

Clinical Validation of FIBER

Includes Scientific Papers, Research Papers,
University Studies & Articles

Clinicals Documentation for Fiber

Main Ingredients and Research

There are 2 kinds of fiber, soluble and insoluble. Soluble fiber dissolves in water; this type of fiber helps to slow the absorption of glucose from the intestines into the blood stream, improving the blood sugar balance and lowering cholesterol. Insoluble fiber does not dissolve in water but instead bulks up the stool and allows for more efficient bowel movements. It also helps to bind excess fats and toxins in the digestive tract so they can be excreted in our bowels. Research has shown that populations consuming larger quantities of fiber have less risk of developing colon cancer.

The average American does not eat enough fiber; to be most effective research shows 40 grams daily is beneficial. You get the most fiber from cereal grains, vegetables, and lentils. There is much less fiber in fruits and none in meats or dairy!

Organic Raw Cold Milled Flax Seeds: Flax seeds need to be milled to allow the digestive tract to absorb the nutrients contained in the seed, whole unmilled flax seed is not digestible by humans. Bulk milled flax seed and oils will be rancid if not processed by the cold milling process. Flax is the best source for Linolenic Acid, an Omega 3 essential fatty acid, and lignans. Christine Northrup, M.D., a leading expert on women's health says, "Flax seed is the highest known source of anti-cancer and phytoestrogenic compounds known as lignans". (1)

Lignans are compounds that are antitumor, antiestrogenic, and antioxidant properties. Donald Rudin, M.D. contends that the level of Linolenic Acid in the American diet has been reduced 80% in the last 100 years. This Omega 3 Fatty Acid deficiency is the basic cause of the increase in mental illness and depression today; including heart attacks, breast and colon cancer, arthritis and severe menstrual cramps.

Even since 650 B.C. Hippocrates wrote about the use of flax to relieve inflammation of mucous membranes for abdominal pains and diarrhea.

Dr Paul Goss at Princess Margaret Hospital in Toronto Canada says results from their flax study encourages the believe that there is a significant biological effect in women that dietary flaxseed may prevent breast cancer.(2)

Organic Raw Cold Milled Hemp Seeds: The Hemp seed fiber is probably one of the most concentrated, complete and balanced sources of essential fatty acids and amino acids. It is extremely high in fiber, about 75%, and is a great source of Omega 6 and Omega 3 fatty acids in the proper ratio. Hemp is also the most potent protein of any plant source as well as the only plant sources of gamma-linolenic acid. The Hemp protein powder is free of the enzyme inhibitor, trypsin and oligosacchrides, found in other protein powders such as soy, that can prevent protein absorption and can cause gas, bloating and other digestive problems. The cold milling ensures that valuable enzymes are not destroyed and vitamins, minerals and nutrients remain intact.(3)

Lactospore™ (*Lactobacillus sporogenes*) is a superior vegan, shelf stable probiotic. Elie Metchnikoff, a Russian physician, termed the word “probiotic”, meaning ‘in favor of life’, found that growth of toxin producing putrefactive organisms in the gastro-intestinal tract could be controlled by implantation of beneficial Lactobacilli in the gut. This product, Lactospore sporogenes, is a probiotic source is from green malt of grains and not from human feces, the source of many other typical acidophilus probiotic products. There are many clinicals and shelf stability studies available that confirm the effectiveness of Lactospore™.

L. Sporogenes, consist of thermostable spores that can withstand lyophilization, survive in gastric secretions and bile of the upper digestive tract to reach the intestine safely. This type of probiotic is different due to use of spores versus a blend of many flora types of organism, the mechanism of a single spore which can survive and proliferate, releasing many multiples of bacteria from one single spore. They improve the digestibility of ingested food constituents and the bioavailability of nutrients, enhances the immune system and is effective in the treatment of a variety of other disorders.(4,5)

In general, Lactospore™ is important because it’s high viable bacterial counts, survival in gastric acidity, proliferating rate of spores in intestinal tract and it’s superior L(+) lactic acid producing capacity which prevents the problem of acidosis.

Noni Fruit Fiber: Is very bitter which acts as a digestive stimulant It has excellent results fighting Candida, fungus, yeast and has great anti-bacterial and anti viral capabilities.

Noni Leaf Fiber: Is a great source of gentle fiber. Our Noni is not treated or subjected to any nutrient destroying heat. Noni is naturally high in minerals, trace minerals and plant fibers. This alkaline nutrient helps balance the pH (potential hydrogen) of the formula.

In general, Noni Fruit and Leaf Fiber is important because it helps balance the pH, is high in trace minerals, acts as a digestive stimulant and is a great source of fiber.

Copper: is a metal that occurs naturally in the environment and in plants and animals, it is essential for maintaining good health and necessary for life. Minerals interact in the body working as a team. One research scientist said ‘to regard copper, iron and zinc as an essential trio’, too much of one can hamper the body’s ability to absorb or process the others.

In general, Copper helps with metabolic activity and is essential for life and maintaining health, and the need for proper functioning of kidney, heart, brain and liver.

Chromium: A biologically active form of chromium participates in glucose metabolism by enhancing the effects of insulin. Studies have also found beneficial effects on blood lipid profiles and can help with fat and protein metabolism. The amount of chromium varies widely in foods but foods high in simple sugar are not only low in chromium but were found to promote chromium loss.

In general, chromium is important due to its enhancing effects of insulin, beneficial effects on lipids, and as an aid with fat and protein metabolism.

Rice Bran: The thin brown layer that is milled off in the processing of white rice, rice bran is just effective as other brans in fighting high cholesterol and providing high-grade fiber. Rice bran is an anti-oxidant compound and can be tolerated by those who are gluten sensitive.

Oat Fiber: A soluble fiber shown to help lower blood cholesterol.

Carrot Fiber: Is an insoluble fiber an important aid in bowel function.

Beet Fiber: Is an insoluble fiber, two of its compounds are betacyanin, a powerful cancer fighting agent, and glutathione peroxidase, an antioxidant enzyme, acts as a bodyguard for the liver cells.

Guar Gum: Used in many foods to bind and enhance water-soluble content. This plant is in the Chickpea family of legumes, cultivated and used in India as a vegetable for its tender pods.

Slippery Elm: An inner tree bark is a gummy, soothing mucilage gel like substance; forms a protective coating for soothing irritated or inflamed mucous membranes along the throat, digestive and gastrointestinal tract. Slippery Elm can help with the discomforts of gastritis, Crohns disease, irritable bowel syndrome (IBS), and ulcerative colitis.

In general, Slippery Elm is beneficial in helping with soothing of inflammation in the gastrointestinal tract, mucous membranes of the throat and with IBS and ulcerative colitis.

FOS - Fructooligosaccharides: Is a simple carbohydrate found naturally in plants such as jerusalem artichokes, onions and bananas but ours is manufactured from chicory bark with the addition of an enzyme to become FOS. The chicory based FOS does not have the same side effects of irritation in the intestines as other sugar based FOS products can. It is a prebiotic, a non-digestible fiber used to keep stomach and bowels healthy, and to nourish and promote friendly bacteria. A prebiotic is a substance that promotes the growth of bacterial species in the gut known as probiotics creating a proper balance of flora.

In general, Fructooligosaccharides is important because it promotes the growth of beneficial bacteria, inhibits the growth of pathogens, facilitates Calcium absorption in intestines and plays a protective role against colon cancer.

Cat's Claw: Is a vine from South America taken for its ability to boost the immune system and as an anti-inflammatory for arthritis, colitis and IBS symptoms, bowel and colon protective and as a complementary therapy for cancer. Dr. Brent Davis, D.C. has referred to cats claw as the "opener of the way" for its ability to cleanse the entire intestinal tract and its effectiveness in treating stomach and bowel disorders.

In general, Cat's Claw cleanses the bowels and detoxifies, stimulates the immune system, helps with inflammation and can aid in DNA cellular repair and prevent cells from mutating.

Bitter Melon: in the Amazon, the leaf and fruit is used for diabetes, to expel gas and to help reduce cholesterol. Studies have shown the ability to enhance cells uptake of glucose, to promote insulin release and to potentiate the effect of insulin.

In general, Bitter Melon is important because it reduces blood sugar, detoxifies, reduces blood pressure and is a good anti-bacterial and anti-viral.

Nopal: More commonly known as Prickly Pear cactus, has 18 amino acids, and helps to strengthen the liver, digestion, kidney, and pancreas. Nopal is great at helping to decrease blood sugar, lower fat and cholesterol by slowing digestion of carbohydrates and slowing insulin production.

In general, Nopal is used for its soluble fiber which helps maintain normal blood sugar levels, its ability to help promote weight loss, reduces appetite and can bring cholesterol levels down.

Boldo: Boldo is legendary in Chile's traditional medicine system for the treatment of liver diseases and gallstones. It is also known as a digestive stimulant that helps the production and secretion of bile. It has anti-inflammatory properties, and supports the gallbladder.

In general, Boldo is used for stimulating bile secretions, helps rid the intestines of parasites, stimulates digestion and protects the liver.

Cumin: used since Egyptian days, is similar to turmeric, it stimulates digestion and relieves bloating. It is used in India to support the generation of heat or 'Chi' in the body. This provides the body the essential heat needed to assist in breakdown and assimilation of food. Most every fiber on the market today does not contain heat generating herbs. They can be heat or Chi depleting.

In general, Cumin is essential due to its generation of chi or heat needed with both digestion and intestinal breakdown and assimilation of food.

Ginger Root: A spicy herb used in many foods for flavoring and to aid digestion. Ginger is the greatest inhibitor of an 5 Lo, an enzyme, a cousin to Cox 2 Inhibitor which helps with inflammation and to support the Prostate. It is also a heating herb. Dozens of clinicals prove gingers benefits to the digestive system.

In general, Ginger root is used for its aid in digestion and soothing of the stomach and intestines and it's support of the prostate.

Stevia leaf (extract): Of 200 species only the Rebuaduana exhibits the intensity of sweetness 300x sweeter than sugar; Indians of Brazil and Paraguay have used Stevia for centuries to sweeten tea and food. Medicinally, it has been used for obesity, infections, hypertension, hypoglycemia, diuretic, and depression and as a cardio tonic. In 2001 scientists in Brazil recorded its ability to lower blood pressure. In Denmark, a published report in 2000, show the glycoside compound, stevioside to stimulate insulin secretion, therefore having potential for treatment of type II Diabetes.

In general, Stevia leaf has been used for its ability to balance the blood sugar, as a natural anti-bacterial and anti-fungal, lowers blood pressure and helps with lowering weight since it is a non-caloric, natural sweetener.

Gymnema Sylvestre: The nickname in India is “sugar destroyer”, has been used in Ayurvedic medicine to block the sweet taste of foods. It also helps with digestion and constipation and block the absorption of glucose in the intestines.

In general, Gymnema Sylvestre, helps with cravings for sugar and carbohydrates, help remove sugar from the blood, supports proper digestion and supports glucose regulation.

Clinical Studies on Lactospore

Fate and Dissemination of *Bacillus subtilis* Spores in a Murine Model

Tran Thu Hoa,¹ Le Hong Duc,² Rachele Isticato,³ Loredana Baccigalupi,³ Ezio Ricca,³ Pham Hung Van,¹ and Simon M. Cutting^{2*}

Laboratory of Microbiology, Ho Chi Minh University of Medicine and Pharmacy, Ho Chi Minh City, Vietnam¹; School of Biological Sciences, Royal Holloway University of London, Egham, Surrey TW20 0EX, United Kingdom²; and Section of Microbiology, Department of General and Environmental Physiology, University Federico II, 80134 Naples, Italy³

Abstract: Bacterial spores are being consumed as probiotics, although little is known about their mode of action. As a first step in characterizing spore probiotics, we have studied dissemination of *Bacillus Subtilis* spores given orally to mice. Our results show they do not appear to disseminate across the mucosal surfaces. However, we found that excreted in the feces of mice was, in some experiments, larger than the original amounts, an intriguing result and might be explained by germination of a proportion of the intestinal tract, followed by limited rounds of cell growth and then sporulation, which raised the interesting question of whether it is the spore or the germinated spore affecting the probiotic effect of bacterial spores.

Clinical trials on Lactobacillus Sporogenes

Summaries:

Gastro-intestinal and associated effects

Clinical trials performed in Japan with LACBON 60 (*L. sporogenes*)

Reports from various hospitals that performed clinical trials on groups of patients suffering from a variety of intestinal disorders and allergic skin diseases are summarized in Table 5.1.

It is evident that the administration of *L. sporogenes* markedly improved the general clinical condition of the subjects and provided relief from intestinal disorders and allergic skin conditions. Allergic skin conditions can be related to an imbalance of intestinal flora⁶⁶ in the subject. This condition was therefore corrected by *L. sporogenes* therapy in these trials.

SUMMARY OF SELECTED CLINICAL REPORTS FROM JAPAN : TRIALS WITH LACBON[□] (*L. sporogenes*)

1. Condition: Acute and chronic intestinal catarrh

No. of subjects: 38

Treatment: 100-600 million spores/ day in divided doses for 2-12 days

Effectiveness rate: 86.8%

Conclusion: Recovery from diarrhea to regular normal stools; general symptoms including anorexia improved

2. Condition: Diarrhea

No. of subjects: 15

Treatment: 75-600 million spores/ day in divided doses for 3-12 days

Effectiveness rate: 100%

Conclusion: Recovery from diarrhea to regular, normal stools from third to fourth day

3. Condition: Constipation

No. of subjects: 10

Treatment: 300-750 million spores / day in divided doses for 2-10 days

Effectiveness rate: 70.0%

Conclusion: Recovery to normal stools and disappearance of abdominal distention

4. Condition: Abnormal intestinal fermentation

No. of subjects: 9

Treatment: 300-600 million spores / day in divided doses for 3-14 days

Effectiveness rate: 100.0%

Conclusion: Vomiting and nausea disappeared; appetite improved; stools became normal and regular; diarrhea and stomach ache cured.

5. Condition: Dyspepsia infantum

No. of subjects: 26

Treatment: 100-200 million spores / day in divided doses for 1-7 days

Effectiveness rate: 84.6%

Conclusion: General conditions and nature of stools improved. Frequency of stools decreased to half or less than that before medication.

6. Condition: Allergic skin diseases

No. of subjects: 5

Treatment: 200-450 million spores / day in divided doses for 4-12 days

Effectiveness rate: 80.0%

Conclusion: Obvious eruptions of strophulus and eczema decreased from the third day (topical therapy employed concomitantly)

7. Condition: Miscellaneous symptoms

No. of subjects: 10

Treatment: 20-50 million spores / day in divided doses for 4-20 days

Effectiveness rate: 80.0%

Conclusion: Response seen in anorexia of nervous type and malnutrition in infants

The above data are cited from clinical reports by: Terumichi Kuniya, Pediatric Clinic of Shinko Hospital, Kobe; Jetsuo Nitta, Medical Clinic of Kugason Hospital; Goro Koide, Pediatric Clinic of Kanto Teishin Hospital; Michio Ogasawara, Medical Clinic of Kahoku Hospital; Susumu Nakazawa, Pediatric Clinic of Ebara Hospital

Study Report: [The Advanced Probiotic, Dr Dilip Kumar, MD, Pharmed Medicare \(p\) Ltd.](#)

Lactobacillus sporogenes -the ultimate probiotic

Lactobacillus sporogenes inhibits the growth of various pathogenic (disease causing) organisms including Candida, Fungal infections, Escherichia coli & others. Help lower serum cholesterol. Probiotics will help eliminate toxins, mucous & boost the immune system.

The ideal bacterium would be:

- Be of human origin;
- Non pathogenic to humans
- Capable of attaching to human intestinal (epithelial) cells and colonizing the gut to prevent Competition from invading pathogens;
- Resistant to acid and bile, able to survive transit from the stomach to the intestines;
- Producing L (+) lactic acid during fermentation.
- High survival rate through processing conditions (during harvesting, drying etc.)
- High stability at room temperature separately or when mixed with other ingredients.
- Lack of potential to mate with potentially pathogenic microbes.
- Exhibit beneficial, health-promoting activity in the host system; and
- Exhibit a high degree of safety.

Lactobacillus sporogenes (Lactopure*) meets all the above criteria, is also naturally microencapsulated. Being a spore is highly resistant to heat, gastric acids and bile. The following are indications of *Bacillus coagulans* (*Lactobacillus sporogenes*) that are not true of other probiotic formulations: The bifido bacteria group is the most common probiotics in the large intestine. They are comparatively delicate, however, and their numbers can be depleted by toxins in the intestines or by other stressors.

Lactobacillus sporogenes (*Bacillus coagulans*) is a probiotic strain uniquely "preencapsulated" in spores that resist the action of antibiotics and gastric juices; it is non-dairy and is cultured on malt.

Clinical Studies on Hemp Seed

Study: Efficacy of Dietary Hemp Seed Oil in Patients with Atopic Dermatitis

Journal of Dermatological Treatment, 2005, Volume 16, Pages 87-94.

[Dr. J.C. Callaway et al, University of Kuopio, Finland](#)

Abstract Background:

Hemp seed oil is a rich and balanced source of omega-6 and omega-3 polyunsaturated fatty acids (PUFAs). Anecdotal evidence indicated that dietary hemp seed oil might be useful in treating symptoms of atopic dermatitis. Patients and methods: Dietary hemp seed oil and olive oil were compared in a 20-week randomized, single-blind crossover study with atopic patients. Fatty acid profiles were measured in plasma triglyceride, cholesteryl and phospholipid fractions. A patient questionnaire provided additional information on skin dryness, itchiness and usage of dermal medications. Skin transepidermal water loss (TEWL) was also measured. Results: Levels of both essential fatty acids (EFAs), linoleic acid (18:2n6) and alpha-linolenic acid (18:3n3), and gamma-linolenic acid (GLA; 18:3n6) increased in all lipid fractions after hemp seed oil, with no significant increases of arachidonic acid (20:4n6) in any lipid

fractions after either oil. Intra-group TEWL values decreased (p50.074), qualities of both skin dryness and itchiness improved (p50.027) and dermal medication usage decreased (p50.024) after hemp seed oil intervention. Conclusions: Dietary hemp seed oil caused significant changes in plasma fatty acid profiles and improved clinical symptoms of atopic dermatitis. It is suggested that these improvements resulted from the balanced and abundant supply of PUFAs in this hemp seed oil.

Study: Hemp Seed as a Nutritional Resource: An Overview

Euphytica, January 2004, Volume 140, No. 1-2, Pages 65-72(8).

[Dr. J.C. Callaway, Department of Pharmaceutical Chemistry, University of Kuopio, Finland](#)

Summary:

The seed of *Cannabis sativa L.* has been an important source of nutrition for thousands of years in Old World cultures. Non-drug varieties of *Cannabis*, commonly referred to as hemp, have not been studied extensively for their nutritional potential in recent years, nor has hemp seed been utilized to any great extent by the industrial processes and food markets that have developed during the 20th century. Technically a nut, hemp seed typically contains over 30% oil and about 25% protein, with considerable amounts of dietary fiber, vitamins and minerals. Hemp seed oil is over 80% in polyunsaturated fatty acids (PUFAs), and is an exceptionally rich source of the two essential fatty acids (EFAs) linoleic acid (18:2 omega-6) and alpha-linolenic acid (18:3 omega-3). The omega-6 to omega-3 ratio (n6/n3) in hemp seed oil is normally between 2:1 and 3:1, which is considered to be optimal for human health. In addition, the biological metabolites of the two EFAs, gamma-linolenic acid (18:3 omega-6; 'GLA') and stearidonic acid (18:4 omega-3; 'SDA'), are also present in hemp seed oil. The two main proteins in hemp seed are edestin and albumin. Both of these high-quality storage proteins are easily digested and contain nutritionally significant amounts of all essential amino acids. In addition, hemp seed has exceptionally high levels of the amino acid arginine. Hemp seed has been used to treat various disorders for thousands of years in traditional oriental medicine. Recent clinical trials have identified hemp seed oil as a functional food, and animal feeding studies demonstrate the long-standing utility of hemp seed as an important food resource.

Clinical Studies on Flaxseed

Study:[Duke University Medical Center, Durham, NC, Xu Lin M.D.](#)

Durham, N.C. - A diet rich in flaxseed seems to reduce the size, aggressiveness and severity of tumors in mice that have been genetically engineered to develop prostate cancer, according to new research from Duke University Medical Center. And in 3 percent of the mice the flaxseed diet kept them from getting the disease at all.

Clinical studies by other researchers have suggested that dietary fiber reduces cancer risk, and omega-3 fatty acids also have shown a protective benefit against cancer. Flaxseed is the richest plant source of omega-3 fatty acids and is high in fiber. Also, flaxseed is a source of lignan, a specific family of fiber-related compounds that appear to play a role in influencing both estrogen and testosterone metabolism. Since testosterone may be important in the progression of prostate cancer, lignan could help inhibit the growth and development of the disease.

"Tumors in the untreated control group were twice the size of tumors in the flaxseed group," said Xu Lin, M.D., research associate, division of urology and lead author of the study. "The tumors were also less aggressive in the flaxseed group, and two of the mice in the flaxseed group did not develop prostate cancer at all. The rates of apoptosis (tumor cell death) were also higher in the flaxseed group. And while it was not statistically significant, the flaxseed group had fewer rates of the cancer spreading to other organs. "

While the results are promising, the researchers say they are not surprising. The study is the third in a series by the Duke Medical Center researchers to show the benefits of flaxseed in reducing the growth and development of prostate cancer.

The first study, published in July 2001 in *Urology*, demonstrated that a low-fat diet supplemented with flaxseed was associated with slower tumor growth. In this pilot study, 25 men with prostate cancer began adding ground flaxseed to their diets for 34 days. At the end of the study, the men saw a drop in testosterone levels and a trend toward lower prostate specific antigen (PSA) levels, a marker for prostate cancer. The diet also was tolerated well and gave the authors hope for this dietary intervention.

The second study, published in the November-December 2001 issue of *Anticancer Research*, examined the effect lignans have on prostate cancer cell lines. This study showed that flaxseed-derived lignans inhibited the growth of three distinct human prostate cancer cell lines through hormonally dependent and independent mechanisms.

"So far we have observed the suppression of prostate cancer in humans, mice and at the cellular level," said Lin. "It's not a fluke or a coincidence. It's an encouraging line of research."

Study in Journal of Clinical Endocrinology and Metabolism, Bahram H. Arjmandi, MD

NEW YORK (Reuters Health) - Flaxseed may help to reduce levels of cholesterol in the blood of postmenopausal women, researchers report.

Overall, total cholesterol fell in the women by an average of 6%, according to the report in the *Journal of Clinical Endocrinology and Metabolism*. While LDL cholesterol fell, so did HDL ("good") cholesterol, resulting in only a minor reduction in the ratio of "bad" to "good" cholesterol.

Flaxseed is a whole grain that can be found in health food stores and some supermarkets. It can be sprinkled on food, or is sometimes used in baked goods, such as muffins or bread. Flaxseed is rich in lignans, a group of phytoestrogens. These plant-based estrogen-like compounds are associated with lower levels of total cholesterol and LDL ("bad") cholesterol, possibly due to their fiber and omega-3 fatty acid content.

In the study, volunteers consumed 40 grams of either ground flaxseed or wheat daily for 3 months. All 36 women who completed the study took a supplement containing 1,000 milligrams of calcium and 400 international units of vitamin D, which helps the body to absorb calcium.

Apolipoprotein B (apo B), a cholesterol-carrying molecule that may be a more sensitive indicator of heart disease risk than cholesterol alone, fell by nearly 8% among women who consumed flaxseed.

There was no reduction in cholesterol among women who took the wheat supplement, report researchers, and neither the flaxseed nor the wheat had any affect on bone metabolism.

"The findings of the present study suggest that flaxseed consumption by postmenopausal women is effective in reducing...known risk factors of coronary heart disease," Dr. Bahram H. Arjmandi from Oklahoma State University in Stillwater and colleagues conclude.

Clinical studies on Chromium

Study: Chromium Picolinate Enhances Skeletal Muscle Cellular Insulin Signaling In Vivo in Obese, Insulin-Resistant JCR:LA-cp Rats.

[Wang ZQ, Zhang XH, Russell JC, Hulver M, Cefalu WT.](#)

University of Alberta, Metabolic and Cardiovascular Diseases Laboratory, Department of Agricultural, Food and Nutritional Science, Edmonton, AB, Canada.

Chromium is one of the few trace minerals for which a specific cellular mechanism of action has not been identified. Recent in vitro studies suggest that chromium supplementation may improve insulin sensitivity by enhancing insulin receptor signaling, but this has not been demonstrated in vivo. We investigated the effect of chromium supplementation on insulin receptor signaling in an insulin-resistant rat model, the JCR:LA-corpulent rat. Male JCR:LA-cp rats (4 mo of age) were randomly assigned to receive chromium picolinate (CrPic) (obese n = 6, lean n = 5) or vehicle (obese n = 5, lean n = 5) for 3 mo. The CrPic was provided in the water, and based on calculated water intake, rats randomized to CrPic received 80 µg/(kg.d). At the end of the study, skeletal muscle (vastus lateralis) biopsies were obtained at baseline and at 5, 15, and 30 min postinsulin stimulation to assess insulin signaling. Obese rats treated with CrPic had significantly improved glucose disposal rates and demonstrated a significant increase in insulin-stimulated phosphorylation of insulin receptor substrate (IRS)-1 and phosphatidylinositol (PI)-3 kinase activity in skeletal muscle compared with obese controls. The increase in cellular signaling was not associated with increased protein levels of the IRS proteins, PI-3 kinase or Akt. However, protein tyrosine phosphatase 1B (PTP1B) levels were significantly lower in obese rats administered CrPic than obese controls. When corrected for protein content, PTP1B activity was also significantly lower in obese rats administered CrPic than obese controls. Our data suggest that chromium supplementation of obese, insulin-resistant rats may improve insulin action by enhancing intracellular signaling.

Clinical studies on Fructooligosaccharides

Study: Fructooligosaccharides and fiber partially prevent the alterations in fecal microbiota and short-chain fatty acid concentrations caused by standard enteral formula in healthy humans.

[Whelan K, Judd PA, Preedy VR, Simmering R, Jann A, Taylor MA.](#)

Nutritional Sciences Research Division, King's College London, UK. kevin.whelan@kcl.ac.uk

The intestinal microbiota are important during enteral tube feeding because they exert colonization

resistance and produce SCFAs. However, the effect of the enteral formula composition on major bacterial groups of the microbiota has not been clearly defined. The aim of this study was to investigate the effect of enteral formulas with and without prebiotic fructooligosaccharides (FOS) and fiber on the fecal microbiota and SCFAs. Healthy subjects (n = 10; 4 men, 6 women) consumed both a standard enteral formula and one containing FOS (5.1 g/L) and fiber (8.9 g/L) as a sole source of nutrition for 14 d in a randomized, double-blind, crossover trial with a 6-wk washout phase. Fecal samples were collected at the start and end of each formula phase, and were analyzed for major bacterial groups and SCFA concentrations using fluorescent in situ hybridization and GLC, respectively. Although there were reductions in total fecal bacteria due to both formula treatments, concentrations were higher after the FOS/fiber formula period compared with the standard formula period (11.2 +/- 0.2 vs. 11.0 +/- 0.2 log(10) cells/g, P = 0.005). The FOS/fiber formula increased bifidobacteria (P = 0.004) and reduced clostridia (P = 0.006). Compared with the standard formula, the FOS/fiber formula resulted in higher concentrations of total SCFA (332.4 +/- 133.8 vs. 220.1 +/- 124.5 micromol/g, P = 0.022), acetate (219.6 +/- 96.3 vs. 136.8 +/- 74.5 micromol/g, P = 0.034) and propionate (58.4 +/- 37.4 vs. 35.6 +/- 25.5 micromol/g, P = 0.02). This study demonstrates that standard enteral formula leads to adverse alterations to the fecal microbiota and SCFA concentrations in healthy subjects, and these alterations are partially prevented by fortification of the formula with FOS and fiber.

Study: The prebiotic characteristics of fructooligosaccharides are necessary for reduction of TNBS-induced colitis in rats.

[Cherbut C, Michel C, Lecannu G.](#)

National Institute for Agricultural Research, Gut Function and Human Nutrition Unit, Nantes, France.
cherbut@nantes.inra.fr

Fructooligosaccharides (FOS) increase the growth of lactic acid bacteria (LAB) and promote butyrate and lactate production. Because of these properties, FOS may benefit intestinal inflammation. The purpose of this study was to investigate the effect of FOS on colitis in rats and determine which factors are involved. Groups of rats with intracolonic trinitrobenzene sulfonic acid (TNBS)-induced colitis received intragastric infusions of 9 g/L NaCl, 1 g/d FOS or 10(11) colony-forming units (cfu)/d LAB (Experiment 1), or intracolonic infusions of 9 g/L NaCl, butyrate, lactate or butyrate + lactate with or without 10(9.5) cfu/d LAB (Experiment 2). Each infusion was administered twice daily for 14 d. Intragastric FOS reduced the gross score for inflammation (P < 0.001), myeloperoxidase (MPO) activity (P < 0.001) and pH (P < 0.001), and increased lactate (P = 0.02) and butyrate concentrations (P < 0.001) as well as LAB counts in the cecum (P < 0.01). Intragastric LAB (10(11) cfu/d) had the same beneficial effects as FOS and modified the cecal composition similarly. High doses of intracolonic butyrate and lactate reduced the indices of inflammation (P < 0.001), whereas administration of the lower concentrations found in the colon tended to decrease (P < 0.1) the gross score for inflammation and MPO activity. Addition of LAB (10(9.5) cfu/d) to the organic acids was necessary to reproduce the significant FOS-induced effects on these variables. Thus, under the experimental conditions used, FOS reduced intestinal inflammatory activity mainly by increasing LAB counts in the intestine.

Clinical Studies on Bitter Melon

Study: The effects of bitter melon (*Momordica charantia*) extracts on serum and liver lipid parameters in hamsters fed cholesterol-free and cholesterol-enriched diets.

[Senanayake GV, Maruyama M, Sakono M, Fukuda N, Morishita T, Yukizaki C, Kawano M, Ohta H.](#)

Department of Biochemistry and Applied Biosciences, Faculty of Agriculture, University of Miyazaki, Miyazaki 889-2192, Japan.

The hypolipidemic effect of dietary methanol fraction (BMMF) extracted from bitter melon (Koimidori variety), at the levels of 0.5% and 1.0%, was examined in male golden Syrian hamsters fed diets supplemented with and without cholesterol. The feeding of BMMF at 0.5% and 1.0% levels in the diets for 4 wk tended to reduce food intake and growth, although there was no difference in food efficiency (weight gain/food intake). An effect of dietary BMMF on serum triglyceride was not seen in hamsters fed diets free of cholesterol, while hypertriglyceridemia induced by dietary cholesterol was significantly lowered in a dose-dependent manner in those fed diets containing the BMMF. Serum total cholesterol concentration also tended to decrease in a dose-dependent manner following feeding of increasing amounts of BMMF in the presence and absence of cholesterol in the diet. The effects of dietary BMMF on liver triglyceride and total cholesterol levels were marginal, although dietary cholesterol caused a marked accumulation of these lipid molecules in the liver. These results suggest that the BMMF contains some components that could ameliorate lipid disorders such as hyperlipidemia.

Clinical Studies on Boldo

Study: Boldine prevents human liver microsomal lipid peroxidation and inactivation of cytochrome P4502E1.

[Kringstein P, Cederbaum AI.](#)

Department of Biochemistry, Mount Sinai School of Medicine, New York, NY 10029, USA.

Boldine, an alkaloid found in the leaves and bark of boldo, prevented the ferric-ATP catalyzed peroxidation of human liver microsomes. Lipid peroxidation, dependent upon electron transfer from NADPH or NADH, was comparably inhibited by boldine, with a $K(I)$ value of about 5 μM . Inactivation and decreased content of human cytochrome P4502E1 as a consequence of incubating microsomes with ferric-ATP and reductant was completely prevented by boldine. However, inactivation of cytochrome P4502E1 by CCl_4 was not prevented by boldine, although the alkaloid prevented CCl_4 -catalyzed lipid peroxidation. This suggests that the CCl_4 inactivation of P4502E1 may be independent of CCl_4 -mediated lipid peroxidation. In view of its low toxicity, lack of effect on P450 activity, and

strong inhibition of peroxidation of human liver microsomal, boldine may be valuable as an antioxidant and hepatoprotective agent.

Clinical Studies on Cumin

Study: Therapeutic role of *Cuminum cyminum* on ethanol and thermally oxidized sunflower oil induced toxicity.

[Aruna K, Rukkumani R, Varma PS, Menon VP.](#)

Department of Biochemistry, Faculty of Science, Annamalai University, Annamalai Nagar 608 002, Tamil Nadu, India.

Ethanol is one of the most widely used and abused drugs, increasing lipid levels in humans and experimental animals. Heating of oil rich in polyunsaturated fatty acids (PUFA) produces various lipid peroxidative end products that can aggravate the pathological changes produced by ethanol. In the present communication, the effect of *Cuminum cyminum* was investigated on alcohol and thermally oxidized oil induced hyperlipidaemia. The results showed increased activity of aspartate transaminase (AST), alkaline phosphatase (ALP) and gamma glutamyl transferase (GGT) and increased levels of cholesterol, triglycerides and phospholipids in the plasma of rats given alcohol, thermally oxidized oil and alcohol+thermally oxidized oil when compared with the normal control group. The levels of tissue (liver and kidney) cholesterol and triglycerides were increased significantly in rats groups given alcohol, thermally oxidized oil and alcohol+thermally oxidized oil when compared with the normal control rats. The levels were decreased when cumin was given along with alcohol and thermally oxidized oil. The level of phospholipids decreased significantly in the liver and kidney of groups given alcohol, thermally oxidized oil and alcohol+thermally oxidized oil when compared with the normal control rats. The level increased when cumin was administered along with alcohol and thermally oxidized oil. The activity of phospholipase A and C increased significantly in the liver of groups given alcohol, thermally oxidized oil and alcohol+thermally oxidized oil when compared with the normal control rats, whereas the activity was decreased with the cumin treatment. The results obtained indicate that cumin can decrease the lipid levels in alcohol and thermally oxidized oil induced hepatotoxicity. Copyright (c) 2005 John Wiley & Sons, Ltd.

Clinical Studies on Nopal

Study: Influence of nopal intake upon fasting glycemia in type II diabetics and healthy subjects.

[Fрати AC, Gordillo BE, Altamirano P, Ariza CR, Cortes-Franco R, Chavez-Negrete A, Islas-Andrade S.](#)

Departamento de Medicina Interna y Medicina Nuclear, Hospital de Especialidades del Centro Medico La Raza, Instituto Mexicano del Seguro Social, D.F.

To assess if the acute hypoglycemic effect of nopal which occurs in diabetic patients also appears in healthy individuals, 500 g of nopal stems (*O. streptacantha* Lem.) were given orally to 14 healthy volunteers and to 14 patients with NIDDM. Serum glucose and insulin levels were measured at 0, 60, 120 and 180 minutes after nopal ingestion. A control test was performed with the intake of 400 ml of water. The intake of nopal by the NIDDM group was followed by a significant reduction of serum glucose and insulin concentration reaching 40.8 ± 4.6 mg/dl ($n = 14$) (mean+SEM) and 7.8 ± 1.5 uU/ml ($n = 7$) less than basal value, respectively, at 180 minutes. (P less than 0.001 vs control test). No significant changes were noticed in the healthy group as compared with the control test (P greater than 0.05). Acute hypoglycemic effect of nopal was observed in patients with NIDDM but not in healthy subjects, thus the mechanisms of this effect differs from current hypoglycemic agents.

Study: Effect of raw and cooked nopal (*Opuntia ficus indica*) ingestion on growth and profile of total cholesterol, lipoproteins, and blood glucose in rats

Cardenas Medellin ML, Serna Saldivar SO, Velazco de la Garza J.

Instituto Tecnologico y de Estudios Superiores de Monterrey, Mexico.

Two different concentrations (approx. 6 and 12%) and two presentations (raw and cooked) of dehydrated nopal were fed to laboratory rats and growth and serum total cholesterol, lipoprotein profile and glucose determined. Samples of raw and cooked nopal were chemically characterized for moisture, protein, ash, crude fiber, ether extract, total dietary fiber, reducing sugars, amino acids, minerals and gross energy. Cooking slightly affected some of the nutrients analyzed. After one month feeding, blood was withdrawn via intracardiac puncture and serum glucose, total cholesterol, HDL, LDL, and VLDL were determined. Rats fed 12% nopal had lower weight gains ($P < 0.05$) when compared with counterparts fed 6% nopal or the control diet. Consumption of nopal did not affect ($P > 0.05$) glucose, total cholesterol and HDL cholesterol levels. However, rats fed raw nopal at the 12% concentration level had a 34% reduction in LDL cholesterol levels; thus, it was concluded that raw nopal had a potentially beneficial effect for hypercholesterolemic individuals

Clinical Studies on Stevia

Study: Mechanism of the hypoglycemic effect of stevioside, a glycoside of *Stevia rebaudiana*.

Chen TH, Chen SC, Chan P, Chu YL, Yang HY, Cheng JT.

Department of Medicine, Taipei Medical University-Wan Fang Hospital, Taipei, Taiwan.

We have studied the effects of stevioside on the glucose and insulin metabolism in 2 models of diabetes in rats, STZ-induced diabetic rats and NIDDM diabetic rats induced by feeding with fructose. Stevioside (0.5 mg/kg), lowered the blood glucose levels in STZ-induced diabetic rats, peaking at 90 min. Stevioside administered twice daily also demonstrated dose-dependent effects in lowering the glucose levels in both diabetic rat models. Stevioside reduced the rise in glucose during glucose tolerance testing in normal rats. Stevioside dose-dependently decreased protein levels of phosphoenol pyruvate carboxykinase (PEPCK) and PEPCK mRNA after 15 days of treatment. Stevioside also reduced insulin resistance in the diabetic animals as shown by the glucose lowering effects of tolbutamide. In conclusion, stevioside was able to regulate blood glucose levels by enhancing not only insulin secretion, but also insulin utilization in insulin-deficient rats; the latter was due to decreased PEPCK gene expression in rat liver by stevioside's action of slowing down gluconeogenesis. Further studies of this agent for the treatment of diabetes appear warranted.

Study: Increase of insulin sensitivity by stevioside in fructose-rich chow-fed rats.

[Chang JC, Wu MC, Liu IM, Cheng JT.](#)

Department of Food Science, National Pingtung University of Science and Technology, Pingtung City, Taiwan, R.O.C.

The intake of dietary fructose has undergone a marked increase around the world, especially the developed countries, in recent times. Stevioside, a glycoside contained in the leaves of *Stevia rebaudiana* Bertoni (Compositae), was used to screen the effect induced by a diet containing 60% fructose on insulin resistance in rats. Single oral administration of stevioside for 90 min decreased plasma glucose concentrations in a dose-dependent manner in rats receiving fructose-rich chow for four weeks. In addition, insulin action on glucose disposal rate was measured using the glucose-insulin index, the product of the areas under the curve of glucose, and insulin during the intraperitoneal glucose tolerance test. Oral administration of stevioside (5.0 mg/kg) in rats given four weeks of fructose-rich chow for 90 min reversed the value of glucose-insulin index, indicating that stevioside has the ability to improve insulin sensitivity in this insulin-resistant animal model. Time for the loss of plasma glucose lowering response to tolbutamide (10.0 mg/kg, i. p.) in fructose-rich chow fed rats was also markedly delayed by repeated stevioside treatment three times daily compared to the vehicle-treated group. The plasma glucose-lowering activity of tolbutamide was introduced to account for varying levels of endogenous insulin secretion, and is widely used as the indicator of insulin resistance development. Thus, it provided the supportive data that repeated oral administration of stevioside delayed the development of insulin resistance in rats on a high-fructose diet. Increased insulin sensitivity by stevioside administration was further identified using the plasma glucose-lowering action of exogenous insulin in streptozotocin-induced diabetic rats (STZ-diabetic rats). Oral administration of stevioside at 0.2 mg/kg three times daily

into STZ-diabetic rats for ten days increased the response to exogenous insulin. Taken together, this demonstrated that oral administration of stevioside improves insulin sensitivity, and seems suitable as an adjuvant for diabetic patients and/or those that consume large amounts of fructose.

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