30652777\_PD.txt

Title: Effectiveness of brief group intervention in the harmful alcohol use in primary health care.

Publication Type: Randomized Controlled Trial

Journal-Name:Revista de saude publica

Journal ID: 0135043

Publication date: 2019/01/18 06:00 [entrez]

OBJECTIVE: To verify the effectiveness of brief group intervention, performed by nurses, in reducing the <P 0> hazardous or harmful alcohol use </> in users of a primary health care service. METHODS: Clinical and randomized trial with follow-up of three months. The sample had 180 individuals with a pattern of hazardous or harmful alcohol use, recruited in a Basic Health Unit in the city of Sao Paulo. A sociodemographic questionnaire and the [T <P 0> Alcohol Use Disorders </> Identification Test (Audit)] were applied. The experimental group underwent the Brief Group Intervention, which had four group sessions, with weekly meetings. The control group received an information leaflet about issues related to alcohol consumption. Both groups participated in the follow-up of three months. The linear mixed model was used for data analysis, in which a 5% significance level was adopted. RESULTS: Forty-four individuals under hazardous or harmful alcohol use completed all phases of the research. The experimental group had a statistically significant reduction (p < 0.01) of about 10 points in Audit score after the brief group intervention [before BGI = 15.89 (SD = 6.62) - <P 0> hazardous use </>; after BGI = 6.40 (SD = 5.05) - low <P 0> hazardous use </>] maintaining the low <P 0> hazardous use </> in follow-up [6.69 (SD = 6.38) - low <P 0> hazardous use </>]. The control group had a statistically significant reduction (p </= 0.01) of about three points in Audit score [before BGI = 13.11 (SD = 4.54) - <P 0> hazardous use </>; after BGI = 9.83 (SD = 5.54) - <P 0> hazardous use </>] and in follow-up presented the mean score of 13.00 (SD = 5.70), indicative of <P 0> hazardous use </>. Differences between the two groups (experimental group versus control group) in reduction of <P 0> consumption </> were statistically significant (p </= 0.01). CONCLUSIONS: Our evidence showed that the brief group intervention performed by the nurse in the primary health care context was effective to reduce <P 0> alcohol consumption </> in individuals with patterns of hazardous or harmful use.

30653086\_PD.txt

Title: Effects of selenium supplementation on <P 0> pregnancy outcome </> and <P 0> disease progression </> in HIV-infected pregnant women in Lagos, Nigeria: Study protocol for a randomised, double-blind, placebo-controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/31 06:00 [medline]

BACKGROUND: Micronutrient deficiencies are common during pregnancy, especially in pregnant women from economically disadvantaged settings where diets with low content of minerals and vitamins are consumed. Selenium is a non-metallic chemical element of great importance to human health. This study will assess the effect of selenium supplementation on major <P 0> pregnancy outcomes </> and <P 0> disease progression </> among HIV-infected pregnant women in Lagos, Nigeria. METHODS: A randomized, double-blind, placebo-controlled trial involving confirmed HIV-positive pregnant women at the Lagos University Teaching Hospital (LUTH) between September 2018 and February 2019. Eligible participants are HIV-infected pregnant women aged 15 to 49 years and have a singleton gestation at 14 to 27 weeks' gestation. At enrolment, 90 women will be randomly assigned into each intervention arm to receive either a daily tablet of 200 mug elemental selenium or placebo. Relevant participants' data will be collected at enrolment and at delivery. Statistical analyses will be carried out using SPSS version 23.0 for Windows. The associations between any 2 groups of continuous variables will be tested using the t test or the Mann-Whitney U test and that of 2 groups of categorical variables with chi-square or Fishers exact test where appropriate. A series of multivariable analyses will also be carried out to identify and control for several possible confounders of the major <P 0> pregnancy outcomes </> and <P 0> HIV disease progression </>. Statistical significance will be defined as P < .05. Ethical approval for the study was obtained from the LUTH's Health Research and Ethics Committee (Approval number: ADM/DCST/HREC/APP/2438; 30th August 2018). DISCUSSION: This trial will assess the effect of selenium supplementation on <P 0> pregnancy outcome </> and <P 0> HIV disease progression </> among HIV-infected pregnant women in Lagos. This will help to determine if routine selenium supplementation in HIV-infected pregnant women will contribute to the improvement in the major <P 38> adverse pregnancy outcomes </> such as <P 0> preterm birth </> and <P 0> low birth weight </> and the <P 0> HIV disease </> surrogate markers such as <P 0> CD4+ cells count </> and <P 0> viral load </>. TRIAL REGISTRATION: PACTR, PACTR201809756724274. Registered on 3rd September 2018, https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=3571.

30653147\_PD.txt

Title: Pre-administration of remifentanil in target-controlled propofol and remifentanil anesthesia prolongs <P 32> anesthesia induction </> in neurosurgical patients: A double-blind randomized controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/29 06:00 [medline]

BACKGROUND: Pre- and co-administration of remifentanil in target-controlled propofol and remifentanil anesthesia are the most common methods in clinical practice. However, anesthesia induction time by timing remifentanil administration was not identified. Therefore, we investigated the <P 32> induction time </> of anesthesia based on type of remifentanil administration in target-controlled anesthesia. METHODS: A total of 60 patients were randomly assigned to 1 of 2 groups: Pre-administered with remifentanil before propofol infusion (Group R, n = 30) and co-administered with remifentanil with propofol (Group N, n = 30). The primary outcome was total <P 32> induction time </> based on the order of remifentanil administration. Secondary outcomes were from start of the propofol infusion <P 0> time to loss of consciousness (LOC) </>, <P 32> rocuronium onset time </>, <P 0> time to [T Bispectral index (BIS)] 60 </>, and <P 0> hemodynamic </> variables. RESULTS: The mean +/- SD of total <P 32> induction time </> was 180.5 +/- 49.0 s in Group N and 246.3 +/- 64.7 s in Group R (mean difference: 65.8 seconds; 95% CI: 35.0-96.5 s, P < .01). <P 0> Time to [T Bispectral index (BIS)] 60 </> and <P 32> rocuronium onset time </> were longer in the Group R (P < .01 and P < .01, respectively). The Delta <P 0> heart rate </> and Delta <P 0> cardiac </> output values were lower in the Group R (P = .02 and P = .04, respectively). <P 0> Injection pain </> was reported by 11 of 28 (39%) in the Group N and in 2 of 28 (7%) in the Group R (difference in proportion: 32%, 95% CI: 10-51%, P = .01). CONCLUSION: Pre-administration of remifentanil in target-controlled propofol and remifentanil anesthesia prolongs total <P 32> induction time </> about 35% compared to co-administration of remifentanil and propofol by decreased CO.

30653490\_PD.txt

Title: A randomized trial of AmBisome monotherapy and AmBisome and miltefosine combination to treat visceral leishmaniasis in HIV co-infected patients in Ethiopia.

Publication Type: Randomized Controlled Trial

Journal-Name:PLoS neglected tropical diseases

Journal ID: 101291488

Publication date: 2019/01/18 06:00 [entrez]

BACKGROUND: Visceral leishmaniasis (VL) in human immunodeficiency virus (HIV) co-infected patients requires special case management. AmBisome monotherapy at 40 mg/kg is recommended by the World Health Organization. The objective of the study was to assess if a combination of a lower dose of AmBisome with miltefosine would show acceptable efficacy at the end of treatment. METHODOLOGY/PRINCIPAL FINDINGS: An open-label, non-comparative randomized trial of AmBisome (30 mg/kg) with miltefosine (100 mg/day for 28 days), and AmBisome monotherapy (40 mg/kg) was conducted in Ethiopian VL patients co-infected with HIV (NCT02011958). A sequential design was used with a triangular continuation region. The primary outcome was <P 0> parasite clearance </> at day 29, after the first round of treatment. Patients with clinical improvement but without parasite clearance at day 29 received a second round of the allocated treatment. Efficacy was evaluated again at day 58, after completion of treatment. Recruitment was stopped after inclusion of 19 and 39 patients in monotherapy and combination arms respectively, as per pre-specified stopping rules. At D29, intention-to-treat efficacy in the AmBisome arm was 70% (95% CI 45-87%) in the unadjusted analysis, and 50% (95% CI 27-73%) in the adjusted analysis, while in the combination arm, it was 81% (95% CI 67-90%) and 67% (95% CI 48-82%) respectively. At D58, the adjusted efficacy was 55% (95% CI 32-78%) in the monotherapy arm, and 88% (95% CI 79-98%) in the combination arm. No major safety concerns related to the study medication were identified. Ten <P 38> SAEs </> were observed within the treatment period, and 4 <P 1> deaths </> unrelated to the study medication. CONCLUSIONS/SIGNIFICANCE: The extended treatment strategy with the combination regimen showed the highest documented efficacy in HIV-VL patients; these results support a recommendation of this regimen as first-line treatment strategy for HIV-VL patients in eastern Africa. TRIAL REGISTRATION NUMBER: www.clinicaltrials.gov NCT02011958.

30658629\_PD.txt

Title: The impact of an exercise program on <P 30> quality of life </> in older breast cancer survivors undergoing aromatase inhibitor therapy: a randomized controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Health and quality of life outcomes

Journal ID: 101153626

Publication date: 2019/01/20 06:00 [entrez]

BACKGROUND: This study evaluated the impact of an exercise program on <P 30> quality of life </> in older breast cancer survivors undergoing aromatase inhibitor therapy. METHODS: Older breast cancer survivors were randomized into two groups: combined training: resistance + aerobic exercise program for nine months (n = 18) or control group (n = 18). <P 30> Quality of life </> was assessed by the questionnaires SF36, EORTC QLQ-C30, and EORTC QLQ-BR23 at baseline, and at three, six, and nine months. The exercise group performed 40 min of resistance exercises on machines followed by 30 min of aerobic training on a treadmill 3x/wk. Repeated measures ANOVA was used to compare the groups over time. RESULTS: Significant time x group interactions and moderate to high effect sizes were found for <P 25> physical functioning </>, <P 0> physical health </>, <P 0> bodily pain </>, <P 31> general health perception </>, <P 0> vitality </>, <P 26> social functioning </>, <P 0> fatigue </>, <P 0> sleep disturbance </>, <P 28> body image </>, and <P 28> upset </> by hair loss, favoring the exercise group. CONCLUSION: This study demonstrated the potential benefits and high clinical relevance of exercise programs to improve <P 30> quality of life </> in older breast cancer survivors undergoing aromatase inhibitor therapy.

30662380\_PD.txt

Title: A Feasibility RCT Evaluating a Play-Informed, Caregiver-Implemented, Home-Based Intervention to Improve the <P 25> Play </> of Children Who Are HIV Positive.

Publication Type: Randomized Controlled Trial

Journal-Name:Occupational therapy international

Journal ID: 9433361

Publication date: 2019/01/22 06:00 [entrez]

Background/aim: In South Africa, contextual factors have been identified as barriers to outdoor, unstructured play. The human immunodeficiency virus (HIV) and resulting progressive HIV encephalopathy (PHE) is a pandemic in this area, associated with development delays that are not addressed by highly active antiretroviral treatment (HAART). This study aimed to describe the <P 28> playfulness </> in children with HIV and PHE on HAART living in challenging socioeconomic areas in South Africa aged 6 months to 8 years and to evaluate the <P 32> feasibility </> and preliminary effectiveness of a play-informed, caregiver-implemented, home-based intervention (PICIHBI) for improving play. Methods: A feasibility randomized control trial allowed for comparison of PICIHBI and conventional one-on-one occupational therapy interventions. Children were filmed playing pre-, mid-, and postintervention, using the [T Test of <P 28> Playfulness </> (ToP)] to assess <P 28> playfulness </>. The PICIHBI comprised of 10 monthly sessions facilitated by an occupational therapist, involving group discussions with caregivers and periods of experiential play. Results: Twenty-four children with HIV and/or PHE were randomized into one of the two intervention groups. Overall, the group (n = 24) had a median score of 0 (lowest item score) on nine of 24 [T Test of <P 28> Playfulness </> (ToP)] items and only had a median score of 3 (highest score) on two items. Pre- to postintervention overall [T Test of <P 28> Playfulness </> (ToP)] scores improved marginally for the PICIHBI group (n = 12) and the conventional group (n = 12). Between-group differences were not significant. The PICIHBI group demonstrated a significant increase in one [T Test of <P 28> Playfulness </> (ToP)] item score at midassessment. No significant ToP item changes were found in the conventional group. Conclusion: Children with HIV were found to have the most difficulty on [T Test of <P 28> Playfulness </> (ToP)] items relating to the <P 25> play </> elements of <P 28> internal control </> and <P 28> freedom from constraints of reality </>. The PICIHBI did not significantly improve children's <P 25> play </> and was not more effective than the conventional intervention. Considerations for feasibility and effectiveness, including barriers to attendance, are discussed.

30664882\_PD.txt

Title: A randomized comparative study between intravenous and intramuscular scorpion antivenom regimens in children.

Publication Type: Randomized Controlled Trial

Journal-Name:Toxicon : official journal of the International Society on Toxinology

Journal ID: 1307333

Publication date: 2019/01/13 00:00 [accepted]

BACKGROUND: Scorpion envenomation and its consequences represented a serious healthcare problem in Upper Egypt and considered to be an important cause of life-threatening emergency particularly in children. METHODS: One hundred patients presented to the emergency department of Assiut University Children Hospital with a history of scorpion sting aged less than 18 years were included in our randomized comparative trial during 2016. Two groups of patients were randomly categorized according to the route of administration of scorpion antivenom; intramuscular and intravenous with 50 patients in each group. Full history, clinical examination, and routine baseline investigations were performed. RESULTS: <P 0> Myocarditis </>, <P 0> encephalopathy </>, <P 0> cardiogenic shock </>, <P 35> ICU admission </>, <P 36> need for mechanical ventilation </>, mean <P 35> hospital stay </> and <P 1> mortality </> were significantly lower in those received intravenous antivenom compared with those received intramuscular one. CONCLUSION: The results of the present study and other experimental and clinical trials confirmed that the administration of the scorpion antivenom by intravenous route has a lower incidence of systemic <P 38> toxicity </>, a better outcome of <P 1> fatal </> complication resulted from envenomation especially <P 0> cardiogenic shock </>, decreased <P 35> need for ICU </> facilities and <P 36> mechanical ventilation </>, shorter <P 35> hospital stay </>, and better overall outcome than the intramuscular route. TRIAL REGISTRATION NUMBER: UMIN-CTR Study Design: trial number: UMIN000022032.

30665323\_PD.txt

Title: Denosumab effects on serum levels of the bone morphogenetic proteins antagonist <P 0> noggin </> in patients with transfusion-dependent thalassemia and osteoporosis.

Publication Type: Journal Article

Journal-Name:Hematology (Amsterdam, Netherlands)

Journal ID: 9708388

Publication date: 2019/03/01 06:00 [medline]

INTRODUCTION: Noggin is an antagonist of bone morphogenetic proteins (BMPs) and has a strong effect on osteogenesis. Osteoporosis is a common complication of transfusion dependent beta-thalassemia (TDT) and denosumab has been recently emerged as a promising therapeutic option. This was a post hoc investigation of serum <P 0> noggin </> levels among TDT patients with osteoporosis who participated in a randomized, placebo-control, phase 2b study. METHODS: Patients received either 60 mg denosumab (n = 32) or placebo (n = 31) every 6 months for 12 months. <P 0> Noggin </> was measured, for the first time in thalassemia patients, at baseline and at 12 months, using a recently developed high sensitivity fluorescent immunoassay. RESULTS: Both groups showed a significant increase in <P 0> noggin </> serum levels (denosumab p < 0.001; placebo p < 0.0001). Interestingly, the increase was higher in the placebo group. Furthermore, we observed a strong correlation between <P 0> noggin </> and <P 0> wrist bone mineral density </> (r = -0.641, p = 0.002) only in the denosumab group. CONCLUSION: In conclusion, higher <P 0> noggin </> levels reflected more BMP inhibition, since our assay detects free bioactive <P 0> noggin </>, which in turn impaired bone formation in placebo group. Therefore, denosumab possibly regulates <P 0> noggin </> and favours bone turnover in TDT patients with osteoporosis through a novel mechanism of action.

30665436\_PD.txt

Title: Vitamin D and probiotic co-supplementation affects <P 0, 28> mental health </>, <P 0> hormonal </>, <P 0> inflammatory </> and <P 0> oxidative stress </> parameters in women with polycystic ovary syndrome.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of ovarian research

Journal ID: 101474849

Publication date: 2019/01/23 06:00 [entrez]

OBJECTIVE: The aim of this study was to determine the effect of vitamin D and probiotic co-administration on <P 0, 28> mental health </>, <P 0> hormonal </>, <P 0> inflammatory </> and <P 0> oxidative stress </> parameters in women with polycystic ovary syndrome (PCOS). METHODS: This randomized, double-blinded, placebo-controlled clinical trial was carried out on 60 subjects, aged 18-40 years old. Subjects were randomly allocated to take either 50,000 IU vitamin D every 2 weeks plus 8 x 10(9) CFU/day probiotic (n = 30) or placebo (n = 30) for 12 weeks. RESULTS: Vitamin D and probiotic co-supplementation, compared with the placebo, significantly improved beck <P 0, 28> depression </> inventory [beta (difference in the mean of outcomes measures between treatment groups) - 0.58; 95% CI, - 1.15, - 0.02; P = 0.04], <P 0> general health </> questionnaire scores (beta - 0.93; 95% CI, - 1.78, - 0.08; P = 0.03) and <P 0, 28> depression </>, <P 0, 28> anxiety </> and <P 28> stress </> scale scores (beta - 0.90; 95% CI, - 1.67, - 0.13; P = 0.02). Vitamin D and probiotic co-supplementation was associated with a significant reduction in total <P 0> testosterone </> (beta - 0.19 ng/mL; 95% CI, - 0.28, - 0.10; P < 0.001), <P 0> hirsutism </> (beta - 0.95; 95% CI, - 1.39, - 0.51; P < 0.001), <P 0> high-sensitivity C-reactive protein (hs-CRP) </> (beta - 0.67 mg/L; 95% CI, - 0.97, - 0.38; P < 0.001) and <P 0> malondialdehyde (MDA) </> levels (beta - 0.25 mumol/L; 95% CI, - 0.40, - 0.10; P = 0.001), and a significant increase in total <P 0> antioxidant </> capacity (TAC) (beta 82.81 mmol/L; 95% CI, 42.86, 122.75; P < 0.001) and total <P 0> glutathione (GSH) </> levels (beta 40.42 mumol/L; 95% CI, 4.69, 76.19; P = 0.02), compared with the placebo. CONCLUSIONS: Overall, the co-administration of vitamin D and probiotic for 12 weeks to women with PCOS had beneficial effects on <P 0, 28> mental health </> parameters, serum total <P 0> testosterone </>, <P 0> hirsutism </>, <P 0> high-sensitivity C-reactive protein (hs-CRP) </>, plasma total <P 0> antioxidant </> capacity (TAC), <P 0> glutathione (GSH) </> and <P 0> malondialdehyde (MDA) </> levels. TRIAL REGISTRATION: This study was retrospectively registered in the Iranian website ( www.irct.ir ) for registration of clinical trials ( IRCT20170513033941N37 ).

30665439\_PD.txt

Title: Effects of ascorbic acid supplementation on <P 0> oxidative stress </> markers in healthy women following a single bout of exercise.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of the International Society of Sports Nutrition

Journal ID: 101234168

Publication date: 2019/01/23 06:00 [entrez]

BACKGROUND: Ascorbic acid is a water-soluble chain breaking antioxidant. It scavenges free radicals and reactive oxygen species (ROS), which are produced during metabolic pathways. Exercise can produce an imbalance between ROS and antioxidants, leading to oxidative stress-related tissue damages. This study was designed to determine the effects of ascorbic acid supplementation on circulating biomarkers of <P 0> oxidative stress </> and <P 0> muscle damage </> following a single bout of exercise. METHODS: In a crossover design with a 1 wk. wash-out period, 19 healthy women performed 30 min moderate-intensity cycling after ingesting 1000 mg of ascorbic acid (AA) or placebo. Blood samples were taken immediately before, immediately after and 30 min post-exercise to determine plasma <P 0> albumin </>, total <P 0> protein </>, <P 0> glucose </>, <P 0> oxidative stress </> and <P 0> muscle damage </> markers. RESULTS: Plasma <P 0> albumin </> and total <P 0> protein </> levels increased immediately after exercise in placebo alongside slight reductions in <P 0> glucose </> (p = 0.001). These effects were absent in AA cohort. <P 0> Ferric reducing </> ability of plasma and <P 0> vitamin C </> levels in AA cohort significantly increased after exercise (p < 0.05). <P 0> Superoxide dismutase </> activity was significantly elevated after exercise (p = 0.002) in placebo but not AA. Plasma <P 0> malondialdehyde </> did not change after exercise in placebo but was significantly decreased in AA (p < 0.05). The exercise protocol promoted slight <P 0> muscle damage </>, reflected in significant increases in total <P 0> creatine kinase </> in all subjects after exercise. On the other hand, plasma <P 0> C-reactive protein </> and <P 0> lactate dehydrogenase </> remained unchanged. CONCLUSION: Supplementation with ascorbic acid prior exercise improves <P 0> antioxidant </> power but does not prevent <P 0> muscle damage </>.