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A randomised trial of nicotine-replacement therapy patches in pregnancy

Nicotine-replacement therapy is effective for smoking cessation outside pregnancy and its use is widely recommended during pregnancy. The study investigated the efficacy and safety of nicotine patches during pregnancy.

In this study, the authors recruited participants from seven hospitals in England who were 16 - 50 years of age with pregnancies of 12 - 24 weeks' gestation and who smoked 5 or more cigarettes per day. Participants received behavioural cessation support and were randomly assigned to 8 weeks of treatment with active nicotine patches (15 mg per 16 hours) or matched placebo patches. The primary outcome was abstinence from the date of smoking cessation until delivery, as validated by measurement of exhaled carbon monoxide or salivary cotinine. Safety was assessed by monitoring for adverse pregnancy and birth outcomes.

Of 1 050 participants, 521 were randomly assigned to nicotine-replacement therapy and 529 to placebo. There was no significant difference in the rate of abstinence from the quit date until delivery between the nicotine-replacement and placebo groups, although the rate was higher at 1 month in the nicotine-replacement group than in the placebo group (21.3% v. 11.7%). Compliance was low; only 7.2% of women assigned to nicotine-replacement therapy and 2.8% assigned to placebo used patches for more than 1 month. Rates of adverse

pregnancy and birth outcomes were similar in the two groups.

Adding a nicotine patch (15 mg per 16 hours) to behavioural cessation support for women who smoked during pregnancy did not significantly increase the rate of abstinence from smoking until delivery or the risk of adverse pregnancy or birth outcomes. However, low compliance rates substantially limited the assessment of safety.

Coleman T, et al. *N Engl J Med* 2012;366:808-818.

Tai Chi and postural stability in patients with Parkinson's disease

Patients with Parkinson's disease have substantially impaired balance, leading to diminished functional ability and an increased risk of falling. Although exercise is routinely encouraged by healthcare providers, few programmes have been proven effective.

In this study, the authors conducted a randomised, controlled trial to determine whether a tailored tai chi programme could improve postural control in patients with idiopathic Parkinson's disease. They randomly assigned 195 patients with stage 1 - 4 disease on the Hoehn and Yahr staging scale (which ranges from 1 to 5, with higher stages indicating more severe disease) to 1 of 3 groups: tai chi, resistance training, or stretching. The patients participated in 60-minute exercise sessions twice weekly for 24 weeks. The primary outcomes were changes from baseline in the limits-of-stability test (maximum excursion and directional control; range 0 - 100%). Secondary outcomes included measures of gait and strength, scores on functional-reach and timed up-and-go tests, motor scores on the Unified Parkinson's Disease Rating Scale, and number of falls.

The tai chi group performed consistently better than the resistance-training and stretching groups in maximum excursion and in directional control. The tai chi group

also performed better than the stretching group in all secondary outcomes and outperformed the resistance-training group in stride length and functional reach. Tai chi lowered the incidence of falls as compared with stretching but not as compared with resistance training. The effects of tai chi training were maintained at 3 months after the intervention. No serious adverse events were observed.

Tai chi training appears to reduce balance impairments in patients with mild-to-moderate Parkinson's disease, with additional benefits of improved functional capacity and reduced falls.

Li F, et al. *N Engl J Med* 2012;366:511-519.

Screening overdiagnoses 6 - 10 women for every death from breast cancer prevented

Researchers estimate that breast cancer would never have become apparent in 15 - 25% of women diagnosed through the Norwegian screening programme. For every 2 500 women invited for screening, 6 - 10 women are overdiagnosed, 20 cases of breast cancer are detected and treated



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early, and one death from breast cancer is prevented.

Previous reports have estimated overdiagnosis in breast cancer screening programmes as between 0% and 54%. Rates of overdiagnosis are difficult to estimate because breast cancer trends irrespective of screening must be taken into account and lead time (the amount of time a diagnosis by mammography precedes a clinical diagnosis) must be adjusted for. The various methods used by researchers yield very different results, and there is no universally accepted method to estimate overdiagnosis.

The current researchers took advantage of a national screening programme that was gradually implemented by geographical region over 9 years. Attendance was high. Only invasive breast cancer was taken into account and carcinoma *in situ* was excluded from the analysis. To account for temporal trends, the incidence of breast cancer with screening was compared with historical incidence in the same region before screening was implemented, as well as with concurrent incidence of breast cancer in countries not yet included in the screening programme. Two different methods were also used to adjust for lead time.

Since 2005, all Norwegian women aged 50 - 69 years have been invited for mammography every 2 years.

Kalager M, et al. *Ann Intern Med* 2012;156:491-499.

Energy drinks: health risks and toxicity

Synthetic, caffeinated high-energy drinks are now common, and targeted at young people. The consumption of these drinks has increased significantly over the past 10 years – 2 in particular (Red Bull and 'V') account for over 97% of sales in this multimillion-dollar industry. As a result, there is an increase in the incidence of toxicity from caffeine overdose reported to hospitals and poison centres.

The main active ingredients of these drinks include varying amounts of caffeine, guarana extract, taurine and ginseng. Additional amino acids, vitamins and carbohydrates make up the remainder of the supposedly beneficial ingredients.

Adverse reactions and toxicity from high-energy drinks are mainly due to their caffeine content. In this study, the authors described the epidemiology and toxicity of caffeinated energy drink exposure in Australia. They used a retrospective observational study analysing data from calls regarding energy drink exposure recorded in the database of the Australian poisons information centre over 7 years to 2010.

Callers reported 297 exposures to energy drinks, which showed an increasing annual trend from 12 in 2004 to 65 in 2010. The median age of the 217 subjects with recreational exposure was 17 years and 57% were male. One hundred recreational users also ingested other substances, mainly alcohol (50) or other caffeinated products (44). The number of energy drinks consumed in one session varied greatly. Most subjects who reported recreational use reported symptoms (87%). The most common symptoms were palpitations, agitation, tremor and gastrointestinal upset. Twenty-one subjects had signs of serious cardiac or neurological

toxicity, including hallucinations, seizures, arrhythmias or cardiac ischaemia. At least 128 subjects (57 with no co-ingestants) required hospitalisation.

The authors concluded that reports of caffeine toxicity from energy drink consumption are increasing, particularly among adolescents, warranting review and regulation of labelling and sale of these drinks.

Gunja N, Brown JA. *Med J Aust* 2012;196:46-49.
doi:10.5694/mja11.10838

SINGLE SUTURE

Mouse space mission brings bone boost

A group of mice have returned to earth after the longest mission any animal has endured in space. The mice were floating around for 91 days to test a way to prevent the breakdown of bone.

Different types of bone cell either build up bone or break it down. For weight-bearing bones, breakdown cells become more active when there is no impact on the bone, such as in microgravity. 'Astronauts experience around 20% to 30% bone loss,' says Sara Tavella at the University of Genoa in Italy. Astronauts exercise and take calcium supplements to limit damage, but it is very difficult to return the bone to its original state back on earth, says Tavella.

To examine other options, her team sent 6 mice up to the International Space Station. Three of the mice were genetically modified to produce extra pleiotrophin (PTN) – a protein involved in bone development. The mice with extra PTN were protected from the breakdown of bone – losing only 3% of the volume of their spine compared with a 41.5% decrease in normal mice.

The protein treatment could be investigated for use in astronauts preparing for space, says Tavella.

New Scientist, 7 April 2012:17. [doi:10.1371/journal.pone.0033179]