RESEARCH

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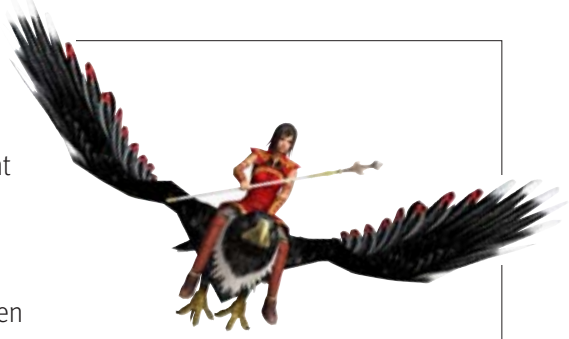

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Venous thrombosis in users of non-oral hormonal contraception

Women who use combined contraceptive transdermal patches or vaginal rings are at an increased risk of venous thrombosis compared with non-users of hormonal contraception, according to this registry based cohort study from Denmark. This did not apply to women using subcutaneous implants or the levonorgestrel intrauterine system: their risk was no higher than that of women not using of hormonal contraception.

The effectiveness of SPARX, a computerised self help intervention for adolescents seeking help for depression: randomised controlled non-inferiority trial

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bmj.com/podcasts
SPARX and spirometry

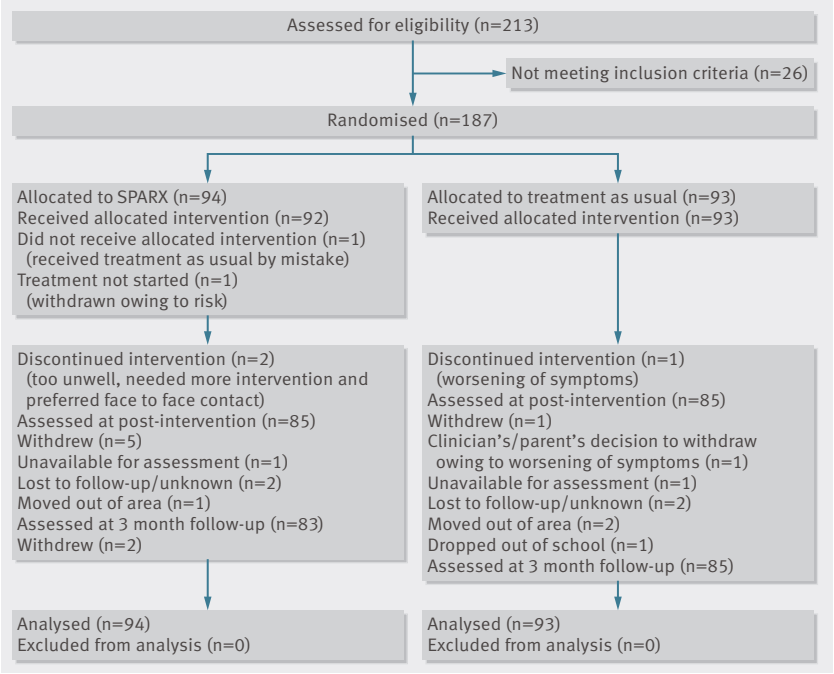
bmj.com
Trailer showing SPARX in action

STUDY QUESTION Is computerised cognitive behavioural therapy at least as effective as treatment as usual in reducing depressive symptoms in help seeking adolescents with depression in primary care settings?

SUMMARY ANSWER Computerised cognitive behavioural therapy was at least as effective as treatment as usual in reducing depressive symptoms in adolescents.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Computerised cognitive behavioural therapy is effective for adults with depression, but little research has been done on its use in adolescents. We developed a specific computerised cognitive behavioural therapy resource (SPARX, Smart, Positive, Active, Realistic, X-factor thoughts) for adolescents and evaluated it in primary healthcare settings in New Zealand.

Design
This was a multicentre, prospective, randomised controlled non-inferiority trial. The interventions were SPARX (a self help computerised cognitive behavioural therapy resource in the form of a three dimensional fantasy based game comprising seven modules, see www.sparx.org.nz) and treatment as usual (comprising primarily face to face counselling delivered by trained clinicians). Research assistants, who administered the primary outcome measure, and the study statistician were blind to allocation, but not the participants and clinicians at the sites.



Participants and setting
Adolescents aged 12-19 and seeking help for depressive symptoms were recruited sequentially from 24 primary healthcare sites in New Zealand (youth clinics, general practices, and school based counselling services).

Primary outcome
Change in score on the children's depression rating scale-revised (CDRS-R), with non-inferiority defined as not worse than 5.5 units inferior change. Scores were collected at baseline, post-intervention, and at three months.

Main results and the role of chance
187 participants (mean age 15.6 years) were recruited (SPARX: n=94, 62.8% female, and treatment as usual: n=93, 68.8% female). 170 (91%, 85 in each group) were assessed after intervention and 168 (90%, 83 and 85, respectively) at three months. Per protocol analyses (n=143) showed that SPARX was not inferior to treatment as usual, with a mean post-intervention reduction in CDRS-R raw score of 10.32 in the SPARX group and 7.59 in the treatment as usual group: between group difference 2.73 (95% confidence interval −0.31 to 5.77; P=0.079). Remission rates were significantly higher in the SPARX arm (n=31, 43.7%) than in the treatment as usual arm (n=19, 26.4%): difference 17.3% (95% confidence interval 1.6% to 31.8%; P=0.030). Response rates did not differ significantly (SPARX n=47, 66.2%, treatment as usual n=42, 58.3%): difference 7.9% (−7.9% to 24%; P=0.332). These results were confirmed on intention to treat analyses.

Harms
We found no difference in adverse events "possibly" or "probably" related to the intervention (11 in each group).

Bias, confounding, and other reasons for caution
The treatment as usual group was heterogeneous. We considered it unethical to leave young people presenting for help untreated.

Generalisability to other populations
Our findings may be generalisable to young people seeking help with mild to moderate depression in primary care.

Study funding/potential competing interests
The New Zealand Ministry of Health funded the study but had no direct involvement in the design, conduct of the study, analysis of the data, or writing up of the results.

Trial registration number
Australian New Zealand Clinical Trials Registry ACTRN12609000249257.

Vaccination against pandemic A/H1N1 2009 influenza in pregnancy and risk of fetal death: cohort study in Denmark

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EDITORIAL by Knight and Lim

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STUDY QUESTION

Is exposure to an adjuvanted pandemic A/H1N1 2009 influenza vaccine during pregnancy associated with increased risk of fetal death?

SUMMARY ANSWER

In this large cohort study, there was no evidence of an increased risk of fetal death associated with exposure to an adjuvanted pandemic A/H1N1 2009 influenza vaccine in pregnancy.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Pregnant women infected with pandemic A/H1N1 2009 influenza were at increased risk of morbidity, mortality, and poor pregnancy outcomes; many countries included pregnant women among the target groups for vaccination. Applying a comprehensive design and adjusting for a large number of potential confounders, this cohort study found no increased risk of the composite primary outcome of fetal death and its components, spontaneous abortion and stillbirth.

Participants

The cohort comprised 54 585 pregnancies; 7062 (12.9%) women were vaccinated against pandemic A/H1N1 2009 influenza during pregnancy.

Design and setting

We carried out a nationwide register based cohort study in Denmark, including all clinically recognised singleton pregnancies that ended between November 2009 and September 2010. Using a unique person identifier we linked individual level data on exposure to an inactivated AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine (Pandemrix; GlaxoSmithKline Biologicals, Rixensart, Belgium) and potential confounders to the study cohort. Cox regression was used to estimate hazard ratios of fetal death comparing H1N1 vaccinated and unvaccinated pregnancies, adjusting for propensity scores.

Main results

Overall, 1818 cases of fetal death occurred (1679 spontaneous abortions and 139 stillbirths). Exposure to the adjuvanted pandemic A/H1N1 2009 influenza vaccine was not associated with an increased risk of the primary outcome of fetal death or the secondary outcomes of spontaneous abortion and stillbirth. Estimates for fetal death were similar in pregnant women with (hazard ratio 0.82, 95% confidence interval 0.44 to 1.53) and without comorbidities (0.77, 0.47 to 1.25).

Bias, confounding, and other reasons for caution

We excluded registered spontaneous abortions with less than six completed weeks of gestation—that is, early pregnancy loss; only a limited number of early pregnancy losses are recognised clinically, therefore inclusion of this period in the analyses would have introduced outcome misclassification. Although we adjusted for many potential confounders, differences might have existed between vaccinated and unvaccinated women associated with both exposure and outcome that we could not measure. Of concern would be factors that could have obscured a risk of fetal death by being associated with both vaccination and reduced risk of fetal death.

Generalisability to other populations

Results from this population based nationwide study in Denmark are principally applicable to similar populations exposed to the AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine. We believe that the results are generalisable to non-adjuvanted vaccines produced from the same virus strain but not to vaccines with other adjuvants.

Study funding/potential competing interests

Grants from the Danish Medical Research Council (postdoctoral grant No 11-115854 to BP) and Lund University (fellowship grant to BP). We have no competing interests.

Association between vaccination against pandemic A/H1N1 2009 influenza in pregnancy and risk of fetal death in nationwide cohort of 54 585 pregnancies in Denmark

Outcome	No of women	No of events	Adjusted hazard ratio* (95% CI)
Fetal death:			
Unvaccinated	47 523	1785	1 (reference)
Vaccinated	7062	27	0.79 (0.53 to 1.16)
Spontaneous abortion:			
Unvaccinated	32 672	1649	1 (reference)
Vaccinated	2736	20	1.11 (0.71 to 1.73)
Stillbirth:			
Unvaccinated	43 663	131	1 (reference)
Vaccinated	7014	7	0.44 (0.20 to 0.94)

*Adjusted for propensity scores.

Read all the latest articles on pandemic flu at the *BMJ* Group portal: http://pandemicflu.bmj.com/

Long term outcomes in men screened for abdominal aortic aneurysm: prospective cohort study

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EDITORIAL by Andermann

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STUDY QUESTION

Is there a relation between aortic diameter and morbidity and mortality in men screened for abdominal aortic aneurysm (AAA)?

SUMMARY ANSWER

Men with an enlarged, but non-aneurysmal, aorta have increased mortality and likelihood of admission to hospital compared with men with a normal aorta. Cardiovascular diseases are the major cause of this increase.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Screening for AAA is effective in reducing mortality from aneurysm, but men with an aneurysm have a higher mortality from other vascular diseases than those without. This increased mortality also affects men with an enlarged, but non-aneurysmal, aorta.

Participants and setting

Men aged 65-74 living in Highland and Western Isles, Scotland, were offered screening for AAA and asked to complete a questionnaire between 2001 and 2003.

Design, size, and duration

After initial screening by ultrasound, long term outcomes were obtained by data linkage to national records of hospital admissions and mortality for 8146 men. We compared time to an event of interest using crude and adjusted Cox proportional hazards regression models. Men were followed for a median 7.4 (interquartile range 6.9-8.2) years.

Main results and the role of chance

Of the 8355 men who attended for screening, 8146 (97.5%) completed the questionnaire and were available for record linkage, representing 86% of the men of the age group in the community. An aneurysm (aortic diameter ≥30 mm) was present in 414 (5.1%) men, and 669 (8.2%) men had an aortic diameter of 25-29 mm. Men with an aneurysm were followed up and treated in line with evidence based protocols. Mortality was significantly related to aortic diameter, with both men with an aneurysm and those with an aortic diameter of 25-29 mm having a significantly higher risk of mortality compared with those with an aortic diameter ≤24 mm. The excess mortality risk in men with an aneurysm was related to both cancer and vascular disease. For men with an aortic diameter of 25-29 mm, vascular disease was responsible for most of the increased mortality. After adjustment for confounders, the 25-29 mm group showed no significant increase in all cause mortality. Both men with an aneurysm and those with an aortic diameter of 25-29 mm had a significantly higher risk of admission to hospital with a range of diseases, including all circulatory disease, respiratory disease, and aneurysm. After adjustment for potential confounders, men with an aortic diameter of ≥25 mm had an increased risk of hypertensive disease, ischaemic heart disease, and chronic obstructive pulmonary disease, whereas the increased risk of cerebrovascular disease, atherosclerosis, peripheral arterial disease, and other diseases of the respiratory system was significant only in the ≥30 mm group.

Bias, confounding, and other reasons for caution

No women were included and relatively few men died, so the study may have lacked power to detect differences for some specific causes of mortality.

Generalisability to other populations

Clear differences in mortality and morbidity related to aortic diameter exist. The benefits of aneurysm detection by AAA screening have been proved. Whether men with an enlarged, but non-aneurysmal, aorta should be rescreened or offered interventions to reduce their cardiovascular risk requires further research.

Study funding/potential competing interests

This project was funded by a grant from the Chief Scientist Office, Scotland (CZG/2/485).

Risk of mortality and first admission to hospital for specific conditions by aortic diameter group

	Aortic diameter (mm)			Crude hazard ratio (99% CI)		Adjusted hazard ratio* (99% CI)	
Outcome	≤24 (n=7063)	25-29 (n=669)	≥30 (n=414)	25-29 mm	≥30 mm	25-29 mm	≥30 mm
All cause mortality	512 (7.2)	69 (10.3)	73 (17.6)	1.46 (1.05 to 2.02)†	2.57 (1.86 to 3.55)†	1.08 (0.73 to 1.59)	2.03 (1.40 to 2.94)†
Discharge diagnosis:							
All circulatory disease	3796 (53.7)	406 (60.7)	329 (79.5)	1.24 (1.09 to 1.42)†	1.92 (1.65 to 2.22)†	1.20 (1.04 to 1.39)†	1.51 (1.27 to 1.79)†
Chronic obstructive pulmonary disease	623 (8.8)	90 (13.5)	73 (17.6)	1.68 (1.25 to 2.24)†	3.13 (2.28 to 4.30)†	1.47 (1.07 to 2.03)†	1.98 (1.37 to 2.86)†

Group with aortic diameter <25 mm is reference category for both crude and adjusted hazard ratios.
*Adjusted for age; number of years lived in Highland; urban-rural status; number of pack years smoked; deprivation 10th; general health; ever had a heart attack, high blood pressure, stroke, or different condition; and a close relative ever had an aortic aneurysm.
†P≤0.01.

Outcomes of elective induction of labour compared with expectant management: population based study

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STUDY QUESTION

What are the risks and benefits of elective induction of labour at term compared with expectant management?

SUMMARY ANSWER

Compared with expectant management, elective induction of labour is associated with a decreased odds of perinatal mortality, with no reduction in rates of spontaneous vertex delivery but an increase in the odds of admission to a neonatal unit.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Evidence on the risks and benefits of induction of labour in the absence of a specific medical indication (elective induction of labour) around term is conflicting. Our findings indicate that elective induction of labour at term can reduce perinatal mortality without increasing the risk of operative delivery, although it may increase the risk of admission to a neonatal unit.

Participants and setting

We carried out a retrospective cohort study using an unselected population database of deliveries in obstetric units in Scotland 1981-2007. We included 1 271 549 women with singleton pregnancies of more than 36 completed weeks' gestation with no contraindication to induction of labour.

Design, size, and duration

Outcomes of elective induction of labour (induction of labour with no recognised medical indication) at 37, 38, 39, 40, and 41 weeks' gestation were compared with those of expectant management—that is, the continuation of pregnancy to either spontaneous labour or induction of labour, or caesarean section at a later gestation. Outcomes examined included extended perinatal mortality, mode of delivery, and admission to a neonatal or special care baby unit. We adjusted outcomes for age at delivery, parity, year of birth, birth weight, deprivation category, and, where appropriate, mode of delivery.

Main results and the role of chance

At each gestation between 37 and 41 completed weeks, elective induction of labour was associated with a decreased odds of perinatal mortality compared with expectant management. There was no reduction in the odds of spontaneous vertex delivery with induction at 37-39 weeks' gestation, and at 40 and 41 weeks there was an increase in the odds of spontaneous vertex delivery in the induction of labour group. Admission to a neonatal unit was increased in association with elective induction of labour at all gestations before 41 weeks. For every 1040 women having elective induction of labour at 40 weeks one neonatal death may be prevented, but this would result in seven more admissions to a neonatal unit.

Bias, confounding, and other reasons for caution

Potential sources of bias are errors in coding, lack of data on all confounders (including body mass index), and change in clinical practice over time.

Generalisability to other populations

The use of an unselected population database is a strength of the study, but the population may not be representative of other settings.

Study funding/potential competing interests

This study was funded by research grant CZG/2/292 from the Chief Scientist Office of the Scottish Government Health Directorate. A report was submitted to the funders after completion of the study and peer reviewed. The funders had no role in the study design, data collection or analysis, or the decision to publish.

Outcomes of induction of labour at 40 weeks' gestation compared with expectant management (delivery >40 weeks). Values are number with outcome/total number in group (percentage) unless stated otherwise

Outcomes	Expectant management	Induction of labour	Adjusted odds ratio* (99% CI)
Perinatal mortality	627/350 643 (0.18)	37/44 764 (0.08)	0.39 (0.24 to 0.63)
Spontaneous vertex delivery	258 665/350 791 (73.7)	35 775/44 778 (79.9)	1.26 (1.22 to 1.31)
Admission to neonatal unit	25 572/350 791 (7.3)	3605/44 778 (8.0)	1.14 (1.09 to 1.20)

*Adjusted for age, parity, period of delivery, deprivation category, and birth weight (and mode of delivery for admission to neonatal unit).