

Subject: Other Main intervention: Drug filename: 11595000.txt

Safety **O: Other** and **O: Other** efficacy **O: Other** of PNU-142633 **I: Drug**, a selective 5-HT_{1D} agonist **I: Drug**, in patients with acute **P: Condition** migraine **P: Condition**.

In this randomized, double-blind, placebo-controlled **I: Control**, parallel-group study, patients received a single 50-mg oral dose of a 5-HT_{1D} agonist, PNU-142633 (n = 34), or matching placebo **I: Control** (n = 35) during an acute migraine attack. No statistically significant treatment effects were observed at 1 and 2 h after dosing, even after stratifying by baseline headache intensity. At 1 and 2 h post-dose, 8.8% and 29.4% of the PNU-142633 group, respectively, and 8.6% and 40.0% of the placebo **I: Control** group, respectively, experienced headache **O: Adverse effects** relief **O: Adverse effects**; 2.9% and 8.8% of the PNU-142633 group and 0% and 5.7% of the placebo **I: Control** group were free **O: Adverse effects** of **O: Adverse effects** headache **O: Adverse effects** pain **O: Adverse effects**. Adverse **O: Adverse effects** events **O: Adverse effects** associated with PNU-142633 treatment included chest **O: Pain** pain **O: Pain** (two patients) and QTc **O: Physical** prolongation **O: Physical** (three patients). Results from this study suggest that anti-migraine efficacy is not mediated solely through the 5-HT_{1D} receptor subtype, although this receptor may contribute, at least in part, to the adverse **O: Adverse effects** cardiovascular **O: Adverse effects** effects **O: Adverse effects** observed with 5-HT agonist medications.

Subject: Cardiovascular diseases Main intervention: Drug filename: 10685722.txt

Efficacy and safety of a fixed low-dose perindopril/indapamide combination in essential hypertension. A randomised controlled study.

This multicenter, double-blind, parallel-group study was designed to assess the efficacy and the safety of fixed low dose combination perindopril 2 mg/indapamide 0.625 mg (Per/Ind) versus atenolol 50 mg (Ate). After a 4-week placebo run-in, 446 hypertensive patients (mean age 58.8 years) were randomised to receive Per/Ind or Ate for 12 weeks. The primary outcome measures were the changes in trough supine systolic and diastolic blood pressure (sSBP and sDBP) between baseline and the last observation. Equivalence was assessed in an intention-to-treat analysis using a two one-sided tests procedure. Per/Ind and Ate decreased sBP by -20.5 mmHg and -20.1 mmHg, respectively; the 90% confidence interval [-2.3; 1.5] of the intertreatment difference (-0.4 mmHg) fell within the predefined equivalence interval [-8; +8 mmHg]. Similarly, the sDBP decreased by -15.1 mmHg (Per/Ind) and -16.2 mmHg (Ate) with an intertreatment difference of 1.1 mmHg whose 90% confidence interval [-0.1; 2.2 mmHg] fell within the predefined equivalence interval [-4; +4 mmHg]; thus antihypertensive efficacy of Per/Ind and Ate were equivalent ($P < 0.001$). In patients older than 65, Per/Ind induces a statistically greater decrease in sSBP than Ate ($P < 0.05$). Per/Ind was well tolerated. Further controlled studies are needed to confirm these results on a long-term period.

Subject: Cardiovascular diseases Main intervention: Physical filename: 11835021.txt

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The Low Energy Safety Study (LESS): rationale, design, patient characteristics, and device utilization.

BACKGROUND A 10-J energy safety margin has traditionally been used in programming implantable cardioverter defibrillators (ICDs). The Low Energy Safety Study (LESS) tests the hypothesis that programming shocks to lower energy margins is safe and effective.

METHODS Patients with standard ICD indications undergo defibrillation threshold testing (DFT) at the time of ICD implant, with reconfirmation of lowest successful energy twice (DFT++). Patients are randomized to 2 groups: the first has the initial 2 shocks for ventricular fibrillation conversion programmed at 2 energy steps above DFT++ (typically 4-6 J, maximum 10 J) with subsequent shocks at maximum energy, and the second has all shocks programmed at maximum energy. Patients are followed up every 3 months for 2 years to assess shock conversion efficacy of spontaneous arrhythmias. In a subgroup of patients, there is a second randomization to energy levels of 0, 1, 2, 3, or 4 steps above implant DFT++ for conversion testing of 3 induced ventricular fibrillation episodes at prehospital discharge, 3 months, and 12 months after implant.

RESULTS Enrollment is complete (72 patients), but follow-up results are pending. There were no significant variations in implant indications and baseline antiarrhythmic drug use over the 3-year enrollment period, although an increase in the percentage of dual-chamber ICDs implanted occurred, with the majority (65%) of implanted ICDs being dual-chamber devices by the end of the enrollment period.

CONCLUSION The results of LESS should facilitate the development of algorithms for programming ICD energy safety margins.

Subject: Other Main intervention: Physical filename: 10080319.txt

Masticatory performance and chewing experience with implant-retained mandibular P: Condition overdentures P: Condition .

The relationship between masticatory performance and chewing experience has not yet been explored for patients with implant-retained overdentures. Although many relationships have been found between parameters of objective and subjective oral function, the structure of these relationships remain unclear. Therefore, we studied in a randomized clinical trial the relationship between the comminution of an artificial test food, i.e. masticatory performance, and the subjective chewing experience. The trial involved a comparison between two groups receiving implant treatment and one group receiving conventional I: Physical complete I: Physical dentures I: Physical (I: Physical CD I: Physical) I: Physical . The implant treatment involved either a mainly implant-supported I: Physical mandibular I: Physical overdenture I: Physical or a transmandibular implant I: Surgical (I: Surgical TMI I: Physical) I: Physical or an implant-tissue-supported I: Physical mandibular I: Physical overdenture I: Physical on two IMZ implants I: Surgical (I: Surgical IMZ I: Surgical) I: Physical . Masticatory O: Physical performance O: Physical as well as chewing O: Mental experience were substantially better for the implant-retained overdentures compared with the complete denture group. No significant differences emerged between the TMI and the IMZ group. A multiple regression analysis did not provide any comprehensibility in the relationship between masticatory O: Physical performance and the variables of chewing experience. In the linear structural relation analysis (LISREL) no direct relationship was found between masticatory O: Physical performance O: Physical and functional O: Physical complaints mandibular device. The results show that an improvement in masticatory O: Physical performance O: Physical does not imply the same improvement in chewing O: Mental experience O: Mental and vice versa.

Subject: Cancer Main intervention: Educational filename: 12096292.txt

Pain O: Pain and fatigue management: results of a nursing randomized clinical trial.

PURPOSE/OBJECTIVES Through a randomized clinical trial, to compare patients undergoing an initial course of chemotherapy who report pain O: Pain and fatigue O: Pain at baseline and who are receiving conventional care alone with those receiving conventional I: Educational care I: Educational plus I: Educational a I: Educational nursing I: Educational intervention I: Educational on outcomes reported at 20 weeks.

SETTING Chemotherapy clinics of two comprehensive and two P: Sample size community cancer centers.

METHODS Interviews were conducted at baseline and 10 and 20 weeks. An 18-week, 10-contact I: Educational nursing I: Educational intervention I: Educational utilizing problem-solving I: Educational approaches I: Educational to symptom I: Educational management and improving physical O: Mental functioning O: Mental and emotional O: Mental health O: Mental was implemented.

SAMPLE The sample consisted of 53 P: Sample size patients in the experimental arm and 50 in the control arm who reported pain O: Pain and fatigue O: Pain at baseline.

VARIABLES Pain O: Pain and fatigue O: Adverse effects, numbers of O: Physical other symptoms O: Physical, and physical symptoms and social-functioning O: Mental subscales O: Mental from the Medical Outcomes Study 36 Short Form.

FINDINGS Patients who received the intervention reported a significant reduction in the number O: Physical of O: Physical symptoms O: Physical experienced and improved physical O: Mental and O: Mental social O: Mental functioning O: Mental. Fewer patients in the experimental arm reported both pain O: Pain and fatigue O: Adverse effects at 20 weeks.

CONCLUSIONS Behavioral I: Educational interventions targeted to patients with pain P: Condition and fatigue can reduce symptom O: Physical burden O: Physical, improve the quality O: Other of O: Other the O: Other daily O: Other life O: Other of patients, and demonstrate the "value-added" role of nursing care for patients undergoing chemotherapy P: Condition.

IMPLICATIONS FOR NURSING These data support the "value-added" role of nursing interventions I: Educational for symptom management and improved quality O: Other of O: Other life O: Other during the course of cancer treatment.

[One-year effect of health I: Educational counseling I: Educational on life style and risk factors of heart P: Condition disease P: Condition].

INTRODUCTION We examined the need for counselling and the effect on willingness O: Mental and ability O: Mental to change life style, and subsequent changes in risk factors for CHD.

MATERIAL AND METHODS All 152 P: Sample size male P: Sex employees in a computer company, 25-45 P: Age years P: Age of P: Age age P: Age , were invited to participate in a controlled intervention study over one year. The subjects were randomised to an intervention group (I group) and a control group. The I group was divided into subgroups based on baseline behaviour and risk factor status. Changes were evaluated after one year. After an initial health examination, participants in the I group were counselled at baseline and at 5 months.

RESULTS Eighty-five (56%) men P: Sex participated. Twenty-nine P: Sample size were assigned to a control group and 56 to an intervention group (I group) (dropouts = 8). An exercise I: Physical group I: Physical (E group) was advised to take up I: Physical aerobics I: Physical exercise I: Physical three I: Physical times/week, a group to reduce the intake of saturated fat and increase fish products, and smokers to stop smoking. Forty were recommended one or more behavioural changes and eight had no need. Thirty-four P: Sample size were willing to make behavioural O: Mental changes O: Mental .

Compared to the control group, the fitness O: Physical level O: Physical increased (p < 0.01) and body O: Physical weight O: Physical decreased in the I group (p < 0.05).

DISCUSSION Individual I: Educational counselling I: Educational promotes regular I: Physical exercise I: Physical with subsequent improvements in CHD risk factors. The diet and smoking I: Educational counselling models were less successful in terms of compliance.

Subject: Cardiovascular diseases Main intervention: Surgical filename: 11022066.txt

Outcomes of early I: Surgical endovascular I: Surgical versus surgical I: Surgical treatment I: Surgical of ruptured P: Condition cerebral P: Condition aneurysms P: Condition . A prospective randomized study.

BACKGROUND AND PURPOSE This prospective study was conducted to compare the outcomes of surgical I: Surgical clipping I: Surgical and endovascular I: Surgical treatment in acute P: Condition Condition (<72 hours) aneurysmal subarachnoid hemorrhage (SAH P: Condition) P: Condition .

METHODS One P: Sample size hundred P: Sample size nine P: Sample size consecutive patients were randomly assigned to either surgical I: Surgical (n=57) or endovascular I: Surgical (n=52) treatment. Clinical O: Mental and O: Mental neuropsychological O: Mental outcome O: Mental was assessed at 3 and 12 months after treatment; MRI of the brain was performed at 12 months. Follow-up angiography was scheduled after clipping and 3 and 12 months after endovascular treatment.

RESULTS One year postoperatively, 43/41 (surgical/endovascular) patients had good or moderate recovery, 5/4 had severe disability or were in a vegetative state, and 9/7 had died O: Mortality (O: Mortality NS O: Mortality) O: Mortality according to intention to treat. Patients with good clinical recovery did not differ in their neuropsychological O: Mental test O: Mental scores O: Mental . Symptomatic O: Physical vasospasm O: Physical (OR 2.47; 95% CI 1.45 to 4.19; P<0.001), poorer Hunt and Hess grade (OR 2.50; 95% CI 1.31 to 4.75; P=0.005), need O: Other for O: Other permanent O: Other shunt O: Physical (OR 8.90; 95% CI 1.80 to 44.15; P=0.008), and larger size of O: Physical the aneurysm (OR 1.22; 95% CI 1.02 to 1.45; P=0.032) independently predicted worsened clinical outcome regardless of the treatment modality. In MRI, superficial brain O: Physical retraction O: Physical deficits O: Physical (P<0.001) and ischemic O: Physical lesions O: Physical in the territory of the ruptured aneurysm (P=0.025) were more frequent in the surgical group. Kaplan-Meier analysis (mean+/-SD follow-up 39+/-18 months) revealed equal O: Mortality survival O: Mortality in both treatment groups. No late rebleedings have occurred.

CONCLUSIONS One-year clinical and neuropsychological outcomes seem comparable after early surgical and endovascular I: Surgical treatment of ruptured P: Condition intracranial P: Condition aneurysms P: Condition . The long-term efficacy O: Other of endovascular I: Physical treatment I: Physical in preventing rebleeding remains open.

Subject: Cardiovascular diseases Main intervention: Surgical filename: 10660161.txt

Regression of left ventricular hypertrophy after stentless versus conventional **I: Surgical** aortic **I: Surgical** valve **I: Physical** replacement **I: Physical** .

The goal of this study was to analyze regression of left ventricular hypertrophy after randomization to conventional biological versus **I: Physical** stentless **I: Physical** aortic **I: Physical** valve replacement. Stentless **I: Drug** (Freestyle, Toronto, n = 106, or conventional **I: Physical** aortic **I: Surgical** valves **I: Surgical** (Carpentier-Edwards, n = 74 **P: Sample size**) were evaluated prospectively. Preoperatively there were no differences with regard to aortic valve pathology, left ventricular function, and **O: Physical** pressure **O: Physical** gradients **O: Physical** between the two patient groups. The **O: Physical** patient **O: Physical** annulus **O: Physical** index **O: Physical** (13.55 vs. 13.46 mm; NS) measured intraoperatively was used as baseline for further comparison. Postoperatively **O: Physical** , left **O: Physical** ventricular **O: Physical** mass **O: Physical** index **O: Physical** was 213+/-77 g/m2 (stentless) compared with 202+/-72 (conventional group) g/m2 (NS), whereas after 6 months it was 141+/-41 g/m2 in the stentless and 170+/-43 g/m2 in the conventional group (P<.05).

Regression **O: Physical** of **O: Physical** left **O: Physical** ventricular **O: Physical** hypertrophy **O: Physical** occurs in all patients after aortic valve replacement. Nevertheless, the use of stentless bioprostheses leads to a significant enhancement, which may result in a reduction of the **O: Physical** cardiac **O: Physical** risk **O: Physical** profile **O: Physical** for the patient.

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The TOM test: a new instrument for assessing theory of mind in normal P: Condition children P: Age and children P: Age with pervasive P: Condition developmental P: Condition disorders P: Condition .

This article describes a first attempt to investigate the reliability and validity of the TOM test, a new instrument for assessing theory of mind O: Mental ability in normal P: Condition children P: Age and children P: Age with pervasive P: Condition developmental P: Condition disorders P: Condition (P: Condition PDDs P: Condition) P: Condition . In Study 1, TOM test scores of normal children (n = 70) correlated positively with their performance on other theory of mind tasks. Furthermore, young P: Age children P: Age only succeeded on TOM items that tap the basic domains of theory of mind (e.g., emotion O: Mental recognition O: Mental) O: Mental , whereas older children also passed items that measure the more mature areas of theory of mind (e.g., understanding of humor O: Mental , understanding of second order beliefs). Taken together, the findings of Study 1 suggest that the TOM test is a valid measure. Study 2 showed for a separate sample of normal children P: Age (n = 12) that the TOM test possesses sufficient test-retest stability. Study 3 demonstrated for a sample of children P: Age with PDDs (n = 10) that the interrater reliability of the TOM test is good. Study 4 found that children with PDDs (n = 20) had significantly lower TOM O: Mental test O: Mental scores O: Mental than children P: Age with other psychiatric P: Condition disorders P: Condition (e.g., children P: Age with Attention-deficit P: Condition Hyperactivity P: Condition Disorder P: Condition ; n = 32), a finding that underlines the discriminant validity of the TOM test. Furthermore, Study 4 showed that intelligence as indexed by the Wechsler O: Mental Intelligence O: Mental Scale O: Mental for Children was positively associated with TOM test scores. Finally, in all studies, the TOM test was found to be reliable in terms of internal consistency. Altogether, results indicate that the TOM test is a reliable and valid instrument that can be employed to measure various aspects of theory of mind.

Subject: Other Main intervention: Other filename: 10968308.txt

The effect of case management on the costs of health care for enrollees in Medicare Plus Choice plans: a randomized trial.

OBJECTIVE To measure the effects of case management on an older population's costs of health care.

DESIGN A 1-year randomized controlled trial.

SETTING Multiple sites of care in San Francisco, California.

PARTICIPANTS Patients aged 65 or older of primary care physicians in a large provider organization bearing financial risk for their care (n = 6409).

INTERVENTION Screening for high risk and provision of social, work-based, case management.

OUTCOME MEASURES Volume and cost of hospital physician, case management, and other health-related services.

RESULTS The experimental group used more case management services than the control group (0.09 vs. 0.02 months per person, $P < .001$). The experimental group's average total payments for health care were slightly lower (\$3148 vs \$3277, $P = .40$).

CONCLUSIONS This study provides no statistically significant evidence that social, work-oriented case management reduces the use or the cost of health care for high-risk older people. Other potentially favorable effects of this type of case management need to be evaluated, as do the effects of other types of case management.

Reduction of stimulus overselectivity with nonverbal differential observing responses.

Three **P: Sample size** individuals with **mental P: Condition** **retardation P: Condition** exhibited stimulus overselectivity in a delayed matching-to-sample task in which two sample stimuli were displayed on each trial. **Intermediate O: Other** **accuracy O: Other** **scores O: Other** indicated that participants could match one of the samples but not both of them. Accuracy in a baseline condition was compared to accuracy with a differential observing response procedure. This procedure prompted participants to make simultaneous identity-matching responses that required observation and discrimination of both sample stimuli. These observing responses were never followed by differential consequences. When observing responses were prompted, participants' **accuracy O: Other** **scores O: Other** improved. In a return to the baseline condition, when differential observing responses were no longer prompted, **accuracy O: Other** returned to intermediate levels. The results show that stimulus overselectivity can be greatly reduced by a behavioral intervention that controls observing **behavior O: Mental** and **verifies O: Mental** **discrimination O: Mental**, but that exposure to such procedures alone may be insufficient for lasting benefits.

Subject: Cardiovascular diseases Main intervention: Psychological filename: 10719133.txt

Blood I: Physical pressure I: Physical biofeedback I: Physical treatment I: Physical of white-coat P: Condition hypertension P: Condition .

OBJECTIVE The objective of the study was to compare blood O: Physical pressure O: Physical (O: Physical BP I: Physical) I: Physical biofeedback I: Physical treatment I: Physical (I: Physical BF I: Physical) I: Physical effects between white-coat hypertension P: Condition and essential P: Condition hypertension P: Condition .

METHODS Fifteen P: Sample size white-coat P: Condition hypertensive P: Condition out-patients and 23 P: Sample size essential hypertension P: Condition out-patients P: Condition were randomly assigned to groups A or B. Subjects in group A underwent BF I: Drug once a week for a total of four sessions. Those in group B visited the clinic only to measure BP and later underwent the same BF.

RESULTS In group A, BP of white-coat hypertensives P: Condition and essential hypertensives P: Condition were significantly reduced by 22/11 and 14/8 mmHg, respectively. In group B, they were unchanged during the same period but later suppressed by BF. Under BF O: Physical , pulse O: Physical and O: Physical respiratory O: Physical rates O: Physical were significantly higher, and elevation O: Physical of O: Physical diastolic O: Physical BP O: Physical due to mental O: Mental stress O: Mental testing O: Mental was better suppressed in white-coat hypertensives P: Condition than in essential P: Condition hypertensives P: Condition .

CONCLUSION This treatment was effective in both types of hypertension O: Physical , and pressor O: Physical response O: Physical stress seems to be important in the differentiated BF effect.