# Abstract

A Randomized, Blind, Placebo-Controlled Cross-Over Study: Exploring the relationship of an exclusive homeopathic weight loss tincture combined with therapeutic nutrition in relation to reversal of visceral adipose fat tissue stores and serum inflammatory markers, which indicate risk factors for leading causes of death, including congestive heart disease and hormone-related cancers.

The placebo-controlled study evaluates subjects' hormonal, physiological, and physical responses to: a patented blend of homeopathic ingredients, (herein after referred to as "Slenderiix"), in conjunction with the methyl-form of B vitamins compounded with adaptogenic herbs, (herein after referred to as Xceler8, and when employed compatibly, are known as The Slenderiiz Weight Loss Program); therapeutic nutrition, optimal hydration from purified water; appropriate nutritional supplementation for optimal metabolism; a detoxifying restorative blend of zeolite minerals and nutrient dense green super-foods, (herein after referred to as "Restoriix"); and a whole food antioxidant-based energy and focus formula for enhanced dopamine utilization and neurotransmitter communication, (herein after referred to as Rejuveniix).

Results found subjects using Slenderiiz lost more than twice as much weight when compared to subjects who just limited daily food intake to1250 calories, without using Slenderiiz products.

Greater improvement in rate of loss and total amount of loss was attained related to whether subjects consumed Slenderiiz products along with foundational Nutritional Supplements and detoxifying with Restoriix, as well as with the addition of Rejuveniix to all of the above.

Visceral adipose fat tissue measures and serum inflammatory markers that indicate health risks were improved. Serum measures related to cholesterol and triglycerides were significantly improved. The cardiac inflammation metric HS-CRP was significantly reduced and blood sugar levels related to glucose, HbA1C and insulin were also improved.

Finally, physical, psychological and emotional changes in the subjects were observed. Subjects losing weight at an increased rate noted increased enthusiasm, energy, and confidence. The psychological impact of being empowered with the knowledge and ability to create a powerfully positive metabolic shift, especially within such a short period of time, was transformational for all test subjects taking ARIIX products, rather than calorie reduction alone.

## Introduction

Finding a product to enhance the effectiveness of healthy lifestyle choices to induce fat loss could significantly reduce the health complications, medical costs and death rates associated with obesity. This study attempts to examine such a product.

These latest figures from the Center for Disease Control (CDC) demonstrate that obesity continues to be a significant public health problem. In 2008, medical costs associated with obesity were estimated at \$147 billion. (1) The average annualized costs for being overweight has been estimated at \$8,365 for obese women and \$6,518 for obese men. (13)

An analysis estimated the 2007 obesity prevalence among adults, by state, from self-reported weight and height data from the Behavioral Risk Factor Surveillance System (BRFSS) found that state-specific obesity prevalence ranged from 18.7% to 32.0%.

Among 2007 BRFSS respondents: 25.6% were obese, 26.4% of men and 24.8% of women were obese. The obesity prevalence ranged from 19.1% for men and women aged 18-29 years; to 31.7% and 30.2%, respectively, for men and women aged 50-59 years. The obesity prevalence was higher in the South (27.3%) and Midwest (26.5%) and lower in the Northeast (24.4%) and West (23.1%). (2)

Curbing obesity by calorie limiting alone is often not effective due to hormonal protective responses. Too low of a daily caloric intake over a sustained period of time, can sabotage long term weight loss by suppressing metabolism, possibly causing the body to lock up fat stores for future survival. Hence, there is often a leveling of the rate at which a low-calorie diet alone will reduce weight and stabilize to an ideal weight long term. In order to reduce risk of obesity-related secondary diseases, complete lifestyle intervention is necessary which addresses nutrient dense nutrition, thereby opening the pathways for optimal metabolism and detoxification.

Within the last five years, the emerging field of epigenetic research has shown that the hormonal implications from the glycemic index values, glycemic load values and toxic chemical burdens from air, water and food are critically linked to whether or not an individual will gain or lose weight---even in the presence of a calorie deficit. Epigenetics is the study of gene regulation, manipulation and the resulting expression of health or disease.

This science is based on the study of cellular "memory" and biological responses involving chromatin modification or remodeling due to variations from environmental input from food, water, air, skin, emotional stress, etc; all factors other than those recorded within or prompted by DNA. Current theory in Epigenetic Research is that chronic degenerative disease is not due to genetic predisposition in most part, but rather 85-95% of environmental input is the cause of these diseases and the (estimated 5-15%) remaining risk factor is related to gene inscription. This suggests that genes have very little innate bearing on daily cell health, when compared to other factors.

Due to the epigenetic and psychoneuroendocrinological observations of the common factors of nutrient deficiency and coexistant presence of toxic load on catalyzing a default mode of human fat storage, this study was created to determine if exceptional fat loss could be observed in conditions of nutrient density through calorie-limited ideal food choices, appropriate nutritional supplementation, appropriate hydration/detoxification with purified water, and cellular detoxification and neurotransmitter rebalancing by means of pharmacological TID dosing with a patented sublingual homeopathic catalyst, and methylcobalamin (B12) compounded with a proprietary blend of adaptogenic herbs, hereinafter referred to as **Slenderiix** and **Xceler8**.

### **Slenderiix Homeopathic Tincture**

Homeopathy is a 200 year old medical discipline with a proven track record of both safety and efficacy. Due to the foundational principles of using natural substances in an infinitesimal dose within a diagnostic method of "like curing like", there are no known contraindications to pharmaceutical drugs. Homeopathic preparations have been regulated under the law since the inception of the Food, Drug and Cosmetic Act, authored by Senator Royal Copeland, M.D., a practicing homeopath, in 1938. (40)

Homeopathic preparations are recognized as drugs under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 201 et seq. Section 201(g)(1) of the FD&C Act, 21 U.S.C. § 321(g)(1), which defines the term "drug" as "articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, (i) or any supplement to any of them . . . ." (40)

Slenderiix employs a modernized approach to homeopathy, blending individual time-proven remedies into one cohesive formula to effectively address all imbalances which contribute to today's epidemic of abnormal weight gain.

Contributing factors include hormonal responses to excessive stress---whether dietary, emotional or environmental; capacity for cellular detoxification, neurotransmitter communication, stable hunger patterns and freedom from addictive behaviors. All of these contribute to systemic flushing of abnormal fat stores, when balance in achieved. Slenderiix was successfully tested in over 10,000 patients prior to ARIIX obtaining exclusivity and beginning in-house beta testing and clinical observation.

The Materia Medica catalogs all methodology within the discipline of homeopathy and references the functions of each remedy as excerpted below:

<u>Ammonium Bromatum</u>: Indicated in chronic laryngeal and pharyngeal catarrh, neuralgic headaches, and obesity.

<u>Avena Sativa</u>: Exhibits selective action on brain and nervous system, favorably influencing their nutritive function. Indicated in nervous exhaustion, sexual debility, and addictive morphine habit. Best tonic for debility after exhausting diseases and sleeplessness, especially of alcoholics. Also addresses nervous states of many chronic female concerns.

<u>Calcarea Carbonica</u>: Chief action is supporting impaired nutritional metabolism; the glands, skin, and bones, being most instrumental in changes evidenced. Needed for increased local and general perspiration [for normal systemic detoxification]... nausea, acidosis, and breathlessness, a jaded state---mental or physical, due to overwork.

<u>Fucus Vesiculosis</u>: A remedy for obesity and non-toxic goiter, thyroid enlargement in obese patients. Digestion is enhanced, normalizing obstinate constipation, and flatulence diminished.

<u>Graphites</u>: An anti-psoric carbon, most active in stout individuals with fairer complexions, with tendencies toward skin affections and constipation, excess fat storage with tendency to obesity, chronic low body temperature, with delayed menstrual history, who become cold easily, may suffer anæmia with redness of face, tendency toward inflammation of the pylorus or duodenal illness.

<u>Ignatia Amara</u>: One of the chief remedies for hysteria. It is especially adapted to the nervous temperament of women who are of sensitive, easily excited nature, quick to react, rapid in execution and change of mental and physical condition, nervous, apprehensive, rigid, trembling who suffer acutely with mental or physical stress.

Lycopodium Clavatum: Supports conditions where ailments are gradually developing with functional weakening regarding digestion, liver function, and predisposition to uric acid metabolism, intolerance to cold and muscular strength. Marked regulating influence upon the glandular (sebaceous) secretions, those benefitting from Lycopodium lack vital heat [indicating lower than optimal metabolism] have poor circulation, with cold extremities, acute temporary pains, and sensitivity to noise and odors.

<u>Nux Vomica</u>: Typical individuals calmed by Nux are thin, spare, quick, active, nervous, and irritable. Especially adapted to digestive disturbances, flatulent abdominal distention and hypochondrial states, Nux may also address conditions such as ravenous hunger, sour taste in mouth, nausea in the morning after eating; weight and pain in stomach, and feeling worse after eating.

<u>Sulfuricum Acidum</u>: This remedy supports those with chronic acidosis, digestive tract abnormalities, and may be evidenced by a craving for stimulants. Tremor and weakness, hurried temperament, hot flashes followed by perspiration with trembling, diminished rate of healing after medical procedures, gastralgia and hypochlorrhydria.

<u>Thyroidinum</u>: Exercises a general regulating influence over the mechanism of the organs of nutrition, growth and development. Used in psoriasis, tachycardia, arrested development in children, linked to improvement in memory, goiter, obesity, mammary tumors, uterine fibroids, fibroid tumors of the breast. Addresses the sensation of faintness and nausea, extreme weakness and hunger, sensitivity to cold and symptoms of Hypothyroidism after acute diseases, i.e, weakness, easy fatigue, weak pulse. (41)

- i. Since the passage of the FD&C Act, the United States Pharmacopoeia and the National Formulary have merged.
- ii. As noted, with the merger of the United States Pharmacopoeia and the National Formulary there are only two "official" compendia.
- iii. Homeopathic drugs are also covered by the Medicare-Medicaid Statute, 42 U.S.C. § 1395x (t), which defines drugs to "include only such drugs . . . as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary or the United States Homeopathic Pharmacopoeia."

#### **Xceler8: Metabolism and Energy Support**

Xceler8 is a patented blend of methylcobalamin (natural B12), biotin, and a synergistic blend of a specific classification of herbs known as *adaptogens*; so named due to their proven ability to improve resilience to stress, increase adaptive responses and to reduce the perception of stress. (42)

The coenzyme form of B12, known as methylcobalamin, provides the foundational structure of the Xceler8 product. This methyl-donating form of B12 is superior to analog chemical copies of B12 that are typically used in pharmaceutical drugs, inexpensive vitamins and "enriched" processed foods. (43) Various methyl donors are required in the body for chemically transforming chemical substances into usable forms for nutritive function. Methyl donors are also used for neutralizing destructive byproducts, such as homocysteine, into benign substances, which would otherwise contribute to disease. Methylcobalamin is the only form of B12 that is able to dispose of homocysteine through methylation and enables the production of SAMe, (S-adenosyl methionine), the most important methyl donor for adequate glutathione levels to be possible. Adequate glutathione synthesis in the body is the hallmark of a strong immune system and high functioning metabolism. (44)

Cyanocobalamin is chemically-derived synthetic or analog vitamin B. The B vitamin portion is cleaved to a cyanide molecule, which requires the presence of a methyl donor to be broken down by the liver to split off the (toxic) cyanide component, allowing the remainder to be converted to the biologically active form of methyl B12. This synthetic cyanocobalamin B12 is typically 100 times cheaper than methylcobalamin, and contributes to system-wide methyl donor depletion, which can cause a relative shift in homocysteine metabolism, increasing significant risk of heart disease, neurological degeneration and measureable age-related brain shrinkage.

"Homocysteine tends to accumulate in the body whenever (methyl or usable) B12 gets deficient. Homocysteine accumulation has been linked with increased risk of cardiovascular disease, chronic fatigue syndrome/fibromyalgia, multiple sclerosis, and Alzheimer's Dementia, among other conditions." (44)

An Oxford University study, published in The Journal of Neurology, reported an estimated 40% of the population is deficient in B12. (45) B12 deficiency is so wide spread because of commonly used pharmaceutical drugs like estrogen containing birth control pills, antacids--- including excessive calcium supplementation; antibiotics, anti-cancer drugs, anti-psychotics, and anti-diabetic medications. All of these directly cause B12 depletion. Without adequate B vitamins to suspend the bile salts in the liver, fat soluble nutrients are not able to be assimilated, resulting in compromised metabolic, neurological and immune function.

Subjects in a study reported in *Neuropsychopharmacology* comparing the effects of methylcobalamin as compared to cyanocobalamin, reported remarkable results in only one week of supplementation. Methyl B12 users reported reduced sleep time, with increased sleep quality and feeling more well-rested upon rising, increased day time energy and ability to concentrate. (46) Restoring appropriate levels of B12 supports healthy energy levels and excellent neurological performance. (43)

Biotin is a coenzyme and B vitamin which, when combined with chromium, has been shown to reverse insulin resistance and support healthy blood sugar levels. Even when tested in isolation, biotin plays a significant role in several key metabolic functions in digestion and blood sugar

regulation. Biotin supports the integumentary (skin) and nervous systems by facilitating repair of nerve damage due to type 2 diabetes, and fosters improved glycemic impact on these systems. (47)

Rhodiola Rosea and Ashwaganda are adaptogenic herbs used traditionally in both Chinese and Ayurvedic Medicine. Adaptogens are defined by their ability to have a normalizing effect on the body, allowing the individual to become more resilient to chronic stressors, whether physical or emotional. Adaptogens are non-toxic plant based therapies that normalize physiological functions which have been disturbed by chronic stress. These work through correction of balance to the neuroendocrine and immune systems. (42)

Adaptogens have been used successfully to treat a milieu of chronic health conditions for over 100 years, contributing to current theory that stress is the number one contributor that drives pathology of all diseases. Specifically, rhodiola has been shown to prevent the excess release of cortisol and adrenaline in response to stress, also blunting the increase in cholesterol and triglycerides typically triggered in response to stress. Rhodiola helps to transport serotonin precursors, reducing depression; and increases body fat to muscle ratio by mobilizing fatty acid stores during exercise, supporting increased fat burning. (42)

Ashwaganda has been used successfully in both India and China as an aphrodisiac, to treat insomnia, anxiety, fibromyalgia and arthritis, and used to promote emotional balance in cases of depression and mental or physical fatigue. (42)

#### **Appropriate Supplementation: Vitamins and Minerals**

**ARIIX's Vitamin and Mineral, known as "Optimals"** contain a signature whole food dried vegetable juice blend that is certified to be grown from GMO-free seeds and without pesticides. This blend includes broccoli, carrot, tomato, beet, spinach, cucumber, Brussels sprout, cabbage, celery, kale, asparagus, green bell pepper, cauliflower, parsley, and wheat grass. The vegetable blend adds important enzymes, peptides, and phytonutrients that support the body's ability to absorb and utilize vitamins and minerals, and to help offset the diets of those who have low daily consumption of vegetables. Rice bran contributes naturally whole complex antioxidants, magnesium, calcium, Vitamin A carotenoids, and nine B vitamins, along with several essential amino acids and phospholipids, which are necessary for maintaining healthy cell membranes.

Every ingredient in the *Optimals* is certified as of non-GMO origin and these products are manufactured in an OTC facility, certified for efficacy, purity and potency by NSF, GMP and the FDA, providing exacting standards of quality assurance, dependability of consistency and purity. Studies have concluded that supplements containing natural food nutrient complexes are better than supplements containing only isolates. [11][12]

Getting appropriate levels of vitamins and minerals every day is essential to not only a high functioning metabolism, but these can be the critical differentiators between vital health and the simple absence of an illness. Because most people in the world are deficient in one or more of the 40 vitamins, minerals and other essential biochemical nutrients necessary every day for minimal survival; and the human body was created with an innate ability to adapt to amazing variables and still survive, we observe most people today experience life, not in a state of vital health, but fluctuating on the continuum between the absence of illness and experiencing illness.

Most individuals are grossly deficient in the critical "Metabolic Supportive Nutrients", which are crucial to appropriate blood sugar control, stress responses, methylation of foods into usable forms that can actually nourish the body at the cellular level, and controlling every enzyme reaction from fluid

regulation to neurotransmitter production. As a nation, Americans are over fed and yet, undernourished and chronically stressed. This chronic state of deficiency results in a down shifting of the metabolism to attempt to spare what nutrient resources are remaining. This is most evidenced by mental sluggishness, poor digestion, daytime fatigue, poor sleep, chronic aches and pains due to inflammation, and cravings that are not satisfied by food. As the brain signals the body to input more nutrients to try to satisfy these vital deficiencies, and people answer these signals with low-nutrient convenience foods---notoriously high in sugar, starch, vegetable oils, chemical additives and stimulants---metabolism continues to down regulate and disease breeds at a faster rate.

Bruce Ames, Ph.D., professor of biochemistry and molecular biology at the University of California, Berkeley, analyzed over a hundred chronic degenerative diseases that are triggered by nutrient deficiencies. These symptoms in the early stages are typically identified by traditional medicine as "typical signs of aging", but with obesity and other metabolic, chronic inflammatory and autoimmune diseases becoming more common in adolescence and children, his revolutionary analysis, "The Triage Theory "(1, 2) has not come too soon. In his observations, he found that over 50 enzymes within the body are completely dependent upon daily intake of adequate amounts of vitamins, minerals and essential fatty acids in order to be catalyzed. Without consistent adequate levels of these three complexes every day, it is impossible for the body's enzymes to begin their work and for humans to experience vital health and optimal metabolism.

These nutrients, which have to be taken in daily, a minimum of twice a day, to replenish fuel necessary for routine cellular renewal throughout the day, are the critical factors which determine whether human genes are prompted to express health or disease. Dr. Ames found that a deficiency of any one of this array of critical micronutrients, posed a threat of oxidative stress damage to cellular integrity and metabolism that was equal to and in some circumstances, greater than 100 times the known damaging effects of radiation! (1,2,3,6) It is established that if individual cells within the organs of the body have a low metabolism due to low fuel levels, then these organs will also be functioning at a lower than optimal level. This means the entire body is then operating in survival mode of a low functioning metabolism, while usually experiencing a default of fat storage to conserve nutrient resources, and creeping closer to chronic degenerative disease.

Continuing his work at the Nutrition and Metabolism Center, Children's Hospital and Research Institute, Oakland, CA; Dr. Ames observes what he describes as a shift within the body toward shortterm survival gene expression as a coping mechanism in times of low nutrient intake. This shifting into survival mode simultaneously requires sacrificing expression of genes that produce long-term health. (4) This means that if we see individuals whose bodies are downshifting and accommodating to low nutrient intake by storing fat abnormally to spare nutrient reserves---this single indicator---belly fat, is enough to indicate life-shortening inflammatory diseases are not far down the timeline, if these nutritional deficiencies are not quickly remediated with therapeutic dosing of these essential nutrients. (5,6) Dr. Ames also postulates that micronutrient deficiencies that trigger the triage response would accelerate cancer, aging, and neurological decline, but would leave critical functions like ATP production, intact.(7)

The National Health and Nutrition Examination Surveys (NHANES) have long reported that the food intake of the following groups of people in the United States does not provide adequate nutrition from all 40 essential nutrients for adequate health: the poor, teenagers, menstruating women, the obese, and the elderly. Opinion has now shifted, according the Estimated Average Requirement (EAR), [see Table 1], that micronutrient levels from food are probably not adequate for anyone else either, to express optimal health without disease. (7)

Nutrient	Population group	% ingesting less than the EAR from food
Minerals		
Iron	Women 14–50 years old	16
Magnesium	All	56
Zinc	All	12
Vitamins		
B6	Women >71 years old	49
Folate	Adult women	16
E	All	93
С	All	31

Westernized diets are typically characterized by excessive calories from starchy carbohydrates and processed oils, and below micronutrient thresholds determined essential for minimal health. Dr. Ames notes that this low consumption of micronutrients accompanied by calorie excess may be the norm with those that are overweight and obese, and contributes to the deadly diseases associated with obesity. "Significant chronic disruption may occur when consumption of micronutrients is below the current RDA (8) but above the level that causes acute symptoms. When one component of the metabolic network is inadequate, there may be a variety of repercussions in metabolism, including acceleration of degenerative diseases."(7)

Due to these findings, high-quality multi-vitamin supplementation is recommended as a low-cost preventative intervention in combination with the healthiest possible food choices. This is the best low cost adjunctive for optimal health and reducing the risk of common age-related diseases associated with obesity, and ultimately death by secondary diseases of CHD and cancer.

Recognized authorities in Nutritional Medicine such as Ray Strand, M.D., Julian Whitaker, M.D., Jane Higdon, Ph.D., Michael Murray, N.D., Phyllis Balch, CNC, Nicholas Perricone, M.D. and six other known figures practicing proactive preventative nutritional medicine, were consulted to create what became known as the Blended Nutritional Standard. (9) This was constructed by employing 18 criteria across 48 ingredients based upon each expert's independent input for optimal therapeutic nutrient recommendations. This Blended Standard has become the bar that therapeutic quality multivitamins are measured against to determine if they are prepared in adequate dosing of non-toxic and effective forms of each nutrient, and if all essential nutrients are present and combined in the correct ratios one to another. The *Optimals* adhere to this Blended Standard.

Dr. Ray Strand, in his book *Healthy for Life*, notes that these nutrients are needed in greater amounts than can usually be obtained by food alone. In his practice, he has personally seen reversal of Type 2 Diabetes in hundreds of patients who optimize their nutrient intake with critical levels of vitamins, minerals and essential fatty acids and who employ the lifestyle modifications described in his Healthy for Life program. He also testifies to incredible gains in glycemic control with Type 1 Diabetics, and reversing the symptoms of metabolic syndrome, thereby preventing the onset of Diabetes in thousands of people worldwide using a similar combination of appropriate supplementation, low-glycemic diet and modest exercise. (10)

### Appropriate Supplementation: Omega 3 Fatty Acids

It is now generally maintained that inflammation is the root cause of the chronic degenerative conditions. Systemic inflammation is indicated by abnormal fat storage, swelling, chronic joint and bone pain, allergies, asthma, and headaches in the early stages; but also heart disease, cancer and neurological diseases, as the above mentioned earlier symptoms continue unchecked.

Anti-inflammatory omega 3 fats in bio-available fish oil lower the production of prostaglandins and cytokines that trigger inflammatory responses. Clinical studies have shown that stress and depression are associated with too many inflammatory cytokines in the body, and not enough anti-inflammatory omega 3 fats are one of the foremost contributors. These two factors typically are present before abnormal fat storage begins, and continue to mount along with unwanted weight. The American Heart Association (AHA) suggests if triglycerides are high (200 mg/dL or higher) (1, 2), taking 2,000-4,000 mg of fish oil with EPA and DHA, along with dietary changes, is an effective way to reduce risk factors within a 90 day period. However, most integrative medicine specialists initially use a therapeutic loading dose with a minimum dose of 4000 mgs of omega 3 oils per day, and for those patients who are severely obese, depressed, or overtly stressed, they may use much higher doses to get significant results within a 90 day time frame. (4)

Omega-Q was included as part of the foundational nutritional therapy at a dose of 4000 mgs/ day, in effort to produce a favorable effect on fat-burning metabolism and serum inflammatory markers within a 12 week period.

Because of the state of the environment today, many fish contain high levels of mercury, PCBs (polychlorinated biphenyls), dioxins and other environmental toxins, which concentrate in fat stores of both the fish and the people who consume them. These fat-soluble toxins lock up fat cells and contribute to the metabolic dysfunction, which is evidenced by not being able to lose weight, even when eating less and exercising more.

Many commonly available brands of fish oil supplements are "purified" with hexane, which is a petroleum derivative. Governing officials allow hexane residues to be present as a tradeoff for the removal of the heavy metal residues common to commercially available fish oils. This residual hexane in most fish oil supplements can accumulate over time and cause considerable nervous system damage. (14) Chemicals that are petroleum derivatives, in general, are suspected to cause endocrine disruption which, over time, is associated with the development of hormone related cancers.

ARIIX has sourced a pristine omega 3 fish oil from the only manufacturer in the world who has patented a unique low temperature, enzyme fermentation purification process which ensures the delicate anti-inflammatory properties are not only kept fully intact, but yields a superior product that is tasteless and odorless, with no unpleasant digestive after-effects that are typical of hexane-distilled or rancid fish oil products common to the shelves of vitamin chains and superstores. Enzyme purification also eliminates chemical waste byproducts, thereby reducing environmental impact resulting from disposing of hexane into the environment.

### **Appropriate Supplementation: Restoriix**

**ARIIX Restoriix** is a blend of zeolite, chia seeds and nutrient-dense organic spirulina, chlorella and chlorophyll. Zeolites are highly alkaline minerals that contain large structural vacancies and carry a negative ionic charge, giving them superior binding adhesion to positively charged pathogenic toxins. The zeolite blend sourced for Restoriix is ultra-purified and certified free of lead and other contaminants, common to earth-sourced minerals. The highest grade nano-sized particles provide for increased surface area adhesion of free radicals and environmental pathogens, as well as a smooth, palatable texture. Zeolite's magnet-like effect attracts impurities and binds them within its honeycomb-like molecular structure, preventing the resorption of toxins as they are excreted from the body through the natural process of digestion.

Chia seeds are a superior source of vegan protein and contain over 30 nutrients. Rich in omega 3 fatty acids, containing more than three times the antioxidant capacity of blueberries, and 35% fiber by weight, chia seeds detoxify the digestive tract while providing nutrients which also rebalance omega 3 to 6 ratios. Insoluble fiber scrubs intestinal walls and loosens impacted debris, while the balance of soluble fiber effectively absorbs up to twelve times its weight in fluids. (36)

Chlorophyll-rich plant foods such as chlorella and spirulina are dense in RNA proteins which repair damaged DNA. Excessive toxic load in the body causes over production of free radicals which mutates DNA, causing premature aging and accelerating disease pathology. Aging and disease are observed when DNA mutations occur within the cells and these damaged cells reproduce. Since chlorophyll is the highest known food source of RNA repair proteins, finding foods sources rich in chlorophyll would inhibit DNA mutations from reproducing, according to Dr. Benjamin Frank's work in RNA diet therapy. Dr. Frank pioneered dietary nucleic acid therapy which has proven RNA and DNA rich supplements reverse symptoms of aging and disease and increase metabolism by increasing cellular energy (ATP) for improving intercellular communication in the body, improving rejuvenation, detoxification, and rapid healing. (35) Marine biologists were first to observe the anti-aging effects of these green sea vegetables on mammals. Ocean mammals consuming large amounts of chlorophyll-rich sea vegetables, including spirulina and chlorella, have no visible signs of aging once they reach adolescence. Chlorella has more than twice the RNA density per gram of any animal protein, making it the richest natural dietary source of these detoxifying nutrients.

Spirulina is high in natural iodine, which nourishes the thyroid, protects all glandular tissues and ultimately supports both immune and metabolic function. To improve metabolism, spirulina has been proven to improve glycemic control and dislipidemia in Type II diabetics. (38) High in metallo-thionine compounds, spirulina has been shown to shield the body from radioactive isotopes by binding to them, making digestive elimination possible. Spirulina's chemo-protective effect has shown potential for use in fighting cancer, as well as detoxifying the kidneys from overuse of antibiotics and analgesics. (37) In Russia a study was conducted on 270 children living in highly radioactive areas, and all showed elevated IgE serum levels. This immune system inflammatory response is typically high due to allergic responses, but was completely normalized in 6 weeks of feeding spirulina twice daily.(38) In addition, spirulina's dense array of phytonutrients phytocyanin, chlorophyll and carotenoids contribute to the anti-inflammatory properties which nourish, as they purify the body.

With an average alkalinity factor of 9.7 pH, negatively charged zeolite minerals bind unwanted toxins and reduce acid pH load at the same time. In addition, when fat is released due to dieting, these toxic stores are freed up and circulate within the body, which can cause significant side effects if they are not completely eliminated by the digestive tract. If toxic load overwhelms these pathways, the possibility of reabsorbing toxins can trigger a protective response of shuttling toxins into fat storage,

represented by a weight loss plateau or rebound weight gain. Detoxification has been shown to effectively protect against these metabolic set-backs.

### **Appropriate Supplementation: Rejuveniix**

Rejuveniix is an energy-boosting blend of low-temperature dehydrated fruit and berry extracts, chosen for their wide variety of polyphenols and bioflavanoids. Effectively combined with green coffee bean extract, kava kava root extract and the amino acid I-theanine, this formula has been observed to provide increased mental clarity, stamina and focus. A unique extraction process leaves exceptionally high levels of the beneficial antioxidant levels intact, while producing a product that contains no fructose.

Rejuveniix also contains a blend of acai, maqui, sea buckthorn and goji berries, as well as mangosteen and noni fruits. This variety of berries and fruits represents a wide range of antioxidant coverage shown to support immune function, heart health and metabolic sufficiency. Represented within Rejuveniix are anthocyanins, xanthones, a variety of carotenoids such as beta carotene and zeaxanthin, and plant sterols known to support heart health, detoxification and modulate oxidative stress.

2010 findings in the British Journal of Nutrition reported therapeutic effects of berries in modulating postprandial glucose response when eaten with high glycemic foods. After consuming a meal with berries, serum levels were drawn at 15, 30 and 150 minutes, and compared to blood glucose responses at the same intervals following a control meal. The results showed that consuming berries along with sucrose had a significant impact on reducing the digestion/absorption of the sucrose as evidenced by decreased serum postprandial glucose. High levels of polyphenol antioxidants in berries are attributed for this compensory affect. (28)

The focus and energy portion of the Rejuveniix formula comes from a balance of the amino acid Itheanine, kava kava root extract and green coffee bean extract. ARIIX only sources the highest quality kava kava root from the Republic of Vanuatu due to superior potency and highest lactone content. This lends properties that support healthy blood pressure and the ability to relax the mind and muscles without sedative effects and loss of mental clarity.

L-theanine is sourced from green tea leaves and directly stimulates the production of alpha brain waves, allowing mental alertness (29) and also increases dopamine, "the satisfaction neurotransmitter", allowing individuals to experience a greater sense of pleasure and fulfillment. (30)

Green Coffee Bean Extract (GBCE) is a rich source of chlorogenic acid, which has been shown to have significant effects on both body mass and reducing body fat when used long term in both overweight and obese subjects. (31) Green coffee bean extract has also been shown to suppress hepatic production of triglycerides, reducing fat accumulation. (32) GCBE also works synergistically with kava kava and I-theanine, enhancing effectiveness.

In comparison, common sources of caffeine contain cafestol and other compounds associated with the negative effects of using caffeine as a stimulant. Research has shown the combination of ingredients in Rejuveniix to support clarity of mind and positive mental outlook by supporting neurotransmitter production and cellular communication, and healthy energy levels. (33)

# Methodology

Twenty three individuals were chosen for the initial study; three men and 20 females ranging in age from 21 to 75. Individuals were selected on the basis of commitment to completing the 12 week course. Subjects were selected due in part to a desire for weight loss, with at least 12, to as much as 120 pounds to lose.

The table below provides the initial weight (in pounds) and variation of both genders.

					Std.	
	Count	Minimum	Maximum	Average	Deviation	
Men	3	228	298	259.3	35.6	
Women	20	132	297.2	182.8	39.9	

Subjects were required to maintain compliance for 12 weeks with a specific nutritionally dense diet, appropriate supplementation, adequate fluid intake, simple exercise, and detoxification and stress management techniques. Examples included keeping a food journal, exercise, personal contact, accountability and counsel.

Subjects were given a 1,250 calorie, low-glycemic, low starch, functional food meal plan that included a minimum amount of healthy fats from coconut oil, avocados and raw sprouted nuts or their cold pressed oils. Because the FDA's defined daily minimum caloric threshold for a "Low-fat Diet" is set at 30% or less of daily calories coming from fat, a minimum of 300 calories of the 1250 allowable calories were specified to be selected from healthy fat.

In addition, to rebalance appropriate ratios of omega 3 fats to omega 6/9 fats within the body quickly, subjects were required to consume 2000 IU of Omega-Q both morning and evening every day for the 12 week trial.

Because sudden excessive amounts of omega 3 fats can have a blood thinning action, subjects were screened for contraindications and there were no subjects who were using anti-coagulant blood thinning medications such as Coumadin/wafarin.

Participants simultaneously excluded all inflammation-causing omega 6 vegetable oils such as canola, soybean, grape seed, olive oil and any other oil which can contribute to inflammatory cytokine production within the body, and/or compete with omega 3 for conversion/uptake. Inappropriate balance of omega 3 to 6 oils blocks the pathway to healing metabolism, alters cell signaling and optimal neurotransmitter and hormone rebalance, and blunts potential of therapeutic efficacy intended by including Omega-Q.

Subjects were instructed to choose at least twice as many non-starchy fresh vegetables as protein portions per meal to provide plenty of fiber rich carbohydrates which are also dense in anti-inflammatory nutrients.

All groups, except the placebo group, were using the Slenderiix and Xceler8 before each meal throughout the 12 week trial. With all groups the following constants remained for the duration of the study period: food selection guidelines and daily calorie max intake, appropriate hydration to include a minimum of 5 (total based on individual weight) refills of the Puritii water bottle daily, with individual increased adjustments for weight-appropriate amounts of water, and a minimum amount of exercise of 20 minutes of walking, 5 times per week.

Subjects were observed and feedback was given, comparing results of individuals with and without the use of Slenderiix and Xceler8; as well as with Slenderiix, Xceler8, foundational Nutritional Supplementation; and a final group who employed all of the above items, plus including Rejuveniix. Subjects committed to weekly counseling and instruction with Dr. Hurt. Before and after, and at fourweek intervals, subjects' measurements, weight and photos were documented. Before and after, a comprehensive blood work panel was drawn and evaluated. This panel consisted of serum inflammatory indicators of the presence of fat storage metabolism, known markers that are precursors to diabetes, heart disease and chronic inflammatory conditions such as cancer. Weight, measurements, and fat store location were documented, reviewed, and compared.

Subjects were stratified randomly into 4 groups. The Table below outlines the particular products taken by each Group in the initial 4 weeks before the crossover, and what products were taken in conjunction with the 1,250 calorie daily consumption.

	Nutrifii Vitamins	Rejuveniix (Energy)	Slenderiix Xceler8	Restoriix (Detox)	1250 C. Diet
Group A	Yes	No	Yes	Yes	Yes
Group B	No	No	Yes	No	Yes
Control Group	Yes	No	No	Yes	Yes
Group D	Yes	Yes	Yes	Yes	Yes

Subjects receiving Nutrifii Nutritional supplements of Vitamins, Minerals, Restoriix, and/or Rejuveniix were to take them as directed on the product label. Omega-Q was given, as noted above, in a dose that is double the label guidelines. All subjects were required to take 15 drops of Slenderiix, under the tongue 10 minutes before each meal. Additionally subjects took 15 drops of Xceler8 under the tongue with breakfast and lunch. Subjects not receiving either Slenderiix or Xceler8 were given a placebo.

Subjects were required to consume 200 calories minimum from organic expeller pressed coconut oil in meal preparation, with the option of an additional 50 calories from raw avocado or raw nuts or organic cold pressed oils. Finally, subjects were required to exclude any foods not listed in the above table, and made specific note to avoid coffee, mint or gum products and artificial sweeteners such as sucralose, aspartame, "Splenda" or "Equal", common to synthetic "diet" or "lite" food replacements. Natural sweeteners, erythritol or Stevia liquid, were allowed.

In addition to the products identified above, all subjects were required to eat 1000 calories worth of the following foods in the following quantities:

- Up to two cups of raw, whole, fresh fruit
- Six or more cups of raw, fresh vegetables
- 10 to 16 ounces of clean (Free Range, Grass Fed, or Wild) protein

The following table identifies the classifications of foods available for subjects during the program.

<u>Protein</u>	<u>Vegetables</u>		<u>Fruits</u>
Bison Beef	Artichokes	Garlic	Apples
Eggs	Arugula	Greens	Blackberries
Salmon	Asparagus	Green Beans	Blueberries
Tuna	Bean Sprouts	Lettuce	Grapefruit
Venison	Broccoli	Mushrooms	Lemons
White fish	Brussels Sprouts	Onions	Limes
	Cabbage	Peppers	Raspberries
	Carrots	Radish	Strawberries
	Cauliflower	Spinach	
	Celery	Tomatoes	
	Cucumbers	Zucchini	

Beyond the diet, subjects were required to drink a minimum of 50% of their respective body weight of water, in ounces each day. Regardless of weight, 100 ounces was the minimum amount of water for each subject each day with no maximum limit.

Finally, subjects were required to participate in an exercise program. Subjects who were currently participating in an exercise routine at the onset of the study were allowed to continue with that program, at the review of Dr. Hurt. Subjects who were non-exercisers were required to walk for at least 20 minutes, a minimum of five days each week.

## Results

Of the initial 23 subjects, 19 completed the program. Results of following a regimen of calorie limited nutrient dense diet, appropriate supplementation, hydration, and detoxification with moderate exercise, coupled with use of specific products yielded statistically significant results compared to reducing calories alone. The table below provides a summary of the average rate of weight loss per day over time.

	Average Weight Loss p/Day in LBS.		
	Week 4	Week 8	Week 12
Group A	0.49	0.42	0.35
Group B	0.45	0.38	0.32
Control Group C	0.23	0.43	0.35
Group D	0.47	0.40	0.36
Avg. of Non-Control Groups	0.47	0.40	0.34
Control Group Calories Only	0.24	0.24	0.24

Since subjects were classified into four equal groups (n=5), an ANOVA was conducted to determine significance across groups. Even given the small sample size created by the factorial design, results show that significant differences existed between groups (F ratio 14.2 p<.01).

After four weeks, subjects in the Control Group C were allowed to take Slenderiix. At the crossover, all of the groups using Slenderiix (A, B, D) had lost an average of 13.1 pounds. In each group, 103.4% more weight loss was observed, than was experienced in the placebo group within the same time frame. Individuals in the placebo group were eating the same meal plan, water and exercise routines as that of the Slenderiix using groups. In addition, placebo group subjects were receiving the exact same nutritional supplementation as the subjects in group A, the only difference in these two groups was between the active Slenderiix for the Group A Subjects, and the inactive placebo product for the Control Group C Subjects. Placebo subjects lost an average of only 6.44 pounds in four weeks, employing the exact same lifestyle efforts, calorie reduction and timeframe as all other groups.

Within this initial 4 week timeframe, placebo subjects were the only group that reported feeling hungry, fatigue and weakness upon exercise, and difficulty at being around food or in the presence of others at mealtimes. By the third week of the program, placebo users were beginning to express difficulty at continuing to participate with the trial for the remaining 9 weeks.

Even though the amount of weight lost within all Slenderiix-using Groups A, B and D reflected less than 1 pound average variance among the three groups, there was a marked difference in the level of enthusiasm, perception of the ease of the program, increased sense of well-being, and continual increase in daytime energy and desire to become more active as time went by, within Group D. This group was supported by not only Slenderiix and Xceler8, but all of the Foundational Supplements, as well as Rejuveniix.

Because of the remarkable difference in positive mental attitude coupled with weight loss success, it was decided Groups A, B, and C would, at the crossover time, convert to the Group D regimen for the 8 week duration of the trial.

Even with a relatively small sample, the difference between groups, as well as individual improvement on pre and post testing of both subjects was statistically significant. Two-tailed results suggest a statistical significance in all groups, except the placebo group, when compared to diet alone.

Т	Tukey-t values across groups compared to diet alone			
	Week 4	Week 8	Week 12	
Group A	t=3.27 p<.05	t=2.90 p<.05	t=2.5 p<.05	
Group B	t=5.05 p<.01	t=3.46 p<.05	t=1.83 p<.10	
Placebo Group C	t=.94 p>.1	t=3.00 p<.05	t=2.5 p<.05	
Group D	t=5.41 p<.01	t=3.89 p<.01	t=2.75 p<.05	
Entire Group	t=3.27 p<.05	t=2.83 p<.05	t=1.91 p<.05	

. . . ...

Furthermore, all groups were found to be significantly different from no diet whatsoever (p<.0001).

It is generally maintained that weight loss that is too rapid and sustained over a long period of time is not optimal. Therefore, the rate of weight decline, reflective of stabilizing metabolism, is provided in the table below.



As the table depicts, over time the rate of weight loss tapers off with each successive month of weight loss. 89.5% of subjects exceeded their personal targeted weight loss goal, projected at the onset of the trial.

Of the two subjects who did not reach their 12 week projected weight goal, one subject was only 1.6 pounds short of the 25 pound projected possible weight loss for females, and the other subject was within 3.8 pounds of study projections. It should be noted that the latter subject had exceeded her personal goal of losing 20 pounds. Once personal expectations were fulfilled at completion of the 7<sup>th</sup> week of the trial, she experienced no additional weight loss in the remaining 5 weeks of the program. This observation supports psychological theory that personal expectations play a significant role in weight loss outcomes in regard to the possibility of subconscious behaviors sabotaging what ultimately may be possible. In total, the rate of weight reduction per day experienced by all Slenderiix using groups consistently exceeded the rate of weight loss compared to calorie restricted diet alone.

Biomarkers which are key indicators of metabolic syndrome, diabetes, cardiac disease and cancer risk factors were measured through serum testing both before and after the 12 week trial. Unfortunately, circumstances limited collection of lab values from every subject, which prevented reporting on every lab value examined. The individuals were to get a selected list of disease markers drawn, which are known in preventative medicine as indicators of fat storage, obesity, diabetes and precursors to heart disease and some cancers. Because these labs were to be ordered and collected by each subject's physician, several physicians declined follow-up labs after the 12 week trial was over. In many cases, this was due to the obvious considerable weight loss and physicians' no longer deemed the labs as medically necessary, which precluded insurance covering the cost of the follow up labs. Due to logistical complications such as this, almost half of subjects were not able to provide follow up lab values for certain tests.

Pre and post measurements taken from subjects who obtained post blood work (n=10) found statistically significant differences in each subject on measures generally associated with improved health, and markers associated with disease. The table below provides the paired-t differences between subjects across all groups (excluding placebo). Given the limited sample size related to factorial design, although statistically significant differences in blood markers were found in ALL groups except the placebo group, the interpretive power of such small samples sizes resulted in the exclusion of reporting certain values for this report.

(Faired-t Differences)			
HDL Cholesterol	t= 8.38	p<.0005	
LDL Cholesterol	t= -8.03	p<.0005	
LDL/HDL Ratio	t= -14.02	p<.0005	
Total Cholesterol	t= -18.96	p<.0005	
Triglycerides	t= -56.94	p<.0005	
VLDL	t= -29.31	p<.0005	

#### Serum Measures (Paired-t Differences)

## Cardiac Inflammation

(Function Differences)			
HS-CRP	t -29.65	p<.0005	

Blood	Sugar	Levels
-------	-------	--------

(Paired-t Differences)			
Glucose	t= -49.41	p<.0005	
HbA1C	t= -23.14	p<.0005	
Insulin	t= -11.91	p<.0005	

#### All metrics in the tables above show statistically significant differences (p<.0005) Negative t-values indicate a drop in repeated measures.

A collection of serum markers that accompany the onset of abnormal fat storage, specifically in the disproportionate deposition of visceral adipose tissue (VAT), have been associated with the pathology of insulin resistance. These blood levels have interrelated relationships in obesity-related disease pathology. Integrative physicians now understand that although individually these lab indicators may enter the health assessment picture at different times due to biochemical individuality, certainly metabolic syndrome is continuing to worsen along with the increased inability to shed excess weight easily. Over time the appearance of more and more of these particular serum markers continue to underscore the depth of the disease pathology that is pushing the patient closer to cardio-metabolic disorders and hormone related cancers, our number one and two causes of death. These serum

levels are as follows: elevated triglycerides, total cholesterol serum insulin; decreased HDL cholesterol and glucose tolerance.

Over time, insulin resistance progressively becomes more severe and continues to affect function of more organs. When serum glucose levels remain elevated, there is increased likelihood of protein glycosylation and overproduction of free-radical producing oxidative stress, which have proven association with initial central obesity, and eventual atherosclerosis, type II diabetes, heart disease and cancers. The body's typical reaction of producing more and more insulin leads to insulin resistance in various locations throughout the body as disease progresses. In the skin, insulin resistance can be revealed as acne, while insulin resistance in the brain over time becomes Alzheimer's---recently given the name Diabetes Type III.

The Serum Measures Chart above reflects that all serum risk factors tested for cardio-metabolic disorders were significantly reduced.

Physical measurements of subjects' chest, waist and hips, before and after, reflected that all Slenderiiz-using subjects lost a significant amount of fat in the waist measurement, indicating decrease in visceral adipose tissue stores, as well as associated mortality risks of central obesity.

Within the first 4 weeks of the trial, several of the placebo subjects, though weight loss was reflected on the scale and visibly in the face and extremities, did not lose any inches from their waist measurement. One placebo subject, whose total loss goal at the onset of the trial was only 12 lbs, reported initial concern over the loss of significant inches in the chest and extremities, without any loss of weight in the midsection measures. After the crossover to the active Slenderiix, subject continued to lose the last few pounds to reach her goal, but also noticed a remarkable redistribution of normal body fat to the more desirable female areas, as her weight stabilized to a new set point during the remaining few weeks on the active product.

All Slenderiix-using groups reflected significant inches lost in the waist measurement, as compared to the chest and hips throughout every stage of the trial. This confirms the ability of the Slenderiiz program to target release of fat stores in the area of dangerous visceral adipose fat. Although the full extent of the mechanisms that allow this to be possible are yet unknown, serum tests reflect a regain in glycemic control, thus reversing the progression of insulin resistance---first heralded by the visible increase in visceral adipose tissue at the waist measurement---and the pathological risks that would have followed in time.

Typically, belly fat stores are protected by cortisol and other stress hormones in a season of calorie deficit, and studies have shown that these fat stores are typically only released after 90 days on an ultra-low calorie diet. The results of the Slenderiiz Weight Loss Program would suggest there is compensory interaction with these stress-related hormones. Exact mechanism of the action observed is yet undetermined, but would warrant further study in this area.

#### Cardio-metabolic Risk Assessors that accompany excess Visceral Adipose Tissue

Typically, as insulin secretion increases, blood triglycerides and glucose levels continue to rise, while HDL levels slowly decrease and VAT begins to accumulate. Since insulin is released in response to too much glucose in the blood, and HbA1c represents the amount of hemoglobin molecules that have had glucose molecules attached to them in the blood stream, these two serum markers typically rise and fall together. Serum levels of insulin within study subjects decreased an average of 27.7%, and correlating HbA1c also decreased 4.4%.

Even though all cholesterol levels were monitored and improved upon, the cholesterol values that are specific to indicate systemic inflammation are now accepted to be most pertinent to reversing the interrelated risks of heart disease and obesity.

The pathology of arterial plaque formation in heart disease has been proven to be caused by several factors effecting inflammatory response to the small vascular injuries that occur from a cascade of reactive events. Over-production of insulin from sugar and starch consumption, increased platelet adhesion due to omega 3 fat deficiency with omega 6/9 excess and antioxidant deficiency, emotional stress, all theses sources of oxidative stress contribute to inflammatory pathology. If inflammation is eliminated, arteries are clear, regardless of total cholesterol levels. Across all cholesterol markers, subjects responded with significant improvements in all areas.

The fraction of cholesterol that indicates potential endothelial inflammatory damage is called Very Low Density Lipoproteins (VLDL). Due to excessive free radical production, when cholesterol is oxidized into VLDL, it indicates an insufficient amount of antioxidants available within the body. VLDL can be significantly reduced by supplementing adequate vitamins, minerals and antioxidants, by modulating increases, beyond standard dosing, appropriate to the level of stress of the individual. This inflammatory marker, VLDL was significantly reduced.

The National Institutes of Health funded the VITAL study to asses the effect of vitamin D and omega 3 supplementation on the prevention of cancer and heart disease. (23) This was a large-scale randomized trial which also made correlations to fasting insulin, glucose, altered cholesterol ratios and the prevalence of metabolic syndrome. Findings proved that the lower the serum vitamin D, the more prevalent these inflammatory makers for insulin resistance progressing to metabolic syndrome. Increasing serum 25(OHD) is associated with a responsive lowering of VAT, triglycerides, triglyceride/HDL-cholesterol ratio. Within this trial period, subjects serum vitamin D increased an overage of 15.7% overall, raising serum levels of 9 out of 10 subjects to reflect an optimal range of 40-69 ng/ml, and the remaining subject at 39.10 ng/ml. Due to the seasonality of the trial beginning fall and ending mid-winter, these results are impressive, considering vitamin D levels typically plummet in winter months and fat stores simultaneously increase.

Higher levels of Highly Sensitive C-Reactive protein are linked to higher occurrences of sudden cardiac death, strokes, peripheral artery disease and myocardial infarction. HS-CRP is an inflammatory particle produced by the liver in response to stressors. Trial subjects averaged a 24% reduction in HS-CRP.

Since about 50% of all heart attacks and strokes effect people with normal total cholesterol levels, anti-aging medicine specialists now look to a combination assessment of the inflammatory HS-CRP along with the ratio of Triglycerides (TG) to High Density Lipoprotein (HDL) cholesterol to offer more effective proactive approaches to risk assessment. (22, 25, 26) As most triglycerides in the blood are indicative of carbohydrates that have been converted into fat that will be stored specifically in the visceral adipose tissue area, reducing serum levels of triglycerides and comparing these levels to sufficient quantity of HDL is a significant indicator of the degree of disease pathology, to identify the patient's place on the continuum between insulin resistance and metabolic syndrome. (24) Data from the Third National Health and Nutrition Examination Survey (NHANES III) indicated that the most frequently noted serum markers among overweight and obese adolescents are high TG (25–30% of adolescents) and low HDL cholesterol levels (40–50% of adolescents). (26)

The table below reflects the results of TG/HDL Ratio improvements within the 12 week period.

TGL/HDL Ratio			
(Paired-t Differences)			
TGL/HDL	t -40.9	p<.0005	

The ratio of TG to HDL is a reliable indicator of the extent of insulin resistance on cholesterol metabolism. (27) Subjects within the Slenderiix Clinical Trial produced a 41% reduction in Triglyceride to HDL ratios, significantly reducing serum-defined insulin resistance and cardio-metabolic risk.

# Conclusions

Results of the study found that all groups statistically lost more weight, than those on no weight loss regimen whatsoever. However, subjects using Slenderiiz lost just over twice as much (103.4%) weight per day (.51 lbs p/day) compared to subjects on either a 1250 calorie diet alone (.24 lbs p/day) as well as the Placebo Group (.23 lbs p/day). Subjects taking Rejuveniix in conjunction with Slenderiiz had a significantly higher (+3%) rate of weight loss.

Subjects taking Slenderiiz also reported increased energy and sense of well-being compared to individuals on diet alone. Subjects taking a placebo reported significant hunger, low energy and intolerance to exercise, in between meal headaches, and difficulty around others eating food, more than all other groups. Subjects who used all ARIIX foundational nutrients, Slenderiiz and Rejuveniix reported the greatest amount of energy and focus, and had the highest rate of weight loss in all groups. Unlike any other group, no single subject taking Slenderiiz and Rejuveniix combined, reported mild to moderate headaches, fatigue and symptoms of detoxification or withdrawal from processed foods with in the first week. Further study on these self-reported benefits of Rejuveniix is warranted.

Typical of overweight individuals, most subjects showed elevated levels of HS-CRP, triglycerides, VLDL cholesterol, total cholesterol, fasting insulin, serum glucose, HbA1C, and depressed levels of HDL and vitamin D, at baseline. Statistically significant improvement occurred for all subjects taking ARIIX Products, in addition to diet and exercise only, across all measures. These results suggest metabolic recovery and turning toward systemic homeostasis, thereby decreasing the risk factors for the secondary diseases of obesity, heart disease and cancer. All subjects on ARIIX products with initially established inflammatory markers for heart disease, excessive systemic inflammation and oxidative stress, showed significant improvements indicating improved health and metabolism.

Triglyceride levels of all subjects taking ARIIX products significantly improved. The average subject experienced a statistically significant decrease of triglyceride levels of (p<.0005). According to Antiaging medicine specialists, the single most important factor to increase life expectancy is the ability to increase HDL cholesterol as high above 40 ng/dL as possible. Within the 12 week period the average increase in HDL cholesterol of 15% brought 90% of subjects within optimal range in all ARIIX groups. This reflects significant (p<.0005) reduction in risk of all causes of disease-related death.

Approximately 90% of subjects achieved their weight loss objective during the study compared to none of the control group subjects. This finding suggests that the faster rate of weight loss, with less physical discomfort, the higher rate of compliance to maintain a weight loss program.

Finally, the physical, psychological and emotional changes in the subjects were observed. Subjects losing weight often comment on increased energy, confidence and enthusiasm to continue their new habits as a continued lifestyle. The psychological impact of being empowered with the knowledge and ability for individuals to create a metabolic shift in a completely new direction in such a short period of time was transformational for all test subjects taking ARIIX products, rather than calorie reduction alone.

Additional longitudinal studies would prove beneficial to evaluate subjects' conformity to the consumption of metabolic supportive supplements, modified diet, and moderate exercise adhered to during the trial.

## References

- 1. Ames, B (2006) Proc. Natl. Acad. Sciences, U.S.A., 103:17589-94.
- 2. Ames, BN (2010) J Nucleic Acids. doi:10.4061/2010/725071.
- 3. Courtemanche C, Huang AC, Elson-Schwab I, Kerry N, Ng BY and Ames BN (2004) Folate deficiency and ionizing radiation cause DNA breaks in primary human lymphocytes: a comparison. *FASEB J* 18:209-11.
- 4. Ames B (2006) Low micronutrient intake may accelerate the degenerative diseases of aging through allocation of scarce micronutrients by triage. *Proc Natl Acad Sciences USA* 103:17589-94.
- 5. Ames BN (2010) Prevention of mutation, cancer, and other age-associated diseases by optimizing micronutrient intake. *J Nucleic Acids: DNA Damage, Mutagenesis, and DNA Repair*doi:10.4061/2010/725071. PMC2945683.
- 6. Lal A and Ames BN (2011) Association of Micronuclei (Chromosome Breaks) with Hematological Diseases and Micronutrient Status. *Mutagenesis.* 26:57-62. PMC3107612.
- 7. PNAS \_ November 21, 2006 \_ vol. 103 \_ no. 47 \_ 17589–17594.
- 8. Fenech M (2003) Nutr Res Rev 16:109-122.
- MacWilliam, Lyle Dean., Arlene MacWilliam, and Gregg Gies. "The Blended Standard: Table of Recommended Daily Intakes." Comparative Guide to Nutritional Supplements: A Compendium of Products Available in the United States and Canada. Vernon, B.C.: Northern Dimensions Pub., 2003. N. pag. Print.
- 10. Strand, Ray D., MD, and Donna K. Wallace. Healthy for Life: Developing Healthy Lifestyles That Have a Side Effect of Permanent Fat Loss. Rapid City, SD: Real Life, 2005. Print.
- 11. Thiel R. Natural vitamins may be superior to synthetic ones. Med Hypo.2000;55(6):461-469.
- 12. King JC, Cousins RJ. Zinc. In Modern Nutrition in Health and Disease, 10 th ed. Lipponcott Williams & Wilkins, Phil., 2005:271-285
- 13. Avi Dor, Ph.D., Christine Ferguson, J.D., Casey Langwith, B.A., and Ellen Tan, M.Sc. A Heavy Burden: The Individual Costs of Being Overweight and Obese in the United States, The George Washington University School of Public Health and Health Services Department of Health Policy, September 21, 20101.
- 14. Agency for Toxic Substances and Disease Registry (July 1999). <u>"Toxicological Profile for</u> <u>n-Hexane"</u>. Atlanta, GA: U.S. Department Of Health And Human Services. p. 269.
- 15. Omega-3 fatty acid supplementation and cardiovascular disease: Thematic Review Series: New Lipid and Lipoprotein Targets for the Treatment of Cardiometabolic Diseases *J. Lipid Res.* 2012 53 :( 12) 2525-2545. First Published on August 17, 2012.

- 16. Circulation. 2002; 106: 2747-2757 doi: 10.1161/01.CIR.0000038493.65177.94.
- 17. Karin M Slivkoff-Clark, Anthony P James, John CL Mamo, "The Chronic Effects of Fish Oil With Exercise on Postprandial Lipaemia and Chylomicron Homeostasis in Insulin Resistant Viscerally Obese Men," Nutr Metab 2012;9.
- 18. Stoll, Andrew L. *The Omega-3 Connection: The Groundbreaking Omega-3 Antidepression Diet and Brain Program.* New York: Simon & Schuster, 2001.
- 19. Tocotrienols: constitutional effects in aging and disease. Schaffer S, Muller WE, Eckert GP. 1: J Nutr. 2005 Feb; 135(2):151-4.
- 20. Eric A. Finkelstein, Justin G. Trogdon, Joel W. Cohen and William Dietz, *Annual Medical Spending Attributable To Obesity: Payer-And Service-Specific Estimates*, *Health Affairs*, 28, no.5 (2009):w822-w831.
- 21. Cynthia L. Ogden, Ph.D.; Margaret D. Carroll, M.S.P.H.; Brian K. Kit, M.D., M.P.H.; and Katherine M. Flegal, Ph.D., *Prevalence of Obesity in the United States*, 2009–2010.
- 22. Bowden, Jonny, and Stephen T. Sinatra. The Great Cholesterol Myth: Why Lowering Your Cholesterol Won't Prevent Heart Disease-- and the Statin-free Plan That Will. Beverly, MA: Fair Winds, 2012. Print.
- 23. Am J Clin Nutr July 2011 vol. 94 no. 1 209-217.
- 24. Weatherby, Dicken, and Scott Ferguson. Blood Chemistry and CBC Analysis: Clinical Laboratory Testing from a Fu.
- 25. Diabetes Care August 2011 vol. 34 no. 8 1869-1874nctional Perspective. Jacksonville, OR: Bear Mountain Pub., 2002. Print. Ferranti SD.
- 26. Gauvreau K, Ludwig DS, Neufeld EJ, Newburger JW, Rifai N Prevalence of the metabolic syndrome in American adolescents: findings from the Third National Health and Nutrition Examination Survey. *Circulation* 2004; 110:2494–2497pmid:15477412.
- 27. Fasting Triglycerides, High Density Lipoprotein, and Risk of Myocardial Infarction, Circulation. 1997; 96: 2520-2525 doi: 10.1161/01 CIR.96.8.2520.
- 28. Br J Nutr. 2010 Apr; 103 (8): 1094-7.
- 29. Perrini, Carolyn. "L-Theanine: How a unique Anxiety Reducer and Mood Enhancer Increases Alpha Waves and Alertness" (<u>http://www.okinawateacompany.com/html/pdf/mood\_3.pdf</u>).
- 30. Yokogoshi H, Kobayashi M, Mochizuki M, Terashima T (1998) "Effect of theanine, rglutamylethylamide, on brain monoamines and striatal dopamine release in conscious rats". Nerochem Res 23 (5): 667-73.
- 31.J Int Med Res. 2007 Nov-Dec; 35 (6): 900-8.
- 32. BMC Complement Altern Med. 2006 Mar 17; 6:9.
- 33. Haskell CF, Kennedy DO, Milne AL, Wesnes KA, Scholey AB (2008). "The effects of Itheanine, caffeine and their combination on cognition and mood". Biol Psychol 77 (2).

- 34. Batmanghelidj, F. Your Body's Many Cries for Water: You're Not Sick; You're Thirsty---Don't Treat Thirst with Medication. [S.I.]: Tagman, 2004. Print.
- 35. Frank, Benjamin S., Benjamin S. Frank, and Philip Miele. Dr. Frank's No-aging Diet: Eat & Grow Younger. New York, NY: Dell Pub., 1977. Print.
- 36. USDA SR-21 Nutrient Data (2010). "Nutrition Facts for Seeds, chia seeds, dried." Nutrition Data. Retrieved 2010-11-29.
- 37. Matsubara et al. "Radioprotective effect of matallo-thionine," Presented at Radial Rays Conference, Tokyo Japan 1985.
- 38. Panam Parikh, Uliyar Mani, and Uma Iyer. Journal of Medicinal Food. December 2001, 4(4): 193-199. doi:10.1089/10966200152744463. Vol: 4 Issue 4: July 7, 2004.
- 39. Dawson-Hughes, Bess; Harris, Susan S.; Ceglia, Lisa; "Alkaline diets favor lean tissue mass in older adults." Am J Clin Nutr March 2008 vol. 87 no. 3 662-665.
- 40. http://www.homeopathic.com/Articles/Introduction\_to\_Homeopathy/The\_Homeopathic\_Ph armacopoeia\_and\_the\_Assura.html "The Homeopathic Pharmacopoeia and the Assurance of Quality" By Jay Bornemann MPH
- 41. "HOMOEOPATHIC MATERIA MEDICA By William BOERICKE." HOMOEOPATHIC MATERIA MEDICA - By William BOERICKE. N.p., n.d. Web. 29 May 2013.
- 42. Castleman, Michael. "Healing Herbs." The New Healing Herbs: The Essential Guide to More than 125 of Nature's Most Potent Herbal Remedies. [Emmaus, Pa.]: Rodale, 2009. 357-358. Print.
- 43.<u>http://www.naturalnews.com/032766\_cyanocobalamin\_vitamin\_B-12.html#ixzz2VNkKQ2Az</u>
- 44. http://www.health101.org/art\_methylcobalamin.htm
- 45. http://news.bbc.co.uk/2/hi/health/7595423.stm
- 46. <u>Neuropsychopharmacology</u>. 1996 Nov;15(5):456-64. Effects of vitamin B12 on performance and circadian rhythm in normal subjects.
- 47. <u>Mayer G</u>, <u>Kröger M</u>, <u>Meier-Ewert K</u>. Source: Sleep Disorder Unit, Hephata Klinik, Schwatmstadt-Treysa, Germany. Natural Medicines Comprehensive Database web site: "Biotin."