probiotic HSO strains that resist gastric acid, brusque temperature changes, chlorine, fluorine and ascorbic acid. It also contains an ionic fulvic acid mineral blend of over 100 naturally occurring vitamins, minerals and enzymes.

This synergistic combination of natural ingredients yields powerful, immuno-modulating and anti-inflammatory effects suggesting specific proteolytic ability to regulate prostaglandin synthesis. The pharmacodynamic mechanisms of its anti-viral, anti-mycotic and antimicrobial efficacy appear to ensue through the stimulation of the discriminatory/non-discriminatory potential of both B-cells and T-cells.

Very few food supplements presently marketed are formulated with the paramount prerequisite of an appropriate Delivery System in mind, ensuring that the components incorporated into the formula effectively reach the organs they are meant to assist.

In a technical sense, the Delivery System incorporated in this given formula consists of physiological carrier electrolyte molecules that are responsible for a great variety of necessary reactions, effectively channeling components to the organs and tissues that need to be addressed. These results are further enhanced by super-charged vegetal extracts that react to form stable polymers (a group of molecules that agglomerate in particular configurations and are capable of penetrating the cell walls by osmosis). In this particular case, it is the micelles that can best be described as very minute and supple saccular entities that are loosely spherical and consist of hydrosoluble shells containing fatty
cores. These micelles are programmed to transport the active reparative and healing molecules to their aimed destination with unerring accuracy. Thus, their lipid core is enabled to carry amino acids, vitamins and other fat-soluble substances. Having penetrated the cell membrane, the micelles decant their contents into the targeted cytoplasmatic intra-cellular environment.

In brief, an efficient Delivery System incorporating micelle-enhancing solutions in charge of transporting the supplement's active principles to the intracellular staging area, stimulates cellular nutrition. Through reverse osmosis, simultaneous waste disposal occurs, thus restoring and intensifying the cells' natural functions.

Such a delivery system is incorporated into the HSO formula known as Primal Defense. This probiotic formulation also employs the Poten-Zyme™ process (Potentiation by Enzymatic activation). This proprietary process is an exclusive, natural process of lacto-fermentation and enzymatic predigestion using 14 strains of beneficial microorganisms within a matrix of carefully selected whole foods. The bioavailability and absorption of nutrients may be increased as much as 5 times by using this unique process.

Primal Defense can be synergistically combined with most supplements. The concept of synergism asserts the combining of specific components in a formula which are not only perfectly compatible, but interact in a manner that enhances the purpose of the supplement(s) it is combined with. The microorganisms act as Interactive Mediator Molecules® (IMM), which proficiently amalgamate dissimilar ingredients, while effectively allowing those ingredients to interact between the components of the formula and the body, thus ensuring their efficacy.

Primal Defense caplets and powder are manufactured in the USA conforming to manifold proprietary processes.

Primal Defense

Active Ingredient Concentration & Bioavailability

Each caplet of Primal Defense contains 1100 mg of a precision blend of HSOs. The HSO blend is isolated by proprietary processes and dried immediately after harvesting, which maintains its viability until it is rehydrated in the gut. The beneficial microorganisms in Primal Defense are cultured on a mixed substrate of whole "super foods." The organisms are then left in their natural whole food form, containing a number of naturally occurring vitamins, minerals, live enzymes and organic acids that are inherent constituents of this whole food blend.

Clinical and laboratory studies carried out in the United States, Europe, Mexico and Puerto Rico have yielded very impressive results. With that in mind, the Apostolic School of Natural Medicine's Clinical Research Division decided to put Primal Defense through our own series of rigorous clinical studies with a specific focus on the treatment of chronic digestive disorders with malabsorption syndrome. What follows are the methods, observations and results of those studies.

Methods

All determinations were carried out according to guidelines described in the 2001 Edition of Official Analytical Methods, published by A.O.A.C. on file with the Federal Register. In addition, standard phase and darkfield microscopy was used.

Observations

Thus, provided that the food supplement tested in this study is being administered conforming to the herein described modus operandi, the author of this protocol stipulates both the synergistic functions and the stable bioavailability of the HSO blend contained in Primal Defense.

No binder or filler substances, such as gluten, starches or sugar were found in the tested material, above identified as Primal Defense. The fermentation and blending processes are proprietary information. For pertinent inquiries contact the manufacturer.

Study Protocol

Inclusion Criteria

- Individuals of both sexes suffering from clinically confirmed Chronic Digestive Disorders and Malabsorption Syndrome who had been resistant to conventional forms of medications. All selected patients were suffering from chronic and painful spastic intestinal contractions, persistent alternating diarrhea, constipation, and consequent non-hematopoiesis-contingent anemia for a minimum of nine months. All subjects were shown to have elevated white blood counts, immune system imbalances, mineral, and enzyme deficiencies.
  - Males and females of ages between 25 and 60 years.
  - Average duration of symptoms, 3 years.
  - Individuals who had not been treated with tranquilizers, anti-depressants, steroids and/or chemotherapeutic drugs for at least 3 months prior to the beginning of the study.
  - Individuals who had not received any prescription medicines for at least 3 months.

Exclusion Criteria

- Individuals declared in critical condition by a licensed health practitioner.
- Individuals afflicted with any acute infectious disease or diabetes, cardiovascular, renal or immediate life-threatening pathologies.
- Allergies to any of the components of the Primal Defense formula.
• Individuals who had been subjected to tranquilizers, antidepressant, chemotherapeutic or steroid drugs less than 3 months prior to the beginning of the study.
• Alcoholics and/or drug addicts.
• Convalescents of any trauma more recent than 3 months.
• Individuals receiving life-supporting prescription medications, which affect the immune and/or nervous system (such as certain hormones, tranquilizers or anti-convulsing drugs).

Study Protocol

1. All participants underwent physical and laboratory examinations prior to the beginning of the study.
2. The study was carried out under a standard, ambulatory, single blind regime.
3. Test treatments began not later than 30 days after the completion of the above tests and examination.
4. The test material consisted in daily 18-caplet oral doses of 1100 mg of Primal Defense (see attached assay) divided in 6 caplets 3 times daily 30 minutes before meals, taken with 8 ounces of pure water, for a 30-day period, followed by 12-caplets taking 4 caplets 3 times per day 30 minutes before meals for a 60-day period.
5. During the entire course of the study, the participants abstained from consuming both prescription and OTC drugs, unless necessary, in which case that particular individual was disqualified from the study.
6. All participants of the study were supplied with test material sufficient for 15-day periods. All participants collected fresh supplies in person every 15 days, at which time they reported their subjective findings to the health practitioner in charge.
7. The study target consisted of determining the palliative or attenuating effects of the herein identified test material in human adults of both sexes afflicted with Chronic Digestive Disorders and Malabsorption Syndrome.
8. At evaluating the final test results, both curative and attenuating effects were defined by the following gradation: Full Remission = A; Partial Remission (symptom palliation with objective proof) = B; Moderate Palliation = C; Unchanged Condition = D; Worsened Condition = E.

9. The study population consisted of 35 male and female adults receiving test material, plus an equal group of control individuals receiving placebos; both groups conforming to parameters specified by the Inclusion Criteria.
10. The duration of the study was 90 days.
11. Diagnostic controls were carried out within 15 days after completing 90 days of administration of the test material.
12. All study participants sign their willingness to partake in this study and their conformity to the rules and regulations of this protocol, prior to the beginning of this study.
13. Any deviation from the above rules disqualified the participant from the study, and was written off as a dropout.
14. The study was carried out under the direction of a duly licensed Doctor of Medicine (MD) or of Naturopathic Medicine (ND), assisted by qualified paramedical associates and registered laboratory technicians.
15. The study was carried out subordinated to the control of the Clinical Research Division of the School of Natural Medicine of the Peoples University of the Americas, at Ponce City, Puerto Rico.
16. Considering that, conforming to the Exclusion Criteria of this study, all participating patients were shown to be resistant to conventional types of medication, the test was carried out under a standard, mono-therapeutic regime.

Note: * Full remission signified entirely - both objectively and subjectively - asymptomatic condition.
* Partial Remission referred to 60% or better improvement.
* Moderate Palliation implied up to 40% improvement.

Primal Defense

Clinical Study Preparation: Primal Defense™ Caplets
• Type of Study: Standard, ambulatory, mono-therapeutic, simple-blind regime, with equivalent control group.
• Preparation Used: Primal Defense caplets
• Ingredients: Primal Defense caplets containing 1100 mg of an all-natural herbs formula disclosed in the attached assay, produced conforming to a proprietary manufacturing process.
• Observations: The tested preparation has been marketed since April 1998.
• Manufacturer: Garden of Life, Inc., West Palm Beach, Florida, USA
• Objectives: Palliation or attenuation of Chronic Digestive Disorders and Malabsorption Syndrome in both sexes.
• Rationale: See abstract.
• Population: 35 individuals of both sexes between ages of 25 and 60 years, with an equivalent control group.
• Criterion: See attached protocol.
• Dosage: 6-caplets oral doses, taken 3 times daily 30 minutes before meals, with 8 ounces of pure water, administered as mono-therapy. (Total of 18 caplets daily) for 30 days followed by 4 caplets taken 3 times per day 30 minutes before meals (Total 12 caplets per day for 60 days).
• Population at conclusion of the study: Not less than 30 participating voluntary patients.
• Date of begin: 01-17-02
• Date of conclusion: 04-19-02
• Duration: 90 days.
• Protocol: Attached.
• Author of the study model & protocol: Peter R. Rothschild, MD, PhD.
• Director of the study: Jesus Garcia MD
• Evaluation: Certified copy attached.
Primal Defense

Evaluation of the Concluded Study

Patient Group (Active Product)
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<tr>
<th>Gradation</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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</table>
Test group population at the beginning of the study: 35 adults.
Test group population at the conclusion of the study: 31 adults.

Observations

1. All determinations were performed according to the norm guidelines set by WHO for standard, ambulatory, non-invasive clinical examination methods.
   Each patient underwent CBC and SMAC-24 laboratory determinations were carried out not more than 30 days before and 15 days after the trials.

2. The end results of the study indicated that Primal Defense caplets qualified as an accomplished specific therapy for Chronic Digestive Disorders and Malabsorption Syndrome. It is evident that the preparation did indeed trigger regulatory neuro-immune reactions, inducing healing processes of this pathological condition.

Control Group (Placebo)

<table>
<thead>
<tr>
<th>Gradation</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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</table>
Control group population at the beginning of the study: 35 adults
Control group population at the conclusion of the study: 14

The health practitioners in charge of the study report: the obtained results revealed that Primal Defense caplets constitute an effective treatment for the palliation and attenuation of Chronic Digestive Disorders and Malabsorption Syndrome with marked improvements in blood counts, modulation of the immune system and restoration of healthy mineral and enzyme levels.

In order to determine the possible enduring capabilities of this natural preparation, it is recommended that further tests, as well as follow-up examinations, of the participating patients be carried out over more extended periods.

Summing up the results obtained, the Director in charge of this study concludes that Primal Defense caplets contain a natural neuro-immuno-modulatory and regulatory formula that shows significant efficacy in treating Chronic Digestive Disorders and Malabsorption Syndrome, which definitively deserves further, in-depth investigation.

Appendix

It is noteworthy to mention that 16 of the tested patients have reported significant further relief from additional conditions.

Resources

For more information on Primal Defense or to obtain additional research, please contact Garden of Life, Inc. at 800-622-8986 or visit their website at www.gardenofigleusa.com.

References

1. Peter R. Rothschild, MD, PhD; Jesus Garcia Huertas, MD; Progress In Nutrition, Volume 4, S.1, 2002
3. David Strachan; M. Downey; Let Them Eat Dirt; Toronto Star, Jan. 1999