30582753\_PD.tx

Title: Using misoprostol to treat postpartum hemorrhage in home deliveries attended by traditional birth attendants.

Publication Type: Randomized Controlled Trial

Journal-Name:International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics

Journal ID: 0210174

Publication date: 2018/12/21 00:00 [accepted]

OBJECTIVE: To explore the clinical and programmatic feasibility of using 800 mug of sublingual misoprostol to prevent and treat <P 0> postpartum hemorrhage (PPH) </> during home delivery. METHODS: The present double-blind randomized controlled trial included women who underwent home deliveries in Chitral district, Khyber Pakhtunkhwa province, Pakistan, after presenting at healthcare facilities during the third trimester of pregnancy between May 28, 2012, and November 27, 2014. Participants were randomized in a 1:1 ratio to receive either 800 mug of misoprostol or placebo sublingually if PPH was diagnosed, having previously received a prophylactic oral dose of 600 mug misoprostol. The primary outcome, <P 0> hemoglobin </> decrease of 20 g/L or greater from pre- to post-delivery assessment, was compared on a modified intention-to-treat basis. RESULTS: There were 49 patients allocated to receive misoprostol and 38 allocated to receive placebo; the incidence of a 20 g/L decrease in <P 0> hemoglobin </> was similar between the groups (20/43 [47%] vs 19/33 [58%], respectively; P=0.335). CONCLUSION: There was no significant difference in clinical outcomes between the two trial arms. ClinicalTrials.gov:NCT01485562.

30583518\_PD.txt

Title: Navy Beans Impact the <P 0> Stool Metabolome </> and <P 0> Metabolic </> Pathways for Colon Health in Cancer Survivors.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2018/12/17 00:00 [accepted]

Colorectal cancer (CRC) is the third leading cause of cancer-related death in the United States and emerging evidence supports that increased consumption of legumes, such as navy beans, can reduce risk. Navy bean consumption was previously shown to modulate host and microbiome metabolism, and this investigation was performed to assess the impact on the human <P 0> stool metabolome </>, which includes the presence of <P 0> navy bean metabolites </>. This 4-week, randomized-controlled trial with overweight and obese CRC survivors involved consumption of 1 meal and 1 snack daily. The intervention contained 35 g of cooked navy bean or macronutrient matched meals and snacks with 0 g of navy beans for the control group (n = 18). There were 30 statistically significant <P 0> metabolite </> differences in the stool of participants that consumed navy bean at day 28 compared to the participants' baseline (p </= 0.05) and 26 significantly different <P 0> metabolites </> when compared to the control group. Of the 560 total <P 0> metabolites </> identified from the cooked navy beans, there were 237 possible <P 0> navy bean-derived metabolites </> that were identified in the stool of participants consuming navy beans, such as <P 0> N-methylpipecolate </>, <P 0> 2-aminoadipate </>, <P 0> piperidine </>, and <P 0> vanillate </>. The microbial <P 0>(S2) metabolism of amino acids <P 0> and fatty acids </> were also identified in stool after 4 weeks of navy bean intake including <P 0> cadaverine </>, <P 0> hydantoin-5 propionic acid </>, <P 0> 4-hydroxyphenylacetate </>, and <P 0> caprylate </>. The stool relative abundance of <P 0> ophthalmate </> increased 5.25-fold for navy bean consumers that can indicate glutathione regulation, and involving cancer control mechanisms such as detoxification of xenobiotics, antioxidant defense, proliferation, and apoptosis. <P 0> Metabolic </> pathways involving <P 0> lysine </>, and <P 0> phytochemicals </> were also modulated by navy bean intake in CRC survivors. These <P 0> metabolites </> and <P 0> metabolic </> pathways represent an acute response to increased navy bean intake, which merit further investigation for improving colonic health after long-term consumption.

30583763\_PD.txt

Title: Use of a robotic walking aid in rehabilitation to reduce <P 28> fear of falling </> is <P 32> feasible </> and <P 32> acceptable </> from the end user's perspective: A randomised comparative study.

Publication Type: Randomized Controlled Trial

Journal-Name:Maturitas

Journal ID: 7807333

Publication date: 2018/11/13 00:00 [accepted]

Objectives To determine the <P 32> acceptability </> and <P 32> feasibility </> of the use of a robotic walking aid to support the work of physiotherapists in reducing <P 28> fear of falling </> in the rehabilitation of elderly patients with 'psychomotor disadaptation' (the most severe form of post-fall syndrome). Study design 20 participants with psychomotor disadaptation admitted to an academic rehabilitation ward were randomised to receive physiotherapist care supported by the SafeWalker(R) robotic walking aid or standard care only, for ten days. SafeWalker(R) supports the body weight whilst securing postural stability without relying on upper body strength or high cognitive demand. Main outcome measures The primary outcome was the <P 32> feasibility </> and <P 32> acceptability </> of rehabilitation sessions at five and ten days based on (i) questionnaires completed by patient and physiotherapist, (ii) the number of <P 25> steps </> performed during sessions, (iii) <P 32> replacement </> of a robotic session by a conventional one. Results The mean age of the participants was 85.2 years. They had lost their ability to perform some basic living activities. Patients in the intervention group found that the rehabilitation sessions were <P 32> easier </> (p = 0.048). No robotic rehabilitation session had to be <P 32> replaced </> by conventional rehabilitation. There were no statistical differences between the two groups on the other outcome measures. Conclusion We demonstrated the <P 32> feasibility </> and <P 32> acceptability </> of the use of a robotic walking aid from the perspective of both older individuals and physiotherapists. This could fill the gap between devices that fully compensate for walking and those which allow patients to maintain residual mobility.

30584287\_PD.txt

Title: A randomized-controlled trial pilot study examining the effect of extracorporeal magnetic innervation in the treatment of stress urinary incontinence in women.

Publication Type: Randomized Controlled Trial

Journal-Name:Clinical interventions in aging

Journal ID: 101273480

Publication date: 2019/02/12 06:00 [medline]

Introduction: Peri- and postmenopausal women frequently suffer from urinary incontinence (UI). Generally, UI becomes more severe with age. It impacts physical, mental, and social functioning as well as the quality of life, often leading to depression. Extracorporeal magnetic innervation (ExMI) is a relatively new conservative treatment method for UI. Objective: The aim of the study was to assess the effectiveness of ExMI in the treatment of stress UI in women. Methods: A total of 52 women were included in the analysis: 28 participants were allocated to the experimental group (EG) and 24 to the control group (CG). The average age was 65.41 years (+/-SD 4.08). EG patients completed ExMI therapy. The treatment sessions lasted for 15 minutes, and occurred three times a week, for 4 weeks. No therapeutic intervention was applied to the CG. To objectify the treatment outcomes in both groups before and after the treatment, we measured myostatin concentration and performed the <P 0> urinary incontinence severity </> assessment ([T The Revised <P 0> Urinary Incontinence </> Scale]), perceived <P 28> self-efficacy </> assessment (General <P 28> Self-Efficacy </> Scale), and <P 0, 28> depression </> severity assessment ([T Beck <P 0, 28> Depression </> Inventory]). Results: The authors compared the EG results at the initial and final assessments and found a statistically significant improvement in severity of <P 0> urinary incontinence </> (P=0.001) and <P 0, 28> depression </> severity (P=0.006), and a decrease in <P 0> myostatin </> concentration (P</=0.001). The authors did not find any statistically significant differences between all measured variables for the CG at the initial and final assessments. Furthermore, there were no statistically significant differences between all measured variables for the EG and the CG at the final assessment. Conclusion: Further trials are needed to determine optimal treatment protocols for various UI types and to evaluate long-term outcomes of the ExMI treatment.

30584459\_PD.txt

Title: A Double-Blind Placebo-Controlled Randomized Trial Evaluating the Effect of Polyphenol-Rich Herbal Congee on <P 0> Bone Turnover </> Markers of the Perimenopausal and Menopausal Women.

Publication Type: Randomized Controlled Trial

Journal-Name:Oxidative medicine and cellular longevity

Journal ID: 101479826

Publication date: 2018/10/16 00:00 [accepted]

Based on the benefit of polyphenolic compounds on osteoporosis, we hypothesized that the polyphenol-rich herbal congee containing the combined extract of Morus alba and Polygonum odoratum leaves should improve <P 0> bone turnover </> markers in menopausal women. To test this hypothesis, a randomized double-blind placebo-controlled study was performed. A total of 45 menopausal participants were recruited in this study. They were randomly divided into placebo, D1, and D2 groups, respectively. The subjects in D1 and D2 groups must consume the congee containing the combined extract of M. alba and P. odoratum leaves at doses of 50 and 1500 mg/day, respectively. At the end of an 8-week consumption period, all subjects were determined serum <P 0> bone </> markers including <P 0> calcium </>, <P 0> alkaline phosphatase </>, <P 0> osteocalcin </>, and <P 0> beta CTX </>. In addition, the <P 0> hematological </> and blood <P 0> clinical chemistry </> changes, and total <P 0> phenolic </> content in the serum were also determined. The results showed that the menopausal women in D2 group increased serum <P 0> alkaline phosphatase </>, <P 0> osteocalcin </>, and total <P 0> phenolic </> compounds content but decreased <P 0> CTX </> level. Clinical safety assessment failed to show toxicity and <P 38> adverse effects </>. Therefore, herbal congee containing the combined extract of M. alba and P. odoratum leaves is the potential functional food that can decrease the risk of osteoporosis.

30584461\_PD.txt

Title: Dark Chocolate Intake Positively Modulates <P 0> Redox </> Status and Markers of <P 0> Muscular Damage </> in Elite Football Athletes: A Randomized Controlled Study.

Publication Type: Randomized Controlled Trial

Journal-Name:Oxidative medicine and cellular longevity

Journal ID: 101479826

Publication date: 2018/12/26 06:00 [entrez]

Intensive physical exercise may cause increase oxidative stress and muscular injury in elite football athletes. The aim of this study was to exploit the effect of cocoa polyphenols on <P 0> oxidative stress </> and <P 0> muscular injuries </> induced by intensive physical exercise in elite football players. <P 0> Oxidant/antioxidant </> status and markers of <P 0> muscle damage </> were evaluated in 24 elite football players and 15 controls. Furthermore, the 24 elite football players were randomly assigned to either a dark chocolate (>85% cocoa) intake (n = 12) or a control group (n = 12) for 30 days in a randomized controlled trial. <P 0> Oxidative stress </>, <P 0> antioxidant status </>, and <P 0> muscle damage </> were assessed at baseline and after 30 days of chocolate intake. Compared to controls, elite football players showed lower <P 0> antioxidant power </> and higher <P 0> oxidative stress </> paralleled by an increase in <P 0> muscle damage </> markers. After 30 days of dark chocolate intake, an increased <P 0> antioxidant power </> was found in elite athletes assuming dark chocolate. Moreover, a significant reduction in <P 0> muscle damage </> markers (<P 0> CK </> and <P 0> LDH </>, p < 0.001) was observed. In the control group, no changes were observed with the exception of an increase of <P 0> sNox2-dp </>, <P 0> H2O2 </>, and <P 0> myoglobin </>. A simple linear regression analysis showed that <P 0> sNox2-dp </> was associated with a significant increase in <P 0> muscle damage </> biomarker release (p = 0.001). An in vitro study also confirmed that polyphenol extracts significantly decreased oxidative stress in murine myoblast cell line C2C12-derived. These results indicate that polyphenol-rich nutrient supplementation by means of dark chocolate positively modulates <P 0> redox </> status and reduced exercise-induced <P 0> muscular injury </> biomarkers in elite football athletes. This trial is registered with NCT03288623.

30586261\_PD.txt

Title: Halobetasol and Tazarotene: Further Defining the Role of a Unique Fixed Combination Topical Lotion in Moderate-to-Severe Plaque Psoriasis

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of drugs in dermatology : JDD

Journal ID: 101160020

Publication date: 2019/02/05 06:00 [medline]

Background: A unique fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) lotion has been shown to be effective in psoriasis using [T Investigator Global Assessment (IGA)] tools to assess erythema, plaque elevation, and scaling. However, these do not consider changes in [T Body Surface Area (BSA)]. The [T IGAxBSA] composite tool is a simple, effective, validated alternative for measuring improvement in psoriasis severity. It correlates well with the [T Psoriasis Area and Severity Index (PASI)] and demonstrates sensitivity to changes from baseline in patients with both mild and moderately severe disease. Objective: To further define the role of a fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) lotion in moderate-to-severe plaque psoriasis using the [T IGAxBSA] composite tool. Methods: Post hoc analysis of 212 patients with moderate-to-severe plaque psoriasis randomized (2:2:2:1) to HP/TAZ lotion, HP, TAZ, or vehicle once-daily for 8 weeks, with a 4-week posttreatment follow-up. Efficacy assessments using the validated [T IGAxBSA] composite tool. Results: HP/TAZ lotion demonstrated statistically significant superiority at week 8 (versus TAZ and vehicle) and week 12 (versus HP, TAZ, and vehicle). By week 8, HP/TAZ lotion achieved a 63.5% reduction in mean [T IGAxBSA] composite score (P<0.001 versus TAZ and vehicle), that was sustained four weeks posttreatment (P<0.001 versus TAZ and vehicle and P=0.003 versus HP). A 25% and 50% improvement in [T IGAxBSA] was achieved within 1.9 and 4.6 weeks, respectively, and 47.5% of patients achieved IGAxBSA-75 by week 8. Limitations: This post hoc analysis was limited to patients with moderate-to-severe plaque psoriasis with IGA >/=3 and BSA involvement (3%-12%). Conclusions: HP/TAZ lotion was associated with significant and rapid reductions in <P 0> disease severity </> as assessed by the [T IGAxBSA] composite tool. The addition of tazarotene affords sustained benefits posttreatment. J Drugs Dermatol. 2018;17(12):1290-1296.

30586843\_PD.txt

Title: Metabolizable <P 0> Energy </> from Cashew Nuts is Less than that Predicted by Atwater Factors.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2018/12/18 00:00 [accepted]

Recent studies have demonstrated that the energy provided by several tree nuts is less than that predicted by the Atwater factors, though energy available from cashews has never been assessed. The objective of this study was to evaluate the metabolizable energy in cashew nuts. Eighteen healthy adults were enrolled in a randomized, crossover study with two treatment periods. Subjects were fed a fully controlled base diet for 4 weeks with either no additions or with the addition of 42 g/day (1.5 servings) of cashew nuts, with the final treatment diets being isocaloric. Complete diet collections were analyzed for nitrogen (for protein), fat, energy, and carbohydrate by difference. During the final week of each intervention phase, subjects collected all feces and urine produced, and these were also analyzed for <P 0> nitrogen </> (feces and urine), <P 0> energy </> (feces and urine), and <P 0> fat </> (feces). The resulting data were used to calculate the metabolizable energy of cashews and the digestibility of macronutrients. The average available energy (calorie) content of a 28 g serving of cashew nuts was 137 kcal (+/-3.4 kcal SEM) and ranged from 105 to 151 kcal. The mean value of 137 kcal/serving is 16% lower (p < 0.0001) than what is typically found on food labels. Digestibility of energy, fat, protein, and carbohydrate was lower for the cashew-containing diet compared to the control diet (92.9% vs. 94.9%, p < 0.0001 for energy; 96.1% vs. 97.8%, p = 0.0009 for fat; 90.1% vs. 91.2%, p = 0.0012 for protein; 92.9% vs. 94.9%, p < 0.0001 for carbohydrate; for the cashew-containing diet vs. the control diet, respectively). In conclusion, cashews provide fewer calories than the values predicted by the Atwater factors, as found on current food labels.

30587165\_PD.txt

Title: The addition of simvastatin administration to cold storage solution of explanted whole liver grafts for facing ischemia/reperfusion injury in an area with a low rate of deceased donation: a monocentric randomized controlled double-blinded phase 2 study.

Publication Type: Clinical Trial, Phase II

Journal-Name:BMC surgery

Journal ID: 100968567

Publication date: 2018/12/28 06:00 [entrez]

BACKGROUND: Liver transplantation is the best treatment for end-stage liver disease. The interruption of the blood supply to the donor liver during cold storage damages the liver, affecting how well the liver will function after transplant. The drug Simvastatin may help to protect donor livers against this damage and improve outcomes for transplant recipients. The aim of this study is to evaluate the benefits of treating the donor liver with Simvastatin compared with the standard transplant procedure. PATIENT AND METHODS: We propose a prospective, double-blinded, randomized phase 2 study of 2 parallel groups of eligible adult patients. We will compare 3-month, 6-month, and 12-month <P 0> graft survival </> after LT, in order to identify a significant relation between the two homogenous groups of LT patients. The two groups only differ by the Simvastatin or placebo administration regimen while following the same procedure, with identical surgical instruments, and medical and nursing skilled staff. To reach these goals, we determined that we needed to recruit 106 patients. This sample size achieves 90% power to detect a difference of 14.6% between the two groups survival using a one-sided binomial test. DISCUSSION: This trial is designed to confirm the effectiveness of Simvastatin to protect healthy and steatotic livers undergoing cold storage and warm reperfusion before transplantation and to evaluate if the addition of Simvastatin translates into improved <P 0> graft </> outcomes. TRIAL REGISTRATION: ISRCTN27083228

30587761\_PD.txt

Title: The Effects of Oral Magnesium Supplementation on <P 0> Glycemic Response </> among Type 2 Diabetes Patients.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2018/10/29 00:00 [accepted]

BACKGROUND: Magnesium (Mg) supplementation may help control glycemic response among type 2 diabetes (T2D) patients. OBJECTIVE: This study means to determine whether Mg supplementation improves <P 0> glycemic control </> indicators in patients with T2D. METHODS: After one week of the dietary stabilization phase, 42 T2D patients were stratified according to sex, age, fasting blood sugar (FBS) and Mg levels and then randomly allocated into two groups. The intervention group was on 250 mg/day of elemental Mg for three months while the control group did not receive any type of supplements throughout the intervention period. RESULTS: The daily administration of 250 mg of elemental Mg indicated a significant improvement in <P 0> HbA1C </> (8.32 to 7.96%, p < 0.001), <P 0> insulin </> levels (IL) (15.56 to 12.18 muIU/mL, p < 0.001), <P 0> C-peptide </> (2.28 to 1.90 ng/mL, p = 0.001), <P 0> HOMA.IR </> (6.16 to 4.44, p < 0.001) and <P 0> HOMA.beta </> % (59.99 to 52.37, p = 0.036) of the intervention group when compared with the control group after three months of intervention. CONCLUSION: The results of this study revealed that oral Mg supplementation reduces <P 0> insulin resistance </> and improves the <P 0> glycemic control </> indicators among T2D patients. TRIAL REGISTRATION: current controlled trials PHRC/HC/32/15. Registered 5 October 2015.