30547749\_PD.txt

Title: Effectiveness of repellent delivered through village health volunteers on <P 0> malaria </> incidence in villages in South-East Myanmar: a stepped-wedge cluster-randomised controlled trial protocol.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC infectious diseases

Journal ID: 100968551

Publication date: 2018/12/15 06:00 [entrez]

BACKGROUND: To combat emerging drug resistance in the Greater Mekong Sub-region (GMS) the World Health Organization and GMS countries have committed to eliminating malaria in the region by 2030. The overall approach includes providing universal access to diagnosis and treatment of malaria, and sustainable preventive measures, including vector control. Topical repellents are an intervention that can be used to target residual malaria transmission not covered by long lasting insecticide nets and indoor residual spraying. Although there is strong evidence that topical repellents protect against mosquito bites, evidence is not well established for the effectiveness of repellents distributed as part of malaria control activities in protecting against episodes of malaria. A common approach to deliver malaria services is to assign Village Health Volunteers (VHVs) to villages, particularly where limited or no services exist. The proposed trial aims to provide evidence for the effectiveness of repellent distributed through VHVs in reducing <P 0> malaria </>. METHODS: The study is an open stepped-wedge cluster-randomised controlled trial randomised at the village level. Using this approach, repellent (N,N-diethyl-benzamide - 12% w/w, cream) is distributed by VHVs in villages sequentially throughout the malaria transmission season. Villages will be grouped into blocks, with blocks transitioned monthly from control (no repellent) to intervention states (to receive repellent) across 14 monthly intervals in random order). This follows a 4-week baseline period where all villages do not receive repellent. The primary endpoint is defined as the number of individuals positive for <P 0>(E1) Plasmodium falciparum and <P 0> Plasmodium vivax infections </> diagnosed by a rapid diagnostic test. Secondary endpoints include <P 0> symptomatic malaria </>, Polymerase Chain Reaction (PCR)-detectable <P 0> Plasmodium spp Infections </>, molecular markers of <P 0> drug resistance </> and <P 0> antibodies specific for Plasmodium spp Parasites </>. DISCUSSION: This study has been approved by relevant institutional ethics committees in Myanmar and Australia. Results will be disseminated through workshops, conferences and peer-reviewed publications. Findings will contribute to a better understanding of the optimal distribution mechanisms of repellent, context specific effectiveness and inform policy makers and implementers of malaria elimination programs in the GMS. TRIAL REGISTRATION: Australian and New Zealand Clinical Trials Registry ( ACTRN12616001434482 ). Retrospectively registered 14th October 2016.

30547750\_PD.txt

Title: Repeated doses of Praziquantel in Schistosomiasis Treatment (RePST) - single versus multiple praziquantel treatments in school-aged children in Cote d'Ivoire: a study protocol for an open-label, randomised controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC infectious diseases

Journal ID: 100968551

Publication date: 2018/12/15 06:00 [entrez]

BACKGROUND: Large scale administration of the anthelminthic drug praziquantel (PZQ) to at-risk populations is the cornerstone of schistosomiasis control, although persisting high prevalence of infections in some areas and growing concerns of PZQ resistance have revealed the limitations of this strategy. Most studies assessing PZQ efficacy have used relatively insensitive parasitological diagnostics, such as the Kato-Katz (KK) and urine-filtration methods, thereby overestimating cure rates (CRs). This study aims to determine the efficacy of repeated PZQ treatments against <P 0> Schistosoma mansoni infection </> in school-aged children in Cote d'Ivoire using the traditional KK technique, as well as more sensitive antigen- and DNA-detection methods. METHODS: An open-label, randomised controlled trial will be conducted in school-aged children (5 to 18 years) from the region of Taabo, Cote d'Ivoire, an area endemic for S. mansoni. This 8-week trial includes four two-weekly standard doses of PZQ in the "intense treatment" intervention group and one standard dose of PZQ in the "standard treatment" control group. The efficacy of PZQ will be evaluated in stool samples using the KK technique and real-time PCR as well as in urine using the point-of-care circulating cathodic antigen test and the up-converting phosphor, lateral flow, circulating anodic antigen assay. The primary outcome of the study will be the difference in <P 0> cure </> rate of intense versus standard treatment with PZQ on individuals with a confirmed S.mansoni infection measured by KK. Secondary outcomes include the difference in <P 0> cure </> rate and <P 0> intensity </> reduction rate between the intense and standard treatment groups as measured by the other diagnostic tests, as well as the accuracy of the different diagnostic tests, and the safety of PZQ. DISCUSSION: This study will provide data on the efficacy of repeated PZQ treatment on the clearance of S.mansoni as measured by several diagnostic techniques. These findings will inform future mass drug administration policy and shed light on position of novel diagnostic tools to evaluate schistosomiasis control strategies. TRIAL REGISTRATION: The study is registered at EudraCT (2016-003017-10, date of registration: 22 July 2016) and ( NCT02868385 , date of registration: 16 August 2016).

30550321\_PD.txt

Title: How mindfulness training promotes <P 28> positive emotions </>: Dismantling acceptance skills training in two randomized controlled trials.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of personality and social psychology

Journal ID: 0014171

Publication date: 2018/12/15 06:00 [pubmed]

Mindfulness meditation interventions-which train skills in monitoring present-moment experiences with a lens of acceptance-have shown promise for increasing positive emotions. Using a theory-based approach, we hypothesized that learning acceptance skills in mindfulness interventions helps people notice more positive experiences in daily life, and tested whether removing acceptance training from mindfulness interventions would eliminate intervention-related boosts in positive affect. In 2 randomized controlled trials (RCTs) of stressed community adults, mindfulness skills were dismantled into 2 structurally equivalent interventions: (a) training in both monitoring and acceptance (Monitor + Accept) and (b) training in monitoring only (Monitor Only) without acceptance training. Study 1 tested 8-week group-based Monitor + Accept and Monitor Only interventions compared with a no treatment control group. Study 2 tested 2-week smartphone-based Monitor + Accept and Monitor Only interventions compared with an active control training. In both studies, <P 28>(E2) end-of-day and <P 28> momentary positive affect </> and <P 28> negative affect </> were measured in daily life for 3 days pre- and post-intervention using ambulatory assessments. As predicted, across 2 RCTs, Monitor + Accept training increased <P 28> positive affect </> compared with both Monitor Only and control groups. In Study 1, this effect was observed in <P 28> end-of-day positive affect </>. In Study 2, this effect was found in both <P 28>(E2) end-of-day and <P 28> momentary positive affect </> outcomes. In contrast, all active interventions in Studies 1 and 2 decreased <P 28> negative affect </>. These studies provide the first experimental evidence that developing an orientation of acceptance toward present-moment experiences is a central mechanism of mindfulness interventions for boosting <P 28> positive emotions </> in daily life. (PsycINFO Database Record (c) 2018 APA, all rights reserved).

30551654\_PD.txt

Title: Role of Lactobacillus rhamnosus (FloraActive) 19070-2 and Lactobacillus reuteri (FloraActive) 12246 in Infant Colic: A Randomized Dietary Study.

Publication Type: Journal Article

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2018/12/10 00:00 [accepted]

Infant colic is a common condition of unknown pathogenesis that brings frustration to families seeking for effective management. Accumulating evidence suggests that some single strains of lactobacilli may play a positive dietary role in attenuation of colic in exclusively breastfed infants. The objective of this study was to evaluate a mixture of two Lactobacillus strains in decreasing <P 28>(S1) infant cry <P 28> and fuss </> in this population. Infants aged 4(-)12 weeks received L. rhamnosus 19070-2 and L. reuteri 12246 in a daily dose of 250 x 10(6) CFU, 3.33 mg of fructooligosaccharide, and 200 IU of vitamin D(3) (84 infants, probiotic group) or just vitamin D(3) (84 infants, control group) for 28 days. <P 28>(E1) Cry and <P 28> fuss time </> were measured with validated [T Baby's Day Diary] on days 0 and 28. At baseline, mean (SD) duration of <P 28>(E1) cry and <P 28> fuss time </> was comparable in the probiotic and control groups: 305 (81) vs. 315 (90) min., respectively (p = 0.450). On day 28, mean <P 28>(E1) cry and <P 28> fuss time </> became statistically different: 142 (89) vs. 199 (72), respectively (p < 0.05). Mean change in <P 28>(E1) cry and <P 28> fuss time </> from day 0 through day 28 was -163 (99) minutes in the probiotic and -116 (94) minutes in the control group (p = 0.019). Our findings confirm that lactobacilli decrease <P 28>(E1) cry and <P 28> fuss time </> and provide a <P 0> dietary support </> in exclusively breastfed infants with colic.

30551783\_PD.txt

Title: The immediate <P 0> sensorimotor </> effects of elbow orthoses in patients with lateral elbow tendinopathy: a prospective crossover study.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of shoulder and elbow surgery

Journal ID: 9206499

Publication date: 2018/08/29 00:00 [accepted]

BACKGROUND: Counterforce orthoses are used to manage lateral elbow tendinopathy, and their effectiveness in improving motor function has been documented. Little is known about the impact of bracing on sensory function. The objective of this study was to investigate the immediate effectiveness of 2 counterforce orthoses in improving the <P 0> sensorimotor </> abilities of the hand in patients with lateral elbow tendinopathy. METHODS: In this crossover, randomized controlled trial, <P 0> elbow proprioception </>, <P 0> pain severity </>, <P 25> pain-free grip strength </>, and <P 25> finger dexterity </> were measured in 50 participants with a diagnosis of lateral elbow tendinopathy. Outcomes were measured in 3 randomized conditions (no brace, forearm band, or elbow sleeve). Data were analyzed using 1-way repeated-measures analysis of variance for each outcome measure. RESULTS: Better scores were observed with the forearm band, as compared with no orthosis, for multiple outcomes including <P 0> joint position reproduction </> score at 70 degrees of elbow flexion (P = .006), <P 0> pain </> (P < .001), <P 25> grip strength </> (P = .01), and <P 0> dexterity </> (P < .001). The elbow sleeve yielded better scores than no orthosis for the following outcomes: <P 0> joint position reproduction </> score at 110 degrees (P < .001), <P 0> pain </> (P < .001), and <P 25> grip strength </> (P = .012). No statistically significant difference was found between the orthoses' effects on <P 0> pain </> reduction and <P 25> grip strength </> (P > .05). The forearm band showed better scores on <P 0> joint position reproduction </> at 70 degrees compared with the elbow sleeve (P = .006), whereas the elbow sleeve showed better scores at 110 degrees (P < .001). CONCLUSION: Our results support the mechanisms occurring with the use of either of the described orthotic interventions. Future randomized trials with longer-term outcomes that include sensorimotor mechanisms might enhance our understanding of the comparative effectiveness.

30552510\_PD.txt

Title: Effects of botulinum toxin type A on the treatment of dry eye disease and tear cytokines.

Publication Type: Randomized Controlled Trial

Journal-Name:Graefe's archive for clinical and experimental ophthalmology = Albrecht von Graefes Archiv fur klinische und experimentelle Ophthalmologie

Journal ID: 8205248

Publication date: 2018/11/08 00:00 [revised]

PURPOSE: To determine the effects of botulinum toxin type A (BTX-A) injection on <P 0>(S2) dry eye signs <P 0>, symptoms </>, and tear <P 0> cytokine </> levels in patients with intractable dry eye disease (DED). METHODS: In this prospective study, patients with intractable DED were randomized to a BTX-A (group A) or control group (group B). Patients were injected with BTX-A or normal saline in the medial part of the upper and lower eyelids. Before and at 2 weeks, 1 month, 2 months, and 4 months after injection, <P 0> dry eye signs </>; <P 0> tear film break-up time (TBUT) </>, [T Schirmer I test], <P 0> corneal fluorescein staining (CFS) </>, and <P 0> symptoms </>; [T <P 0> ocular surface disease </> index (OSDI)]; and frequency of <P 36> lubricants </> were assessed. The tear levels of <P 0> matrix metalloproteinase (MMP)-9 </> and <P 0> serotonin </> were measured before and at 1 month after injection. RESULTS: Fifty-two eyes from 26 patients (mean age, 57.7 years) were included. The <P 0> tear film break-up time </> was higher at 2 weeks and at 1 month in group A. The Schirmer I test and [T <P 0> ocular surface disease </> index] scores were also better in group A for up to 2 months. The <P 0> corneal fluorescein staining </> grades in group A were significantly lower until 4 months. Repeated measures analysis of variance (RMANOVA) demonstrated significant differences between the two groups over time for the Schirmer I test (p = 0.002), <P 0> corneal fluorescein staining </> (p = 0.025), [T <P 0> ocular surface disease </> index](p = 0.020), and frequency of <P 36> lubricants </> (p = 0.029). The <P 0> MMP-9 conversion </> rate of group A (76.92%) was significantly higher than that of group B (38.46%, p = 0.005). The tear <P 0> serotonin </> level in group A was reduced from 2.76 +/- 0.34 to 1.73 +/- 0.14 ng/mL (p < 0.001). No <P 38> complications </> were observed during the study. CONCLUSION: BTX-A injection into the medial part of eyelid improves <P 0>(S2) dry eye signs <P 0> and symptoms </> and reduces tear <P 0> cytokine </> levels. BTX-A is thus a potential treatment option for patients with intractable DED.

30554611\_PD.txt

Title: Intermittent exercise-heat exposures and intense physical activity sustain <P 0> heat acclimation </> adaptations.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of science and medicine in sport

Journal ID: 9812598

Publication date: 2018/06/12 00:00 [accepted]

OBJECTIVES: To determine if intermittent exercise-heat exposures (IHE) every fifth day sustain <P 0> heat acclimation (HA) </> adaptations 25 days after initial HA. DESIGN: Randomized control trial. METHODS: Sixteen non-heat acclimatized men heat acclimated during 10-11 days of exercise in the heat (40 degrees C, 40% RH). A <P 0> heat stress </> test (120min, 45% V O2peak) before (Pre HA) and after HA (Post HA) in similar hot conditions assessed <P 0> heat acclimation </> status. Pair-matched participants were randomized into a control group (CON; n=7) that exercised in a temperate environment (24 degrees C, 21%RH) or IHE group (n=9) that exercised in a hot environment (40 degrees C, 40%RH) every fifth day for 25 days following HA (+25d) with out-of-laboratory <P 25>(S1) exercise intensity <P 25> and duration </> recorded. Both groups completed +25d in the hot condition. RESULTS: Both groups <P 0> heat acclimated </> similarly (p>0.05) evidenced by lower <P 0> heart rate (HR) </>, <P 0>(E1) thermoregulatory, <P 0> physiological, and <P 0> perceptual responses </> (<P 0> perceived exertion </>, <P 0> fatigue </>, <P 0> thermal sensation </>) Pre HA vs. Post HA (p</=0.05). At +25d, post-exercise <P 0> heart rate </> (p=0.01) and <P 0> physiological strain </> index (p<0.05) but neither <P 0> Tre </> (p=0.18) nor <P 0> sweat </> rate (p=0.44) were lower in IHE vs. CON. In IHE only, post-exercise <P 0> Tre </> and <P 0> perceptual responses </> at Post HA and +25d were lower than Pre HA (p</=0.01). +25d post-exercise <P 0> epinephrine </> was higher in CON vs. IHE (p=0.04). <P 25> Exercise intensity </> during out-of-lab exercise and +25d post-exercise <P 0> heart rate </> were correlated (r=-0.89, p=0.02) in IHE. CONCLUSIONS: Exercise-heat exposures every fifth day for 25 days and regular intense physical activity after HA sustained <P 0> heart rate </> and <P 0> Tre </> adaptations and reduced <P 0>(E1) perceptual and <P 0> Physiological strain </> during exercise-heat stress approximately 1 month later.

30554783\_PD.txt

Title: Pegbelfermin (BMS-986036), a PEGylated fibroblast growth factor 21 analogue, in patients with non-alcoholic steatohepatitis: a randomised, double-blind, placebo-controlled, phase 2a trial.

Publication Type: Journal Article

Journal-Name:Lancet (London, England)

Journal ID: 2985213R

Publication date: 2018/07/27 00:00 [accepted]

BACKGROUND: Pegbelfermin (BMS-986036), a PEGylated human fibroblast growth factor 21 (FGF21) analogue, has previously been shown to improve markers of metabolism and liver fibrosis in obese patients with type 2 diabetes. In this phase 2a study, we aimed to evaluate the safety and efficacy of pegbelfermin in patients with non-alcoholic steatohepatitis. METHODS: In this multicentre, randomised, double-blind, placebo-controlled, parallel-group, phase 2a study, we recruited adults (aged 21-75 years) with a body-mass index of at least 25 kg/m(2), biopsy-confirmed non-alcoholic steatohepatitis (fibrosis stage 1-3), and a hepatic fat fraction of at least 10% when assessed by magnetic resonance imaging-proton density fat fraction. These patients were enrolled at 17 medical centres in the USA. Eligible patients were stratified by type 2 diabetes status and they were randomly assigned (1:1:1) by a computer-based system to receive subcutaneous injections of placebo once a day, 10 mg pegbelfermin once a day, or 20 mg pegbelfermin once a week, all for 16 weeks. Participants, the study team administering treatment, and investigators analysing outcomes (who were independent of the study team and had no further involvement) were masked to treatment groups. The primary outcomes were safety and the absolute change in <P 0> hepatic fat fraction </> after 16 weeks of treatment. All patients who were randomly assigned to groups and received the study drug or placebo were included in the primary analyses. This trial was registered with ClinicalTrials.gov, number NCT02413372. FINDINGS: Between May 12, 2015, and Aug 4, 2016, 184 overweight or obese patients with non-alcoholic steatohepatitis were screened for study inclusion. Of these, 95 (52%) patients were excluded because they no longer met study criteria and 80 (43%) patients entered the placebo lead-in phase. After further exclusions, 75 (94%) patients were randomly assigned to groups, received at least one dose of treatment (25 patients to receive 10 mg pegbelfermin once a day; 24 patients to receive 20 mg pegbelfermin once a week, and 26 patients to receive placebo), and were included in the primary analysis. A prespecified interim analysis at week 8 showed a greater than expected change in the primary outcome and supported early closing of patient enrolment, since this analysis indicated that the full planned sample size was not needed. We observed a significant decrease in absolute <P 0> hepatic fat fraction </> in the group receiving 10 mg pegbelfermin daily (-6.8% vs -1.3%; p=0.0004) and in the group receiving 20 mg pegbelfermin weekly (-5.2% vs -1.3%; p=0.008) compared with the placebo group. Most <P 38> adverse events </> were mild; the most common events were <P 0> diarrhoea </> in eight (16%) of 49 patients treated with pegbelfermin and two (8%) of 26 patients treated with placebo and <P 0> nausea </> in seven (14%) patients treated with pegbelfermin and two (8%) patients treated with placebo. There were no <P 1> deaths </>, <P 32, 38> discontinuations due to adverse events </>, or treatment-related <P 38> serious adverse events </>. INTERPRETATION: Treatment with subcutaneously administered pegbelfermin for 16 weeks was generally well tolerated and significantly reduced <P 0> hepatic fat fraction </> in patients with non-alcoholic steatohepatitis. Further study of pegbelfermin is warranted in patients with non-alcoholic steatohepatitis. Additional studies that use liver biopsies would allow for the assessment of pegbelfermin's effects on liver histology. Moreover, further studies should allow assessments of the safety and effectiveness of pegbelfermin in a larger number of patients. FUNDING: Bristol-Myers Squibb.

30557279\_PD.txt

Title: Effects of Instruction on Parent <P 25> Competency </> During Infant Handling in a Neonatal Intensive Care Unit.

Publication Type: Randomized Controlled Trial

Journal-Name:Pediatric physical therapy : the official publication of the Section on Pediatrics of the American Physical Therapy Association

Journal ID: 8912748

Publication date: 2019/02/13 06:00 [medline]

PURPOSE: The primary purpose of this study was to investigate the effectiveness of 3 different methods for delivering instruction on infant handling to parents in the neonatal intensive care unit (NICU). METHODS: Ninety-six parents in the NICU received instruction. Parents were taught the same 3 infant-handling techniques after random assignment to the (1) direct, (2) video, or (3) written-pictorial instructional groups. After baseline competency assessment, parents received instruction according to their group. A masked evaluator assessed parent <P 25> performance </>, and parents rated <P 32> instructional </> effectiveness. RESULTS: All groups significantly improved <P 25> handling </> performance. The direct and video groups performed 2 <P 25> handling </> activities significantly better than the written-pictorial group. No significant differences were found between the direct and video groups. All groups perceived the instruction as effective. CONCLUSIONS: Direct and video instructions are equally effective in teaching parents to perform simple <P 25> whole motor </> tasks in the NICU, and parents <P 32> welcome the instruction </>.

30557295\_PD.txt

Title: Hippotherapy in Rehabilitation Care for Children With Neurological Impairments and Developmental Delays: A Case Series.

Publication Type: Randomized Controlled Trial

Journal-Name:Pediatric physical therapy : the official publication of the Section on Pediatrics of the American Physical Therapy Association

Journal ID: 8912748

Publication date: 2019/02/13 06:00 [medline]

PURPOSE: This report assesses <P 25> functional mobility </> in children with neurological impairments and documented gross motor delays, before and after receiving either hippotherapy or standard outpatient physical therapy (PT). SUMMARY OF KEY POINTS: This is a case-series report using data previously collected for a discontinued randomized controlled trial, in which participants received hippotherapy or standard outpatient clinic PT for a 12-week treatment period. Results demonstrated both subjective and objective <P 25> functional mobility </> improvements after treatment in participants receiving hippotherapy and standard outpatient PT, as determined by the [T Peabody <P 25> Developmental Motor </> Scales-2], the [T Pediatric Evaluation of <P 25> Disability </> Inventory], and the [T <P 25> Goal Attainment </> Scaling]. STATEMENT OF CONCLUSION AND RECOMMENDATIONS FOR CLINICAL PRACTICE:: When compared with standard outpatient PT, hippotherapy appears to be a viable treatment strategy for children aged 2 to 5 years with neurological impairments and gross motor delays, but additional research in this area is needed to validate findings.