# RESEARCH

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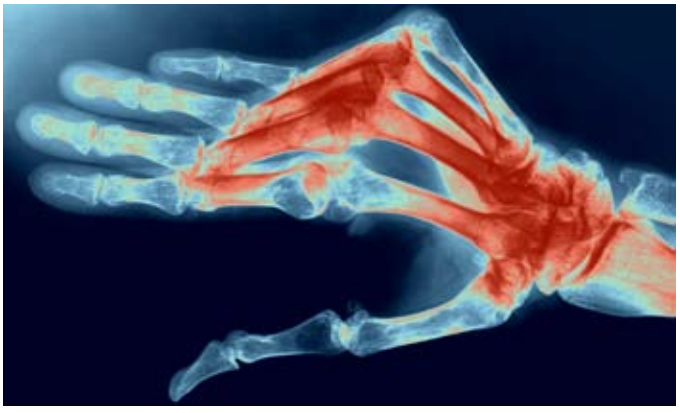
## WHAT OUR READERS ARE SAYING

**Elevated rheumatoid factor and long term risk of rheumatoid arthritis**

In this study of 9712 participants without rheumatoid arthritis recruited from the general population of Copenhagen (see page 15), the long term risk of developing rheumatoid arthritis was up to 26 times higher in those with raised concentrations of rheumatoid factor, while the 10 year absolute risk of developing the disease was 32%. In a rapid response, two rheumatologists qualify this finding:

"Testing for rheumatoid factor (RF) and anti-cyclic citrullinated protein (anti-CCP) antibodies in patients without symptoms or signs of an inflammatory arthritis is problematic on several levels. Firstly, it raises the question about what to do if the test is positive; a referral to a rheumatologist for a patient with no clinical suspicion of an inflammatory arthritis but with a positive RF, as suggested in the article, is not indicated and would, in our opinion, result in wasted resources for the health service and for patients. Repeatedly testing for RF in these patients represents an even greater waste of resources. Secondly, a false positive test can lead to unnecessary patient distress as it is still perceived by many as a test for rheumatoid arthritis. Routine screening of patients without clinical features of an inflammatory arthritis is not recommended. Based on preprobability testing, the likelihood of someone with no features of an inflammatory arthritis and a positive RF developing rheumatoid arthritis remains low…We believe that the findings of the study are of academic interest only. At present, we should continue to rely on the clinical skills of primary care physicians to guide referral to rheumatologists, rather than blood tests of limited diagnostic value."



SOVEREIGN, ISM/SPL

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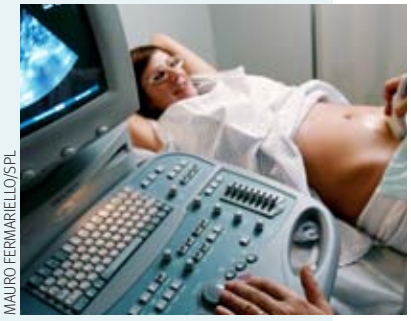
**Opiate substitution treatment and HIV transmission in people who inject drugs**

Use of injected drugs is a major risk factor for the acquisition and transmission of HIV, and about 5-10% of HIV infections are attributable to injecting drug use worldwide. This international study finds that opiate substitution treatment is associated with a substantial reduction in the risk of HIV infection among people who inject drugs, and suggests that increased coverage would be a welcome advance.

**Accuracy of single progesterone test to predict early pregnancy outcome in women with pain or bleeding**



MAURO FERMARIELLO/SPL

According to this meta-analysis of cohort studies, a single progesterone measurement for women in early pregnancy presenting with bleeding or pain and inconclusive ultrasound assessments can rule out a viable pregnancy. The authors caution, however, that the test cannot distinguish women with an ectopic pregnancy from those with an early normal pregnancy or a miscarriage and should not be used for this purpose.

**Benzodiazepine use and risk of dementia**

In this prospective population based study of 1063 men participants who were free of dementia and did not start taking benzodiazepines until at least the third year of follow-up, new use of benzodiazepines was associated with increased risk of dementia. The result was robust in pooled analyses across cohorts of new users of benzodiazepines throughout the study and in a complementary case-control study. Considering the extent to which benzodiazepines are prescribed and the number of potential adverse effects of this drug class in the general population, indiscriminate widespread use should be cautioned against, say the authors.

# Effect of classroom based cognitive behavioural therapy on symptoms of depression in high risk adolescents: pragmatic cluster randomised controlled trial

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EDITORIAL by Merry and Stasiak

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## STUDY QUESTION

How effective is classroom based cognitive behavioural therapy (CBT) compared with attention control and usual school provision for adolescents at high risk of depression?

## SUMMARY ANSWER

Although classroom based CBT was associated with high levels of fidelity and adherence, there was no evidence that it reduced depressive symptoms in high risk adolescents when implemented under everyday conditions.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Classroom based psychological programmes can be effective in preventing depression in adolescents but have not been evaluated under real world conditions comparing interventions with appropriate control groups. A classroom based CBT programme was not effective in reducing symptoms of depression in high risk adolescents compared with usual school provision and attention control.

### Design

Three arm parallel cluster randomised controlled trial. Adolescents in year groups 8-11 were randomly assigned in a 1:1:1 ratio to cognitive behavioural therapy (CBT), attention control, or usual school provision. Allocation was balanced by school, year, number of students and classes, frequency of lessons, and timetabling. Participants were not blinded to treatment.

### Participants and setting

Adolescents (n=5030) aged 12-16 from eight UK schools in year groups 8-11. 1064 (21.2%) were defined as being at high risk of depression.

### Primary outcomes

Outcomes were collected by self completed questionnaire administered by researchers. The primary outcome was symptoms of depression assessed at 12 months by the short mood and feelings questionnaire among those identified at baseline as being at high risk of depression. Secondary outcomes included negative thinking, self worth, and anxiety.

### Main results and the role of chance

Primary outcome data were collected from 846 (79.5%) high risk participants. At 12 months adjusted mean scores on the short mood and feelings questionnaire did not differ between trial arms. The trial arms also did not differ for self worth and anxiety.

### Harms

When compared with usual school provision classroom based CBT showed evidence of a small but potentially harmful effect on negative thinking (1.95, 95% confidence interval 0.25 to 3.66, P=0.02). Adolescents receiving CBT reported more negative thoughts.

### Bias, confounding, and other reasons for caution

The CBT programme was designed for adolescents aged 12-15, and therefore the inclusion of 16 year olds could have reduced the effects. We relied on ratings of depressive symptoms from self report and did not undertake any interviews for diagnostic purposes. Delivering the intervention to all children while targeting those at high risk of depression may have compromised the potency of the intervention.

### Generalisability to other populations

The cohort was representative of UK schools for ethnicity, deprivation (eligibility for free school meals), rates of pupils' absence, and academic ability (examination results and proportion of children with identified special educational needs).

### Study funding/potential competing interests

This study was funded by the National Institute of Health Research Health Technology Assessment (06/37/04). The views and opinions are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, National Health Service, or Department of Health. We have no competing interests.

### Trial registration number

Current Controlled Trials ISRCTN19083628.

**Primary and main secondary outcomes for high risk participants, for classroom based cognitive behavioural therapy (CBT) compared with each of usual school provision and attention control personal, social, and health education (PSHE). Values are mean (standard deviation) scores unless stated otherwise**

| | Usual school provision | | Adjusted difference* (95% CI) at 12 months: CBT *v* usual school provision | Classroom based CBT | | Adjusted difference* (95% CI) at 12 months: CBT *v* attention control | Attention control PSHE | |
|---|---|---|---|---|---|---|---|---|
| Variables | Baseline | 12 months | | Baseline | 12 months | | Baseline | 12 months |
| SMFQ | 10.56 (4.93) | 6.81 (5.70) | 0.97 (−0.20 to 2.15) | 10.64 (4.91) | 8.22 (6.45) | −0.63 (−1.85 to 0.58) | 10.60 (4.67) | 8.50 (5.88) |
| CATS | 12.20 (9.28) | 8.18 (8.68) | 1.95 (0.25 to 3.66) | 12.40 (9.21) | 10.48 (10.00) | 0.29 (−1.48 to 2.07) | 13.35 (8.99) | 10.63 (9.94) |
| RSE | 15.88 (4.80) | 17.39 (5.34) | 0.12 (−0.81 to 1.05) | 15.54 (4.70) | 16.93 (5.65) | −0.13 (−1.12 to 0.87) | 15.36 (4.38) | 16.68 (5.25) |
| RCADS | 24.07 (10.69) | 19.27 (11.64) | 1.48 (−0.64 to 3.59) | 25.04 (10.80) | 22.16 (12.38) | −0.60 (−2.88 to 1.67) | 24.29 (11.01) | 22.27 (11.74) |

SMFQ=short mood and feeling questionnaire (range 0-26); CATS=children's automatic thoughts scale (range 0-40); RSE=Rosenberg self esteem scale (range 0-30); RCADS=revised child anxiety and depression scale (range 0-75).
*Adjusted for number of students, number of classes, frequency of delivery, school, and value of outcome measure at baseline.

# Exposure to diagnostic radiation and risk of breast cancer among carriers of BRCA1/2 mutations: retrospective cohort study (GENE-RAD-RISK)

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## STUDY QUESTION

What is the risk of breast cancer after exposure to diagnostic radiation in women with BRCA1/2 mutations?

## SUMMARY ANSWER

Among BRCA1/2 mutation carriers, exposure to diagnostic radiation before age 30 is associated with an increased risk of breast cancer at dose levels considerably lower than those at which increases have been found in other cohorts exposed to radiation.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Epidemiological studies on the association between diagnostic radiation and risk of breast cancer in BRCA1/2 mutation carriers have shown inconclusive results. While previous studies were based only on mammography or radiography, we additionally investigated other types of diagnostic exposures in carriers and calculated one estimate of total radiation dose. Any exposure to diagnostic radiation before the age of 30 was associated with an increased risk of breast cancer among BRCA1/2 mutation carriers

### Participants and setting

We included 1993 women who were tested in a clinical setting (such as a clinical genetic centre), identified as carriers of BRCA1 or BRCA2 mutations, and aged 18 or older. Women were recruited into the GENE-RAD-RISK cohort study (response 78%) in 2006-09 and took part in three large ongoing national cohort studies of carriers in France (GENEPSO), the United Kingdom (EMBRACE), and the Netherlands (HEBON).

### Design, size, and duration

The GENE-RAD-RISK study is a retrospective cohort study among carriers of BRCA1/2 mutations. Women reported their history of exposure to diagnostic radiation in a standardised questionnaire containing indication based questions on lifetime exposure to fluoroscopy, conventional radiography of the chest/shoulders, mammography, chest/shoulder computed tomography, and other diagnostic procedures that use ionising radiation involving the chest or shoulders. We estimated cumulative breast dose as an approximation of breast dose from the sum of the age and calendar specific number of self reported diagnostic procedures multiplied by nominal estimates of breast dose.

### Main results and the role of chance

Any exposure to diagnostic radiation before the age of 30 was associated with an almost twofold increased risk of breast cancer (hazard ratio 1.90, 95% confidence interval 1.20 to 3.00), with a dose-response pattern. Analyses on the different types of diagnostic procedures showed a pattern of increasing risk with increasing number of radiographs before age 30 compared with no exposure. A history of mammography before age 30 was also associated with an increased risk of breast cancer (1.43, 0.85 to 2.40)

Chance is an unlikely explanation for our findings as the overall pattern indicates increased risks and hazard ratios are already increased, albeit non-significantly, for the lowest dose category and remain increased for all categories of higher dose.

**Analyses of estimated cumulative breast dose of diagnostic radiation received before age 30 and risk of breast cancer among BRCA1/2 mutation carriers**

| Exposure | Person years | Cases | Hazard ratio (95% CI)* |
|---|---|---|---|
| Never | 1679 | 57 | 1.00 |
| Ever | 2108 | 83 | 1.90 (1.20 to 3.00) |
| Dose category: | | | |
| <0.0020 Gy | 874 | 33 | 1.63 (0.96 to 2.77) |
| 0.0020-0.0065 Gy | 574 | 22 | 1.78 (0.88 to 3.58) |
| 0.0066-0.0173 Gy | 413 | 14 | 1.75 (0.72 to 4.25) |
| ≥0.0174 Gy | 245 | 14 | 3.84 (1.67 to 8.79) |

*Results of main analysis among 1122 BRCA1/2 mutation carriers who received diagnosis of breast cancer or were censored within five years before questionnaire completion; main analysis was conducted in this subcohort of carriers to correct for potential survival bias arising from exclusion of exposed carriers who died from breast cancer long before questionnaire completion.

### Bias, confounding, and other reasons for caution

The results should be interpreted with caution because of the retrospective nature of our study, though we consider recall bias to be unlikely. Other studies on the Dutch cohort have shown that the extent of the observed misclassification of self reported history of diagnostic radiation was small and mainly non-differential by disease status. To correct for potential survival bias arising from the exclusion of exposed women who died from breast cancer long before questionnaire completion, we carried out our main analyses on carriers with a diagnosis of breast cancer or who were censored within the five years before questionnaire completion—that is, recent cases.

### Generalisability to other populations

The results of our study are relevant for BRCA1/2 mutation carriers with a spectrum of mutations as observed (UK, France, and The Netherlands).

### Study funding

See bmj.com. We have no competing interests.

# Elevated rheumatoid factor and long term risk of rheumatoid arthritis: a prospective cohort study

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EDITORIAL by Simard and Holmqvist

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## STUDY QUESTION

Are elevated plasma concentrations of rheumatoid factor in people without rheumatoid arthritis associated with long term development of rheumatoid arthritis?

## SUMMARY ANSWER

Yes, individuals from the general population with elevated rheumatoid factor have up to 26-fold increased long term risk of rheumatoid arthritis, and up to 32% 10 year absolute risk of rheumatoid arthritis.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

zRheumatoid arthritis is an autoimmune disease affecting 0.5-2% of the population, but there is no good clinical predictor for long term development of rheumatoid arthritis. Patients with elevated plasma rheumatoid factor level but without indication of joint symptoms are at increased risk of developing rheumatoid arthritis and should be referred to a rheumatologist for surveillance and possibly early intervention.

### Participants and setting

General population cohort of 20-100 year old white Danish individuals without rheumatoid arthritis at study entry from the Copenhagen area.

### Design, size, and duration

We identified 9712 individuals from the Copenhagen City Heart Study who met the inclusion criteria. Blood was drawn in 1981-83, and baseline plasma IgM rheumatoid factor levels measured and categorised as <25, 25-50, 50.1-100, and >100 IU/mL. Participants were followed until 10 August 2010 (28 years), in which time 183 developed rheumatoid arthritis.

### Main results and the role of chance

The cumulative incidence of rheumatoid arthritis increased with increasing rheumatoid factor category ($P_{trend}$<0.0001). During 28 years' follow-up, multivariable adjusted hazard ratios for rheumatoid arthritis were 3.6 (95% CI 1.7 to 7.3) for rheumatoid factor levels of 25-50 IU/mL, 6.0 (3.4 to 10) for 50.1-100 IU/mL, and 26 (15 to 46) for >100 IU/mL, compared with <25 IU/mL ($P_{trend}$<0.0001). The highest absolute 10 year risk of rheumatoid arthritis of 32% was observed in 50-69 year old women who smoked and had rheumatoid factor levels >100 IU/mL. All results were highly significant, ruling out the probability of chance findings.

### Bias, confounding, and other reasons for caution

These data do not serve as evidence that rheumatoid factor plays a causal role in the pathogenesis of rheumatoid arthritis. Elevated rheumatoid factor should be viewed as a marker of autoimmune pathogenesis associated with future risk of rheumatoid arthritis. The present study selected a sample representative of the general population, and only individuals without known rheumatoid arthritis entered into the study.

### Generalisability to other populations

As we studied white people only, our results may not necessarily apply to other races. However, there are no data to suggest that these results should not apply to all races.

### Study funding/potential competing interests

No competing interests declared.

**Risk of rheumatoid arthritis by level of rheumatoid factor, length of follow-up, and hospitalisations for rheumatoid arthritis**

| | | Any rheumatoid arthritis hospitalisation | | | ≥2 rheumatoid arthritis hospitalisations | | |
|---|---|---|---|---|---|---|---|
| | | 28 years of follow-up | | | 28 years of follow-up | | |
| Rheumatoid factor (IU/mL) | No of participants | No of events | Hazard ratio (95% CI) | Hazard ratio (95% CI) | No of events | Hazard ratio (95% CI) | Hazard ratio (95% CI) |
| <25 | 9294 | 147 | | 1 (reference) | 77 | | 1 (reference) |
| 25-50 | 176 | 8 | | 3.6 (1.7 to 7.3) | 7 | | 5.8 (2.6 to 13) |
| 50.1-100 | 187 | 14 | | 6.0 (3.4 to 10) | 12 | | 10 (5.4 to 19) |
| >100 | 55 | 14 | | 26 (15 to 46) | 11 | | 37 (19 to 70) |
| | | | | $P_{trend}$<0.0001 | | | $P_{trend}$<0.0001 |
| | | 10 years of follow-up | | | 10 years of follow-up | | |
| Rheumatoid factor (IU/mL) | No of participants | No of events | Hazard ratio (95% CI) | Hazard ratio (95% CI) | No of events | Hazard ratio (95% CI) | Hazard ratio (95% CI) |
| <25 | 9294 | 41 | | 1 (reference) | 24 | | 1 (reference) |
| 25-50 | 176 | 4 | | 6.0 (2.1 to 17) | 4 | | 10 (3.7 to 32) |
| 50.1-100 | 187 | 10 | | 14 (6.7 to 28) | 8 | | 21 (8.9 to 48) |
| >100 | 55 | 8 | | 39 (18 to 85) | 7 | | 57 (24 to 136) |
| | | | 0.5 1 3 10 35 90 | $P_{trend}$<0.0001 | | 0.5 1 3 10 35 90 | $P_{trend}$<0.0001 |

# Use of population based background rates of disease to assess vaccine safety in childhood and mass immunisation in Denmark: nationwide population based cohort study

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## STUDY QUESTION

Can population based background rates of disease be used to assess the safety of newly introduced vaccines in mass immunisation?

## SUMMARY ANSWER

Incorporating background rates of disease based on age, sex, and seasonal distribution can strengthen vaccine safety assessment and provide an evidence based focus for discussing the incremental risk of newly introduced vaccines in areas with public distrust and low vaccine acceptance.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Few previous studies have examined background incidence of diagnoses that are often associated with vaccine safety concerns. Use of unique Danish medical registries has enabled calculation of age and sex specific incidence of selected diagnoses primarily of autoimmune genesis among children and adolescents; these data may be useful in distinguishing events temporally associated with vaccine exposure from those events caused by exposure.

**Outcomes temporally associated with vaccination per 1 000 000 people in hypothetical cohort**

| Outcome | Predicted No within 7 days of vaccination | Predicted No within 42 days of vaccination | Predicted No within 182 days of vaccination |
|---|---|---|---|
| Acute infectious and post-infectious polyneuritis (Guillain-Barré syndrome) | 0.13 | 0.77 | 3.29 |
| Acute transverse myelitis | 0.07 | 0.42 | 1.78 |
| Optic polyneuritis | 0.12 | 0.69 | 2.98 |
| Facial nerve palsy | 1.32 | 7.94 | 34.03 |
| Anaphylactic shock | 0.28 | 1.67 | 7.16 |
| Seizure | 36.38 | 218.27 | 935.45 |
| Multiple sclerosis | 0.8 | 4.79 | 20.54 |
| Autoimmune thrombocytopenia | 0.06 | 0.37 | 1.59 |
| Type 1 diabetes mellitus | 3.39 | 20.37 | 87.3 |
| Juvenile and rheumatoid arthritis | 3.21 | 19.24 | 82.47 |
| Narcolepsy | 0.09 | 0.55 | 2.37 |
| Death of unknown cause | 0.35 | 2.09 | 8.98 |
| Any adverse event | 45.92 | 275.5 | 1180.7 |
| Any adverse event excluding seizure | 9.26 | 55.59 | 238.24 |

### Participants and setting

All liveborn infants delivered in Denmark after 1 January 1980.

### Design, size, and duration

Nationwide population based cohort study. Study participants were followed from date of birth until hospital admission for selected outcome diagnoses, death, first emigration, age 18 years, or 31 December 2009. Main outcome measures were incidence of selected diseases. The predicted count of events for 1 000 000 people (a hypothetical vaccine cohort) was calculated for follow-up times of up to 182 days.

### Main results and the role of chance

The study included 2 300 227 liveborn infants yielding 37 262 404 person years of follow-up; median follow-up time was 16.8 person years. Incidence of outcome diagnoses spanned from 0.32 per 100 000 person years for autoimmune thrombocytopenia to 189.82 per 100 000 person years for seizure. Seasonal differences were most pronounced for anaphylactic shock, seizure, and multiple sclerosis. Even for rare outcomes, numerous events were predicted in the hypothetical vaccine cohort. We predicted that 20 cases of type 1 diabetes mellitus, 19 of juvenile or rheumatoid arthritis, eight of facial nerve palsy, and five of multiple sclerosis per 1 000 000 children would occur within 42 days after vaccination.

### Bias, confounding, and other reasons for caution

Only hospital discharge diagnoses and emergency room visits were included. Although the diagnoses selected for this analysis are generally handled in the hospital setting, some patients could have been treated exclusively in the primary sector and hence not recorded in our material. We also did not review medical charts to validate the accuracy of diagnoses. Furthermore, since study participants were followed up to the first recorded admission for diagnosis of a selected outcome, subsequent events were not included in our analyses.

### Generalisability to other populations

We extracted data from a vaccine exposed population of primarily white people, and our findings should be extrapolated with care to populations of different vaccine exposure, race, ethnicity, and environment.

### Study funding/potential competing interests

The study was funded solely by the Department of Infectious Diseases, Aarhus University Hospital, Denmark. The authors declare no competing interests.

# Use of relative and absolute effect measures in reporting health inequalities: structured review

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**Response on bmj.com**

"King et al have interpreted the preference for relative effect measures (as opposed to absolute ones) as a choice made by researchers in the presentation of their results. This is not always true. The use of one type of measures as opposed to the other is often related to the design of the study rather than to the presentation of the results."
Sam Harper, assistant professor, McGill University, Montreal

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## STUDY QUESTION

What is the frequency of reporting absolute and relative measures of effect in health inequalities research?

## SUMMARY ANSWER

Health inequalities are most commonly reported using only relative effect measures; few studies report both absolute and relative effect measures.

## WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Reporting guidelines recommend using both absolute and relative measures of effect whenever possible. Contrary to these recommendations, less than 10% of studies of social inequalities in health reported both types of effect measure.

### Selection criteria for studies

We did a literature search for all studies in 2009 that reported quantitative evidence on social inequalities in health, published in 10 leading medical, public health, and epidemiology journals: *American Journal of Epidemiology*, *American Journal of Public Health*, *BMJ*, *Epidemiology*, *International Journal of Epidemiology, JAMA*, *Journal of Epidemiology and Community Health*, *The Lancet*, *The New England Journal of Medicine*, and *Social Science and Medicine*. We included only articles reporting original research results with a quantitative measure of health inequality in the full text. We excluded review articles, systematic reviews, editorials, and commentaries unless they contained original empirical results.

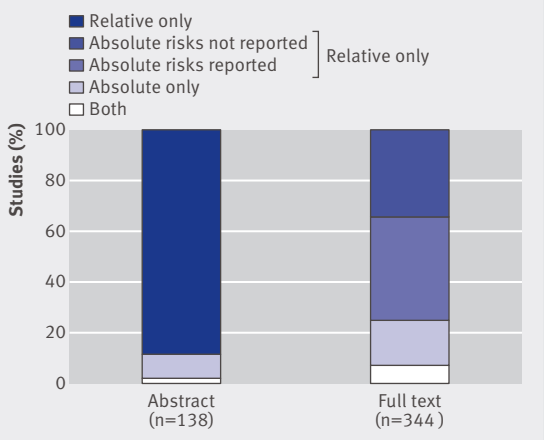
### Primary outcome

The main outcomes were the frequency and proportion of studies reporting absolute measures of effect, relative measures of effect, or both, in abstract and full text, and the reporting of absolute risks in studies reporting only relative effect measures.

### Main results and role of chance

Of 344 articles, 122 (35%, 95% confidence interval 30% to 41%) reported only relative measures in the abstract; 13 (3.8%, 1.8% to 5.8%) reported only absolute measures, and 3 (0.9%, 0% to 1.9%) reported both absolute and relative measures in the abstract. In the full text, 258 (75%, 70% to 80%) of all articles reported only relative measures; 119 (46%, 40% to 52%) of these did not report absolute risks. Sixty-one (18%, 14% to 22%) articles reported only absolute measures in the full text, and 25 (7.3%, 4.5% to 10%) reported both absolute and relative measures. These results were consistent across journals, exposures, and outcomes.

**Reporting of relative and absolute effect measures in abstract and full text**




### Bias, confounding, and other reasons for caution

Our study was limited to a sample of 10 journals in one calendar year. Selecting different journals or time periods, or using different search terms, may have produced different results. We analysed articles as a whole rather than analysing each reported measure separately. Examining each measure separately may have produced a different result.

### Study funding/potential competing interests

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## BMJ pico: advice to authors

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