

RESEARCH

The *BMJ* is an Open Access journal. We set no word limits on *BMJ* research articles, but they are abridged for print. The full text of each *BMJ* research article is freely available on bmj.com

1079 RESEARCH NEWS All you need to read in the other general medical journals

THIS WEEK'S RESEARCH QUESTIONS

- 1082** Does a high intake of dietary fibre or whole grains reduce the risk of developing colorectal cancer?
- 1083** Does integrated care for chronic physical diseases and depression improve disability and quality of life outcomes?
- 1084** Can an additional review based on reporting guidelines, such as STROBE and CONSORT, improve the quality of manuscripts reviewed by a biomedical journal?
- 1085** Can an accurate formula be developed to help allocate NHS funds to general practices in England for commissioning hospital care, based on the health needs of individuals in each practice?

Co-targeting physical and mental illness for healthy ageing

As people live longer and the population of older people living with chronic diseases grows, so too does the proportion of older people with comorbid depression, says editorialist Dilip V Jeste (p 1076). Coexisting mental and physical problems may add up to more than the sum of their parts, and studies show that treatment for depression reduces disability in patients with arthritis, diabetes, heart disease, and chronic pain. But the potential of such treatment to improve the lives of chronically ill people as they age is often overlooked. Previous trials of treatment to control diabetes and cardiovascular risk factors suggest that although these treatments can prevent major events in the long term, they don't seem to improve functioning and quality of life—outcomes that might be improved by treatment for depression.

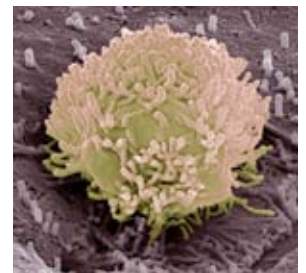
Michael Von Korff and colleagues (p 1083) aimed to harness the power of simultaneous treatment for mental and chronic physical illness, to enhance “successful ageing.” In a randomised controlled trial, they investigated an integrated care programme in 14 US primary care clinics. The 12 month intervention, called TEAMcare, combined a treat to target programme for diabetes and coronary heart disease with collaborative care for depression. They found that this approach reduced social role disability—the extent to which health interfered with work, family life, and social life—and improved global quality of life in the middle aged and older people who participated. However, they report, the trial was underpowered to evaluate disability outcomes, so the small observed improvement in functioning should be interpreted in the light of other studies.



Fibre and colorectal disease: are all fibres equal?

It's difficult to give patients specific and accurate advice about what to eat or avoid in an evidence based way. Randomised controlled trials of foods are problematic—it's hard to randomise people to a specific diet, let alone follow them up until they manifest major medical diagnoses years later. So researchers are left with observational research, and trying to dampen down the statistical noise from the numerous other lifestyle choices people make, to better characterise the links between diet and disease, such as fibre and colorectal cancer.

Recent, large scale studies suggest a link between fibre and colorectal cancer, and there are biological theories to support the possibility that this link is causal. But, is there a dose response? Are all fibres equal? Is it all about bulk, or are there other properties of specific fibrous foods—such as fruit and vegetables or wholegrains—that are important? Dagfinn Aune



and colleagues have done a systematic review and meta-analysis to investigate (p 1082). The authors find a modest link, with the usual cautions that these data are observational, and that by combining studies the potential for confounding has not been reduced. It is a strength that the authors have looked at the source of fibre and not just total fibre from all foods, write Anne Tjønneland and Anja Olsen in a linked editorial (p 1075). It seems whole grains, in particular, are associated with lowered risk of colorectal cancer; they are already known to be of benefit in cardiovascular disease. For doctors counselling patients, this latest association adds to the list of conditions that whole grains, such as oats and other cereals, might help to prevent.

RESEARCH ONLINE: For these and other new research articles see www.bmj.com/research

Perinatal and maternal outcomes by planned place of birth for women with low risk pregnancies

Results of a study by the Birthplace in England Collaborative Group support a policy of offering women with low risk pregnancies a choice of birth setting—at home or in a midwifery unit (doi:10.1136/bmj.d7400).

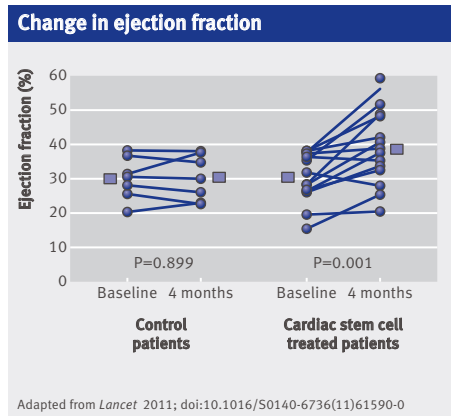
Overdiagnosis from non-progressive cancer detected by screening mammography

Arnaud Seigneurin and colleagues conducted a modelling study and found that overdiagnosis for invasive cancers was smaller than expected in a French population offered organised and individual screening (doi:10.1136/bmj.d7017).



All you need to read in the other general medical journals
 Alison Tonks, associate editor, *BMJ* atonks@bmj.com

First few patients do surprisingly well after new cell therapy for heart failure



Adapted from *Lancet* 2011; doi:10.1016/S0140-6736(11)61590-0

The heart contains stem cells that can transform into myocytes. Researchers have already used cardiac stem cells to repair damaged and failing myocardium in rodents, dogs, and pigs, and they are now turning their attention to humans with severe heart failure, caused by at least one old myocardial infarct. The first 16 people to be treated had intracoronary infusions of their own stem cells around four months after coronary artery bypass surgery. Their left ventricular function improved significantly during the next four months (average left ventricular ejection fraction among 14 analysed rose from 30.3% to 38.5%; P=0.001) and improved still further in the eight patients who had repeat echocardiography after one year. Left ventricular ejection fraction did not change in seven untreated controls.

This small phase I study was designed to explore feasibility and safety. The researchers were a little surprised by the magnitude of the benefits, which included an average 24% reduction in the size of old infarcts and substantial improvements in symptoms and quality of life for treated patients. Each patient's stem cells were isolated from their right atrial appendage, and were harvested during bypass surgery. Stem cell treatment caused no serious adverse events.

The early success of cardiac stem cells may help invigorate a flagging line of inquiry that has suffered lately from disappointments and setbacks, says a linked editorial (doi:10.1016/S0140-6736(11)61648-6). More patients and longer follow-up come next, then hopefully a

fully blinded, tightly controlled, and well powered randomised trial.

Lancet 2100; doi:10.1016/S0140-6736(11)61590-0

Whole body vibration is not recommended for postmenopausal women

Twenty minutes a day of standing on an oscillating platform did nothing for the bone mineral density or bone structure of postmenopausal women in a recent trial. The treatment, known as whole body vibration, went on for 12 months. Researchers compared two different frequencies with no treatment. Neither frequency had a measurable effect on bone at the distal tibia, distal radius, femoral neck, hip, or lumbar spine.

The 202 participants had low bone mineral densities (T scores between -1 and -2.5) at the start of the trial, but no osteoporosis. They took calcium and vitamin D supplements for the whole year. The vibrating platforms, used at home and unsupervised, caused no serious side effects, but a handful of women blamed the vibrations for nuisance symptoms such as numbness, weakness, nausea, headache, and bladder discomfort. Three stopped treatment early because of dizziness, shin pain, and foot pain.

This is the biggest trial of whole body vibration to test a low magnitude treatment in postmenopausal women, say the authors. They do not recommend it. A state of the science review published alongside the trial does not recommend whole body vibration either—the evidence is still too patchy and the target group too unclear. This kind of treatment is currently unregulated.

Ann Intern Med 2011;155:668-79

Ann Intern Med 2011;155:680-6

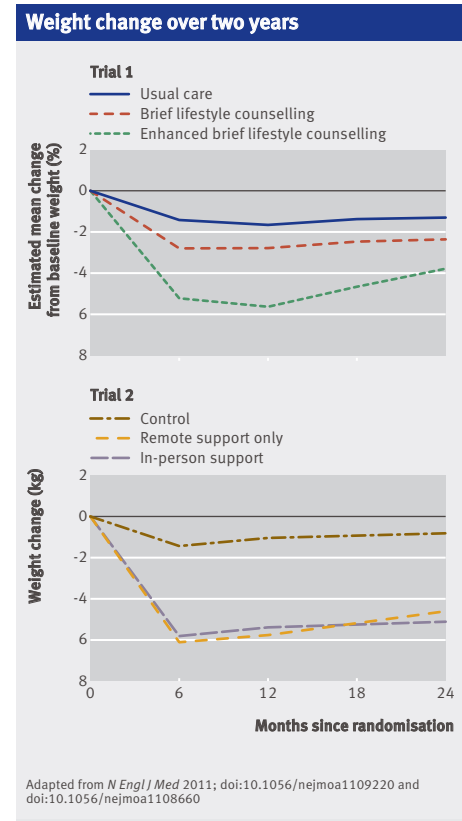
Series of trials compares primary care treatments for obese adults

In 2008, US researchers began a series of three trials to find the best way for primary care practices to help obese patients lose weight. Two are now complete. In the first, patients given brief counselling by lifestyle coaches once a month plus their choice of weight loss drug or

liquid meal replacement lost significantly more weight over two years (4.6 kg) than those given brief counselling alone (2.9 kg) or usual care (1.7 kg). All participants followed an energy controlled diet, tried to do three hours of physical activity a week, and undertook scheduled quarterly visits with their primary care doctor.

In the second trial, remote support by telephone, email, and online worked better than self directed weight loss (4.6 kg v 0.8 kg; P<0.001) and just as well as remote support with extra face to face contact (5.1 kg). Weight loss coaches delivered both active interventions in this trial, which also lasted two years. A similar proportion of patients in both active groups lost at least 5% of their original body weight (38.2% of those on remote support only; 41.4% of those on additional face to face contact; 18.8% of controls).

Both trials struggled with falling attendance at face to face sessions in the second year, and remote coaching could be the best way forward, says a linked editorial (doi:10.1056/nejme1111487). Now we need to know which, if any, of these strategies are cost effective, who will pay if they are, and whether they can work



Adapted from *N Engl J Med* 2011; doi:10.1056/nejmoa1109220 and doi:10.1056/nejmoa1108660



“The plump boy who played Piggy in *Lord of the Flies* grew up to be quite lanky . . . this analysis of four Finnish cohort studies shows that the lucky Piggies who cast off their childhood corpulence have the same cardiovascular risk as adults who were never fat”

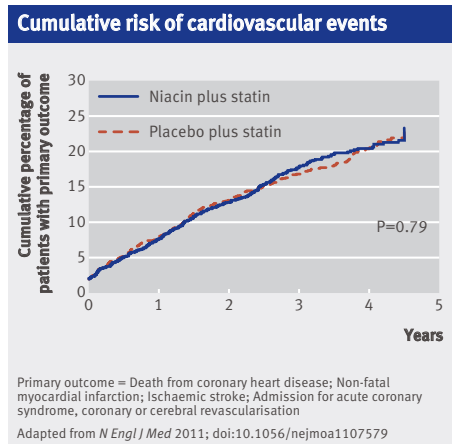
Read Richard Lehman's journal blog at bmj.com/

well enough to prevent diabetes and reduce cardiovascular risk. Participants in both trials were treated free of charge.

N Engl J Med 2011; doi:10.1056/nejmoa1109220

N Engl J Med 2011; doi:10.1056/nejmoa1108660

Niacin adds little, if anything, to intensive treatment with statins



The role of niacin in adults with cardiovascular disease remains in doubt after a large trial found that this drug did not prevent heart attacks, strokes, or other serious cardiovascular events when added to intensive treatment with statins.

Niacin is best known for increasing serum concentrations of high density lipoprotein-cholesterol, but the 25% increase reported in this trial did not prevent a single cardiovascular event (16.4% (282/1718) v 16.2% (274/1696); hazard ratio 1.02, 95% CI 0.87 to 1.21). An editorial (doi:10.1056/nejme1112346) described the results as “chillingly null.” The trial ended 18 months early.

The authors tested 1500-2000 mg of niacin a day against a placebo in 3414 adults. All were given simvastatin with or without ezetimibe to maintain serum concentrations of low density lipoprotein-cholesterol at 1-2 mmol/L. Half of the participants took additional niacin for a mean of three years.

Niacin's place in the therapeutic armoury for these patients has always been built on shaky foundations, says the editorial. These new results do little to justify the \$800m (£510m; €595m) a year spent in the US on extended release brands alone. Flushing can be a prob-

lematic side effect, and these authors were also troubled by a few extra cases of ischaemic stroke in patients taking niacin.

Other trials are already on the way and should report by 2013. Then we can decide whether to retire niacin for good, says the editorial.

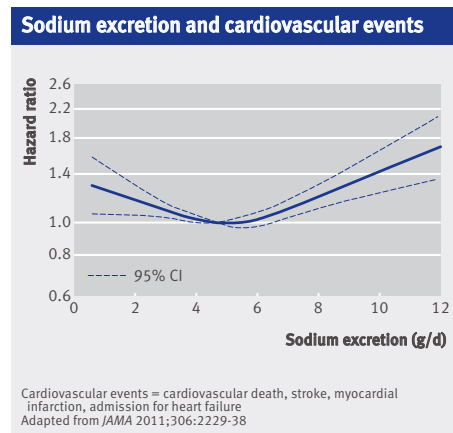
N Engl J Med 2011; doi:10.1056/nejmoa1107579

High (and very low) salt intake is linked to cardiovascular events, including death

Encouragement to eat less salt has been a common feature of public health advice in recent years, although guidelines disagree about the intake we should be aiming for. Many observers believe the lower the better, although a recent analysis identified a J shaped association between sodium excretion (as a proxy for intake) and cardiovascular events in high risk adults.

Those excreting 4-6 g of sodium a day had the lowest risk of cardiovascular events, including death from cardiovascular disease (15.2% (2148/14 156)). Risk was significantly higher in those who excreted more (>8 g: 24.1% (204/847); fully adjusted hazard ratio 1.49, 95% CI 1.28 to 1.75) or less (<2 g: 1.21, 1.03 to 1.43; 2-3 g: 1.16, 1.04 to 1.28) than this reference amount. Should agencies that recommend no more than 1.5 g a day rethink their advice?

Not yet, says a linked editorial (p 2262). We have good evidence from randomised trials that eating less salt protects cardiovascular health. There is always room for more trials, to fine tune the safe range, but the principle



is established and shouldn't be overturned by observational work, however powerful and sophisticated it is. The J shape looks convincing, but adults on the “upstick” at the lower end of the curve may be avoiding salt because they are already ill. Isolating the effects of salt from other dietary habits is another challenge for observational studies, says the editorial, and estimating sodium excretion from one early morning urine sample was a particular challenge for this one. Policy makers should stand firm for now.

JAMA 2011;306:2229-38

Fewer INR tests for selected adults taking warfarin?

Stable patients taking warfarin may be able to switch from monthly to three monthly blood tests if results from a preliminary trial are confirmed. Less frequent testing of international normalised ratio (INR) looked safe and resulted in fewer changes of dose for adults on long term treatment who had not had their dose adjusted for at least six months.

Less frequent testing made no difference to the proportion of time patients spent within the therapeutic range for INR (71.6% v 74.1%, judged to be statistically non-inferior) or the proportion of test results well outside the normal range. All 250 patients attended a single anticoagulation clinic in Canada. Most had atrial fibrillation or a replacement heart valve.

Everyone in the trial had a blood test every four weeks, to maintain masking. True results were reported every 12 weeks for those assigned to the longer interval. Doctors received sham results the rest of the time, unless the true result was extreme enough to require an urgent dose adjustment. This happened only twice.

In the real world, adults monitored every 12 weeks would not have monthly contact with a health professional, or the option of a rescue adjustment, say the authors. So it is too early to recommend a wholesale switch of strategy. Further trials without these safety nets can now go ahead, including at least one that is big enough to look for thromboembolic events, bleeding, and deaths.

Ann Intern Med 2011;155:653-9

Cite this as: *BMJ* 2011;343:d7549

Dietary fibre, whole grains, and risk of colorectal cancer: systematic review and dose-response meta-analysis of prospective studies

Dagfinn Aune,¹ Doris S M Chan,¹ Rosa Lau,¹ Rui Vieira,¹ Darren C Greenwood,² Ellen Kampman,³ Teresa Norat¹

EDITORIAL
by Tjønnealand and Olsen

¹Department of Epidemiology and Biostatistics, School of Public Health, Imperial College London, St Mary's Campus, London W2 1PG, UK

²BioStatistics Unit, Centre for Epidemiology and Biostatistics, University of Leeds, Leeds, UK

³Division of Human Nutrition, Wageningen University and Research Centre, Wageningen, Netherlands

Correspondence to: D Aune
d.aune@imperial.ac.uk

Cite this as: *BMJ* 2011;343:d6617
doi: 10.1136/bmj.d6617

This is a summary of a paper that was published on bmj.com as *BMJ* 2011;343:d6617

STUDY QUESTION Does a high intake of dietary fibre or whole grains reduce the risk of developing colorectal cancer?

SUMMARY ANSWER Intake of dietary fibre, cereal fibre, and whole grains was associated with a reduced risk of colorectal cancer. The association between intake of fruit fibre, vegetable fibre, or legume fibre and risk of colorectal cancer was not significant.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

A 2007 report from the World Cancer Research Fund Report stated that dietary fibre probably protects against colorectal cancer. It is, however, unclear whether specific types of fibre or whole grains are associated with the risk of colorectal cancer, and questions remain about the shape of the dose-response relation between fibre intake and colorectal cancer. This study suggests that, in addition to a high total dietary fibre intake, cereal fibre and whole grains may reduce the risk of colorectal cancer.

Selection criteria for studies

We searched PubMed and several other databases for relevant studies up to December 2010, with no language restrictions, along with the reference lists of all the studies that were included in our analysis and those listed in the published meta-analyses. To be included the study had to have a prospective cohort, case-cohort, or

nested case-control design and to investigate the association between intake of dietary fibre or whole grains and incidence of colorectal cancer. We used random effects models to calculate summary relative risks and 95% confidence intervals for the association between dietary fibre and whole grains and risk of colorectal cancer. To clarify the dose-response relation between fibre and whole grain intakes and risk of colorectal cancer we carried out both linear and non-linear dose-response analyses.

Primary outcome

The primary outcome was the incidence of colorectal cancer.

Main results and role of chance

The summary relative risk of colorectal cancer for each 10 g/day intake was 0.90 (95% confidence interval 0.86 to 0.94, $I^2=0\%$, 16 studies) for total dietary fibre, 0.93 (0.82 to 1.05, $I^2=23\%$, nine studies) for fruit fibre, 0.98 (0.91 to 1.06, $I^2=0\%$, nine studies) for vegetable fibre, 0.62 (0.27 to 1.42, $I^2=58\%$, four studies) for legume fibre, and 0.90 (0.83 to 0.97, $I^2=0\%$, eight studies) for cereal fibre. The summary relative risk for an increment of three servings daily of whole grains was 0.83 (0.78 to 0.89, $I^2=18\%$, six studies).

Bias, confounding, and other reasons for caution

Evidence of small study bias was lacking with Egger's test and Begg's test and by inspection of the funnel plots. The results persisted in most subgroup analyses when stratified by study characteristics such as duration of follow-up, sex, geographical location, number of cases, and adjustment for confounding factors. In these analyses, evidence of heterogeneity between subgroups was lacking. Nevertheless, because the observed associations were of weak to moderate size and no studies reported results stratified by confounding factors, we cannot exclude the possibility of residual confounding.

Study funding/potential competing interests

This work was funded by the World Cancer Research Fund (grant No 2007/SP01) as part of the Continuous Update Project. We have no competing interests.

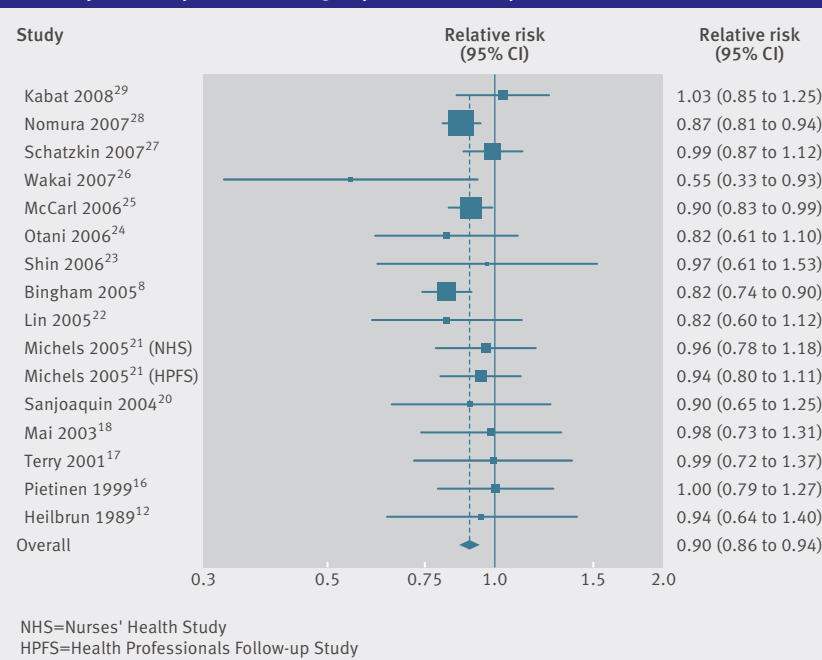
Response on bmj.com

"Cereal fibre and whole grains are rich in inositol hexaphosphate (IP6) that has been proven to reduce experimental cancers, not just of the colorectum but of other organs as well"

Abulkalam M Shamsuddin, University of Maryland School of Medicine, Baltimore, USA

Click "respond to this article" to have your say on bmj.com

Dose-response analysis for each 10 g/day intake of dietary fibre and risk of colorectal cancer



Functional outcomes of multi-condition collaborative care and successful ageing: results of randomised trial

Michael Von Korff,¹ Wayne J Katon,² Elizabeth H B Lin,¹ Paul Ciechanowski,² Do Peterson,¹ Evette J Ludman,¹ Bessie Young,³ Carolyn M Rutter^{1,4}

EDITORIAL by Jeste

¹Group Health Research Institute, 1730 Minor Avenue, Seattle, WA 98101, USA

²Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine, Seattle, Washington

³Veteran's Affairs Puget Sound Health Care System and Division of Nephrology, Department of Medicine, University of Washington School of Medicine, Seattle

⁴Department of Biostatistics, University of Washington School of Public Health, Seattle

Correspondence to: M Von Korff vonkorff.m@ghc.org

Cite this as: *BMJ* 2011;343:d6612
doi: 10.1136/bmj.d6612

This is a summary of a paper that was published on bmj.com as *BMJ* 2011;343:d6612

STUDY QUESTION Does integrated care for chronic physical diseases and depression improve disability and quality of life outcomes?

SUMMARY ANSWER Patients who received integrated care that covered both chronic physical disease and comorbid depression experienced reduced social role disability and enhanced global quality of life.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Previous trials of disease management interventions to improve blood pressure and glycaemic control have not found consistent associated benefits for functional status or health related quality of life, whereas depression treatment has been found to improve these outcomes among depressed patients with comorbid chronic physical disease. The current trial shows that collaborative care for depression and chronic physical disease can be integrated to improve disability and quality of life outcomes, as well as outcomes associated with depression and risk factors for chronic disease.

Design

A cluster randomised controlled trial of multi-condition collaborative care for depression and poorly controlled diabetes or risk factors for coronary heart disease, or both, compared with usual care.

Participants and setting

In 14 primary care clinics in Seattle, Washington, patients were identified with diabetes and/or coronary heart disease with blood pressure above 140/90 mm Hg, low density lipoprotein concentrations above 3.37 mmol/L, or glycated haemoglobin 8.5% or higher and PHQ-9 depression scores of 10 or higher.

Primary outcomes

Social role disability (Sheehan disability scale), global qual-

ity of life rating, and WHODAS-2 scales measuring activities of daily living.

Main results and role of chance

Compared with patients allocated to usual care, improvements from baseline on the Sheehan disability scale (−0.9, 95% confidence interval −1.5 to −0.2; $P=0.006$) and global quality of life (0.7, 0.2 to 1.2; $P=0.005$) were significantly greater at six and 12 months among intervention patients. There was a trend toward greater improvement for activity of daily living disabilities (−1.5, −3.3 to 0.4; $P=0.10$). Collaborative care for depression and poorly controlled diabetes or risk factors for heart disease, or both, resulted in associated improvements in functional outcomes and health related quality of life as well as improved control of blood pressure, blood glucose, lipids, and depressive symptoms.

Harms

One patient in the intervention group who was already receiving statins before enrolment was admitted to hospital for statin induced myopathy. No other adverse events were related to the intervention.

Bias, confounding, and other reasons for caution

The trial was underpowered to evaluate disability outcomes so results should be interpreted in light of other trials evaluating effects of depression treatment on disability outcomes among patients with comorbid chronic disease.

Generalisability to other populations

Trial results are consistent with other studies reporting improved disability and quality of life outcomes from depression treatment among depressed chronic disease patients, suggesting that results might be generalisable to other populations.

Study funding and potential competing interests

This study was supported by grants MH041739 and MH069741 from the National Institute of Mental Health Services Division, Bethesda, MD, and by Group Health Cooperative. WJK serves on boards for Eli Lilly and Wyeth and has given lectures for Eli Lilly, Wyeth, Forest, and Pfizer. EHBL serves on the board of the Physician Post Graduate Press External Advisory Board, has given lectures for the University of Washington relevant to dissemination of the IMPACT and TEAMcare interventions, and developed a CME on adherence for Health Star Communications. PC is the founder of Samepage, an organisation that provides consultation and educational tools for improving patient-provider relationships.

Trial registration

Clinical Trials NCT00468676.

Functional outcome measures according to integrated care (intervention) or usual care at 6 and 12 months

Outcome	Integrated care		Usual care		P value for differences	
	No of patients	Mean (SD)	No of patients	Mean (SD)	12 months	6 and 12 months
Sheehan social role disability scale (0-10): higher rating indicates greater disability						
Baseline	106	5.6 (2.4)	107	5.1 (2.6)	—	—
6 months	97	3.7 (3.2)	96	4.2 (2.6)	—	0.006
12 months	92	3.8 (3.0)	92	4.5 (2.9)	0.015	—
Global quality of life rating (0-10): higher rating indicates greater quality of life						
Baseline	106	4.2 (1.9)	107	4.7 (1.8)	—	—
6 months	97	5.8 (2.4)	96	5.2 (1.8)	—	0.005
12 months	92	6.0 (2.2)	92	5.2 (1.9)	0.010	—
WHODAS-2 activities of daily living (0-4): higher rating indicates greater disability						
Baseline	105	15.8 (9.6)	108	13.8 (9.6)	—	—
6 months	97	12.3 (10.7)	96	12.4 (9.8)	—	0.1
12 months	92	12.9 (10.0)	92	12.9 (11.2)	0.2	—

WHODAS=World Health Organization disability assessment schedule.

Effect of using reporting guidelines during peer review on quality of final manuscripts submitted to a biomedical journal: masked randomised trial

E Cobo,^{1,2} J Cortés,² J M Ribera,^{1,3,4,5} F Cardellach,^{1,6} A Selva-O'Callaghan,^{1,3,7} B Kostov,⁸ L García,² L Cirugeda,⁹ D G Altman,¹⁰ J A González,² J A Sànchez,² F Miras,² A Urrutia,^{1,3,4} V Fonollosa,^{1,3,7} C Rey-Joly,^{1,3,4} M Vilardell^{1,3,7}

¹Medicina Clínica, Elsevier-Barcelona, Barcelona 08021, Spain

²Universitat Politècnica Catalunya, Barcelona

³Universitat Autònoma de Barcelona, Barcelona

⁴Hospital Germans Trias I Pujol, Badalona, Spain

⁵José Carreras Leukaemia Research Institute, Catalan Institute of Oncology, ICO, Badalona

⁶Universitat de Barcelona and Hospital Clínic, Barcelona

⁷Vall D'Hebron Hospital, Barcelona

⁸Primary Health Care Center Les Corts, GESCLINIC, Barcelona

⁹Centre for Research in Environmental Epidemiology, Barcelona

¹⁰Centre for Statistics in Medicine, University of Oxford, Oxford, UK

Correspondence to: E Cobo
erik.cobo@upc.edu

Cite this as: *BMJ* 2011;343:d6783
doi: 10.1136/bmj.d6783

This is a summary of a paper that was published on bmj.com as *BMJ* 2011;343:d6783

STUDY QUESTION Can an additional review based on reporting guidelines such as STROBE and CONSORT improve the quality of manuscripts reviewed by a biomedical journal?

SUMMARY ANSWER We provide evidence that an additional review improves paper quality, but the observed effect was smaller than hypothesised.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Reporting guidelines have been developed to improve manuscript quality and transparency in biomedical journals. In our study, additional reviews based on reporting guidelines did improve manuscript quality, although our evidence relied on prespecified secondary outcomes and analysis. In the reporting phase, authors seemed to have difficulties in adhering to high methodological standards; awareness of reporting guidelines during the design and execution of a study might improve manuscript quality.

Design

We undertook a masked randomised trial to compare papers receiving a conventional peer review alone with those receiving a conventional review and an additional review. The additional review searched for missing items from reporting guidelines such as STROBE and CONSORT. Fifty papers per group allowed for 80% power.

Participants and setting

Original research manuscripts received by the *Medicina Clínica* journal, based in Barcelona, Spain, from May 2008 to April 2009 and considered suitable for publication.

Primary outcome

Overall manuscript quality on a 1 (low) to 5 (high) Likert scale. Main statistical comparison was between groups as allocated, using mean scores adjusted for minimisation factors.

Main results and the role of chance

Of 126 consecutive papers sent for conventional peer review, 34 were rejected on the basis of the conventional review. The remaining 92 papers were allocated to receive conventional reviews alone (n=41) or additional reviews (n=51). Additional reviews resulted in an improvement in manuscript quality (0.25, 95% confidence interval -0.05 to 0.54). More papers with additional reviews than with conventional reviews alone improved in quality from baseline (22 (43%) v eight (20%); difference 23.6% (3.2% to 44.0%); number needed to treat 4.2 (2.3 to 31.2); relative risk 2.21 (1.10 to 4.44); fig). Four papers assigned to the conventional review group deviated from protocol; they received an additional review based on reporting guidelines (as indicated by numbers after the plus signs in the figure).

Bias, confounding, and other reasons for caution

The second editorial decision in the selection process had a higher rejection rate than during the previous year (27% v 17%), resulting in the study having a slightly lower power than that designed for 100 papers. Evaluators were not entirely masked to allocation when handling papers. Although the Goodman score was specifically developed to measure quality improvement during the peer review process, it has not been updated since the development of reporting guidelines.

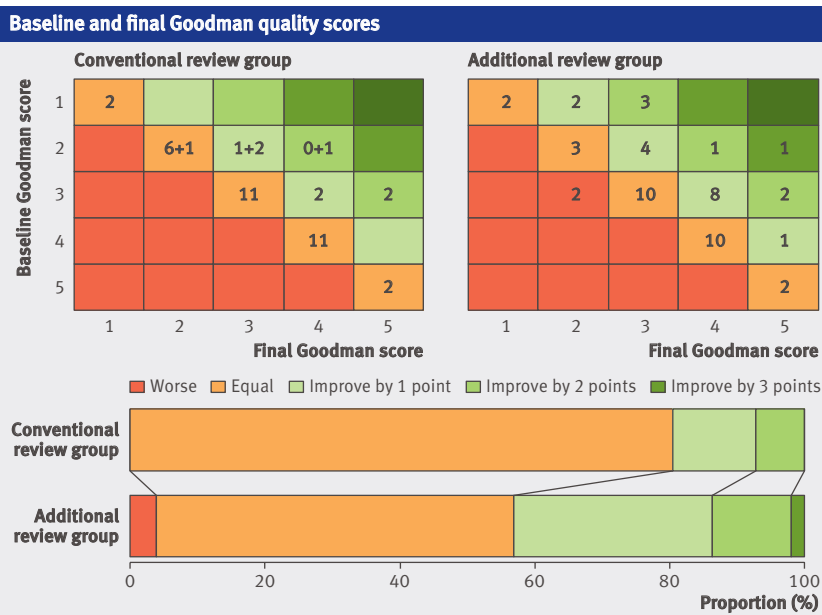
Generalisability to other populations

Since our trial was conducted on only one journal and the intervention relied on a single statistician, external validity was limited.

Study funding/potential competing interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf and declare that: JC, LG, LC, BK, and FM are supported by the "Bioestadística para no estadísticos" learning programme; they have no relationships with companies that might have an interest in the submitted work in the previous 3 years; their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and they have no non-financial interests that may be relevant to the submitted work.

Trial registration number Although registries do not include randomised trials investigating peer review, the protocol design was submitted to sponsored research projects (Instituto de Salud Carlos III, PI081903).



A person based formula for allocating commissioning funds to general practices in England: development of a statistical model

Jennifer Dixon,¹ Peter Smith,² Hugh Gravelle,³ Steve Martin,⁴ Martin Bardsley,¹ Nigel Rice,³ Theo Georghiou,¹ Mark Dusheiko,³ John Billings,⁵ Michael De Lorenzo,⁶ Colin Sanderson⁷

EDITORIAL by Bevan

¹The Nuffield Trust, London W1G 7LP, UK

²Imperial College Business School and Centre for Health Policy, London SW7 2AZ

³Centre for Health Economics, University of York, York YO10 5DD, UK

⁴Department of Economics, University of York

⁵Graduate School of Public Service, New York University, New York NY 10012-9604, USA

⁶Health Dialog, Portland, ME 04101, USA

⁷Department of Health Services Research and Policy, London School of Hygiene and Tropical Medicine, London WC1E 7HT

Correspondence to: J Dixon jennifer.dixon@nuffieldtrust.org.uk

Cite this as: *BMJ* 2011;343:d6608
doi: 10.1136/bmj.d6608

This is a summary of a paper that was published on bmj.com as *BMJ* 2011;343:d6608

bmj.com

More about changes to the NHS in England at bmj.com/nhsreforms

STUDY QUESTION Can an accurate formula be developed to help allocate NHS funds to general practices in England for commissioning hospital care, based on the health needs of individuals in each practice?

SUMMARY ANSWER With existing routine datasets and innovative data linkage, a formula was developed that predicted 77% of the variation in the next year's costs of hospital care by practices.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Previous formulae have not been accurate enough to apply to small populations covered by a single general practice. This formula includes much more information on each unique individual registered with a general practice and, if application of the formula is combined with appropriate arrangements for managing financial risk, could be used to allocate budgets fairly and safely to practices for commissioning.

Objective

To develop a formula for allocating resources for commissioning hospital care to all general practices in England based on the health needs of the people registered in each practice.

Participants and setting

All people registered with a general practice in England at 1 April 2007 and all hospital use (inpatient, day case, and outpatient care) of each registered patient over the period 2005-6, 2006-7, and 2007-8, except mental health and maternity care.

Design

Over 200 prospective multivariate statistical models were developed in which routinely collected information from 2005-6 and 2006-7 on each individual and the area in which they lived were linked and used to predict their costs of hospital care in 2007-8. A random sample of five million people was used to develop the models, which were validated on two further samples—another random sample of five million people, and five million people drawn from a random sample of practices. The predictive power of the models was tested using a range of metrics. Comparisons of predicted costs (using the formula) with “actual costs”

(actual activity × national tariff or national reference cost) incurred in 2007-8 were calculated by individual and by practice.

Main results and the role of chance

The models that were most predictive of future costs of individuals, and the costs of populations of practices, included person level information (age, sex, and ICD-10 diagnostic codes recorded in each inpatient admission) and a range of area level information (dummy variables denoting which primary care trust a practice was located in, and a set of data that might indicate health needs (such as socioeconomic deprivation) and supply of health facilities locally). After accounting for person level variables, area level variables added little explanatory power. The best models for resource allocation could predict upwards of 77% of the variation in costs at practice level and about 12% at person level (table). With these models, we would expect about a sixth of practices to have predicted costs exceeding their “actual” costs by ≥10% in any budget year and a sixth would undershoot their predicted costs by that amount. Smaller practices would be most likely to be in these groups.

Bias, confounding, and other reasons for caution

In developing the formula for allocations to practices, we did not exclude rare and high cost services. If these were excluded (as is being proposed in the new Health and Social Care Bill), the proportion of practices in which the difference between actual and predicted costs exceeded 10% would drop. The analysis depends on accurate data, but the large samples taken for the analysis and the inclusion of hospital specific variables in the analysis led to robust models.

Generalisability to other populations

The models are generalisable to all patients registered with a general practice in England.

Study funding/competing interests

The study was funded by the Department of Health. NR and HG were unpaid members of the Department of Health's Advisory Committee on Resource Allocation (ACRA) during the period of the analysis, and CS was an unpaid member of the technical advisory group to ACRA.

Performance of recommended model for predicting costs of hospital* care for commissioning general practices

Predictive power (R ²)		Practices with differences between actual and predicted costs ≤10%†			
Individual level‡	Practice level‡	Actual costs overestimated		Actual costs underestimated	
		≤5%	≤10%	≤5%	≤10%
0.1229	0.7735	19%	35%	19%	33%

*All hospital care excluding maternity services and mental healthcare.

†Validated with individual level sample (n=5 205 747).

‡Validated with practice level sample (n=797 practices, 5 445 559 individuals).