Clinical Data:
Karma Wellness Water

FUNCTIONAL VARIETIES:

Karma Mind (Mental Alertness)

Karma Spirit (Mood Elevation)

Karma Balance (Immunity Booster)

Karma Body (Fitness Accelerator)

Karma Vitality (Healthy Hydration)

Common Vitamin Package for All 5 SKUs

Common Vitamin Packet:

It is important to provide a constant as a base in all 5 beverage products to build from. In order to tie in all 5 products together, common vitamin blends were used. These vitamins play a role in general health and wellness.

B-Vitamins, B3, B5, B6 and B12 are water-soluble vitamins that play a critical role in metabolism. They help the body metabolize and obtain energy from fats, carbohydrates and proteins. B-vitamins are also essential in maintaining a healthy nervous system (USDA 2010 and Warlaw 1999).

Vitamins A&E are fat-soluble vitamins. Vitamin A is needed to support healthy vision, cell development, skin health and immune function. Vitamin E functions as an antioxidant, protecting cell membranes from oxidative damage. It is needed for the formation of red blood cells and for the maintenance of nervous tissue and immune function. Vitamin E is sometimes referred to as the anti-aging vitamin because it protects the body from cellular damage that results form aging (Medline Plus 2010 and Warlaw 1999).

References:

Medline Plus. 2010. Encyclopedia vitamins. http://www.nlm.nih.gov/medlineplus/ency/article/002399.htm

The United States Department of Agriculture. 2010. Inside the pyramid- why is it important to eat whole grains? http://www.mypyramid.gov/pyramid/grains_why_print.html

Warlaw GM. 1999. Perspectives in Nutrition 4th Ed. Water soluble vitamins and fat soluble vitamins. McGraw-Hill Companies, Boston MA pg 372-387, 394-401, 413-444.

Mind

Caffeine Clinical Summary:

Health Platform: Brain Health

Caffeine is one of the most commonly used ingredients in colas and energy drinks on the market today. It is a xanthine alkaloid naturally found in tea, coffee and cocoa. Caffeine affects the body's metabolism and can stimulate the nervous system increasing alertness and mood.

A 2009 UK study compared the effects of caffeinated gum (40 mg), placebo gum and no gum conditions on mood and attention. The study was a double blind placebo controlled study with volunteers being randomly assigned to one of the three conditions. 118 young adults participated in the study. The results were that caffeinated gum was associated with a more positive mood and better performance on tasks requiring sustained attention. The caffeine improved the speed of encoding of new information which was consistent with previous findings. In conclusion, chewing caffeinated gum has been shown to improve performance efficiency and mood by its alerting and energizing effects. The profile of caffeine effects is what one would predict from the existing caffeine literature and such effects may be beneficial in real-life situations (Smith 2009).

A 2009 US study determined if caffeine intake can have beneficial effects in "aged" APPsw mice that were impaired in working memory. At 4-5 weeks into caffeine treatment, those impaired transgenic mice given caffeine exhibited vastly superior working memory compared to the continuing impairment of control transgenic mice. Even with pre-existing and substantial Abeta burden, aged APPsw mice exhibited memory restoration and reversal of AD pathology, suggesting a treatment potential of caffeine in cases of established Alzheimer's disease (Arendash et al, 2009).

A UK study recently examined the effects of ingesting a performance bar, containing caffeine, before and during cycling exercise on physical and cognitive performance. This study involved 24 well-trained cyclists consuming the products (a performance bar containing 45 g of placebo beverage. In conclusion, caffeine in a performance bar can significantly improve endurance performance and complex cognitive ability during and after exercise. These effects may be salient for sports performance in which concentration plays a major role (Hogervorst et al, 2008).

References:

Arendash GW, Mori T, Cao C, Mamcarz M, Runfeldt M, Dickson A, Rezai-Zadeh K, Tane J, Citron BA, Lin X, Echeverria V, Potter H. 2009. Caffeine reverses cognitive impairment and decreases brain amyloid-beta levels in aged Alzheimer's disease mice. Journal of Alzheimers Disease 17(3):661-680.

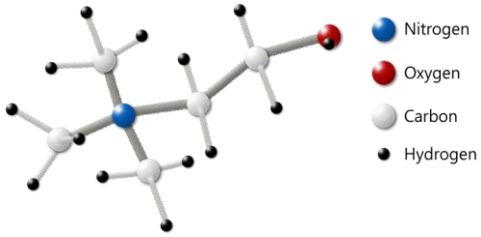
Hogervorst E, Bandelow S, Schmitt J, Jentjens R, Oliverira M, Allgrove J, Carter T, Gleeson M. 2008. Caffeine improves physical and cognitive performance during exhaustive exercise. Medicine and Science in Sports and Exercise 40(10):1841-1851.

Smith A. 2009. Effects of caffeine in chewing gum on mood and attention. Human Psychopharmacology 24(3):239-247.

Choline Clinical Summary:

Health Platform: Brain Health

Choline is essential in the manufacturing of important neurotransmitters. Crucial for proper brain function, choline supports clarity and good memory. Choline helps support brain cell membranes and insures proper nerve cell conductivity.



Brain choline uptake decreases with age. Due to the important role of choline in neuronal structure and function, this change may contribute to onset of late life neurodegenerative diseases, especially dementia, based on a study done on 28 young and old adults (Cohen et al, 1995).

Choline is a component of important biological compounds such as the neurotransmitter acetylcholine in the brain. Clinical studies show that it is essential for normal liver function and plays a critical role in generating second messengers for cell membrane signal transduction. Therefore, choline should be considered as an essential nutrient for humans (Canty and Zeisel, 1994).

A study was done on 51 men and women aged 18-70 years to assess choline's effect on DNA damage to lymphocytes. All subjects fed the choline-deficient diet had lymphocyte DNA damage, twice that found when they were fed the control diet. (Costa et al, 2006).

Choline intake was inversely associated with homocysteine (a risk factor for many chronic diseases), as shown by a study performed on 1477 women by Harvard University (Chiuve et al, 2007).

References:

Canty DJ, Zeisel SH. 1994. Lecithin and choline in human health and disease. Nutrition Reviews 52(10):327-339.

Chiuve et al. 2007. The association between betaine and choline intakes and the plasma concentrations of homocysteine in women. AJCN 86(4):1073-1081.

Cohen at al. 1995. Decreased brain choline uptake in older adult. An in vivo proton magnetic resonance spectroscopy study. JAMA 274(11).

Costa et al. 2006. Choline deficiency increases lymphocyte apoptosis and DNA damage in humans. AJCN 84(1):88-94.

Siberian Ginseng Extract (*Eleutherococcus senticosus*) Clinical Summary:

Health Platform: Brain Health

Siberian Ginseng has been consumed for centuries in China and Russia. It supports good memory and mental function. Siberian Ginseng is known for its ability to restore vigor, increase longevity, enhance overall health, and stimulate a good memory.

Quality of life is significantly affected by chronic fatigue and often those dealing with chronic fatigue seek advice from a doctor. Many patients use herbal treatments due to the lack of general remedies. Seventy six subjects were given Siberian ginseng for a two month duration, and the severity and length of their fatigue was significantly reduced (Hartz et al, 2004).

In healthy humans an acute administration of an eleutherococcus extract considerably improved short-term memory (Arushanian et al, 2003).

Good scientific evidence has been documented about increased endurance and mental performance being observed in patients with mild fatigue and weakness in several trails testing Eleutherococcus senticosus. Adaptogens such as Siberian ginseng can be classified as a pharmacological group of herbal preparations that increase acceptance to mental fatigue and enhance attention and mental endurance in situations of diminished performance (Panossian and Wikman, 2009).

Animal studies show that ginseng can alter manifestations of stress, fatigue, and learning. Due to Siberian ginseng's accredited physiological effects there is a possibility of it promoting cognitive performance or mood. According to this study, single doses of ginseng particularly produced cognitive benefits such as improved memory (Kennedy and Scholey, 2003).

References:

Arushanian EB, Baida OA, Mastiagin SS, Popova AP, Shikina IB. 2003. Effect of eleutherococcus on short-term memory and visual perception in healthy humans. Eksperimental'naia I Klinicheskaia Farmakologiia 66(5):10-3.

Hartz AJ, Bentler S, Noyes R, Hoehns J, Logemann C, Sinift S, Butani Y, Wang W, Brake K, Ernst M, Kautzman H. 2004. Randomized controlled trail of Siberian ginseng for chronic fatigue. Psychological Medicine 34(1):51-61.

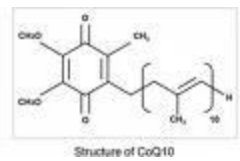
Kennedy DO and Scholey AB. 2003. Ginseng: potential for the enhancement of cognitive performance and mood. Pharmacology Biochemistry and Behavior 75(3): 687-700.

Panossian A and Wikman G. 2009. Evidence-based efficacy of adaptogens in fatigue, and molecular mechanisms related to their stress-protective activity. Current Clinical Pharmacology 4(3):198-219.

<u>Coenzyme Q10 Clinical Summary:</u>

Brain Health, Antioxidant, Heart Health

CoQ10 is located in the mitochondria and supports their energy producing pathways to help fuel the body's daily activity. Recently, research has shown positive effects of CoQ10 on patients with Alzheimer's disease.



Structure of CoQ10

A Chinese clinical study in mice addressed one of the neuropathological features of Alzheimer's disease (AD) - namely, the deposition of senile plaques containing beta-amyloid (A beta). The effect of Coenzyme Q10, an endogenous antioxidant and a powerful free radical scavenger was tested. Results indicated that oxidative stress in the brain of the transgenic mice, may promote A beta 42 overproduction. CoQ10 would be beneficial for the therapy of Alzheimer's disease (Yang et al, 2008).

Another mice study (China) tested the hypothesis that supplemental intake of the diet supplement Coenzyme Q10 could delay brain atrophy in 4 mice genotypes. The resultant data analysis indicated that CoQ10 may have therapeutic potential in the prevention and treatment of mild cognitive impairment (MCI) and Alzheimer's disease (Li et al, 2008).

A United States study involving 35 medically ill patients (average age of 71) evaluated an integrative treatment approach on cognitive performance that included vitamins and supplements (multivitamins, vitamin E, alpha-lipoic acid, omega-3 and Coenzyme Q10). Results showed that the integrative treatment not only protracted cognitive decline for 24 months but even improved cognition, especially memory and frontal lobe functions (Bragin et al, 2005).

A Japanese in vitro study tested the hypothesis that inhibition of the formation of beta-amloid fibrils (fAbeta), as well as the destabilization of preformed fAbeta in the central nervous system (CNS) may be an attractive therapeutic target for the treatment of Alzheimer's disease. Coenzyme Q10 dose-dependently inhibited fAbeta formation from amyloid beta-peptide (Abeta). The study concludes that CoQ10 could be a key molecule for the development of therapeutics for Alzheimer's disease (Ono et al, 2005).

References:

Bragin V, Chemodanova M, Dzhafarova N, Bragin I, Czerniawski JL, Aliev G. 2005. Integrated treatment approach improves cognitive function in demented and clinically depressed patients. American Journal of Alzeheimer's Disease and other Dementias 20(1):21-26.

Li G, Jack CR, Yang XF, Yang ES. 2008. Diet supplement CoQ10 delays brain atrophy in aged transgenic mice with mutations in the amyloid precursor protein; an in vivo volume MRI study. Biofactors 32(1-4):168-178.

Ono K, Hasegawa K, Naiki H, Yamada M. 2005. Preformed beta-amyloid fibrils are destabilized by coenzyme Q10 in vitro. Biochemical and Biophysical Research Communications 330(1):111-116.

Yang X, Yang Y, Li G, Wang J, Yang ES. 2008. Coenzyme Q10 attenuates beta-amyloid pathology in the aged transgenic mice with Alzheimer presenilin 1 mutation. Journal of Molecular Neuroscience 34(2):165-171.

Guarana Extract (Paullinia cupana) Clinical Summary:

Health Platform: Brain Health and Weight Loss

Guarana is an herb easily recognized by consumers. It is often found in energy drinks and is known for its natural caffeine content, energizing and mental stimulation effects.

A double-blind, counterbalanced, placebo-controlled study (n= 36) assessed the acute mood and cognitive effects throughout the day of four different doses of a standardized guarana extract. Guarana improved secondary memory performance and increased alert and content mood ratings. This research supports previous findings of cognitive improvements following 75 mg guarana extract (Haskell et al, 2007).

A 2004 a double-blind, counterbalanced, placebo-controlled study, the cognitive and mood effects of separate single doses of: 75 mg of a dried ethanolic extract of guarana (12% caffeine), 200 mg of Panax ginseng and their combination were assessed in 28 healthy young (18-24) participants. In comparison to placebo, all three treatments resulted in improved task performance throughout the day. Given the low caffeine content (9 mg) of this dose of guarana extract, the effects are unlikely to be attributable to its caffeine content alone (Kennedy et al, 2004).

A recent study (2001) studied the effect of a herbal preparation containing guarana, yerba mate and damiana on gastric emptying and weight loss over 10 days and 45 days and weight maintenance over 12 months. The herbal preparation significantly delayed gastric emptying and induced significant weight loss over 45 days in overweight patients. Maintenance treatment given in an uncontrolled context resulted in no further weight loss, nor weight regain in the group as a whole (Andersen 2001).

References:

Andersen T, Fogh J. 2001. Weight Loss and delayed gastric emptying following a South American herbal preparation in overweight patients. Journal of Human Nutrition and Dietetics 14(3):243-50.

Haskell CF, Kennedy DO, Wesnes KA, Milne AL, Scholey AB. 2007. A double-blind, placebo-controlled, multi-dose evaluation of the acute behavioural effects of guarana in humans. Journal of Psychopharmacology 21(1):65-70.

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Vitamin D Clinical Summary:

Health Platform: Bone & Joint Health and Vitality

Vitamin D is a fat-soluble vitamin found in very low quantities in animal and plant foods. It's essential for skeletal growth and bone mineralization. Vitamin D is naturally formed on human skin after exposure to sunlight.

GlaxoSmithKline and the Department of Defense (U.S.) conducted a double-blind, placebo-controlled randomized clinical trial of calcium and vitamin D supplementation in 5201 female Naval recruits. During 8 weeks of basic training, supplementation with 2000 mg calcium and 800 IU vitamin D/day decreased incidence of stress fracture by 25%. In concluding, generalizing the findings to the population of 14,416 females who entered basic training at Great Lakes during the 24 months of recruitment, calcium and vitamin D supplementation for the entire cohort would have prevented about 130 persons per year from fracturing. Such a decrease in SFx (stress fractures) would be associated with a significant decrease in morbidity and financial costs (Lappe, Principal Investigator 2008).

A 2004 Italian study assessed the effects of calcium supplementation combined with Vitamin D on bone mineral density (BMD) and bone mineral content (BMC) in a representative sample of peri-and post-menopausal women in a double-blind, randomized controlled trial. Results showed that the change in total BMD in the calcium group was significantly different from that in the placebo group ($P \leq 0.005$). The placebo group lost a total BMD at a rate of about 0.4% per year. Conclusion: results showed the positive effect of calcium and Vitamin D supplementation in women both peri-and post menopausal status; for this reason a supplementation of calcium and Vitamin D should be recommended as a strategic option in helping to prevent early postmenopausal bone loss. (Di Daniele et al, 2004)

The effects of three years of dietary supplementation with calcium and vitamin D on bone mineral density, biochemical measures of bone metabolism, and the incidence of nonvertebral fractures was studied in 176 men and 213 women 65 years of age or older who were living at home. They received either 500 mg of calcium plus 700 IU of vitamin D3 (cholecalciferol) per day or placebo. The difference between the calcium-vitamin D and placebo groups was significant at all skeletal sites after one year, but it was significant only for total-body mineral density in the second and third years. The conclusions were that in men and women 65 years of age or older who are living in the community, dietary supplementation with calcium and vitamin D moderately reduced bone loss measured in the femoral neck, spine and total body over the three-year study period and reduced the incidence of nonvertebral fractures (Dawson-Hughes et al) .

A recent meta-analysis study indicated that Vitamin D intakes greater than 500 International Units (IU) were associated with a 13 percent reduction in the risk of type-2 diabetes. In addition, researchers reported that people with the highest blood levels of Vitamin D (more than 25 nanograms per milliliter) had a 43 percent lower risk of developing type-2 diabetes than people with the lowest blood levels of Vitamin D (less than 14 nanograms per milliliter). Both results are based on a meta-analysis of eight observational cohort studies and 11 randomized controlled trials measuring Vitamin D and diabetes (Mitri et al, 2011).

A 2009 British study involving 99 post-menarchal 12-14 old females investigated the relationship of baseline serum Vitamin D content and its correlation with muscle power and force. Jumping mechanography was used to measure muscle power, velocity, jump height and the Esslinger Fitness Index was performed (a two-legged counter movement jump and force from multiple one-legged hops). In conclusion, Vitamin D was significantly associated with muscle power and force in adolescent girls (Ward et al, 2009).

References:

Dawson-Hughes B, Harris SS, Krall EA, Dallal GE. 1997. Effect of calcium and vitamin D supplementation on bone density in men and women 65 years of age or older. New England Journal of Medicine 337(10):670-676.

Di Daniele N, Carbonelli MG, Candeloro N, Iacopino L, De Lorenzo A, Andreoli A. 2004. Effect of supplementation of calcium and Vitamin D on bone mineral density and bone mineral content in peri-and post-menopause women: A double-blind, randomized, controlled trial. Pharmacological Research 50(6):637-641.

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Mitri J, Muraru MD, Pittas AG. 2011. Vitamin D and type 2 diabetes: a systematic review. European Journal of Clinical Nutrition published online ahead of print, dol: 10.1038/ejcn.2011.118.

Ward KA, Das G, Berry JL, Roberts SA, Rawer R, Adams JE, Mughal Z. 2009. Vitamin D status and muscle function in post-menarchal adolescent girls. Journal of Clinical Endocrinology and Metabolism 94(2):559-563.

Spirit

Yerba Mate Extract (Ilex paraguariensis) Clinical Summary:

Health Platforms: Brain Health, Weight Loss and Antioxidant

Yerba mate is a commonly used ingredient in many beverages. It contains antioxidant properties and helps improve energy, cognitive function and mood.

The antioxidant properties of an aqueous extract prepared from an infusion of Yerba Mate was investigated. The extract inhibited the enzymatic and non-enzymatic lipid peroxidation in rat liver microsomes in a concentration dependent fashion. The results suggest that the ingestion of extracts of Ilex paraguariensis could contribute to increasing the antioxidant defense of an organism against free radicals attack (Schinella et al, 2000).

A 2008 study assessed the effects of a hydroalcoholic extract of Ilex paraguariensis on the short and long-term learning and memory or rats with the social recognition, Morris water maze and the step-down inhibitory avoidance tasks. The results substantiate the traditional use of mate tea for the improvement of cognition and concludes that the yerba mate extract modulates short and long-term learning and memory probably through its antagonists action on adenosine receptors (Prediger et al, 2008).

A recent diet study involved the determination of the vascular responses in rats fed standard and high-cholesterol diets that included extractable fractions of Ilex paraguariensis. The chronic oral administration of I. paraguariensis extract in hypercholesterolemic-diet rats resulted in a significant reduction in serum levels of cholesterol and triglycerides (Paganini et al, 2005).

A 2009 study evaluated the effects of yerba mate extract on weight loss, obesity-related biochemical parameters, and the regulation of adipose tissue gene expression in high-fat diet-induced obesity in mice. Thirty animals were randomly assigned to three groups. The study found that obese mice treated with yerba mate exhibited marked attenuation of weight gain, adiposity, a decrease in epididymal fat-pad weight, and restoration of the serum levels of cholesterol, triglycerides, LDL cholesterol, and glucose. In conclusion, the data showed that yerba mate extract has potent antiobesity activity in vivo. Additionally, it was observed that the treatment had a modulatory effect on the expression of several genes related to obesity (Arcari et al, 2009).

References:

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Paganini Stein FL, Schmidt B, Furlong EB, Souza-Soares LA, Soares MC, Vaz MR, Muccillo Baisch AL. 2005. Vascular responses to extractable fractions of Ilex paraguariensis in rats fed standard and high-chloresterol diets. Biol Res Nurs. Oct;7(2):146-56.

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Schinella GR, Troiani G, Davila V, de Buschiazzo PM, Tournier HA. 2000. Antioxidant effects of an aqueous extract of Ilex paraguariensis. Biochem Biophs Res Commun 269(2):357-60.

Pomegranate Extract (Punica granatum) Clinical Summary:

Health Platform: Antioxidant and Bone & Joint Health

Pomegranate is a popular, well-recognized fruit by consumers. It is known for its powerful antioxidant activity and has been shown to support cardiovascular and heart health, maintain proper immune function, and promote overall health and well-being.

A 2006 Japanese double-blind, placebo controlled trial to clinically evaluate the protective and ameliorative effects of ellagic acid-rich pomegranate extract on skin pigmentation after UV irradiation suggested that ellagic acid-rich pomegranate extract, ingested orally, has an inhibitory effect on a slight pigmentation in the human skin caused by UV irradiation (Kasal et al, 2006).

A recent United States study was designed to evaluate a standardized preparation of pomegranate extract using collagen-induced arthritis (CIA) in mice (a widely used animal model of rheumatoid arthritis). Consumption of the pomegranate extract potently delayed the onset and reduced the incidence of CIA in mice. Severity of arthritis was also significantly lower in the pomegranate extract fed animals. Histopathology of the arthritic joints from pomegranate extract fed mice demonstrated reduced joint infiltration by the inflammatory cells, and the destruction of bone and cartilage were alleviated (Shukla et al, 2008).

A 2008 Chinese study recruited 26 elderly subjects, divided them into 2 groups, apple juice (low in antioxidant capacity) and pomegranate juice (high in antioxidant capacity) were consumed by separate groups daily for 4 weeks. It was concluded that daily consumption of pomegranate

juice is potentially better than apple juice in improving antioxidant function in the elderly. Because the plasma ascorbic acid, vitamin E, and reduced glutathione contents did not differ significantly between the 2 groups in this study, the phenolics may be the functional components contained in pomegranate juice that accounted for the observations (Guo et al, 2008).

References:

Guo C, Wei J, Yang J, Xu J, Pang W, Jiang Y. 2008. Pomengranate juice is potentially better than apple juice in improving antioxidant function in elderly subjects. Nutrition Research 28(2):72-77.

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Shukla M, Gupta K, Rasheed Z, Khan KA, Haqqi TM. Consumption of hydrolysable tannins-rich pomegranate extract suppresses inflammation and joint damage in rheumatoid arthritis 24(7-80:733-743).

Acai Extract (Euterpe oleraceae) Clinical Summary:

Health Platform: Antioxidant

Acai fruit has an abundance of nutrients ranging from vitamins to phytochemicals. Acai is a powerful antioxidant that aids in maintaining general well-being and an active lifestyle throughout life. Acai is considered by many to be the most nutritionally dense of any fruit in the world.

A 2008 study was performed to determine the health effect in humans of consumption of acai pulp and clarified acai juice compared to applesauce and a non-antioxidant beverage as controls. This acute four-way crossover clinical trial showed that plasma antioxidant capacity was significantly increased by the acai pulp. Individual increases in plasma antioxidant capacity of up to 2.3-3-fold for acai juice and pulp, respectively were observed. Results demonstrated the absorption and antioxidant effects of anthocyanins in acai in plasma in an acute human consumption trial (Mertens-Talcott et al, 2008).

A recent study evaluated the antioxidant capacities of freeze-dried acai fruit pulp/skin powder by different assays with various free radical sources. It was found to have exceptional activity against superoxide in the superoxide scavenging (SOD) assay, the highest of any food reported to date against the peroxyl radical as measured by the oxygen radical absorbance capacity assay, and mild activity against both the peroxynitrite and hydroxyl radical. The SOD of acai was 1614 units/g, an extremely high scavenging capacity for oxygen. Acai was found to be a potential cyclooxygenase (COX)-1 and COX-2 inhibitor (Schauss et al, 2006).

A study at the University of Florida (2006) showed that extracts from acai berries triggered a self-destruct response in up to 86 percent of leukemia cells tested. This was one of the first studies to investigate the benefits of acai; polyphenolic fractions at 0.17-10.7 microM were found to reduce cell proliferation from 56 to 86% likely due to caspase-3activation (apoptosis). This study demonstrated that acai offers a rich source of bioactive polyphenolics and confirmed the importance of investigating whole food systems when evaluating the potential health benefits of individual phytochemical compounds (Del Pozo-Insfran et al, 2006).

References:

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Ashwagandha Extract (Withania somnifera) Clinical Summary:

Health Platform: Brain Health

Ashwagandha is an herb used in Ayruvedic medicine. It is considered an adaptogen meaning it helps protect the body from many types of stress (physical and mental).

The adaptogenic activity of a standardized extract of Ashwagandha (WS) roots was investigated against a rat model of chronic stress (CS) in a 2003 Indian study. The stress procedure was mild and involved administration of unpredictable foot shock once daily for 21 days to adult male Wistar rats. CS induced numerous stress symptoms including significant hyperglycemia, glucose intolerance, male sexual dysfunction, cognitive deficits and mental depression. These CS induced perturbations were attenuated by WS (25 and 50 mg/kg po), administered 1 hour before foot shock for 21 days. The results indicate that WS has significant antistress adaptogenic activity, confirming the clinical use of the plant in Ayurveda (Bhattacharya et al, 2003).

A 2009 Indian study investigated the protective effect of Withania somnifera, used in ayurvedic traditional treatment systems, on gentamiciin (GEN)-induced nephrotoxicity. Root extract of three different doses of W. Sominifera (viz., 250,500, and 750 mg/kg) was administered orally to rats for 14 days before GEN treatment and thereafter concurrently with GEN (100 mg/kg) for 8 days. Nephrotoxicity was evident in GEN-treated rats confirmed histopathologically by tubular necrosis. In contrast, W. somnifera (500 mg/kg) significantly reversed these changes as evidenced microscopically when compared to other two doses of W. somnifera (250 and 750 mg/kg). Thus, results suggested the nephroprotective effect of Withania somnifera, which could be by enhancing antioxidant activity with natural antioxidants and scavenging the free radicals (Jeyanthi et al, 2009).

Another 2009 Indian study addressed the role of stress in male fertility and tested the ability of W. somnifera to combat stress and treat male fertility in a controlled test format involving infertile individuals (heavy smokers-N = 20, psychologically stressed-N = 20, and infertile-unknown etiology-N = 20) versus a control group of fertile men (N = 60).
Subjects were given root powder of W. somnifera at a rate of 5 g/day for 3 months. Measuring various biochemical and stress parameters before and after treatment, suggested a definite role of stress in male infertility and the ability of W. somnifera to treat stress-related infertility. Treatment resulted in a decrease in stress, improved the level of anti-oxidants and improved overall semen quality in a significant number of individuals (Mahdi et al, 2009).

References:

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Jeyanthi T, Subramanian P. 2009. Nephroprotective effect of Withania somnifera: a dose-dependent study. Renal Failure 31(9) 814-821.

Mahdi AA, Shukla KK, Ahmad MK, Rajender S, Shankhwar SN, Singh V, Dalela D. Withania somnifera improves semen quality in stress-related male fertility. Evidence-based complementary and alternative medicine (Epub ahead of print).

Ginseng Extract (Panax ginseng) Clinical Summary:

Health Platform: Brain Health

Panax ginseng is a common ingredient used in many energy drink products on the market. It is considered an adaptogen, a substance that strengthens the body, helping it return to normal when it has been subjected to prolonged stress.

A 2007 Brazilian study examined the treatment efficacy of Korean Red Ginseng (Panax Ginseng) in impotent men with erectile dysfunction (ED). A total of 60 patients presenting mild or mild to moderate ED were enrolled in a double-blind, placebo-controlled study in which the efficacies of KRG and a placebo were compared. The five-item version of the International Index of Erectile Function score after the treatment was significantly higher in the KRG group compared with that before the treatment. There was no difference before and after the treatment in the placebo group. In conclusion, the data show that KRG can be an effective alternative to the invasive approaches for the treatment of male ED (de Andrade et al, 2007).

A recent study (Korean) studied the effect of Panax ginseng extract (PGE) on lipid peroxidation and scavenger enzymes induced by an acute exhaustive exercise in sedentary humans. PGE administration significantly increased exercise duration until exhaustion by 1.5 minutes. The study concluded that the findings supported scientific claims that ginseng has ergogenic properties in facilitating recovery from exhaustive exercise (Kim et al, 2005).

A 2009 double-blind, placebo-controlled study investigated the effects of tissue-cultured mountain ginseng extract (TMGE) on male patients with erectile dysfunction (ED). The effects of the TMGE and the placebo were analyzed using the Korean version of the International Index of Erectile Function (IIEF) questionnaire. The IIEF scores were significantly higher than the baseline scores in the group treated with the TMGE whereas no significant improvement was observed in the placebo group. The erectile function of patients in the TMGE-treated group significantly improved, suggesting that TMGE could be utilized for improving erectile function in male patients (Kim et al, 2009).

A 2008 Korean study investigated the clinical efficacy of Panax ginseng in the cognitive performance of patients with Alzheimer Disease (AD) in an open-label study. Cognitive performances were monitored using the mini-mental state examination (MMSE) and the Alzheimer assessment scale (ADAS) during 12 weeks of the ginseng treatment and at 12 weeks after the ginseng discontinuation. After ginseng treatment, the cognitive subscale of ADAS and the MMSE score began to show improvements and continued up to 12 weeks. After

discontinuing ginseng, the improved ADAS and MMSE scores declined to the levels of the control group. These results suggest that Panax ginseng is clinically effective in the cognitive performance of AD patients (Lee et al, 2008).

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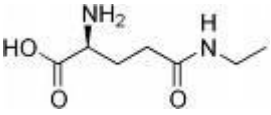
L-Theanine Clinical Summary:

Health Platform: Brain Health, Immunity, Holistic Sleep

L-Theanine is an amino acid commonly found in green tea. Some studies have shown it penetrates the brain and produces significant increases in concentrations of the neurotransmitters serotonin and dopamine. Low levels of both serotonin and dopamine are associated with signs of depression. L-theanine can produce feelings of relaxation by increasing the production of GABA.



In a 1999 Japanese study in human volunteers, α (alpha) waves were generated on the occipital and parietal regions of the brain surface within 40 minutes after oral administration of theanine (50-200 mg), signifying relaxation without causing drowsiness. Brain waves are classified into four types based on mental conditions and the generation of α waves is considered to be an index of relaxation. Theanine also decreased blood pressure significantly in hypertensive rats (Juneja et al, 1999).

A 2007 study at Nagoya University (Japan) examined whether L-theanine influences psychological and physiological states under stress. Using a mental arithmetic task as an acute stressor, twelve participants underwent 4 separate trials, including a placebo or nothing at all. Results showed that L-theanine intake resulted in a reduction in heart rate and salivary immunoglobulin A relative to the placebo control condition (classic stress responses) (Kimura et al, 2007).

A 2007 English study (Northumbria University) investigated the acute cognitive and mood effects of L-theanine (250 mg), and caffeine (150 mg), in isolation and in combination. In addition to improving Rapid Visual Information Processing (RVIP) accuracy and mental fatigue ratings, the combination led to faster simple reaction time, faster numeric working memory reaction time and improved sentence verification accuracy. Headache and tired ratings were reduced and alert ratings increased (Haskell et al, 2007).

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Grape Seed Extract Clinical Summary:

Health Platform: Antioxidant, Heart Health, Immunity, Inside Beauty, Joint and Bone Health

Grape Seed Extract is a powerful antioxidant that helps vitamin C enter the body's cells. It upholds proper immune function and also helps maintain skin health and joint function.

Grape seed extract protects from oxidative damage by the inhibition of lipid peroxidation, based on a clinical study done on Wistar abino rats (Dulundu et al, 2007). Another clinical study done on neonatal rats also indicated that treatment with grape seed extract suppressed lipid peroxidation (Feng et al, 2005).

Based on a clinical study performed on hypercholesterolemic subjects, supplementation with grape seed extract significantly reduced oxidized LDL, a biomarker of cardiovascular disease (Bagchi and others, 2003). Grape seed proanthocyanidins have been shown to have cardioprotective effects through their ability to remove free radicals, based on a clinical study done on rats (Pataki et al, 2002).

Grape seed proanthocyanidins have been found useful to attenuate the adverse health effects of UV radiation in the skin, based on a clinical study performed on SKH-1 hairless mice (Katiyar, 2008). Another clinical study conducted on mice showed that topical application of grape seed proanthocyanidins helped promote dermal wound healing (Khanna et al, 2002).

Grape seed proanthocyanidins have been shown to have a beneficial effect on bone formation and strength. This is based on a clinical study performed on 40 male Wistar rats (Yahara et al, 2005).

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Vitamin D Clinical Summary:

Health Platform: Bone & Joint Health and Vitality

Vitamin D is a fat-soluble vitamin found in very low quantities in animal and plant foods. It's essential for skeletal growth and bone mineralization. Vitamin D is naturally formed on human skin after exposure to sunlight.

GlaxoSmithKline and the Department of Defense (U.S.) conducted a double-blind, placebo-controlled randomized clinical trial of calcium and vitamin D supplementation in 5201 female Naval recruits. During 8 weeks of basic training, supplementation with 2000 mg calcium and 800 IU vitamin D/day decreased incidence of stress fracture by 25%. In concluding, generalizing the findings to the population of 14,416 females who entered basic training at Great Lakes during the 24 months of recruitment, calcium and vitamin D supplementation for the entire cohort would have prevented about 130 persons per year from fracturing. Such a decrease in SFx (stress fractures) would be associated with a significant decrease in morbidity and financial costs (Lappe, Principal Investigator 2008).

A 2004 Italian study assessed the effects of calcium supplementation combined with Vitamin D on bone mineral density (BMD) and bone mineral content (BMC) in a representative sample of peri-and post-menopausal women in a double-blind, randomized controlled trial. Results showed that the change in total BMD in the calcium group was significantly different from that in the placebo group ($P \leq 0.005$). The placebo group lost a total BMD at a rate of about 0.4% per year. Conclusion: results showed the positive effect of calcium and Vitamin D supplementation in women both peri-and post menopausal status; for this reason a supplementation of calcium and Vitamin D should be recommended as a strategic option in helping to prevent early postmenopausal bone loss. (Di Daniele et al, 2004)

The effects of three years of dietary supplementation with calcium and vitamin D on bone mineral density, biochemical measures of bone metabolism, and the incidence of nonvertebral fractures was studied in 176 men and 213 women 65 years of age or older who were living at home. They received either 500 mg of calcium plus 700 IU of vitamin D3 (cholecalciferol) per day or placebo. The difference between the calcium-vitamin D and placebo groups was significant at all skeletal sites after one year, but it was significant only for total-body mineral density in the second and third years. The conclusions were that in men and women 65 years of age or older who are living in the community, dietary supplementation with calcium and vitamin D moderately reduced bone loss measured in the femoral neck, spine and total body over the three-year study period and reduced the incidence of nonvertebral fractures (Dawson-Hughes et al) .

A recent meta-analysis study indicated that Vitamin D intakes greater than 500 International Units (IU) were associated with a 13 percent reduction in the risk of type-2 diabetes. In addition, researchers reported that people with the highest blood levels of Vitamin D (more than 25 nanograms per milliliter) had a 43 percent lower risk of developing type-2 diabetes than people with the lowest blood levels of Vitamin D (less than 14 nanograms per milliliter). Both results are based on a meta-analysis of eight observational cohort studies and 11 randomized controlled trials measuring Vitamin D and diabetes (Mitri et al, 2011).

A 2009 British study involving 99 post-menarchal 12-14 old females investigated the relationship of baseline serum Vitamin D content and its correlation with muscle power and force. Jumping mechanography was used to measure muscle power, velocity, jump height and the Esslinger Fitness Index was performed (a two-legged counter movement jump and force from multiple one-legged hops). In conclusion, Vitamin D was significantly associated with muscle power and force in adolescent girls (Ward et al, 2009).

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Balance

Zinc (Zn) and Vitamin C Clinical Summary:

Health Platform: Antioxidant, Eye Health and Immunity

Zinc is an essential trace element for all forms of life. Zn is involved in many aspects of cellular metabolism. It plays important roles in growth and development, the immune response, neurological function, and reproduction. Vitamin C is a water-soluble vitamin that has many functions. It is required for the synthesis of collagen and neurotransmitters that are critical to brain function and are known to affect mood. Vitamin C is a powerful antioxidant that can protect proteins, lipids (fats), carbohydrates, and nucleic acids (DNA and RNA), from damage by free radicals.

The 2007 Australian Blue Mountains Eye Study assessed the relationship between baseline dietary and supplement intakes of antioxidants and the long-term risk of incident age-related macular degeneration (AMD). Of 3654 baseline participants (1992-1994) initially 49 years or older, 2454 were reexamined after 5 years, 10 years, or both. Conclusions for this cohort study were: higher dietary lutein and zeaxanthin intake reduced the risk of long-term incident AMD. This study confirmed the Age-Related Eye Disease Study finding of protective influences from zinc against AMD (Tan et al, 2007).

A Bolivian study in 1996 investigated the effect of a daily zinc supplementation (2 mg per kg) as an immunostimulatory treatment to accelerate the immune rehabilitation of children suffering from severe protein-energy malnutrition. Children with daily zinc supplementation showed faster thymic recovery than the control and reached immune recovery in one month while another month was needed for control children. Zinc supplementation hastened immune recovery that coincided with nutritional recovery and the duration of hospitalization was shortened (Chevalier et al, 1996).

A 2006 Swiss review documents the large number of randomized controlled intervention trials with intakes of up to 1 g of vitamin C and up to 30 mg of zinc that are now available. These trials document that adequate intakes of vitamin C and zinc ameliorate symptoms and shorten the duration of respiratory tract infections including the common cold. Furthermore, vitamin C and zinc reduce the incidence and improve the outcome of pneumonia, malaria, and diarrhea infections, especially in children in developing countries (Wintergerst et al, 2006).

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Vitamin D Clinical Summary:

Health Platform: Bone & Joint Health and Vitality

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Lappe JM (Principal Investigator). 2008. Calcium and vitamin D supplementation decreases incidence of stress fractures in female navy recruits. ClinicalTrials.gov Identifier: NCT00476346.

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Ward KA, Das G, Berry JL, Roberts SA, Rawer R, Adams JE, Mughal Z. 2009. Vitamin D status and muscle function in post-menarchal adolescent girls. Journal of Clinical Endocrinology and Metabolism 94(2):559-563.

Pomegranate Extract (Punica granatum) Clinical Summary:

Health Platform: Antioxidant and Bone & Joint Health

Pomegranate is a popular, well-recognized fruit by consumers. It is known for its powerful antioxidant activity and has been shown to support cardiovascular and heart health, maintain proper immune function and promote overall health and well-being.

A 2006 Japanese double-blind, placebo controlled trial to clinically evaluate the protective and ameliorative effects of ellagic acid-rich pomegranate extract on skin pigmentation after UV irradiation suggested that ellagic acid-rich pomegranate extract, ingested orally, has an inhibitory effect on a slight pigmentation in the human skin caused by UV irradiation (Kasal et al, 2006).

A recent United States study was designed to evaluate a standardized preparation of pomegranate extract using collagen-induced arthritis (CIA) in mice (a widely used animal model of rheumatoid arthritis). Consumption of the pomegranate extract potently delayed the onset and reduced the incidence of CIA in mice. Severity of arthritis was also significantly lower in the pomegranate extract fed animals. Histopathology of the arthritic joints from pomegranate extract fed mice demonstrated reduced joint infiltration by the inflammatory cells, and the destruction of bone and cartilage were alleviated (Shukla et al, 2008).

A 2008 Chinese study recruited 26 elderly subjects, divided them into 2 groups, apple juice (low in antioxidant capacity) and pomegranate juice (high in antioxidant capacity) were consumed by separate groups daily for 4 weeks. It was concluded that daily consumption of pomegranate juice is potentially better than apple juice in improving antioxidant function in the elderly. Because the plasma ascorbic acid, vitamin E, and reduced glutathione contents did not differ significantly between the 2 groups in this study, the phenolics may be the functional components contained in pomegranate juice that accounted for the observations (Guo et al, 2008).

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Acai Extract (Euterpe oleraceae) Clinical Summary:

Health Platform: Antioxidant

Acai fruit has an abundance of nutrients ranging from vitamins to phytochemicals. Acai is a powerful antioxidant that aids in maintaining general well-being and an active lifestyle throughout life. Acai is considered by many to be the most nutritionally dense of any fruit in the world.

A 2008 study was performed to determine the health effect in humans of consumption of acai pulp and clarified acai juice compared to applesauce and a non-antioxidant beverage as controls. This acute four-way crossover clinical trial showed that plasma antioxidant capacity was significantly increased by the acai pulp. Individual increases in plasma antioxidant capacity of up to 2.3-3-fold for acai juice and pulp, respectively were observed. Results demonstrated the absorption and antioxidant effects of anthocyanins in acai in plasma in an acute human consumption trial (Mertens-Talcott et al, 2008).

A recent study evaluated the antioxidant capacities of freeze-dried acai fruit pulp/skin powder by different assays with various free radical sources. It was found to have exceptional activity against superoxide in the superoxide scavenging (SOD) assay, the highest of any food reported to date against the peroxyl radical as measured by the oxygen radical absorbance capacity assay, and mild activity against both the peroxynitrite and hydroxyl radical. The SOD of acai was 1614 units/g, an extremely high scavenging capacity for oxygen. Acai was found to be a potential cyclooxygenase (COX)-1 and COX-2 inhibitor (Schauss et al, 2006).

A study at the University of Florida (2006) showed that extracts from acai berries triggered a self-destruct response in up to 86 percent of leukemia cells tested. This was one of the first studies to investigate the benefits of acai; polyphenolic fractions at 0.17-10.7 microM were found to reduce cell proliferation from 56 to 86% likely due to caspase-3activation (apoptosis). This study demonstrated that acai offers a rich source of bioactive polyhenolics and confirmed the importance of investigating whole food systems when evaluating the potential health benefits of individual phytochemical compounds (Del Pozo-Insfran et al, 2006).

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Antioxidant Tea Blend Clinical Summary:

Health Platform: Antioxidant, Immunity, Inside Beauty

WILD provides proprietary antioxidant tea blend containing rooibos extract, grape seed extract, white tea extract and green tea extract. Each of these ingredients are powerful antioxidants that work synergistically together to support immune function and general health and well-being.

Rooibos extract:

Recent studies indicated significant activity of rooibos against negative effects associated with oxidative damage. The antioxidant properties have been examined and are connected to aspalathin, which demonstrated significant activity as compared with other teas and commercial antioxidants. Rooibos tea extracts are used for cosmetics because of their beneficial effects on skin conditions (PDR).

Rooibos showed potent antioxidant and antimutagenic activities in vitro. In vivo study using animal model demonstrated that rooibos has potent antioxidant, immune-modulating, and chemo-preventive actions (McKay and Blumberg, 2007).

Based on an animal study, flavonoids from rooibos, act as antioxidants and their radioprotective effects may be caused by scavenging effect towards free radicals such as hydroxyl radicals. It can be concluded that the human diet should contain flavonoids from plants including rooibos which are crucial as antioxidants (Shimoi and others, 1996).

Grape seed extract:

Grape seed extract protects from oxidative damage by the inhibition of lipid peroxidation, based on a clinical study done on Wistar albino rats (Dulundu and others, 2007). Another clinical study done on neonatal rats also indicated that treatment with grape seed extract suppressed lipid peroxidation (Feng and others, 2005).

Based on a clinical study performed on hypercholesterolemic subjects, supplementation with grape seed extract significantly reduced oxidized LDL, a biomarker of cardiovascular disease (Bagchi and others, 2003). Grape seed proanthocyanidins have been shown to have cardioprotective effects through their ability to remove free radicals, based on a clinical study done on rats (Pataki and others, 2002).

Grape seed proanthocyanidins have been found useful to attenuate the adverse health effects of UV radiation in the skin, based on a clinical study performed on SKH-1 hairless mice (Katiyar, 2008). Another clinical study conducted on mice showed that topical application of grape seed proanthocyanidins helped promote dermal wound healing (Khanna and others, 2002).

Grape seed proanthocyanidins have been shown to have a beneficial effect on bone formation and strength. This is based on a clinical study performed on 40 male Wistar rats (Yahara and others, 2005).

White tea extract:

Based on a clinical study performed on 80 post-menopausal women, a novel dietary supplement containing white tea extract caused improvement in skin condition, structure, and firmness after 6 months (Skovgaard and others, 2006).

A nutrient complex containing white tea extract had been shown to improve imperfections in epidermal and dermal structure and composition. This is based on a study done on fibroblasts from 68 females with a wide age range (Lacroix and others, 2007).

White tea showed antioxidant effects in vivo which can be noticed not only in plasma but also in organs. This is proven by a clinical study done in mice (Koutelidakis and others, 2009). Antioxidants are known to scavenge free radicals that cause cellular damage.

White tea extract exhibited strong radical scavenging activity, as shown by an in vitro study (Calzuola and others, 2006).

Green tea extract:

Continuous consumption of green tea EGCG may prevent UV-induced damages on skin. This is based on a clinical study done in female hairless rats (Jeon and others, 2009). Green tea polyphenols inhibit UVB-induced skin tumor development through reduction in skin inflammation (Meeran and others, 2008).

Based on a clinical study done on Japanese women and men with visceral fat-type obesity, regular consumption of green tea extract high in catechins caused reduction in body fat, systolic blood pressure, and LDL cholesterol, implying that the consumption of green tea extract helps decrease obesity and cardiovascular disease risks (Nagao and others, 2007).

Moderate intake of EGCG (a catechin from green tea) can improve health of overweight individuals doing regular exercise by reducing heart rate and glucose concentration in plasma (Hill and others, 2007).

Daily intake of tea containing 690 mg catechins for 12 weeks decreased body fat, indicating that the intake of catechins might be valuable to prevent and improve diseases related with lifestyle, mainly obesity (Nagao and others, 2005).

Based on a clinical study done in 10 healthy men, green tea extract may be responsible for controlling body composition through sympathetic activation of thermogenesis, fat oxidation, or both (Dulloo and others, 1999).

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Cranberry Extract (Vaccinium macrocarpon) Clinical Summary:

Health Platform: Immunity and Antioxidant

Cranberry is a well-known fruit and widely consumed. It is an excellent source of antioxidants and is commonly used to maintain a healthy urinary tract and support a healthy immune system.

A recent open label pilot study examined the ability of a concentrated cranberry preparation to prevent urinary tract infections (UTIs) in women with a history of recurrent infections. Women between the ages of 25 and 70 years old were included with a history of a minimum of 6 UTIs in the proceeding year. The women took one capsule twice daily for 12 weeks containing 200 mg of a concentrated cranberry extract standardized to 30% phenolics. During the study none of the women had a UTI. Two years later, eight of the women who continue to take cranberry, continue to be free from UTIs. The study concluded that a cranberry preparation with a high phenolic content may completely prevent UTIs in women who are subject to recurrent infections (Bailey et al 2007).

A French study (double-blind, randomized, placebo-controlled cross over) determined the efficacy of the consumption of cranberry juice versus placebo with regard to the presence of in vitro bacterial anti-adherence activity in the urine of healthy volunteers. A dose dependent significant decrease in bacterial adherence associated with cranberry consumption was observed. The conclusion was that cranberry juice provides significant anti-adherence activity against different E. coli uropathogenic strains in the urine compared with placebo (Di Martino et al 2006).

A 2009 Scottish study compared the effectiveness of cranberry extract with low-dose trimethoprim in the prevention of recurrent urinary tract infections (UTIs) in older women. In concluding, trimethoprim had a very limited advantage over cranberry extract in the prevention of recurrent UTIs in older women and had more adverse effects. The findings will allow older

women with recurrent UTIs to be treated with cranberry extract whose use does not carry the risk of antimicrobial resistance or super-infection with Clostridium difficile or fungi like other treatments (McMurdo et al 2009).

A 2007 Czech Republic study assessed the effect of an 8 week consumption of dried cranberry juice (DCJ) on 65 healthy young women. A 1200 mg amount of DCJ/day resulted in a statistically significant decrease in serum levels of advanced oxidation protein products. In conclusion, cranberry fruits are effective not only in the prevention of urinary tract infection but also for the prevention of oxidative stress (Valentova et al 2007).

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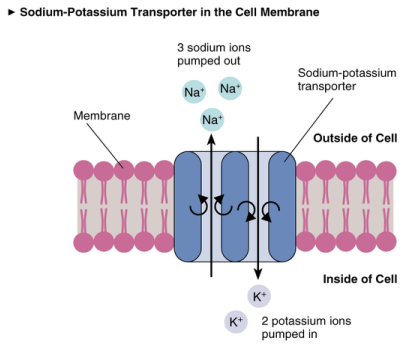
Body

Sodium and Potassium:



Sodium is the major positive ion (cation) in fluid outside of cells. Excess sodium is excreted in the urine. Sodium regulates total body water and the actual transmission of sodium in and out of individual cells plays a critical role in various body functions. For example, processes in the brain, nervous system and muscles require electrical signals for communication. The movement of sodium, an electrolyte (conducts electricity) is key in generation of these electrical signals. Significant variation in sodium levels can cause cells to malfunction and extremes in blood sodium levels can even be fatal. A normal blood sodium level is 135-145 milliEquivalents/liter (Stoppler et al, 2010).

Interestingly, our entire body, including all cells and organs resides in a fluid medium containing a variety of minerals, including magnesium, sodium, potassium, calcium and phosphates. Within each cell, there is more potassium than sodium in the fluid. Outside the cell, the fluid has more sodium than potassium. Chloride acts to assist and complement both electrolytes. The delta or difference between the sodium-potassium distribution is important as it affects the osmotic gradients within and outside the cells; that, in turn, impacts hydration in the body, pH levels in the blood and even nervous and muscular systems (Peters J 2006).

Potassium is an essential macromineral in human nutrition with a wide range of biochemical and physiological roles (Natural Health Information Centre 2010). The functions of potassium in the body include:

- Regulates heart function
- Reduces blood pressure
- Essential for protein and nucleic acid synthesis
- Required for normal fluid balance
- Fundamental for normal nerve and muscle function
- Converts glucose into glycogen (muscle fuel)
- Important role in kidney function
- Helps lungs eliminate carbon dioxide
- Needed to maintain acid/alkali balance

Epidemiological studies have shown an inverse relationship between potassium intake and blood pressure. Other studies have reported an inverse relationship between potassium intake and stroke. Also there are an abundance of in vitro and animal data suggesting that high potassium intake may protect against cardiovascular disease (PDR for Nutritional Supplements, 2001)

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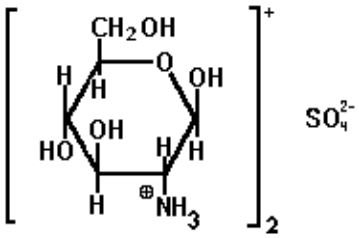
Glucosamine Clinical Summary:

Health Platform: Bone & Joint Health

Glucosamine is found in cartilage and plays and important role in its health and resiliency. As we age, we lose glucosamine in cartilage and this can lead to the onset and progression of a variety of joint issues.



A 2002 Czechoslovakian study was designed to determine whether long-term (3 year) treatment with glucosamine sulfate can modify the progression of joint structure and symptom changes in knee osteoarthritis. Two hundred and two patients with knee osteoarthritis were randomized to receive oral glucosamine sulfate, 1500 mg once a day versus a placebo. Changes in radiographic minimum joint space width were measured in the medial compartment of the tibiofemoral joint, and symptoms were assessed using the algo-functional indexes of Lequesne and WOMAC. Osteoarthritis was of mild to moderate severity at enrollment and a Lequesne index score of less than 9 points. Progressive joint space narrowing with placebo was -0.19 mm; conversely, there was no average change with glucosamine sulfate use with a significant difference between the two groups. Symptoms improved modestly with placebo use but as much as 20% to 25% with glucosamine sulfate use, with significant final differences on the Lequesne index and the

WOMAC total index and pain, function and stiffness subscales. In conclusion, long-term treatment with glucosamine sulfate slowed the progression of knee osteoarthritis (Gatterova et al, 2002).

A 2007 Spanish study assessed the effects of the prescription formulation of glucosamine sulfate (1500 mg administered once daily) on the symptoms of knee osteoarthritis during a 6-month treatment course. Three hundred eighteen patients were enrolled in this randomized, placebo-controlled, double-blind trial in which acetaminophen, the currently preferred medication for symptomatic treatment for osteoarthritis was used as a side comparator. Patients were randomly assigned to receive glucosamine sulfate 1500 mg once daily (n= 106), acetaminophen 3 gm/day (n= 108), or placebo (n= 104). The primary efficacy outcome measure was the change in the Lequesne index after 6 months. The results were that glucosamine sulfate was more effective than placebo in improving the Lequesne score; the Lequesne score for acetaminophen was not significantly different from that of the placebo. In conclusion, the findings of this study indicate that glucosamine sulfate at the oral once-daily dosage of 1500 mg is more effective than placebo in treating knee osteoarthritis symptoms (Herrero-Beaumont et al, 2007).

A Belgian study (2001) assessed the effects of glucosamine sulfate on the long-term progression of osteoarthritis joint structure changes and symptoms. This study involved a randomized, double-blind placebo controlled trial, in which two hundred and twelve patients with knee osteoarthritis were given 1500 mg oral glucosamine sulfate or placebo once daily for 3 years. Weightbearing, anteroposterior radiographs of each knee in full extension were taken at enrollment and after one and three years. Mean joint-space width of the medial compartment of the tibiofemoral joint was assessed by digital image analysis, whereas minimum joint space was measured by visual inspection with a magnifying lens. Symptoms were scored by the WOMAC osteoarthritis index. The findings were that the 106 patients on placebo had a progressive joint-space narrowing while there was no significant joint-space loss in the 106 patients on glucosamine sulfate. As assessed by WOMAC scores, symptoms worsened slightly in the placebo group compared with the improvement observed after treatment with glucosamine sulfate. The conclusion was that the long-term combined structure-modifying and symptom-modifying effects of glucosamine sulfate suggest that it could be a disease modifying agent in osteoarthritis (Reginster et al, 2001).

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Calcium & Vitamin D Clinical Summary:

Health Platform: Bone & Joint Health

Calcium is the most common mineral in the human body. About 99% of the calcium in the body is found in bones and teeth. Calcium is essential for the maintenance of strong bones. In order for the body to absorb calcium, vitamin D is needed. Vitamin D can be synthesized by the body from UV light or be obtained from the diet.

GlaxoSmithKline and the Department of Defense (U.S.) conducted a double-blind, placebo-controlled randomized clinical trial of calcium and vitamin D supplementation in 5201 female Naval recruits. During 8 weeks of basic training, supplementation with 2000 mg calcium and 800 IU vitamin D/day decreased incidence of stress fracture by 25%. In concluding, generalizing the findings to the population of 14,416 females who entered basic training at Great Lakes during the 24 months of recruitment, calcium and vitamin D supplementation for the entire cohort would have prevented about 130 persons per year from fracturing. Such a decrease in SFx (stress fractures) would be associated with a significant decrease in morbidity and financial costs (Lappe, Principal Investigator 2008).

A 2004 Italian study assessed the effects of calcium supplementation combined with Vitamin D on bone mineral density (BMD) and bone mineral content (BMC) in a representative sample of peri-and post-menopausal women in a double-blind, randomized controlled trial. Results showed that the change in total BMD in the calcium group was significantly different from that in the placebo group ($P \leq 0.005$). The placebo group lost a total BMD at a rate of about 0.4% per year. Conclusion: results showed the positive effect of calcium and Vitamin D supplementation in women both peri-and post menopausal status; for this reason a supplementation of calcium and Vitamin D should be recommended as a strategic option in helping to prevent early postmenopausal bone loss. (Di Daniele et al, 2004)

The effects of three years of dietary supplementation with calcium and vitamin D on bone mineral density, biochemical measures of bone metabolism, and the incidence of nonvertebral fractures was studied in 176 men and 213 women 65 years of age or older who were living at home. They received either 500 mg of calcium plus 700 IU of vitamin D3 (cholecalciferol) per

day or placebo. The difference between the calcium-vitamin D and placebo groups was significant at all skeletal sites after one year, but it was significant only for total-body mineral density in the second and third years. The conclusions were that in men and women 65 years of age or older who are living in the community, dietary supplementation with calcium and vitamin D moderately reduced bone loss measured in the femoral neck, spine and total body over the three-year study period and reduced the incidence of nonvertebral fractures (Dawson-Hughes et al) .

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Vitality

Green Tea Extract (Natural Caffeine) Clinical Summary:

Health Platform: Antioxidant, Heart Health, Immunity, Inside Beauty, Weight Management

Catechins, including EGC, are a class of polyphenols found in green tea. Catechins act as powerful antioxidants that capture and neutralize free radicals and have beneficial effects for weight management, heart health, vitality and overall health and wellness! Green tea is also a natural source of caffeine that provides energy!

Based on a clinical study done on Japanese women and men with visceral fat-type obesity, regular consumption of green tea extract high in catechins caused reduction in body fat, systolic blood pressure, and LDL cholesterol, implying that the consumption of green tea extract helps decrease obesity and cardiovascular disease risks (Nagao et al, 2007).

Green tea intake is related with decreased mortality because of its positive effect on cardiovascular disease. This is based on a prospective cohort study done on 40530 Japanese adults aged 40 to 79 years. Participants were followed up for up to 11 years for all-cause mortality and for 7 years for cause-specific mortality (Kuriyama et al, 2006).

Moderate intake of EGCG (a catechin from green tea) can improve health of overweight individuals doing regular exercise by reducing heart rate and glucose concentration in plasma. However, loss of body fat may need a higher intake of EGCG or other catechins (Hill et al, 2007).

Based on an animal study done in Switzerland, dietary intake of EGCG should be considered as an important natural treatment for obesity. This effect is partly mediated through a direct influence on adipose tissue (Wolfram et al, 2005).

Daily intake of tea containing 690 mg catechins for 12 weeks decreased body fat, indicating that the intake of catechins might be valuable to prevent and improve diseases related with lifestyle, mainly obesity (Nagao et al, 2005).

Based on a clinical study done in 10 healthy men, green tea extract may be responsible for controlling body composition through sympathetic activation of thermogenesis, fat oxidation, or both (Dulloo et al, 1999).

Continuous consumption of green tea EGCG may prevent UV-induced damage on skin. This is based on a clinical study done in female hairless rats (Jeon and others, 2009). Green tea polyphenols inhibit UVB-induced skin tumor development through reduction in skin inflammation (Meeran et al, 2008).

Green tea alleviates oxidative damage by improving antioxidant defense, tissue integrity and energy metabolism, based on a study performed on rats (Khan et al, 2009). Antioxidants are known to scavenge free radicals that cause cellular damage.

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Wolfram S, Raederstoff D, Wang Y, Teixeira SR, Elste V, Weber P. 2005. Teavigo (epigallocatechin gallate) supplementation prevents obesity in rodents by reducing adipose tissue mass. Ann Nutr Metab 49(1):54-63.

Vitamin D Clinical Summary:

Health Platform: Bone & Joint Health and Vitality

Vitamin D is a fat-soluble vitamin found in very low quantities in animal and plant foods. It's essential for skeletal growth and bone mineralization. Vitamin D is naturally formed on human skin after exposure to sunlight.

GlaxoSmithKline and the Department of Defense (U.S.) conducted a double-blind, placebo-controlled randomized clinical trial of calcium and vitamin D supplementation in 5201 female Naval recruits. During 8 weeks of basic training, supplementation with 2000 mg calcium and 800 IU vitamin D/day decreased incidence of stress fracture by 25%. In concluding, generalizing the findings to the population of 14,416 females who entered basic training at Great Lakes during the 24 months of recruitment, calcium and vitamin D supplementation for the entire cohort would have prevented about 130 persons per year from fracturing. Such a decrease in SFx (stress fractures) would be associated with a significant decrease in morbidity and financial costs (Lappe, Principal Investigator 2008).

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The effects of three years of dietary supplementation with calcium and vitamin D on bone mineral density, biochemical measures of bone metabolism, and the incidence of nonvertebral fractures was studied in 176 men and 213 women 65 years of age or older who were living at home. They received either 500 mg of calcium plus 700 IU of vitamin D3 (cholecalciferol) per day or placebo. The difference between the calcium-vitamin D and placebo groups was significant at all skeletal sites after one year, but it was significant only for total-body mineral density in the second and third years. The conclusions were that in men and women 65 years of age or older who are living in the community, dietary supplementation with calcium and vitamin D moderately reduced bone loss measured in the femoral neck, spine and total body over the three-year study period and reduced the incidence of nonvertebral fractures (Dawson-Hughes et al) .

A recent meta-analysis study indicated that Vitamin D intakes greater than 500 International Units (IU) were associated with a 13 percent reduction in the risk of type-2 diabetes. In addition, researchers reported that people with the highest blood levels of Vitamin D (more than 25 nanograms per milliliter) had a 43 percent lower risk of developing type-2 diabetes than people with the lowest blood levels of Vitamin D (less than 14 nanograms per milliliter). Both results are based on a meta-analysis of eight observational cohort studies and 11 randomized controlled trials measuring Vitamin D and diabetes (Mitri et al, 2011).

A 2009 British study involving 99 post-menarchal 12-14 old females investigated the relationship of baseline serum Vitamin D content and its correlation with muscle power and force. Jumping mechanography was used to measure muscle power, velocity, jump height and the Esslinger Fitness Index was performed (a two-legged counter movement jump and force from multiple one-legged hops). In conclusion, Vitamin D was significantly associated with muscle power and force in adolescent girls (Ward et al, 2009).

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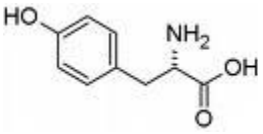
L-Tyrosine Clinical Summary:

Health Platform: Brain Health

L-tyrosine is a precursor to several important neurotransmitters in the brain. It has been shown to maintain proper brain function- aiding in focus and alertness as well as reducing feelings of stress and fatigue.



Cognitive and motor performances are important in several situations and are impaired by sleep deficiency. Tyrosine was given to healthy young men to look at the effects on cognitive and motor performance after a night of sleep deficiency. Various tests were preformed on the men and tyrosine improved performance on several tests. The conclusion was that tyrosine enhanced at least some aspects of cognitive and motor performance after sleep deficiency (Magill et al, 2003).

One study had subjects stay awake for over 24 hours. The behavioral effects of tyrosine during a period of constant work through out the night were examined. The group of subjects that received the tyrosine showed vast improvement in regards to the typical performance decline (Neri et al, 1995).

Another study took place during a challenging military combat training course with 21 cadets, where half of the cadets were given a protein drink supplemented with tyrosine and the other half of the cadets received protein drinks without tyrosine. The group that was supplemented with tyrosine performed better on a tracking and a memory test than the other group. Tyrosine supplementation may reduce the effects of stress and fatigue on cognitive task performance (Deijen et al, 1999).

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Maca Root (*Lepidium meyenii*) Clinical Summary:

Health Platform: Sexual Health, Vitality

Maca is a South American herb traditionally used to promote sexual health and vitality.

A double-blind clinical trail involving 50 Caucasian men dealing with mild erectile dysfunction (ED) used two different tests to determine if a maca extract would help with ED. The results showed that maca had a significant effect on their subjective perception of sexual and general well-being (Zenico et al, 2009).

A study done on rats showed that maca root stimulates spermatogenesis (the process where the sperm cell develops) in male rats by acting on its initial stages (Gonzales et al, 2001).

Sixty male rats were treated daily for 15 days with maca. The conclusions of this test were that both acute and chronic oral administration of maca significantly improves sexual performance parameters in male rats (Cicero et al, 2001).

Mice and rats were fed maca for 22 days and it was determined that maca enhanced sexual function of the mice and rats. This was established by an increase in the number of complete intromissions and the number of sperm-positive females in normal mice and a decrease in the latent period of erection in male rats with erectile dysfunction. This study also revealed for the first time the aphrodisiac activity of maca (Zheng et al, 2000).

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Resveratrol Clinical Summary:

Health Platforms: Heart Health, Vitality

Resveratrol is a polyphenol found in the skin of red grapes and Japanese knotweed. It is often associated with anti-aging and vitality. Resveratrol has been credited with explaining the French Paradox: the low incidence of heart disease among the French even though they have similar risk factors. This is attributed to their high consumption of red wine.

A recent review article, now in press, indicates that resveratrol has a high therapeutic potential for the treatment of cardiovascular diseases. Progression of atherosclerosis is characterized by atheroma instability and plaque disruption followed by local thrombosis which constitutes the clinical indications of acute coronary syndrome; resveratrol exerts diverse biological actions on both progression and regression of atherosclerosis. LDLs play an important role in the formation of atherosclerotic plaques and in the endothelial inflammatory pathway. Oxidation of LDL is the main cause of endothelial injury and resveratrol was found to protect lipids from peroxidative degradation and inhibited the uptake of oxidized LDLs in the vascular wall. The article concludes that the protective role of resveratrol was supported by detail finding at the cellular and molecular level (Das et al, 2010).

A randomized, placebo-controlled, double-blind cross-over human study conducted at the University of South Australia in 2009 measured the resveratrol effects on cardiovascular health. The resveratrol was readily absorbed and significantly improved blood vessel function compared to the placebo at all three dose levels as assessed by acute flow-mediated dilation (a key indicator of blood vessel function and cardiovascular health) (Berry et al, 2009).

In a 2010 study, 19 overweight/obese men or post-menopausal women with untreated borderline hypertension consumed three doses of resveratrol and a placebo at weekly intervals in a double-blind, randomized crossover comparison. There was a significant dose effect of resveratrol on plasma resveratrol concentration and on flow-mediated dilatation (FMD). Flow-mediated dilation of the brachial artery is a biomarker of endotheial function and cardiovascular health. Impaired FMD is associated with several cardiovascular risk factors including hypertension and obesity. In conclusion, the results of this acute study demonstrated a dose-related improvement in FMD that correlated with increased plasma resveratrol concentrations. FMD (flow-mediated dilatation) was significantly increased by each dose of resveratrol compared with placebo (Wong et al, 2010).

A 2006 study evaluated the effects of resveratrol on middle-aged mice on a high calorie diet. Resveratrol shifted the physiology of these middle-aged mice towards that of mice on a standard diet and significantly increased their survival. Parametric analysis of gene set enrichment revealed that resveratrol opposed the effects of high-calorie diet in 144 out of 153 significantly altered pathways. In conclusion, these data showed that improving general health in mammals using small molecules is an attainable goal, and pointed to new approaches for treating obesity-related disorders and diseases of ageing (Baur et al, 2006).
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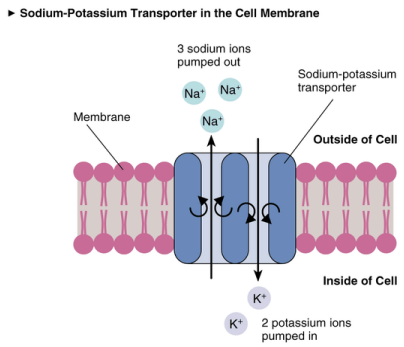
Sodium, Potassium and Magnesium:



Sodium is the major positive ion (cation) in fluid outside of cells. Excess sodium is excreted in the urine. Sodium regulates total body water and the actual transmission of sodium in and out of individual cells plays a critical role in various body functions. For example, processes in the brain, nervous system and muscles require electrical signals for communication. The movement of sodium, an electrolyte (conducts electricity) is critical in generation of these electrical signals.

Significant variation in sodium levels can cause cells to malfunction and extremes in blood sodium levels can even be fatal. A normal blood sodium level is 135-145 milliEquivalents/liter (Stoppler et al, 2010).

Interestingly, our entire body, including all cells and organs resides in a fluid medium containing a variety of minerals, including magnesium, sodium, potassium, calcium and phosphates. Within each cell, there is more potassium than sodium in the fluid. Outside the cell, the fluid has more sodium than potassium. Chloride acts to assist and complement both electrolytes. The delta or difference between the sodium-potassium distribution is important as it affects the osmotic gradients within and outside the cells; that, in turn, impacts hydration in the body, pH levels in the blood and even nervous and muscular systems (Peters J 2006).

Potassium is an essential macromineral in human nutrition with a wide range of biochemical and physiological roles (Natural Health Information Centre 2010). The functions of potassium in the body include:

- Regulates heart function
- Reduces blood pressure
- Essential for protein and nucleic acid synthesis
- Required for normal fluid balance
- Fundamental for normal nerve and muscle function
- Converts glucose into glycogen (muscle fuel)
- Important role in kidney function
- Helps lungs eliminate carbon dioxide
- Needed to maintain acid/alkali balance

Epidemiological studies have shown an inverse relationship between potassium intake and blood pressure. Other studies have reported an inverse relationship between potassium intake and stroke. Also there are an abundance of in vitro and animal data suggesting that high potassium intake may protect against cardiovascular disease (PDR for Nutritional Supplements, 2001).

Magnesium is necessary for every major biological process, including cellular energy and the synthesis of nucleic acids and proteins. It is necessary for normal functioning of muscle and nervous tissue and participates in the formation of bones and teeth. Magnesium is the second most abundant intracellular cation with potassium being the most abundant. The total body magnesium content of an adult is about 25 grams with about 50%-60% existing in the bone. Magnesium influences both matrix and mineral metabolism in bone. Magnesium depletion can cause cessation of bone growth and increased bone fragility (PDR for Nutritional Supplements, 2001).

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