ORAL PRESENTATIONS – SESSION A

REEEVALUATING (−)-HYDROXYCITRIC ACID IN METABOLIC SYNDROME.

(−)-Hydroxycitric acid (HCA) remains controversial with regard to the comparative bioavailability and efficacy of different salts, the impact of the fat content of the diet and mechanisms of action. Recent in vitro, animal and clinical evidence suggest that a reevaluation is in order for HCA and its place in the category of inhibitors of ATP:citrate lyase for preventing and treating cardiovascular and metabolic diseases. Many of actions of HCA cannot be explained in terms of ATP:citrate lyase and therefore invite alternate explanations as to mechanisms of action. Current evidence supports benefits in most or all areas of the Metabolic Syndrome. Some, but not all HCA salts modulate blood pressure, blood sugar disposal, insulin sensitivity and corticosteroid metabolism as well as exhibiting the expected effects on blood lipids, especially triglycerides. Monovalent HCA salts (especially potassium) appear to be the most active, but calcium seems to interfere both with bioavailability and with efficacy. Small amounts of magnesium acting as a counter ion, in contrast, are at worst neutral in effect. Cell culture studies have demonstrated that a potassium-magnesium hydroxycitrate accentuates glucose uptake in cardiomyocytes and hepatocytes even in the absence of insulin, with a trend towards an additive effect in cardiomyocytes. This same salt in an animal model reduced circulating insulin levels by approximately one half while maintaining normal blood glucose. Pilot data in human type 2 presenting diabetics confirm that the HCA salt acts similarly in humans. The likely mechanisms of action have been revealed in computational docking studies indicating that HCA at the cellular level exhibits its highest affinity for the insulin receptor followed by 11-β-hydroxysteroid dehydrogenase, which regulates glucocorticoid access to steroid receptors and influences blood glucose/pressure, and farnesoid X receptor (FXR), which reduces triglyceride levels.

KONJAC GLUCOMANNAN DIETARY SUPPLEMENTATION CAUSES SIGNIFICANT FAT LOSS IN COMPLIANT OVERWEIGHT ADULTS. Preuss HG, Michalek J, Bagchi D, Kaats GR: 1. Georgetown University Medical Center, Washington, DC; 2. University of Texas at San Antonio, San Antonio, TX; 3. University of Houston, Houston, TX; 4. Health and Medical Research Foundation, San Antonio, TX

We compared changes in body composition and blood chemistries between participants taking either 3 grams glucomannan/300 mg calcium or placebo under free-living conditions for 60 days.
during a holiday season (October-December). These two groups were further divided into compliant and non-compliant groups for additional assessments. We carried out a randomized, double-blinded, placebo-controlled protocol to evaluate changes. Baseline and ending Dual Energy X-ray Absorptiometry (DEXA) and 42-chemistry blood analyses were performed. A questionnaire assessing protocol compliance was administered at study end. To be compliant, participants consistently consumed the required number of capsules approximately 30 minutes before eating over 80% of time as determined by the questionnaire and subsequent post-study telephone confirmations. Eighty participants who completed the study were identified as to their compliant or non-compliant status. We found no statistically or clinically significant differences between the Active Treatment and Placebo groups concerning body composition at end of study. However, after corrections for compliance (dosing and/or timing), t-tests between the compliant Active Treatment and compliant Placebo groups revealed highly significant beneficial differences in the Active group in: scale weight, percent body fat, and fat mass. Taking supplement correctly was also associated with reduced circulating total and LDL cholesterol. Initially, overall data suggested no statistically significant favorable effects of the glucomannan preparation on body composition. However, when the recommended regimen was followed correctly, glucomannan supplementation in the compliant Active Treatment subjects generally facilitated loss of body fat without significant concomitant loss of lean mass or bone density. This strengthens the necessity of seriously considering compliance in weight loss studies. This study also revealed the validity of a technique using a post-study anonymous questionnaire to ascertain compliance.

EFFECTS OF DIFFERENT FIBERS ON SUGAR-INDUCED BP ELEVATIONS IN HYPERTENSIVE RATS: FOCUS ON VISCOSITY. Preuss HG1, Bagchi D2, Clouatre D3, Perricone NV3: 1. Georgetown University Medical Center, Washington, DC; 2. Univ. of Houston, Houston, TX; 3. Glykon Technologies, Seattle, Washington; 4. Michigan State University, East Lansing, MI.

Animal models have consistently shown that excess intake of certain dietary sugars significantly increases systolic blood pressure (SBP). However, concomitant intake of some soluble fibers can overcome this phenomenon. Similar associations are now becoming apparent at a clinical level. Hypothesizing that the more viscous the fiber the greater the lowering of sugar-induced SBP elevations, the present study compares ability of several fibers with differing viscosities to overcome sugar-elevated SBP. 64 spontaneously hypertensive rats (SHR) were divided into 8 groups of 8 based on diet supplied. Group 1 received a diet composed of 52% starch w/w, while Groups 2-8 were fed w/w 18% sucrose/34% starch. Each group receive the following fiber in feed at 6% w/w: Group 1 and 2 – cellulose; 3 – mustard mucilage; 4 – hydrolyzed guar; 5 – psyllium; 6 – carboxymethylcellulose (CMC); 7 – pectin; and 8 – guar. Following testing, guar was arbitrarily classified as highly viscous, and CMC, pectin, and psyllium, as moderately viscous. Hydrolyzed guar, mustard mucilage and the insoluble fiber cellulose were designated weakly viscous. In general, ability of fiber to overcome sugar-elevated SBP in SHR correlated positively with viscosity - the more viscous the fiber, the greater the effect. Only guar prevented sucrose-induced SBP elevations completely over two months. CMC, pectin, and psyllium delayed onset of the sugar-elevated SBP rise for roughly six weeks, while cellulose, mustard mucilage, and, to some extent, hydrolyzed guar were essentially unable to influence sucrose-induced SBP elevations. With exception of hydrolyzed guar, the in vivo xylose absorption test, correlated to some extent with fiber viscosity and effects on SBP. In conclusion, adding sucrose to rodent feed in concentrations simulating those found in the average American diet increases SBP significantly in SHR. Only the most viscous fiber tested, guar, was able to completely prevent sucrose-induced elevations over two months of study. Moderately viscous fibers delayed the increase in SBP, but did not prevent it. This raises a question concerning long-term effectiveness of soluble fibers under clinical conditions on sugar-induced blood pressure elevations.

CONSUMPTION OF CANNED FRUITS AND VEGETABLES IS ASSOCIATED WITH GREATER TOTAL VEGETABLE AND FRUIT CONSUMPTION, BETTER DIET QUALITY AND INCREASED NUTRIENT INTAKE IN CHILDREN: NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 2001-2010. Freedman MR, Fulgoni V., Department of Nutrition,
The objective of this study was to assess, using NHANES 2001-2010 data, the consumption of canned fruits and vegetables (CF+CV) by children, and to analyze dietary and physiological differences among consumers and non-consumers. NHANES data were based on one 24-hour recall. Diet quality was calculated using the Health Eating Index-2010 (HEI). Children (n=2,066) who consumed CF+CV as compared to non-consumers, had higher total vegetable intake (2.7±0.05 v 2.1±0.03) and total higher total fruit intake (2.8±0.08 v 2.4±0.04). Their Healthy Eating Index-2010 (HEI) score was significantly higher (P<0.0001) than non-consumers (45.8 ± 0.5 v 43.3 ± 0.3, consumers v. non-consumers, respectively). Children who consumed CF+CV also ate more protein, fiber, vitamin A, calcium, magnesium, potassium, and choline, and less fat. Sodium intake was not different in children who consumed CF+CV, as compared to non-consumers. These data show that consumption of CF+CV was associated with higher nutrient intakes, and a higher diet quality in children. While children who consumed CF+CV ate more energy and total sugar, their body weight, body mass index (BMI), and blood pressure was comparable to non-consumers. CF+CV thus make important contributions to the diets of American children.

EXERCISE IN YOUNG ADULTHOOD AND INTAKE OF FRUIT AND VEGETABLES: TRANSFER AS CO-OCCURRENCE AND TRANSFER AS CARRY-OVER. Jayawardene W, Lohrmann D, Torabi M, School of Public Health Bloomington, Indiana University, Bloomington, IN.

Objectives: To determine transfer effects between exercise frequency (EF) & fruit/vegetable intake frequency (FVF) during ages 18 through 31.
Methods: 6244 respondents of the National Longitudinal Survey of Youth-1997 were followed at ages 18-22(Time-1), 23-27(Time-2), & 27-31(Time-3). Repeated measures ANOVA & multiple regression determined if the transition of EF between Times 1 & 2 was associated with simultaneous & sequential changes in FVF, adjusting for sex, race, education, income, & BMI.
Results: Adequate FVF increased with age. Males reported higher EF & females higher FVF. EF transition was linearly associated with concurrent FVF. A significant effect of Time-2 EF on Time-3 FVF emerged, after accounting for baseline FVF.
Conclusion: Newly engaging in & continuing exercise may establish exercise habits that improve FVF. Interventions that facilitate transferring self-regulatory psychological resources across behaviors likely will enhance this effect.

NUTRITIONAL MODULATION OF THE RETINA. Kaushal S, Retina Specialty Institute, Gainesville, FL.

The neurosensory retina is a thin diaphanous structure attached to the inner wall of the back of the eye. It serves as the photographic film of the eye and is a laminated integrated circuit that subserves all aspects of visual perception. Accordingly, the retina is the most metabolically active tissue in the body per unit weight and the eye has the largest blood supply per unit weight in the human body. Given the unusual metabolic demands of retina, there is a role for nutrition and nutritional supplements in retinal health. The biology of retinal activity will be briefly reviewed. Additionally, the critical, pathogenetic events that cause retina diseases like diabetic retinopathy and age-related macular degeneration (AMD) including oxidative stress, inflammation, microglial activation and cell death will also be reviewed and experimental studies presented that demonstrate how they can be mitigated by nutrition and nutritional supplements.

ORAL PRESENTATIONS – SESSION B

EMERGING NUTRITIONAL MARKERS PREDICT CAROTID IMT REGRESSION. Masley SC, University of South Florida, St Petersburg, FL; Roetzheim R, University of South Florida, Tampa,
Introduction: CVD remains the number one cause of mortality in the western world. Carotid intima-media thickness (IMT) is a safe & reliable predictor of future CVD risk.

Objective: The study assesses which nutritional factors best predict a change in IMT.

Methods: A prospective cross-sectional analysis of 289 men & women undergoing health & cardiovascular risk screening every 1-2 years at an outpatient wellness center in Florida. This study reflects the first visit at the clinic, & a second visit that occurred on average 2.8 years later. These subjects ranged in age from 23-65 (mean = 48.2). In addition to testing, subjects received nutrition, fitness, & health coaching.

3-Day food diaries were analyzed using Nutribase 7 software. Mean IMT scores used high resolution B-mode ultrasonography of the common carotid arteries. Each subject had ≥10 images collected from the far wall of both distal 1 cm of the common carotid arteries at end diastole. The carotid intimal thickness was measured as a continuous variable, using bivariate linear regression, adjusting for age & gender; as our site IMT precision was = 3%, we selected a 4% change as significant.

Results: The bivariate analyses showing a significant association with a ≥4% reduction in IMT in 62 of 288 subjects; they were a decrease in: BMI (p=0.047), body fat (p=0.025), or an increase in dietary intake of: magnesium (p=0.0001), fiber (p=0.017), vitamin D (p=0.016), vitamin K (p=0.001), potassium (p=0.001), & calcium (p=0.024. The following were not associated with an IMT reduction—intake of: omega-3, fish, protein, carbohydrate, fat, saturated fat, alcohol, caffeine, folate, vit B12, sodium, or zinc, or mercury RBC level.

Conclusions: A reduction in IMT score over 2.8 years is associated with a decrease in: BMI, body fat; or, an increase in intake of: magnesium, fiber, vitamins K & D, potassium, & calcium.
amins and enzymatic and non-enzymatic antioxidants. Pertinent to this discussion, recent evidence points to an intricate relationship between Vitamins A, D, E, and K (specifically Vitamin K2). The former three determine the amount and activity of specific proteins by regulating gene transcription, nuclear RNA processing, and messenger RNA stability and degradation. Vitamin K2 may not affect gene expression, but through gamma carboxylation (activation) of Vitamin K dependent proteins, like Osteocalcin, and MGP (matrix gla protein), it can prevent, slow down, and possibly reverse the degenerative effects of aging, ensuring enhanced longevity.

**COMPARISON OF DIFFERENCES BETWEEN USING SCALE WEIGHT CHANGES OR A BODY COMPOSITION IMPROVEMENT INDEX AS OUTCOME MEASURES FOR EVALUATING THE SAFETY AND EFFICACY OF WEIGHT LOSS INTERVENTIONS AND TREATMENT PLANS.** Kaats GR\(^1\), Preuss HG\(^2\), Nugent S\(^3\), Integrative Health Technologies, San Antonio, TX; Georgetown University Medical Center, Washington, DC; Mannatech International, Coppell, TX.

Objective: The widespread use of the body mass index or scale weight to evaluate the efficacy of weight loss interventions and treatment plans provides measurements of the amount, but not the kind, of weight that was lost or gained. Thus, depletion of metabolically lean and bone mass (FFM), typically considered negative outcomes, are included as positive outcomes the same as fat loss. However, a proposed Body Composition Improvement (BCI) index differentiates changes in fat and FFM scoring losses of fat and gains of FFM as positive outcomes, gains of fat and losses of FFM as negative treatment outcomes. The BCI is the net of these calculations. This study was designed to compare the two measures to see if the differences between the two were statistically and clinically meaningful.

Methods: We used a data set of 3,987 subjects aged from 17-87, ethnicity and residing in almost every State in the U.S. All subjects completed baseline and ending measurements of scale weight and DEXA body composition (fat and FFM) in conjunction with their participation in a variety of weight loss interventions. Since, as measures of change, scale weight and the BMI are virtually identical, we compared only scale weight changes with the BCI to ascertain the difference between using one or the other as outcome measures. Three calculations were made for each subject: (1) changes between baseline and end-of-study scale weight; (2) the BCI, and (3) the difference between (1) and (2).

Results: There was a significant difference between scale weight changes and the BCI (\(p<.0001\)). The mean difference between these two outcome measures was 7.76 lbs., 99% confidence interval: 7.73-7.79; (\(p < .00001\)). The distribution of difference scores between the two outcome measures is shown in the frequency table below in groupings of 5 lb. categories.

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<td>% of Sample</td>
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<td>1.6%</td>
<td>2.3%</td>
<td>6.8%</td>
<td>14.6%</td>
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Conclusions: These data provide compelling evidence of a significant difference between using scale weight or the BCI as outcome measures. If one accepts the BCI as the more accurate outcome measure, the failure to have used it in the past may have led to inappropriate acceptance or rejection of previous evaluated weight loss treatment plans.

**THE EFFECT OF LIFE MODIFICATION TREATMENT ON SERUM LIPIDS OF SCHOOL CHILDREN WITH ATHEROSCLEROTIC FAMILY BACKGROUND.** Szamosi T, 2nd Department of Medicine Faculty, Semmelweis University, Budapest, Hungary.

Alterations of different risk factors in young ages may prevent the early development of atherosclerosis. Schoolchildren (517 girls, 493 boys, age: 7-17 yrs.) were investigated before and after a 2 years long life modification treatment whose parents had coronary heart disease before their age 55. Serum lipids (total, HDL and LDL cholesterol, total triglyceride, apo A-I, apo B,
lipoprotein (a)), active vitamin D were measured. Significant decrease of the fasting serum triglyceride/HDL cholesterol rate was detected after the two years long care. A close significant correlation was found between the D vitamin level and the serum total triglyceride/HDL cholesterol rate. The decrease of the fasting serum triglyceride/HDL cholesterol rate may support the prevention of early atherosclerosis.

**CHRONIC VITAMIN D ENRICHED MUSHROOM INTAKE IMPROVED FUNCTIONAL FITNESS AND BODY COMPOSITION IN OLDER MEN AND WOMEN.** Williams BT¹, Marsales HR², Millaen AE³, Burton HW², Browne RW⁴, Horvath PJ²,¹ Dept. of Physiology and Biophysics,² Dept. of Exercise and Nutrition Sciences,³ Dept. of Epidemiology and Environmental Health,⁴ Dept. of Bio-technical and Clinical Laboratory Sciences, University at Buffalo, Buffalo, NY.

Vitamin D and mushrooms benefit weight management and muscle function. Our objective was to determine the effect of vitamin D fortified mushrooms on serum 25(OH)D status, body composition and functional fitness in 17 vitamin D insufficient, older adults (53.6±9.8y, BMI=32.2±10.6, 25(OH)D=24 ng/mL). They ate two Portabella caps/week for 12 weeks of either non-enriched (Control, n=8) or vitamin D2 enriched mushrooms (14000 IU D2 by UV irradiation) (VitD, n=9). Measures were taken at baseline and 12 weeks.

The VitD group achieved sufficient D status (≥30 ng/mL) by elevation in 25(OH)D2 (P=0.003) without affecting D3. The VitD group lost 1.7±0.6 kg body weight (P=0.02), primarily through fat loss with no caloric intake/expenditure change. Eight foot up and go times were 15% faster in the VitD group and 14% faster in the Control group (P=0.001, P=0.002, respectively). Sit to stand repetitions increased 30% in the VitD group and 24% in the Control group (P=0.006, P=0.001, respectively). Thirty second arm curl test improved 16% only in the VitD group (P=0.04).

After the addition of mushrooms to the habitual diet, lower body functional fitness improved and the D2 enriched Portabella mushrooms improved body composition, 25(OH)D status, and upper body functional fitness.

**POSTER PRESENTATIONS**

**IMPROVING INPATIENT GLYCEMIC CONTROL THROUGH MODIFICATION OF CARBOHYDRATE CONTROLLED DIETS.** Dixon JV, Diabetes & Endocrine Institute, Morristown Medical Center, Morristown, NJ.

To improve the glycemic control of our hospitalized patients, the percentage of calories from carbohydrate provided in “carbohydrate controlled” diets was reduced from 50% to 35% of total kcal.

Phase 1: All “carbohydrate controlled” diet meal patterns were adjusted to contain no more than 35 percent of the total kcal from carbohydrate spread out over 3 meals and one bedtime snack. Anecdotal observations indicate improved glycemic control with the lower percent carbohydrate controlled diet. More formalized data collection will begin in the near future.

Phase 2: (In process) The new carbohydrate meal plans provided to patients will highlight lower glycemic index choices available for each meal and be presented to patients with a simple educational flyer reviewing basic diabetes nutrition education and encouraging intake of lower glycemic index choices. Inpatient nutrition education materials and menus will be coordinated in this approach.

**CONCORD GRAPE JUICE IMPROVES ENDOTHELIAL FUNCTION IN OVERWEIGHT, OLDER ADULTS.** Dorsey PG, Holbrook M, Carey M, LeLeiko RM, Flint N, Rodrigues I, Aasen J, Eber-
hardt RT, Vita JA, Whitaker, Cardiovascular Institute of Boston University Medical Center, Boston, MA.

Epidemiological studies suggest that flavonoid-rich foods may reduce cardiovascular risk. Prior studies showed improved endothelial function after drinking flavonoid-containing beverages, including Concord grape juice; however, these studies were limited by small sample size or lack of a control group. We conducted a randomized, double-blind, placebo controlled, cross-over study comparing the effects of Concord grape juice (12oz./day, 700mg total polyphenols) to a calorically matched placebo beverage on vascular function in overweight, older participants (age ≥ 50, BMI ≥ 25). Participants (N=51, 70% female, age 56±7 years, BMI 32.8±3.9) consumed each beverage for 4 weeks with a 2 week rest period between beverages. Participants refrained from drinking other flavonoid-containing beverages. Vascular function was measured at each visit after consuming no beverage overnight (chronic effects) and 2-hours after drinking 12oz at each visit (acute and acute-on-chronic effects). Chronic grape juice consumption increased flow-mediated dilation and there was a tendency for worse function during placebo consumption (Figure). There was no acute effect of beverage consumption on vascular function. Acute-on-chronic Concord grape juice consumption improved flow-mediated dilation (7.4±3.9 to 9.2±4.0%) compared to the placebo beverage (8.1±3.9 to 8.1±4.2%, p=0.02). There were no effects of grape juice consumption on arterial stiffness, blood pressure, or reactive hyperemia. There were no adverse changes in weight, glucose, or insulin levels following grape juice consumption. Our findings are consistent with a beneficial effect of Concord grape juice on endothelial function in older, overweight individuals, a cohort representative of a large segment of the population. These results provide further support for the current recommendation for a diet rich in fruits and vegetables as a strategy to reduce cardiovascular risk.

LIPID LEVELS IN COLLEGE AGE STUDENTS: DIFFERENCES BETWEEN MALES AND FEMALES. Evenson A, Byrne J, Nutrition Department, The College of Saint Benedict/Saint John’s University, Saint Joseph, MN.

The objectives were to determine the distribution of lipid levels in late adolescent/young adults and to examine if differences exist between sexes. Fasting finger-stick blood samples were collected to measure lipid profiles including total cholesterol, LDL, HDL and TAG in undergraduate students ages 18-23 (n=1014). The Lipids Research Clinics Prevalence Study criteria were used as cutoff values to examine prevalence of dyslipidemia. Independent samples t-tests were used to compare results between males and females. Mean concentrations for total cholesterol, LDL, HDL, and TAG were 106.35 mg/dL, 88.81 mg/dL, 53.76 mg/dL and 91.20 mg/dL respectively. Borderline high concentrations of total cholesterol,
LDL, and TAG were found in 13.4%, 9.5% and 13.4% of total participants. High concentration of total cholesterol, LDL, and TAG were found in 2.4%, 0.9%, and 10.6% of participants respectively. For HDL concentration, 7.9% and 17.7% of participants were found to have borderline low and low concentrations respectively. Overall lipid profiles indicated that 84.2%, 89.6%, 74.5%, and 76% of participants had acceptable total cholesterol, LDL, HDL, and TAG concentrations respectively. Total cholesterol and HDL concentrations were significantly different based on sex, with females having higher values. No significant difference was found for LDL and TAG concentrations between sexes.

In this sample of 18-23 year olds, the majority had measured plasma lipids meeting the criteria for acceptable. Average total cholesterol and HDL is higher for females in this population. Ongoing data collection will be examined to determine if cut-offs for determining risk in late adolescent/young adults should be segregated by sex.

**EFFECT OF CHROMIUM DINICOCYSTEINATE SUPPLEMENTATION ON BIOMARKERS OF INFLAMMATION, OXIDATIVE STRESS, AND INSULIN RESISTANCE IN TYPE 2 DIABETIC SUBJECTS.** Jain SK, Caldito G, Kahlon G, Levine SN, Bass PF, Departments of Pediatrics and Medicine, Louisiana State University Health Sciences Center, Shreveport, LA.

Chromium is an essential micronutrient. Diabetic patients with a subclinical chromium deficiency are linked to elevated blood glucose, insulin and lipid levels. This study examined the hypothesis that supplementation with chromium can help management of diabetes. Type 2 diabetic subjects, aged 30-55 years were enrolled into this study. The study consisted of a 1-month placebo run-in period followed by random assignment to one of the three groups: placebo (P), chromium picolinate (CP, 400 µg Cr³⁺/day), or CDNC (400 µg Cr³⁺/day) for 3 months. Subjects continued to receive standard medical care for diabetes during the study. Subjects were stratified according to the medical treatment received for managing diabetes at the start of the study. The results were analyzed from type 2 diabetic subjects (n=43) taking only metformin and randomly assigned to receive either placebo (P, n=13), chromium-picolinate (CP, 400 µgCr³⁺/day, n=12) or chromium-dinicocysteinate (CDNC, 400 µg Cr³⁺/day, n=18) on biomarkers at baseline and at 3 months of supplementation. There was a significant decrease at 3 months in insulin resistance (p=0.01) in the CDNC compared to both placebo and CP groups. The CDNC group showed a significant reduction in insulin levels (p=0.03), protein carbonyl (p=0.02) and TNF-α (p=0.03) compared to the placebo group. The CP group showed a significant reduction in protein-carbonyl levels (p=0.03) versus placebo. Reductions in insulin resistance (p=0.01), insulin (p=0.04), blood glucose (p=0.02) and TNF-α levels (p=0.005) were seen in the CDNC group compared to baseline; no significant change in these biomarkers was observed in the P and CP groups. When controlling for medication, CDNC supplementation showed beneficial effects on blood markers of vascular inflammation, insulin resistance and oxidative stress compared to placebo plus a significant decrease in insulin resistance compared to the CP group. This suggests that CDNC supplementation has potential as an adjunct therapy for type 2 diabetic subjects.

Keywords: Chromium; Insulin resistance; Vascular inflammation; Oxidative stress, Diabetes

**SALACIA RETICULATA (OHT-88) MODULATES CARBOHYDRATE AND LIPID METABOLISM.** Deshpande J1,3, SrivastavaV1, Ghanam K1, Bhattacharya A1, Doyle L2, Juturu V3

1OmniActive Health Technologies, Thane, India; 2National Institute of Nutrition, Hyderabad, India, 3OmniActive Health Technologies Inc., Morristown, NJ.

_Salacia reticulata_ (S. reticulata) is a herbal medicine in Ayurvedic medicine. The extract of _S. reticulata_ showed preventive effects on obesity and various metabolic disorders. The aim of this study was to elucidate the therapeutic efficacy of the extract of _Salacia reticulata_ (OHT-88) and modulation of carbohydrate and lipid metabolism. In _vitro_ studies were conducted to study the effect of _S. reticulata_ [OHT-88] on α-glucosidase, pancreatic lipase and HMG-CoA reductase. The activity of α-glucosidase was assessed using mammalian α-glucosidase extracted from rat intestinal acetone powder (Sigma) and p-nitrophenyl L-D glucopyranoside (PNPG) as an artificial
substrate. Pancreatic lipase activity was assessed using pancreatic porcine lipase and 4-methylumbelliferyl oleate (MU Oleate) as substrate. Lipase activity was measured using a fluorescence kinetic assay. HMG-CoA reductase was the rate-limiting step in cholesterol synthesis. The activity of HMG-CoA reductase was assessed using HMG-CoA reductase assay kit (Sigma CS1090). S. reticulata [OHT-88] showed a significant inhibitory effect on α-glucosidase (Fig.1). S. reticulata demonstrated a significant inhibitory effect against pancreatic lipase, compared to orlistat (Figure 2). S. reticulata inhibited HMG-CoA only at higher concentration (1mg/ml). These results suggest the effects of S. reticulata in modulating gastrointestinal carbohydrate and lipid digestion and absorption, may be advocated as a candidate for obesity-diabetes prevention and phytotherapy.

Figure 1 Alpha glucosidase Inhibition

![Alpha glucosidase Inhibition](image1)

Figure 2: Pancreatic Lipase inhibition

![Pancreatic Lipase inhibition](image2)

SOLUBLE CURCUMIN (CURCUWIN™) IN THE PREVENTION OF DIABETIC RETINOPATHY VIA MODULATION OF ANTI-OXIDANT ACTIVITY AND GENETIC PATHWAYS – IN VIVO MODEL. Shankaranarayanan J1, Deshpande J1, Bhanuprakash Reddy G2, Sreenivasa Reddy S2, Juturu V3,1, OmniActive Health Technologies, Thane, India; 2National Institute of Nutrition, Hyderabad, India; 3OmniActive Health Technologies Inc., Morristown, NJ.

The aim of the present study was to investigate the protective effects of Curcuminoids from Regular Curcumin Powder (95% Curcuminoids), and UltraSOL™ Nutrient System with Curcumin (CurcuWIN™ Turmeric Extract, 20% curcuminoids) in dry powder forms on retina and metabolic markers on streptozotocin-induced (STZ) diabetic rats. Male Wistar strain (WNIN) rats (2 months old; 213±14 g BW) were randomly assigned into 4 groups: control group (C), diabetic group (STZ-diabetic rats, D), Diabetic +Soluble curcumin (SC, CurcuWIN™) and Diabetic +Regular curcumin (RC). Daily food intake, weekly body weights, fasting glucose levels and HbA1C were assessed. Electroretinogram, immunohistochemistry and immunofluorescence were performed in all treatment groups. At the end of 12 weeks, rats were euthanized and retinas harvested for histological and molecular analysis. In diabetic rats (D) amplitude of OPs were reduced (334.2 µV) compared to normal control (C) animals. Curcumin resulted in significant changes in OP amplitudes suggested by sum of OPs, RC (445.7) and SC (455.3). Treatment with curcumin prevented gross morphological changes to a significant extent in diabetic retina. Treatment with RC and SC prevented loss of Rho protein expression, NGF protein expression in diabetic retina indicated by intensified fluorescence. Treatment with RC and SC showed decreased protein expression in diabetic retina indicated by lower HIF1A positive fluorescence indicating the prevention of hypoxia in the retinas. Treatment with RC did not affect the VEGF over expression in diabetic retina but the SC reduced the VEGF expression. In diabetic rats the mRNA levels of GFAP are up regulated drastically, while treatment with SC significantly prevented its increase but there is no significant effect of RC treatment. Therefore, soluble curcumin has a therapeutic potential in the treatment of diabetic retinopathy (DR) and more effective than regular curcumin.

OUTCOMES OF A 3-MONTH EMPLOYEE WELLNESS WEIGHT LOSS CHALLENGE: A PHYSICIAN-SUPERVISED, STRUCTURED MEAL REPLACEMENT PROGRAM. McManus JF, Lau FC, Daggy BP, Shaklee Research Center, Pleasanton, CA.
The current study evaluated the effect of a physician-guided weight loss program in a workplace setting. Participants received free physician consultations and were advised to use a customizable 3-meal-a-day structured meal plan featuring 2 meal replacements daily. Participants were able to purchase the program at a discounted price and were incentivized with cash prizes at the end of the challenge based on percent of initial body weight lost. There were 7 physician-supervised consultations and weigh-ins: at baseline and at 15-day intervals thereafter for 3 months. To be included in the analysis, participants were required to complete the baseline plus 3 additional weigh-ins. Missing data were imputed using last-observation-carried-forward method. Student’s t-test was used for comparisons between two time points. For comparison of reduction in body weight at different time points, ANOVA was used. P-values less than 0.05 were considered to be statistically significant.

Of 106 participants who enrolled in the challenge, 76 (72%) were completers, with a mean body weight 190 lb and mean BMI of 30 kg/m$^2$ at baseline; 65% of completers were female. Completers lost an average of 9.6 lb or 5.1% of initial body weight ($p<0.0001$) after 3 months. A categorical shift in weight classification was observed, with 7 of 29 obese participants at baseline shifting to BMI<30 after 3 months. The effect of this program was seen in the first 2 weeks, with a significant weight loss of 4.3 lb ($p<0.0001$). Sub-analysis indicated that men lost significantly more weight than women after two weeks (5.7 lb vs. 3.9 lb; $p<0.05$).

The 3-month results indicate that this structured meal replacement program combined with physician supervision exhibited a good completion rate and significant & clinically meaningful weight loss. Long-term studies are warranted to evaluate the effects of this program on weight loss and weight loss maintenance over an extended period of usage.

EFFECT OF A STRUCTURED MEAL REPLACEMENT PROGRAM ON WEIGHT LOSS: AN EIGHT-WEEK MOBILE-APP ASSISTED INTERVENTION. Lau FC, Daggy BP, McManus JF, Shaklee Research Center, Pleasanton, CA.

Recent studies have shown that structured meal replacement plans combined with educational support and tools via the Internet may be effective in achieving and maintaining weight loss goals. Here we assessed the initial weight loss outcomes from a commercial program in subjects self-monitoring their weight loss progress through online tools.

Participants selected a customizable 3-meal-a-day structured meal plan featuring 2 meal replacements daily. Self-reported data were collected via a mobile-app. A total of 417 participants (mean age 45.3 years and mean BMI of 31.5 kg/m$^2$ at baseline; 80% females) completed an 8-week program. Weekly data were analyzed on individuals reporting their body weight. Data were normalized by baseline transformation. Two-tailed t-test was used for baseline comparison at specific time points and ANOVA was used for comparisons at different time points. P-values <0.05 were considered statistically significant.

At the end of 8 weeks, significant reductions in body weight (9.7 lb; $p<0.0001$) and BMI (1.5 kg/m$^2$; $p<0.0001$) were observed as compared to the initial values. Categorical shift towards effective weight loss occurred such that the percent of obese subjects was reduced from 51 to 42%. Gender-stratified analysis demonstrated that men lost significantly more weight than women (-5.9% vs. -4.6%; $p<0.0001$). A significant body weight reduction was seen at the end of first week (2.7 lb; $p<0.0001$).

The findings thus far suggest that this structured meal replacement program promoted a healthy weight loss in a relatively short time frame. Long-term studies are underway to evaluate the effects of this program on weight loss and weight loss maintenance over an extended period of usage.

CROSS-SECTIONAL ANALYSIS OF TELOMERE LENGTH IN PEOPLE 33-80 YEARS OF AGE: EFFECTS OF DIETARY SUPPLEMENTATION. Harley CB,$^1$ Chan J,$^1$ Blauwkamp M,$^1$ Lau FC,$^2$ McManus JF,$^2$ Watson B,$^1$, Hytopoulos E,$^1$, Daggy BP,$^2$ $^1$Telomere Diagnostics Inc., Menlo Park, CA; $^2$Shaklee Research Center, Pleasanton, CA.
Telomere length has been associated with aging, aging-related diseases, adverse conditions, and mortality. Moreover, studies in humans suggest a causal role of short telomeres or accelerated telomere shortening in disease and mortality risk. A previous cross-sectional study has shown that supplement usage significantly improved various health parameters and nutritional status. The objective of the current cross-sectional study was to explore the effect of dietary supplementation on telomere length.

The normal range of telomere lengths was determined from saliva samples in a population of healthy, non-smoking subjects aged 33-80 from the San Francisco Bay Area (control group, n=324 (147 males and 177 females)) who took no more than 3 supplements daily. The telomere lengths of heavy supplement users (supplement group, n=80), the majority of whom took more than 12 supplements at least 4 days per week, were compared to the age-matched control group. Disease and smoking status were not exclusion criteria for the supplement group. Telomere length was measured by quantitative PCR to determine the telomere-to-single copy gene (T/S) ratio. Change in T/S ratio over time was fitted to a linear regression. Blood biomarkers were also assessed.

Overall, women had longer telomeres than men in the control group, but this trend was reversed in the supplement group. T/S ratio of the supplement group was 11.2% greater than that of the control group (p<0.0001). Supplementation resulted in a greater treatment effect in men vs. women (p<0.005). By linear regression, the rate of change in T/S ratio was reduced by 40% in the supplement group vs control. Blood biomarkers in both groups were comparable and were within the normal physiological ranges.

The results of this cross-sectional study suggest that heavy dietary supplementation significantly attenuated telomere shortening in subjects compared to a healthy control group. Longitudinal studies are warranted to further explore the link between nutritional supplementation and healthy aging in the context of reduced rate of telomere shortening.

**IS DIETARY FIBER THERAPEUTICALLY BENEFICIAL? A SYSTEMATIC REVIEW OF PUBLISHED META-ANALYSES ON FIBER. McRae, M**, National University of Health Sciences, Lombard, Illinois.

Dietary fiber is recognized as a food component that is important for preventing and managing a variety of diseases. To examine the efficacy of dietary fiber’s role as a therapeutic agent, a systematic review of all published meta-analyses found in PubMed was performed. A total of 36 meta-analyses were found. All 8 meta-analyses on cholesterol showed significant reductions in total cholesterol and LDL cholesterol. All 6 meta-analyses on fasting blood glucose and all 4 meta-analyses on HbA1c found significant reductions. The relative risk of developing type II diabetes was significantly reduced in two meta-analyses. Two meta-analyses found a significant decrease in diastolic blood pressure, and 3 meta-analyses found a significant reduction in the relative risk of stroke. The relative risk of developing colorectal cancer was significantly reduced in 3 separate studies.

**NUTRITIONAL STATUS OF PATIENTS TREATED AT A CENTER SPECIALIZING IN SPINAL DISEASES. Pereira AS, Santos RLB, Vargas ICS, Department Fundamental Nutrition, School of Nutrition, Federal University of the State of Rio de Janeiro, Rio de Janeiro, Brazil.**

Patients with degenerative spine disease usually show overweight and inflammatory process. The objective of the present work was to evaluate the nutritional status of patients attended in nutrition service of public hospital reference in spine diseases. This study was realized between January and June of 2014. The anthropometric status was evaluated by weight and height using digital scale and stadiometer Welmy. Biochemical evaluation was made by the institution laboratory. Food consumption was verified by a 24 hours recall. Parameters of Nutritional surveillance (SISVAN) were used to classify the nutritional status. Food consumption was evaluated using food composition tables. Of the 40 subjects,
29 patients participated in the study, eleven showed no haematological and / or biochemical evaluation. Of this total, 65.52% were female. The mean age was 55.58 ± 10.75 months for women and 52.00 ± 8.87 months for men. Weight averages were for women and men, respectively: 81.26 ± 16.61 kg and 90.12 ± 12.09 kg, since for height were 1.60 ± 0.07 m and 1.71 ± 0.05 m, respectively. The mean BMI was 30.69 ± 3.45 kg/m2 for men and 31.49 ± 5.04 kg/m2.

The prevalence of normal weight and overweight were: 17.24% and 82.76%. Men showed average for glucose (113.50 ± 30.60 mg / dL), LDL (148.50 ± 112.99 mg / dL) and waist circumference (101.20 ± 6.49 cm). While women showed average for glucose (99.32 ± 26.98 mg / dL), LDL (104.00 ± 19.24 mg / dL) and waist circumference (94.42 ± 19.98 cm). Men showed average for Total Energy Value (TEV) (1879.40 ± 685.55 kcal), percentage of carbohydrate (53.89 ± 9.32), percentage of protein (19.71 ± 9.94), percentage of lipids (26.40 ± 11.45), fibers (24.39 ± 7.70 g), Omega 6 (7.47 ± 5.66 g) and Omega 3 (0.70 ± 0.38 g). The women showed average for Total Energy Value (TEV) (1384.30 ± 520.31 kcal), percentage of carbohydrate (52.74 ± 11.73), percentage of protein (17.27 ± 6.97), Percent lipids (29.99 ± 13.68), fibers (22.36 ± 8.61 g), Omega 6 (6.63 ± 5.07 g) and Omega 3 (1.19 ± 1.58 g).


The objective of the present work was to compile all original scientific literature related to glutamine supplementation by adult men and women practicing different levels of physical activity, evaluating its possible effects on performance, strength or endurance exercises, body composition and immune function. This work aimed to review systematically and meta-analyze data from previously published articles with original scientific contributions. Using electronic indexed data bases (Scopus and NCBI) in addition to manual search in different Rio de Janeiro city public University libraries (UNIRIO, UFRJ e UERJ). The following key-words were used: “supplement”, “glutamine”, “performance” and “body composition”, limited to works written in English, Portuguese and Spanish. Inclusion criteria: adult individuals, strength or endurance training and L-glutamine or glutamine peptide supplementation, published between January/2000 and September/2013. After the application of selection criteria, 113 remained to full reading and judicious selection. After final exclusions, 12 works were selected and qualitative/quantitative data processed. This systematic review was able to show that glutamine supplementation seems to lower feelings of fatigue, improve the physical performance, muscle recovery, raise exercise-induced plasma Interleukin-6 levels, show ergogenic effects through rehydration and partially or fully prevent suppression of neutrophil function, hyperammonemia and apoptosis of human lymphocytes from athletes under diverse tested conditions. It may have none or little effect in Immunoglobulin-A values and short-term supplementation seems to be ineffective in weight lifting performance.

Metabolic Abnormalities in Patients Preparing for Male Infertility Management. Altema E, Rothkopf MM, Seaman E, Morristown Medical Center, Morristown, NJ.

Obesity and Metabolic Syndrome are known to influence male sexual function and fertility. Weight loss has been suggested as an adjunctive approach for improving testosterone levels and sperm counts. In this study, we conducted an evaluation of possible contributing metabolic disturbances among patients referred in preparation of male infertility management.

3 male obese patients with sexual dysfunction and infertility were evaluated. Each was seen by a metabolic physician and a registered dietician. Initially, each patient underwent testing for insulin resistance, impaired glucose tolerance, major vitamin and mineral deficiency, hyperlipidemia, and hormonal imbalance. All patients were counseled on the concepts relating to carbohydrate restriction as a possible treatment modality for their condition.

All 3 patients had impaired glucose tolerance and insulin resistance. 2 patients had low total and free testosterone. 1 patient had hypothyroidism. 2 patients had vitamin D deficiency. One patient...
had hyperprolactinemia with a level of 19 ng/ml (normal range=4-15). This patient underwent pituitary MRI evaluation which revealed a diffusely enlarged gland.

Obese patients referred in preparation of male infertility management may demonstrate significant metabolic abnormalities including impaired glucose tolerance, insulin resistance, hypotestosteronism, hypothyroidism, hyperprolactinemia and vitamin D deficiency. These findings underscore the importance of a thorough metabolic evaluation in patients with male infertility.

EFFECT OF METABOLIC MANAGEMENT IN A TYPE 2 DIABETES (T2DM) PATIENT WITH INSULIN ALLERGY (IA). Scalan D, Rothkopf MM, Morristown Medical Center, Morristown, NJ.

The American Academy of Clinical Endocrinologist 2013 Clinical Algorithm for the treatment of T2DM identified lifestyle modification and pharmaceutical options to treat type 2 diabetes. At our Center, we utilize aggressive lifestyle and incretin-mimetic therapy in T2DM patients with retained endogenous insulin capacity. This approach may have special utility in T2DM patients with IA. A 63 year old male with a 20 year history of T2DM presented at a weight of 282.2 pounds, and a BMI of 34.32. He had been on insulin for 10 years and developed IA. Despite being to insulin by an allergist, his IA persisted and precluded him from achievement of glycemic control. His fasting glucose (FBG) was 152 mg/dl and the glycated Hb (A1C) was 8.6% despite glargine insulin (glargin) 50 units BID, 6 units of prandial lispro insulin (lispro), metformin 1000 BID and sitiglertin 100 mg/d. We started a strict low carbohydrate diet and recommended exercise. A metabolic workup was ordered.

After 4 weeks, he lost 1.5 pounds and his glargine was reduced to 35 units BID. The metabolic workup revealed a C-Peptide of 4.1 ng/ml and a proinsulin of 20.1 pmol/L indicating sufficient insulin production. His Homa IR score was 9.95, indicating severe insulin resistance. Liragluditide 1.8 mg daily was added. After 8 weeks, he had lost of total of 11.7 pounds. His glargine was reduced to 15 units BID. His FBGs were 80 to 150 mg/dl, pre-dinner glucose were 93 to 166 mg/dl. He had several episodes of morning hygoglycemia. His evening meal lispro was reduced to 4 units. After another 12 weeks, he had lost of total of 13.7 pounds. His prandial lispro was reduced to 3 units. His A1C decreased from 8.6% to 6.9%.

This patient demonstrated weight loss, improved glycemic control and reduction of exogenous insulin intake through adherence of a low carbohydrate diet, and the addition of an incretin mimetic. Of note, he was able to accomplish these improvements without exercise. Our treatment approach combining lifestyle and incretin-mimetic therapy may have special utility in the T2DM patient with IA.

AREA UNDER THE CURVE RATIO SCORE: A NOVEL APPROACH TO INTERPRETING INSULIN RESISTANCE WITH THE ORAL GLUCOSE TOLERANCE TEST. Sawhney A, Rothkopf MM, Rothkopf Z, Morristown Medical Center, Morristown, NJ.

Introduction: A reliable method for assessing insulin resistance (IR) does not exist for the clinic setting. Our center utilizes clinical data (acanthosis nigrans, central obesity, hyperandrogenism) and an oral glucose tolerance test with insulin response (OGTT-Ins) to determine if a patient has IR. However, interpreting the OGTT-Ins curves is subjective and sometimes difficult to reproduce. The development of a numerical method to interpret the data may improve OGTT interpretation and diagnostic precision.

Methods: The charts of 50 adult patients at center with a diagnosis of obesity (BMI >30), clinical IGT, and IR were retrospectively reviewed. Each patient had previously undergone a 75 gram, multi sample, 3-hour oral glucose tolerance test with insulin response (OGTT-Ins). Data from the paired glucose and insulin levels obtained at 0, 30, 60, 90, 120 minutes was analyzed. Data from the OGTT-Ins was used to construct curves. Inclusion criteria for the glucose curves included serum glucose levels that exceeded: 100 at 0 minutes, 180 at 30 minutes, 150 at 60 minutes and 140 at 90 and 120 minutes. Inclusion criteria for the insulin curves included serum insulin levels that exceeded: 17 at 0 minutes, 100 at 30 minutes and 60 minutes and a 4:1 glucose to insulin ratio at 90 and 120 minutes. The area under the curves (AUC) was calculated using the trapezoid
approximation method for the sample data between 0 and 120 minutes. The AUC for glucose (AUC-g) and insulin (AUC-i) and the ratio of AUC-g and AUC-i were calculated. The ratio of AUC-g and AUC-i was recorded as a glucose to insulin AUC ratio “score” (AUC-sc).

Results: 10 patients did not meet inclusion criteria. The analyzed data set contained 40 patients. AUC-g ranged from 10.695 to 28.845 with a mean of 18.022.88+/-4460.18. The AUC-i ranged from 4,230 to 29,107.5 with a mean of 12,391.73+/-5,787.19. AUC-sc ranged from 0.568 to 4.06 with a mean of 1.77+/-0.85.

Conclusion: Calculation of the AUC-g, AUC-i and AUC-sc can assist in interpreting the data from a OGTT and OGTT-Ins. In our study population an AUC-sc less of < 4.06 correlated with the clinical presence of IR.

COMBINATION THERAPY WITH LIRAGLUTIDE AND LAPROSCOPIC GASTRIC BANDING (LAGB) TO ACHIEVE TYPE 2 DIABETES RESOLUTION (T2DMR). Rothkopf MM, Melzer OA, Rothkopf ZS, Morristown Medical Center, Morristown, NJ.

Background: LAGB surgery can achieve T2DMr in ~50% of cases, especially in patients with diabetes of recent onset. But, procedures such as gastric bypass (RYGB) and biliopancreatic diversion (BPD) yield higher rates of T2DMr, presumably because they enhance incretin entero-hormone stimulation. Postprandial glucagon-like peptide-1 (GLP-1) increases after RYGB and BPD, but not after LAGB. Incretin pharmacotherapy to enhance T2DMr after LAGB is generally avoided because of concern for vomiting and band slippage. We have previously described our experience with the administration of exenatide in diabetic LAGB patients. In this report, we examine the T2DMr effect of liraglutide in diabetic LAGB patients.

Methods: After IRB approval, the charts of 36 LAGB diabetic patients who were administered liraglutide post-operatively between 2010 and 2013 were retrospectively reviewed. Any adverse effects were noted. Patients whose diabetes resolved after liraglutide were selected for intensive analysis. Age, gender, initial weight, post-LAGB weight, post-LAGB hemoglobin A1C (hbA1C), post-liraglutide weight and post-liraglutide hbA1C were recorded in these cases. The data was analyzed using a paired, two-tailed t-test.

Results: There were no reports of band slippage among LAGB patients receiving liraglutide. 11 patients (30.5%) with long standing diabetes (13.87±4.08 years) experienced T2DMr after liraglutide. T2DMr patients ranged in age from 50 to 70, with a mean age of 61.1 years. Seven (63.6%) were female, 4 were male. The pre-LAGB weight was 239.25±36.06, which reduced to 195.8±31.5 post-LAGB (p<.001). The post-LAGB hbA1C in this group was 7.5±1.36 prior to liraglutide administration. After liraglutide, weight decreased slightly 188.5±27.41 (p=.06) whereas hbA1c decreased significantly to 6.18±.61 (p=.001).

Conclusion: Nearly a third of persistently diabetic LAGB patients experienced T2DMr after liraglutide with a significant decrease in hbA1c. Liraglutide was well tolerated in LAGB patients with no reports of band slippage. A modest, non-significant improvement in weight loss was seen after liraglutide administration. Further study is needed to better define the role of incretin pharmacotherapy in persistently diabetic patients after LAGB and other gastric restrictive procedures.

THE MODIFIED ATKINS DIET: AN APPROACH TO PROMOTE PATIENT COMPLIANCE. Roque S, Rothkopf MM, Morristown Medical Center, Morristown, NJ.

A Modified Atkins diet (MAD), including the option of inducing ketogenesis, has been suggested as an adjunctive approach for adult patients with recalcitrant seizure disorder. Such nutritional management has the potential of reducing seizure activity and the need for anti-convulsant medications. The MAD was created at Johns Hopkins Hospital in an effort to create a less restrictive dietary option for children and adolescents. It has since gained popularity among the adult population as well.

Historically, the initiation of a MAD in adults is still quite restrictive, with a 15 gram carbohydrate/day induction, which may be increased to 20-30 grams/day after 1 month. In our Metabolic Center, we previously evaluated 12 patients with seizure disorder for initiation of a MAD. In the
process, we identified metabolic abnormalities including insulin resistance, impaired glucose tolerance, hyperlipidemia, vitamin D deficiency, vitamin A deficiency, vitamin B12 deficiency, decreased testosterone, elevated prolactin, and decreased free T3. Not only have some of our patients seen a reduction in seizure activity, but upon successful initiation of a MAD, we have seen improvement in their metabolic abnormalities.

There are a variety of ways to initiate a MAD and possibly induce ketogenesis. At our Metabolic Center, we prefer to take a more gradual approach in an effort to reduce patient resistance to the MAD. The majority of our patients will be started on a 40 gram carbohydrate/day plan, which is a higher carbohydrate allowance. Patients are provided with dietary counseling by an epilepsy-focused Registered Dietitian. They receive tools to aide with carbohydrate counting, a written protocol with specific guidelines, as well as sample meal plans. Patients are not required to weigh or measure foods with the exception of counting carbohydrates, as there is no strict fat:protein+carb ratio to adhere to. They are encouraged to liberally include healthy fats to promote ketogenesis. Patients follow up with the Metabolic Physician and Registered Dietitian approximately every 4 weeks. If no change in seizure activity is seen, carbohydrates will be further reduced as clinical need guides us.

Of our 12 patients following a MAD, 5 required further carbohydrate restriction in order to promote results. Of those 5 patients, 4 did achieve reduction in seizure activity once we counseled them on a lower daily carbohydrate allowance. Compliance was assessed at follow up visits by dietary recall and/or review of the patient’s food journal. We feel our approach of initiating the MAD at a higher carbohydrate level and decreasing only if needed allows our patients to live a less restrictive lifestyle, which will enhance patient compliance long term, without compromising results.

VARIANT PHENYLKETONURIA (PKU) DISCOVERED AFTER ROUX-EN Y GASTRIC BY-PASS (RYGB). Rothkopf MM, Melzer OA, Bertha NA, Morristown Medical Center, Morristown, NJ.

Introduction: Subclinical inborn errors of metabolism (IEM) may go unnoticed until adulthood. PKU is an autosomal recessive condition resulting from mutations in the phenylalanine hydroxylase (PAH) gene or PAH co-factor tetrahydrobiopterin (BH4). Classic PKU presents with levels of phenylalanine (Phe) > 1200 µmol/L, whereas non-classic, or variant PKU (V-PKU) have Phe levels < 600 µmol/L. Dietary Phe restriction is essential to prevent neurologic damage in all forms of PKU. Therefore, it is important to recognize clues that may lead to diagnosis.

Case description: A 31 year old morbidly obese female was referred to our service with nausea, vomiting, dehydration and malnutrition 2.5 months after RYGB. She received parenteral nutrition, was diagnosed with symptomatic cholecystitis, and underwent successful laparoscopic cholecystectomy. She reported a lifelong history of aspartame (Asp) intolerance which became problematic post-operatively because of its presence in bariatric protein supplements. She had no significant family history and underwent age-appropriate childhood screening. She had normal early neurologic development but required special education to complete high school. She tolerated dietary protein, but favored excessive starches, which led to her obesity. Our metabolic evaluation revealed an elevated level of Phe at 120 nmol/ml (normal 35-80), decreased level of tyrosine (Tyr) at 27 nmol/ml (normal 31-90) and elevated Phe/Tyr ratio of 4.4 (normal <3). These findings are consistent with V-PKU.

Discussion: Most classical PKU cases are diagnosed at birth through mandatory newborn screening. The literature contains sparse reports of missed PKU patients, including adults who were born before newborn screening took place in the 1960s. V-PKU or hyperphenylalaninemia (HPA) may go undetected because the Phe levels are not high enough to detect through newborn screening methods. Asp is a Phe containing compound which must be avoided in patients with all forms of PKU and HPA.

Conclusion: This patient’s Asp intolerance was a significant clue to her eventual diagnosis of V-PKU. Metabolic physicians must be prepared to diagnose subclinical IEM in adults. V-PKU or HPA should be suspected in Asp-sensitive patients and ruled out by amino acid analysis.
TREATMENT DILEMMA: A PATIENT (PT) WITH VITAMIN D DEFICIENCY (VDD) AND SARCOIDOSIS. Haverstick L, Rothkopf MM, Morristown Medical Center, Morristown, NJ.

A 43 year old female was referred for metabolic weight management. She is 59” tall and weighs 188.2 pounds. Her BMI is 38.00, Obesity class II. Her past medical history is positive for sarcoidosis. She was treated with steroids and methotrexate which caused significant weight gain. She underwent a metabolic evaluation including a three hour glucose tolerance test, vitamin levels and hormone levels along with a comprehensive metabolic profile, NMR lipid panel and CBC with differential. Her results revealed reactive hypoglycemia, insulin resistance, VDD. Her vitamin D (VD) was low at 20.5 ng/ml. Her serum calcium was normal at 9.0 mg/dl. The National Osteoporosis Society (NOS) has developed a practical clinical guideline for patient management of Vitamin D (VD) and bone health. Based on recommendations from the Institute of Medicine (IOM), it answers key questions related to the best measure to assess VD status, which pts to screen for VDD, and gives treatment and monitoring guidelines to assess the response to treatment. The goals of treatment are to correct the deficiency in a timely manner and avoid toxicity.

For most pts diagnosed with VDD, the decision to treat is fairly straightforward. This is not the situation when the pt has VDD and sarcoidosis. Disorders of calcium metabolism are frequently encountered in sarcoidosis, an inflammatory disease of unknown etiology which often leads to the development of granulomas in diffuse organs of the body. Hypercalcemia and hypercalciuria with decreased bone mass, are frequently encountered. These defects are due to increased production of 1,25 Dihydroxy VD (calcitriol) in activated macrophages. The result is an increase in gut calcium absorption and resorption of calcium in the bone. 25 OH VD is the direct precursor of calcitriol.

What would be the recommendation for treating VDD in a pt with sarcoidosis who is at risk for developing hypercalciumia and nephrocalcinosis? Our approach is to start by determining the extent of VDD along with serum calcium and parathyroid hormone (PTH) levels. Angiotensin converting enzyme levels (ACE) should be evaluated to determine sarcoidosis activity. In our practice, we withheld VD in pts with active sarcoidosis. Further research is needed to determine when treatment should be started, the type of VD and level of supplementation, the length of therapy and the correct process of monitoring to reduce risk and improve outcomes for improved bone health.

MERATRIM® MODULATES ADIPOGENESIS AND LIPOLYSIS IN 3T3-L1 ADIPOCYTES. Saiyed ZM¹, Lugo JP¹, Hull J¹, Xu W¹, Trimurtulu G², Krishnaraju AV², Sengupta K², ¹InterHealth Nutraceuticals, Benicia, CA; ²Laila Nutraceuticals, Vijayawada, India.

Meratrim® is a novel formulation containing extracts from Sphaeranthus indicus flower heads and Garcinia mangostana fruit rind. Clinical studies have demonstrated that Meratrim is effective and well-tolerated for weight management. The objective of the current study was to evaluate the possible mechanisms by which Meratrim exerts its weight-reducing benefits. Differentiation of mouse 3T3-L1 pre-adipocytes to mature adipocytes was used to assess the anti-adipogenic properties of Meratrim, while its lipolytic activity was measured in mature adipocytes by monitoring the release of the lipolytic by-product glycerol. We also tested the effect of Meratrim on expression of key biomarkers that control adipogenesis and lipogenesis. Meratrim markedly down-regulated the expression of lipogenic markers including fatty acid synthase, peroxisome proliferator-activated receptor gamma (PPARγ), adipocyte-differentiation related protein (ADRP), and cluster of differentiation 36 (CD36) but increased adiponectin. These effects were dose-dependent. 3T3-L1 cells treated with Meratrim also exhibited smaller lipid droplets and increased glycerol release into cell culture medium, consistent with increased lipolysis. Meratrim treatment further reduced the expression and the recruitment of perilipin onto the membrane of lipid droplets, which may increase hydrolysis of stored lipids by lipases. Increases in the phosphorylation of AMP-activated protein kinase (AMPK) and acetyl CoA carboxylase, both of which regulates fatty acid β-oxidation and synthesis further supports Meratrim’s potential to stimulate lipolysis. Collec-
tively, these observations imply that Meratrim downmodulates adipocyte differentiation, fatty acid synthesis and uptake of cholesteryl esters by adipocytes, while increasing fatty acid β-oxidation

**HESPERIDIN SUPPLEMENTATION MODULATES INFLAMMATORY RESPONSES FOLLOWING MYOCARDIAL INFARCTION.** Haidari F, Heybar H, Jalali MT, Ahmadi Engali K, Helli B, Shirbeigi E, Nutrition and Metabolic Diseases Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

Objective: A growing number of studies suggested a crucial role for a variety of inflammatory mediators in myocardial infarction. Recently, several flavonoids have been shown to have cardioprotective and anti-inflammatory properties. Therefore, the aim of this study was to investigate the effect of Hesperidin—a common constituent of citrus fruits—on the serum levels of inflammatory markers and adipocytocines in patients with myocardial infarction.

Methods: Seventy-five patients with myocardial infarction were participated in this randomized, double-blind controlled clinical trial and were assigned to two intervention and control groups. Subjects consumed 600 mg/day pure Hesperidin supplement and placebo in intervention and control group, respectively for 4 wk. Serum concentration of inflammatory markers and adipocytocines were measured at the baseline and end of the intervention.

Results: Consumption of 600 mg/day Hesperidin significantly decreased the serum levels of E-selectin and increased adiponectin and HDL-C concentrations in patients with myocardial infarction. The improvement in other inflammatory markers, such as IL-6, hs-CRP, leptin, and other lipid profile was also observed at the end of the intervention, compared with the baseline values, but the difference between the Hesperidin and placebo groups was not statistically significant (P>0.05).

Conclusion: Hesperidin supplementation could compensate decreased levels of adiponectin and HDL-C, and increased levels of E-selectin in patients with myocardial infarction. These results support the concept that certain flavonoids in the diet can be associated with significant health benefits, including heart health.

**PATTERN OF USE AND EFFECT OF GYM SUPPLEMENTS – A CROSS-SECTIONAL STUDY.** Singh K*, Sain AK, Goel D, Vashishth D, Ahad F, Sharma H, Sharma P, Dr. Aditi, Rahul Bansal Department of Community Medicine, Subharti Medical College, Meerut, India.

Increasing sedentary lifestyle in people living in metropolitan cities has increased the use of gym supplements in order to lose weight. The environment created in the fitness centres promotes use of stereotypes and aesthetic products. These products seem to enhance sports performance and physical appearance. We conducted a cross-sectional study to find out pattern of use and the effects of gym supplements in the gym attenders of Meerut. We investigated effects of taking supplements in our study subjects using a predesigned close ended questionnaire.

Study involved 50 individuals (18-55 years of age) of Meerut taking gym supplements on regular basis (more than thrice a week). Pre-designed questionnaire was used as the study tool.

Mean age 36 years. (2%) Majority of people are of 20 years out of which 9 out of 50 are attending gym regularly i.e. 5 days in a week to improve muscle mass and energy status. The most common adverse effect associated is fatigue in 34% gym goers i.e. (17 out of 50), which was followed by loss of appetite (12%) i.e. (6 out of 50). Besides this hair loss and diarrhea were also observed. Liver injury and kidney related problems were found to be 1 out of 50.

In conclusion, gym attenders are mostly conscious about their diet as well as intake of gym supplements. However, they are unwilling to give up taking supplements, having faced dependence and withdrawal symptoms.

**THE DEVELOPMENT AND VALIDATION OF THE FAMILY EATING AND ENVIRONMENTAL DIMENSIONS INDEX.** Tabbakh T, Freeland-Graves J, Department of Nutritional Sciences, University of Texas at Austin, Austin, TX.
The home environment is an important setting for the development of obesity during adolescence. Thus, it is a prime target for obesity-prevention interventions. At present, there is a paucity of psychometrically sound instruments that assess the home environment of adolescents. The goal of this research was to develop a questionnaire, the Family Eating and Environmental Dimensions (FEED) Index. This tool includes multiple components of the home, including psychological, social, and environmental domains. Items were generated based on a literature review and a focus group. The resultant questionnaire was evaluated for content validity by an expert panel. The final version was administered to 100 mother-adolescent dyads for validity and reliability. Sub-scales on the questionnaires exhibited high construct validity, internal consistency reliability and test-retest reliability. The FEED Index is a promising tool for assessment of the home environment of young adolescents.


Myostatin inhibits satellite cell activation and muscle growth. Fortetropin, a natural dietary supplement, suppresses serum myostatin. We investigated the effects of Fortetropin on skeletal muscle growth and strength in modestly trained individuals. 45 males in 3 groups received placebo, 1 or 3X dose of Fortetropin for 12 weeks. Subjects participated in a supervised resistance training program. Body composition was measured by DXA and ultrasonography. A significant increase (p<0.05) was observed in lean body mass for the active arms compared to placebo arm. There was a significant increase (p<0.05) in muscle thickness in the active arms as compared to the placebo arm. Our findings indicate that Fortetropin increases lean body mass and muscle thickness in modestly trained males.

RE-FEEDING ASPIRATED DIGESTIVE JUICES TO ENZYMATICALLY INSURE FEEDING CATHETER PATENCY. Moss, G, Biomedical Engineering Department Rensselaer Polytechnic Institute, Troy, NY.

Feeding-decompression catheters are prone to clogging. The digestive juices they remove are invariably discarded. These can be re-fed, to enzymatically dissolve these clogs and prevent blockage of the catheter. As a secondary benefit, they also contain secretory globulins that can protect vulnerable patients against infection by their own colonic organisms. The volume of aspirate is relatively low. The flow can be increased with a "controlled leak" between the feeding and suction channels, analogous to an A-V fistula. Dual lumen feeding-decompression catheters were modified by micro-drilling a pin-hole connection between the distal feeding and aspiration channels. This increased the volume of aspirate to be re-cycled for flushing ten-fold, from ~1.5 ml to ~15 ml per cycle. A pair of collection burettes was positioned five feet above the patient. Continuous suction was applied alternately, at 30 second intervals, to each burette. These chambers were connected by one-way valves to the catheter’s aspiration and feeding channels. The filtered aspirate was directed by the one-way valves to the burette on suction for collection and degassing. Excess was removed automatically when necessary to avoid overfeeding. The valves directed the gravity flow of degassed aspirate, which had been collected the previous cycle from the burette now off suction. This joined the continuous 3,000 ml/day flow of elemental diet. When total inflow (feedings plus fed aspirate) exceeded peristaltic outflow from the feeding site, excess rose in the collection burette. Volume >30 ml overflowed, to be discarded before causing local duodenal distention and the harmful complex of "overfeeding."
In our experience, 3 - 4 liters/day of aspirated digestive secretions were temporarily removed and degassed by this automatic system. The permanently removed fluid was only ~200 ml/day after resective surgery, before the adverse symptoms of “overfeeding” could be triggered. The degree of presumed protection that is afforded against catheter clogging has not yet been objectively determined. We reported that experimental and clinical immediately postoperative enteral nutrition at ≥3,000 kcal/day resulted in accelerated wound healing, enhanced immune competence, and decreased length of stay.

THE EFFICACY OF A POPULAR LOW-CARBOHYDRATE WEIGHT LOSS PROGRAM: AN OPEN-LABEL, REMOTE STUDY USING A PROPRIETARY ELECTRONIC COMPLIANCE SYSTEM. Udani JK¹, Pakdaman MN¹, ¹Medicus Research, Agoura Hills, CA.

The benefits of a remote study include the convenience for study participants, the ability to recruit nationwide, and direct digital data collection. The Dukan diet is a protein based diet widely followed in France. Using our past experience as a virtual CRO, we aimed to design a remote study to assess the efficacy of The Dukan Diet in supporting and maintaining healthy weight loss. Healthy volunteers who have been determined by the Dukan Diet web-based system to be 25 pounds or more above their calculated “true weight” were enrolled into this open-label, remote study. Individuals who previously participated in the Dukan Diet were excluded. Participants complete a web-based screening tool, followed by telephone screening and remote clinical evaluation. If qualified, participants receive a proprietary smartphone application-based compliance software and are enrolled in a 24-week online coaching program. Forty-nine individuals successfully completed the run-in period as well as the “attack” and “cruise” phases of the The Dukan Diet. Mean weight at baseline was 188.7 +/- 34.2 pounds. A statistically significant weight loss of 1.9 pounds was demonstrated by week 2 (p<0.001). By week 24, the mean weight was 176.9 +/- 34.2 pounds, corresponding to a mean weight loss of 11.7 pounds compared to baseline (p<0.0001).

Our data demonstrates a statistically significant, steady weight loss among subjects enrolled in the Dukan Diet over the course of 24 weeks. Additionally, the eCompliance application suite, consisting of eFood and eScale is a successful innovative monitoring system that allows daily tracking of study compliance.

DISCLAIMER: 4-week data for this study was presented at the Scripps Scripps 11th Annual Natural Supplements Conference; Jan 29-Feb 1, 2014; San Diego, CA. This current submission is of the completed 24-week study.

EVALUATING THE EFFECT OF CYRUTA®, A-F BETAFOOD®, AND SOYBEAN LECITHIN ON LIPID PROFILE IN A MODERATELY AT-RISK POPULATION: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY. Udani JK¹, Arscott SA², Pakdaman MN¹, ¹Medicus Research LLC, Agoura Hills CA, ²Standard Process Inc. Palmyra WI.

We performed a randomized, double-blind, parallel, placebo-controlled study aimed at comparing the effects of Cyruta, A-F Betafood, and Soybean Lecithin versus placebo in improving the lipid profile in subjects with moderate dyslipidemia. Healthy adults between 30 and 60 years-of-age with either low-density lipoprotein (LDL) > 130 mg/dL or triglycerides > 150 mg/dL and no history of significant cardiovascular disease were randomized to receive either a combination of three dietary supplements or a placebo. Primary endpoints included total cholesterol (TC), LDL, high density lipoprotein (HDL), and triglycerides. Analysis of covariance (ANCOVA) analysis was performed to normalize any discrepancy in baseline means between groups. One hundred sixteen subjects were screened and 59 were randomized to receive either placebo (n=30) or study product (n=29). A total of 42 subjects completed the study (22 in active group, 20 in placebo group). The ANCOVA adjusted total cholesterol at month 6 was found to be 16.56 mg/dL lower in the active (215.16 mg/dL) compared to placebo group (231.72 mg/dL) (p=0.013).
Odds ratio analysis found that after 6 months of intervention, those in the active group had 4.0 times the odds of reduced TC and 6.31 times the odds of reduced LDL cholesterol compared to placebo (p< 0.05)
Consumption of Cyruta, A-F Betafood, and Soybean Lecithin is safe and effective in supporting healthy total and LDL cholesterol without reducing HDL levels. Along with other appropriate dietary and lifestyle modifications, this protocol may offer an additional beneficial strategy for supporting healthy cholesterol levels


ASSESSING THE EFFICACY OF THE GNLD NEOLIFESHAKE PROTEIN-BASED MEAL REPLACEMENT PRODUCT ON WEIGHT LOSS.

Weight management continues to be a huge concern for the population. We aimed to evaluate the efficacy of the GNLD NeoLifeShake protein-based meal replacement product on weight loss and markers of metabolic health among overweight and obese men and women. Overweight and obese subjects were enrolled in a 12-week open-label study where two meals per day were replaced with a 180-calorie shake comprised of 18g protein and 5g dietary fiber. Measured endpoints included weight and anthropometric measures, as well as lipid profile and other biomarkers. The protocol did not enforce any additional dietary restrictions or exercise programs.

A total of 68 individuals were enrolled in the study. The mean age of subjects was 39 +/- 10 years, mean weight was 184 +/- 23.4 lbs and mean BMI was 29.78 +/- 2.50 kg/m². At the end of the study, subjects were found to lose an average of 5.27 pounds compared to baseline (p<0.001). The BMI decreased to 29.12 (p=0.001) kg/m² and hip circumference decreased from 42.82 inches at baseline to 42.28 inches at week 12 (p=0.051). Additionally, low density lipoprotein (LDL) levels decreased from 108.6 mg/dL at baseline to 92.13 mg/dL (p=0.018).

This study demonstrates that in the absence of other changes in diet or exercise, meal replacement with the GNLD NeoLifeShake protein-based product supports a healthy and consistent weight loss and a healthy lipid profile.