

Radiography of the lumbar spine in primary care patients with low back pain: randomised controlled trial

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Abstract

Objective To test the hypothesis that radiography of the lumbar spine in patients with low back pain is not associated with improved clinical outcomes or satisfaction with care.

Design Randomised unblinded controlled trial.

Setting 73 general practices in Nottingham, north Nottinghamshire, southern Derbyshire, north Lincolnshire, and north Leicestershire. 52 practices recruited participants to the trial.

Subjects 421 patients with low back pain of a median duration of 10 weeks.

Intervention Radiography of the lumbar spine.

Main outcome measures Roland adaptation of the sickness impact profile, visual analogue scale for pain, health status, EuroQol, satisfaction with care, use of primary and secondary care services, and reporting of low back pain at three and nine months after randomisation.

Results The intervention group were more likely to report low back pain at three months (relative risk 1.26, 95% confidence interval 1.00 to 1.60) and had a lower overall health status score and borderline higher Roland and pain scores. A higher proportion of participants consulted their doctor in the three months after radiography (1.62, 1.33 to 1.97).

Satisfaction with care was greater in the group receiving radiography at nine but not three months after randomisation. Overall, 80% of participants in both groups at three and nine months would have radiography if the choice was available. An abnormal finding on radiography made no difference to the outcome, as measured by the Roland score.

Conclusions Radiography of the lumbar spine in primary care patients with low back pain of at least six weeks' duration is not associated with improved patient functioning, severity of pain, or overall health status but is associated with an increase in doctor workload. Guidelines on the management of low back pain in primary care should be consistent about not recommending radiography of the lumbar spine in patients with low back pain in the absence of indicators for serious spinal disease, even if it has persisted for at least six weeks. Patients receiving radiography are more satisfied with the care they received. The challenge for primary care is to increase satisfaction without recourse to radiography.

Introduction

Low back pain is a common condition in primary care, with 7% of the adult population consulting for this condition each year.¹ Radiography of the lumbar spine is the most usual investigation for back pain in primary care and accounts for 5% of all radiographic examinations in NHS hospitals.² Despite this, the yield of findings that alter clinical management is low.³⁻⁵

One survey found that more than 80% of doctors would always or sometimes refer patients with recurrent low back pain for radiography, and more than 70% would always or sometimes refer those with a first episode of low back pain lasting for more than one month.⁶ When asked about reasons for requesting radiography, 88% said they did so to reassure patients and 78% said they did so to reassure themselves.⁶ In addition, many patients with low back pain believe they need radiography.^{7,8} Conflicting findings have been found concerning patient satisfaction and referral for radiography,^{3,5,8} and one study found that providing a patient with a diagnostic label increased patient satisfaction.³ A small UK trial of radiography of the lumbar spine at presentation for new episodes of low back pain in primary care found small improvements in psychological wellbeing in the group of patients receiving radiography.⁹

Current guidelines for managing low back pain give conflicting advice regarding radiography of the lumbar spine. Guidelines from the Agency for Health Care Policy and Research suggest radiography if the patient is not improving after four weeks, the Clinical Standards Advisory Group suggest considering radiography after six weeks if there is no improvement, the Royal College of General Practitioners suggest radiography is not indicated in acute back pain of less than four weeks' duration, and the Royal College of Radiologists suggest radiography is not routinely indicated in patients with acute low back pain without indicators for serious spinal disease.¹⁰⁻¹³ In the light of this conflicting advice, we aimed to test the hypothesis that radiography of the lumbar spine in patients in primary care with low back pain of at least six weeks' duration is not associated with improved clinical outcomes or satisfaction with care. We therefore tested the effect of radiography of the lumbar spine on patient outcomes rather than its utility as a diagnostic test.

Participants and methods

All general practices in Nottingham, north Lincolnshire, and southern Derbyshire were invited to take part in the study. Practices in the north of Leicestershire and in the south of north Nottinghamshire were also invited to take part. In total 73 practices took part, of which 52 recruited participants to the trial. The study population comprised patients with low back pain consulting doctors in participating practices between November 1995 and January 1999.

Identification of patients—Patients with low back pain were identified either by searches of computerised medical records based on the Read code used by each practice for low back pain or, in practices not recording all consultations on computer, by the doctor flagging the notes of patients seen with low back pain. The computerised searches were conducted by research nurses.

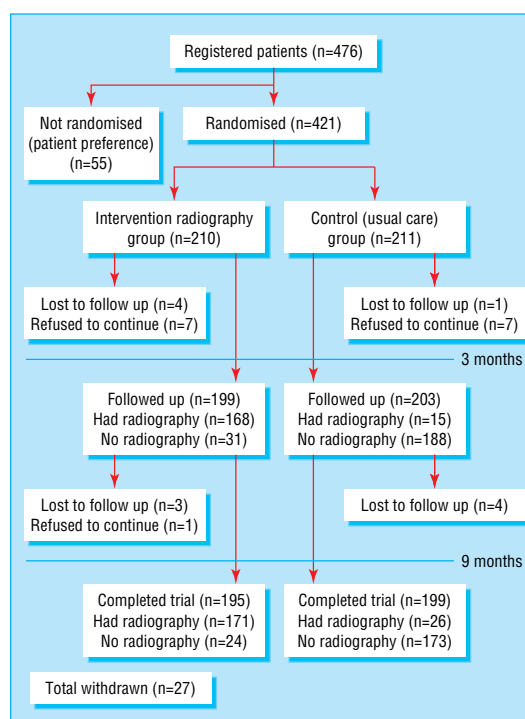
Inclusion and exclusion criteria—Patients were included if they had low back pain on the day of randomisation and for at least the preceding six weeks for the first episode of low back pain. Patients with recurrent low back pain were included if they had pain on the day of randomisation and for at least six weeks in the preceding six months. Patients were excluded if they were outside the age range specified for simple backache in the guidelines of the Clinical Standards Advisory Group and the Royal College of General Practitioners (under 20 or over 55), if they had chronic back pain (persistent pain for more than six months), if they had had radiography of the lumbar spine within the preceding year, had unexplained weight loss or fever, were taking oral steroids, had a history of malignancy, tuberculosis, injecting drug use, or a positive result on a HIV test, had symptoms or signs of a cauda equina lesion, or were pregnant or planning a pregnancy.¹¹ Patients were also excluded if the doctor considered they were unable to give informed written consent—for example, patients with a learning disability.

Ascertaining eligibility—Patients were invited to participate by letter from the general practitioner. Patients responding to the letter were interviewed on the telephone by the research nurses to ascertain eligi-

Table 1 Sociodemographic characteristics of treatment groups at baseline. Values are numbers (percentages) unless stated otherwise

Sociodemographic characteristic	Intervention group (n=210)	Control group (n=211)
Male	90 (43)	84 (40)
Median age (interquartile range)	39 (31-45)	39 (31-46)
White	206 (98)	209 (99)
Married	138 (66)	136 (65)
Lives with dependants	121 (58)	122 (58)
Educational level:		
Degree or above	25 (12)	19 (9)
A level	13 (6)	17 (8)
HND or HNC	8 (4)	6 (3)
O level or GCSE	59 (28)	58 (27)
Employment status:		
Full time employment	114 (54)	126 (60)
Part time employment	49 (23)	43 (20)
Not in paid employment*	44 (21)	41 (19)
Receipt of means tested benefits	47 (22)	43 (20)

*Includes home makers, voluntary workers, and those in full time education.



Flow of participants through trial

bility criteria. Patients who seemed eligible were visited at home where the baseline structured interview and physical examination were undertaken by the research nurse. Eligible patients were then asked to give informed consent before randomisation.

Assignment to treatment group—Randomisation was by individual participant. At the baseline interview the research nurse opened a sealed envelope containing the treatment group allocation. Block randomisation (using blocks of 20) was used to ensure equality of numbers between the two groups. A member of the research team (KF) who was not involved in assigning the participants to treatment group generated the allocation schedule. Participants and research nurses were not blinded to treatment group. In addition the study included a preference arm for participants in which those who did not consent to randomisation could choose whether to have radiography or not.

Intervention—In addition to receiving the usual care provided by the practice for patients with low back pain, patients in the intervention group were given a card to attend for a radiograph of the lumbar spine at their local hospital. They were asked to contact their doctor for the result of the radiography either by telephone or by consulting the doctor, depending on the usual procedure for each participating practice. Participants in the control group received the usual care from their doctor. The doctor was able to request radiography if they considered it clinically necessary at any time.

Primary and secondary outcome measures—The primary outcome measure was difference in the mean Roland score (an adaptation of the sickness impact profile).¹⁴ Secondary outcome measures included a visual analogue scale for pain, EuroQol, including the health status scale,¹⁵ patient satisfaction,^{7,8} duration of

low back pain, duration of certificated sick leave, use of health and other services, and drug use. The research nurse measured primary and secondary outcomes before randomisation and at three and nine months after randomisation by structured face to face interviews. Interviews were conducted by telephone if

the participant was not able to be interviewed face to face.

Sample size—The sample size calculation indicated that 388 patients in total in both arms of the study would allow a change in mean Roland score of 1.5 to be detected with 90% power at the 5% significance level, based on a baseline mean Roland score of 10.1 (SD 4.5). This was obtained from the first 88 patients recruited to the study. The sample size was based on showing a difference between the two groups that we judged would not be clinically important rather than equivalence, as showing equivalence would have required a much larger sample size.

Data analysis—The data were double entered into an Access 97 database and analysed using SPSS for Windows version 8.0. We undertook all analyses on an intention to treat basis. We compared non-normally distributed continuous variables with Mann-Whitney U tests, and we compared categorical variables with χ^2 tests (with Yates correction and Fisher's exact test where appropriate). We calculated relative risks with 95% confidence intervals.

Ethics committee approval—Ethical approval was obtained from the Queens Medical Centre, Nottingham, southern Derbyshire's ethics committee, north Lincolnshire's research ethics committee, north Nottinghamshire health authority, and Leicestershire health authority.

Results

The results presented here relate only to randomised participants; those for the preference arm of the study will be presented elsewhere. Overall, 421 patients were recruited to the study (figure). Overall, 394 (93.6%) participants completed the trial. The attrition rate at nine months did not differ between the treatment groups ($\chi^2 = 0.37$, $df = 1$, $P = 0.54$).

Baseline—Table 1 shows the sociodemographic characteristics of the treatment groups at baseline and table 2 the clinical characteristics of the participants. The treatment groups were similar at baseline.

Three months' follow up—Table 3 shows the clinical characteristics and use of health and other services at three months. Telephone interviews were conducted with two participants in the intervention group and seven in the control group, the remainder having face to face interviews. Although the clinical characteristics had improved from those at baseline more participants in the intervention than control group were still experiencing back pain, and the intervention group perceived their overall health status to be worse and had higher Roland and pain scale scores that were of borderline significance. In addition the intervention group had more consultations with the doctor in the three months after randomisation than the control group. More than 80% of participants in both groups would have chosen radiography if given the choice.

Nine months' follow up—Telephone interviews were conducted with eight participants in the intervention group and 16 in the control group, the remainder having face to face interviews. Table 4 shows the outcome data at nine months. Although more participants in the intervention than control group still had low back pain, this difference was no longer significant. Patients who

Table 2 Clinical characteristics of treatment groups at baseline. Values are numbers (percentages) unless stated otherwise

Clinical characteristic	Intervention group (n=210)	Control group (n=211)
History of low back pain:		
Median No of weeks of episode (interquartile range)	10 (7-15)	10 (7-14)
Median No of weeks of pain in past 6 months (interquartile range)	12 (9-16)	12 (8-15)
Median No of days off work with this episode (interquartile range)	14 (5.5-21)	14 (6-33.25)
Missing values	7	7
Median No of days rested in bed with this episode (interquartile range)	3 (2-7)	4 (2-14)
Previous episodes	166 (79)	169 (80)
Associated lower limb symptoms:		
Pain	95 (45)	90 (43)
Numbness or paraesthesia	35 (17)	42 (20)
Weakness	13 (6)	27 (13)
Associated lower limb signs:		
Straight leg raising of 90 degrees bilaterally	191 (91)	184 (87)
Normal ankle jerks bilaterally	197 (94)	201 (95)
Missing values	1	1
Normal knee jerks bilaterally	201 (96)	198 (94)
Missing values	1	1
Normal light touch sensation	204 (99)	204 (98)
Missing values	3	3
Normal pin prick sensation	204 (99)	204 (98)
Missing values	3	3
No weakness of dorsiflexion of toe	198 (95)	208 (99)
Missing values	1	1
No weakness of dorsiflexion of foot	203 (97)	206 (98)
Missing values	1	1
Thigh wasting >2 cm either leg	5 (2)	4 (2)
Missing values	2	1
Calf wasting >2 cm either leg	3 (1)	2 (1)
Missing values	2	1
Health and functional status:		
Median Roland disability score (interquartile range)	7 (4-11.25)	8 (4-12)
Median pain score (interquartile range)	2 (1-2)	2 (1-2)
Median EuroQol score (interquartile range)	0.69 (0.62-0.76)	0.69 (0.62-0.76)
Missing values	6	14
Median health status score (interquartile range)	70 (50-80)	70 (50-80)
Median satisfaction with consultation (interquartile range)	19 (17-22)	20 (17.75-22)
Missing values	14	21
Use of health and other services:		
Hospital admission	0	0
Outpatient attendance	2 (1)	0
1 visit to doctor	104 (50)	95 (45)
2 visits to doctor	62 (30)	62 (30)
3 visits to doctor	27 (13)	31 (15)
4 visits to doctor	17 (8)	23 (11)
Taken prescribed drug	135 (64)	146 (69)
Taken over the counter drug	135 (64)	154 (73)
Physiotherapy	54 (27)	64 (31)
Missing values	9	6
Osteopathy	22 (11)	14 (7)
Missing values	9	6
Chiropractic	6 (3)	6 (3)
Missing values	9	6
Acupuncture	5 (3)	7 (3)
Missing values	9	6

Table 3 Clinical characteristics of treatment groups at three months' follow up. Values are numbers (percentages) unless unless stated otherwise

Clinical characteristic	Intervention group (n=199)	Control group (n=203)	Relative risk (95% CI) or Z score*	P value
History of low back pain over past 3 months:				
Still has pain	148 (74)	132 (65)	1.26 (1.0 to 1.60)	0.04
Taken time off work	23 (12)	33 (16)	0.73 (0.45 to 1.20)	0.21
Missing values	7	2		
Median No of days off work (interquartile range)	14 (2-35)	14 (3.5-56)	-0.54	0.59
Health and functional status:				
Median Roland disability score (interquartile range)	4 (1-8)	3 (1-7)	-1.93	0.05
Median pain score (interquartile range)	1 (1-2)	1 (0-2)	-1.90	0.06
Median EuroQoL score (interquartile range)	0.80 (0.69-0.88)	0.80 (0.69-0.91)	-0.92	0.36
Missing values	10	13		
Median health status score (interquartile range)	75 (60-90)	80 (70-90)	-2.32	0.02
Missing values	2	1		
Median satisfaction with consultation (interquartile range)	20 (17-23)	21 (19-23)	-1.50	0.13
Missing values	6	5		
Had radiography	168 (84)	15 (7)		
Would have chosen radiography if choice available	143 (85)	175 (89)	0.96 (0.88 to 1.04)	0.29
Missing values	31	6		
Use of health and other services over past 3 months:				
Hospital admission	0	0		
Outpatient attendance	6 (3)	7 (3)	0.93 (0.51 to 1.69)	1.00
Visited doctor	106 (53)	60 (30)	1.62 (1.33 to 1.97)	<0.01
1 visit to doctor	83 (42)	42 (21)		
2 visits to doctor	17 (9)	7 (3)		
≥3 visits to doctor	4 (2)	11 (5)		
Taken prescribed drug	63 (32)	59 (29)	1.06 (0.86 to 1.31)	0.57
Taken over the counter drug	68 (34)	67 (33)	1.03 (0.83 to 1.26)	0.81
Physiotherapy	67 (34)	59 (29)	1.11 (0.91 to 1.37)	0.32
Osteopathy	7 (4)	9 (4)	0.88 (0.50 to 1.55)	0.83
Chiropractic	4 (2)	6 (3)	0.84 (0.37 to 1.73)	0.75
Acupuncture	3 (2)	7 (3)	0.60 (0.23 to 1.55)	0.34

*Mann-Whitney U test (normal approximation).

had radiography still had a higher Roland score of borderline significance. They were also significantly more satisfied with the care they had received at their most recent consultation for low back pain. A large proportion of participants in both groups would still have chosen radiography. Overall, 12% of those randomised to radiography did not attend for the procedure. Thirteen per cent of participants in the control group had radiography during the nine months of follow up. Table 5 shows the findings on radiography for both groups. Around one third of participants in each group had x ray films that were reported as giving normal results. No difference was found in median Roland scores between those whose x ray film gave normal results and those whose x ray film showed some abnormality at either three or nine months' follow up (three months, median = 4, interquartile range 1-8 (normal result on x ray film) versus 4, 1-7 (abnormal result on x ray film) P=0.72; nine months, median = 2, 0-8 (normal result) versus 3, 1-7 (abnormal result) P=0.50).

Discussion

Radiography of the lumbar spine in primary care patients with low back pain of at least six weeks' duration is associated with a greater proportion of patients reporting low back pain at three months, a lower overall health status score, and higher Roland and pain scores of borderline significance. Consultation rates with doctors were higher in the three months

after radiography. Satisfaction with consultations was greater in the group receiving radiography at nine but not three months' follow up. Having an x ray film reported as showing an abnormality made no difference to outcome as measured by the Roland score.

This is the largest published trial to date of outcomes among patients who have had radiography of the lumbar spine. It was adequately powered to detect a small enough difference in the Roland score to ensure a clinically important difference would not be missed. In fact, the findings point towards a longer duration of pain, a reduction in functioning, and more severe pain in those receiving radiography (although the difference in Roland score may not be large enough to be clinically important). None of the findings suggest that the intervention group had any clinical benefit over the control group.

Generalisability

The participants in our trial do represent a select group of patients in primary care in that they had had low back pain for a median of 10 weeks before randomisation. It is a commonly held belief that 90% of episodes of low back pain resolve within eight weeks.¹⁶ A recent UK study in general practice, however, found that 79% of patients consulting with low back still had low back pain or disability three months after the consultation, and 75% still had some pain or disability 12 months after the initial consultation.¹⁷ Our findings are similar in that 70% of

Table 4 Clinical characteristics of treatment groups at nine months' follow up. Values are number (percentages) unless stated otherwise

Clinical characteristic	Intervention group (n=195)	Control group (n=199)	Relative risk (95% CI) or Z score*	P value
History of low back pain over past 6 months:				
Still has pain	126 (65)	113 (57)	1.18 (0.96 to 1.47)	0.11
Taken time off work	26 (13)	25 (13)	1.05 (0.63 to 1.74)	0.87
Missing values	1	4		
Median No of days off work (interquartile range)	11.5 (4-56)	8.5 (2-47.25)	-0.20	0.84
Missing values	2	1		
Health and functional status:				
Median Roland disability score (interquartile range)	3 (0-7)	2 (0-6)	-1.90	0.06
Median pain score (interquartile range)	1 (0-2)	1 (0-2)	-1.38	0.17
Median EuroQol score (interquartile range)	0.80 (0.69-1.00)	0.80 (0.73-1.00)	-1.07	0.28
Missing values	15	10		
Median health status score (interquartile range)	80 (60-90)	80 (70-90)	-1.04	0.30
Missing values	6	1		
Median satisfaction with consultation (interquartile range)	21 (19-23)	19 (16-21)	-2.69	<0.01
Missing values	4	6		
Had radiography	171 (88)	26 (13)		
Would have chosen radiography if choice available	136 (80)	168 (87)	0.92 (0.84 to 1.01)	0.07
Missing values	24	5		
Use of health and other services over past 6 months:				
Hospital admission†	2 (1)	0		0.24‡
Outpatient attendance	18 (9)	12 (6)	1.23 (0.90 to 1.68)	0.23
Day case†	1 (1)	0		0.50‡
Visited doctor	42 (22)	47 (24)	0.94 (0.74 to 1.20)	0.24
1 visit to doctor	21 (11)	32 (16)		
2 visits to doctor	12 (6)	6 (3)		
≥3 visits to doctor	9 (5)	9 (5)		
Taken prescribed drug	56 (29)	49 (25)	1.11 (0.89 to 1.38)	0.36
Taken over the counter drug	69 (35)	57 (29)	1.17 (0.95 to 1.43)	0.15
Physiotherapy	31 (16)	27 (14)	1.10 (0.84 to 1.43)	0.51
Osteopathy	6 (3)	7 (4)	0.93 (0.51 to 1.69)	0.81
Chiropractic	6 (3)	5 (3)	1.11 (0.64 to 1.91)	0.73
Acupuncture	1 (1)	2 (1)	0.67 (0.14 to 3.34)	1.00

*Mann-Whitney U test (normal approximation).

†Relative risk not calculable.

‡Fisher's exact test.

participants still had low back pain at three months' follow up and 61% at nine months' follow up.

Effect of radiography

Why might patients who had radiography of the lumbar spine report a longer duration of pain, more severe pain, reduced functioning, and an overall poorer health status than those who did not have radio-

graphy? The treatment groups were similar at baseline, so differences in the groups cannot explain the poorer outcomes in those who had radiography. Other than radiography the treatment groups received similar care; participants who had radiography were not less likely to receive prescribed drugs or referral to secondary care or physiotherapy than the controls and made similar use of other physical therapies such as osteopathy, chiropractic, and acupuncture. One possible explanation is that radiography encourages or reinforces the patient's belief that they are unwell and may lead to greater reporting of pain and greater limitation of activities.

Despite the improvement in functioning and reduction in severity of low back pain over the follow up period, most participants still had low back pain in both groups and most would have chosen radiography if given the choice. This suggests that patient education in this area is important; and that doctors will need to address within the consultation the patient's expectations of having radiography. At nine months' follow up patients who had radiography were more satisfied with the care given by their doctor at their most recent consultation for low back pain, but there was no difference at three months' follow up. This is interesting as participants who had radiography would have been told the results of this before the follow up interview at three months, but no differ-

Table 5 Findings on radiography. Values are numbers (percentages) unless stated otherwise

Radiography result	Intervention group (n=170)*	Control group (n=22)*
Discovertebral degeneration	116 (69)	12 (55)
No abnormality detected	52 (31)	7 (32)
Deformity	39 (23)	5 (23)
Minor congenital abnormalities	17 (10)	2 (9)
Facet joint degeneration	8 (5)	3 (14)
Posterior arch defects	6 (4)	1 (5)
Other discovertebral disease	4 (2)	0
Alignment abnormalities	3 (2)	0
Bone formation	2 (1)	0
Sacroiliac joint disease	2 (1)	0
Alteration of bone density	2 (1)	0
Total findings reported†	251	30

*Reports unavailable for one participant in intervention group and three in control group.

†More than one finding recorded in 64 reports, two in 44, three in 16, four in three, and five in one.

What is already known on this topic

Several small studies have suggested that radiography of the lumbar spine is not associated with improved patient outcomes but may be associated with increased satisfaction or improved psychological wellbeing

Current guidelines on managing low back pain in primary care give conflicting advice about radiography in patients who have had low back pain for at least one month

What this study adds

In the absence of indications for serious spinal disease, radiography in patients with low back pain was not associated with improved clinical outcomes but was associated with increased satisfaction with care

Guidelines on managing low back pain of at least six weeks' duration in primary care in the absence of indications should be consistent about not recommending radiography

ence was found at that time. It is possible that the longer the pain continues the more important having a "diagnosis" or adequate explanation becomes to the patient. Further work is required to explore the factors contributing to patient satisfaction with care for low back pain so that other strategies can be found that increase satisfaction without recourse to radiography.

Implications of findings

The implications of our findings are that radiography of the lumbar spine in patients in primary care with low back pain of at least six weeks' duration is not associated with improved patient functioning, severity of pain, or overall health status. Radiography of the lumbar spine is associated with an increase in doctor workload. Guidelines on the management of low back pain in primary care should be consistent about not recommending radiography of the lumbar spine in patients with low back pain in the absence of indications for serious spinal disease, even if the pain has persisted for at least six weeks.

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Contributors: DK had the original idea for this study, participated in designing the protocol, recruited the practices, and participated in data analysis, data interpretation, and writing the paper. KF designed the protocol and participated in data analysis, interpretation, and writing the paper. EB participated in data analysis, interpretation, and revising the paper. RK and MP contributed to the design of the protocol, interpretation of the data, and revising the paper. PM undertook the analysis for the economic evaluation of the trial and participated in interpretation of the data and revising the paper. DK and KF will act as guarantors for the paper.

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Competing interests: None declared.

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Corrections and clarifications

Netlines

URLs (uniform resource locators) continue to be a hazard. In Netlines in the issue of 6 January (p 58), by Harry Brown, the URL in the last paragraph was wrong; it should have read www.tripdatabase.com/publications.cfm.

Efficacy and safety of galantamine in patients with mild to moderate Alzheimer's disease: multicentre randomised controlled trial

We have been alerted to some French investigators who should have been mentioned in the acknowledgments of this paper by Gordon K Wilcock and colleagues (9 December, pp 1445-9): Drs Joël Ankri and Renée Sebag-Lanoe and Professors Philippe Robert, J François Dartigues, and Bernard Forette.

Qualitative analysis of psychosocial impact of diagnosis of Chlamydia trachomatis: implications for screening

An eagle eyed reader picked up an obvious mistake in this paper by Barbara Duncan and colleagues (27 January, pp 195-9). In the introduction, infection with *Chlamydia trachomatis* was said to be difficult to detect because it is largely asymptomatic; this should of course have read asymptomatic.