

# Implementation of RCGP guidelines for acute low back pain: a cluster randomised controlled trial

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## SUMMARY

**Background:** The Royal College of General Practitioners (RCGP) has produced guidelines for the management of acute low back pain in primary care.

**Aim:** To investigate the impact on patient management of an educational strategy to promote these guidelines among general practitioners (GPs).

**Design of study:** Group randomised controlled trial, using the health centre as the unit of randomisation.

**Setting:** Primary care teams in north-west England.

**Method:** Twenty-four health centres were randomly allocated to an intervention or control arm. Practices in the intervention arm were offered outreach visits to promote national guidelines on acute low back pain, as well as access to fast-track physiotherapy and to a triage service for patients with persistent symptoms.

**Results:** Twenty-four centres were randomised. Two thousand, one hundred and eighty-seven eligible patients presented with acute low back pain during the study period: 1049 in the intervention group and 1138 in the control group. There were no significant differences between study groups in the proportion of patients who were referred for X-ray, issued with a sickness certificate, prescribed opioids or muscle relaxants, or who were referred to secondary care, but significantly more patients in the intervention group were referred to physiotherapy or the back pain unit (difference in proportion = 12.2%, 95% confidence interval [CI] = 2.8% to 21.6%).

**Conclusion:** The management of patients presenting with low back pain to primary care was mostly unchanged by an outreach educational strategy to promote greater adherence to RCGP guidelines among GPs. An increase in referral to physiotherapy or educational programmes followed the provision of a triage service.

**Keywords:** low back pain; guidelines; education, professional; randomised controlled trials.

## Introduction

LOW back pain is a major economic burden.<sup>1</sup> Most patients have benign disease and should recover quickly, but psychosocial factors may determine chronicity of symptoms.<sup>2</sup> The Clinical Standards Advisory Group (CSAG) and the Royal College of General Practitioners (RCGP) recommend that responsibility for acute low back pain management should shift from secondary to primary care, where the aim should be a rapid return to normal function.<sup>3,4</sup> For uncomplicated episodes of acute low back pain, RCGP guidelines for general practice, updated in early 1999, advise against the use of lumbar spine X-rays, bed rest and secondary referral, and recommend simple analgesia, gentle exercise and the consideration of physical therapies.<sup>3</sup> Diagnostic triage is considered essential to identify the minority of patients with serious pathology or intractable pain who require access to specialist care.<sup>3,4</sup>

Guidelines alone do not modify clinical behaviour, but a Cochrane systematic review suggests that educational outreach visits may be effective.<sup>5</sup> A randomised controlled trial was undertaken to investigate the impact on patient management of an outreach educational strategy to promote national guidelines on acute low back pain among general practitioners (GPs). GPs were also offered fast-track access to physiotherapy and a triage service to facilitate onward referral of patients with persistent symptoms because it was felt that it would be inappropriate to attempt to change primary care practice in the absence of a secondary care service that also reflected contemporary views on how back pain should be managed.

## Method

Patients were eligible for this study if they were aged between 18 and 64 years, registered with a GP in Birkenhead, Wallasey or West Wirral Primary Care Groups (PCGs), and had consulted their GP about an episode of acute low back pain for which they had not already sought advice during the preceding 6 months.

The 54 general practices within the three PCGs were aggregated into health centres by combining practices that shared premises or partners, and were then stratified by PCG. Within each stratum, a random sample of centres, proportional in size to the total number of centres within that stratum, were approached for consent to participate in the study. If a centre refused to participate it was replaced following random selection from the remaining centres within its stratum.

Each centre was given a unique identifier, and randomisation was then undertaken by the Centre for Cancer

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**HOW THIS FITS IN***What do we know?*

A systematic review suggests that educational outreach visits may be effective in modifying professional behaviour. This study evaluated the impact of such a strategy to promote adherence to national guidelines on acute low back pain management by general practitioners.

*What does this paper add?*

The educational outreach visits failed to further modify professional behaviour supporting recent concerns about the limited impact of this type of intervention. By 1999, primary care management of back pain may have improved substantially, but the higher than expected uptake of triage service suggests that general practitioners and patients still desire reassurance from a specialist opinion. Attempts to further promote adherence to guidelines in this area may need to focus on patient, as well as professional, education.



Epidemiology. The unit of randomisation was the health centre. A minimisation procedure with a random element was used to assign centres to an intervention or control group; the minimisation factors used were: PCG, large (more than 3500) or small (fewer than 3500) health centre population, and computerised or manually stored health records. The Wirral Local Research Ethics Committee approved the study.

All GPs in the health centres allocated to the intervention arm were sent a letter offering them a visit from the 'guideline team', followed by a telephone call to the practice manager to arrange an appointment with the GP in their practice. At least two members of the guideline team attended each visit; members included senior representatives from the musculoskeletal directorate, physiotherapy services and the health authority. Members of the guideline team facilitated a structured interactive discussion with the GP, which was based on the 'elaboration likelihood model of persuasion'.<sup>6</sup> This discussion was used to: raise awareness of the RCGP guidelines, adapted to the local context; emphasise the key messages in the guidelines; identify potential barriers to implementation; and suggest strategies for overcoming the barriers identified. GPs were given a poster reinforcing guideline recommendations and a copy of a text recommended by the RCGP for patients.<sup>7</sup> Referral forms for access to fast-track physiotherapy were distributed at this session, as were forms for direct access to the back clinic of patients who had failed to respond to conservative management within 6 weeks. These forms incorporated the RCGP guidelines, including the flagging of symptoms that suggested that patients needed immediate direct referral for specialist opinion. Information provided by GPs on the back clinic referral form was used to triage patients to the most appropriate service: hospital specialities, pain clinic, physiotherapy or educational programmes provided by the back pain unit. Practices were revisited when their experiences of implementing the guidelines were discussed.

Practices in the control arm did not receive a visit from members of the guideline team and did not have direct access to the back clinic. GPs referred patients to open

access physiotherapy using standard referral forms.

From the time they consented to participate, GPs were asked to log every patient presenting to them with acute low back pain: the practice was reimbursed £1 for each patient identified. A research assistant screened the records of these patients to confirm eligibility and to extract data on patient characteristics and clinical management during the 3-month period following first consultation. The study ran from the end of April 1999, when the first guideline team visit took place, to the end of 1999. The two study groups were compared with respect to the rate of referral for lumbar spine X-rays, issuing of sickness certification, referral to secondary care (excluding physiotherapy and the back pain unit), and prescription of muscle relaxants and opioid analgesics. Analysis was by an intention-to-treat approach. Comparisons were made using  $\chi^2$  statistics adjusted for the cluster randomised design,<sup>8</sup> and 95% confidence intervals constructed as appropriate.<sup>9</sup> Logistic regression models, adjusted for the cluster randomised design, were used to explore the impact on the estimates of effect on outcome of those factors used in the minimisation procedure.<sup>10</sup>

Sample size estimates were based on the rate of referral for lumbar spine X-rays. Historical data indicated that 6.4 per 1000 practice population were referred each year for lumbar spine X-rays, with a mean cluster size of 5170 and an intra-cluster correlation coefficient (ICC) of 0.002. To detect a relative decrease in the frequency of referral of 75%, it was estimated that 70 438 adults aged between 18 and 64 years of age would be required to achieve a study power of 80% at the 5% two-sided significance level. Assuming a mean practice size of 3000, 24 practices were needed.

**Results**

Forty-five centres were available, from which 24 were approached for consent to randomisation; 5 centres which refused were replaced. Twelve centres were then randomised to the intervention group, and 12 to the control group; the characteristics of these centres are shown in Table 1. Immediately following randomisation, one centre in the control group withdrew from the study, and did not contribute patient information.

It was proposed that baseline data would be collected from all practices before randomisation, but this was only available for 19 centres because of the delay in recruiting the 5 replacement centres. Analysis of the 365 available patients suggests that the intervention and control groups were similar with respect to the proportion of patients referred for lumbar spine X-rays (20.4% and 21.1%, respectively), issued with a sickness certificate (24.8% and 25.9%, respectively), prescribed opioids or muscle relaxants (21.9% and 21.1%, respectively), and referred to secondary care (3.6% and 5.3%, respectively).

Immediately after randomisation, all practices in the intervention arm were notified about the guideline team visit and 11 of the 12 centres in the intervention group were first visited by the team within 3 months, with the remaining centre visited within 5 months. During the 8-month study period, 2187 eligible patients presented with acute low back pain: 1049 in the intervention group and 1138 in the control group. (Figure 1). The characteristics of the patients are shown in

Table 1. Distribution of centre characteristics.

	Intervention	Control
Total number of centres	12	12 <sup>a</sup>
Location		
West Wirral PCG ( <i>n</i> )	5	7
Birkenhead PCG ( <i>n</i> )	5	3
Wallasey PCG ( <i>n</i> )	2	2
Mean health centre size (adults aged 15 to 64 years)	3762	3790
Centres with computerised data storage ( <i>n</i> )	7	7

PCG = Primary care group. <sup>a</sup>One centre withdrew following randomisation (minimisation factors = Birkenhead PCG, small health centre population, and manual storage).

Table 2. Characteristics of the 2187 patients presenting with acute back pain during the study period.

	Intervention <i>n</i> = 1049	Control <i>n</i> = 1138
Total number of patients		
Mean age in years (SD)	42.2 (12.1)	41.3 (12.5)
Female sex (%)	568 (54.1)	618 (54.3)
Previous history of back pain (%)	378 (36.0)	416 (36.6)

SD = standard deviation.

Table 2. The estimated annual consultation rate for acute low back pain was 35 per 1000 adults in the intervention group, compared to 38 per 1000 in the control group. There were no significant differences between study groups with respect to the proportion of patients who were referred for X-ray (difference = 1.4%; 95% CI = -4.1% to 6.8%), issued with a sickness certificate (difference = -1.5%; 95% CI = -10.3% to 7.3%), prescribed opioids or muscle relaxants (difference = -0.03%; 95% CI = -5.5% to 5.4%) or referred to secondary care (difference = 1.1%; 95% CI = -0.3% to 2.6%) (Table 3). Significantly more patients in the intervention group were first referred to physiotherapy or to educational programmes at the back pain unit compared to the control group, (26.0% and 13.8%, respectively; difference = 12.2%; ICC = 0.0563;  $\chi^2 = 6.49$ , 1 degree of freedom [df];  $P = 0.01$ ; 95% CI for difference in proportion = 2.8% to 21.6%). A total of 121 (11.5%) patients in the intervention arm were referred to the triage service within the follow-up period. Of the 273 referrals to physiotherapy or the back pain unit by GPs in the intervention group, 110 (40.3%) were directed to these services by the back clinic triage service.

In a multivariate analysis, adjustment for factors used in the minimisation procedure had no substantial impact on the estimates of effect on outcome between study groups (data not shown). Similar findings were also observed when the analysis was restricted to the last 5 months of the study (data not shown).

## Discussion

An educational strategy based on RCGP guidelines failed to change the management of patients with acute low back pain in primary care. More patients in the intervention arm were first referred to physiotherapy or educational programmes, but most of these additional referrals were made by the triage service set up to facilitate the management of cases that had not resolved within 6 weeks. Annual consultation rates in this study were half those observed in the fourth national morbidity survey in general practice,<sup>11</sup> but similar rates of radiological investigation, referral to sec-

ondary care, and prescription of opioids and muscle relaxants have been reported elsewhere.<sup>12-14</sup>

### Interpretation of study findings in the context of previous research

The outreach educational strategy used in this study was based on theoretical models<sup>6</sup> and included components considered to be important in the modification of health professional behaviour: it was practice-based and multifaceted; guidelines were authoritative, evidence-based and brief; the discussion between the guideline team and GPs was interactive, incorporating social marketing techniques; the multidisciplinary team incorporated local experts, and the intervention was piloted with another group of GPs before the trial.<sup>15-17</sup> Both the RGCP and the CSAG emphasise the role of physiotherapy in simple back pain, and the provision of fast-track access to physiotherapy in the intervention group was designed to overcome a previously identified barrier to the use of this service locally.<sup>3-5</sup> The guideline team took longer than anticipated to complete their first visit to practices, but similar results were observed when the analysis was restricted to the last 5 months of the study, when all practices had been visited. A further visit by the guideline team was intended to reinforce messages and provide feedback, but these visits were only just complete by the end of the study period and it is not possible to determine their additional impact. The Cochrane systematic review of the effectiveness of outreach educational visits to modify clinical behaviour was last substantially updated in 1997.<sup>5</sup> Several trials of outreach education have been published since, and not all have demonstrated an improvement in adherence to best practice.<sup>17</sup> These interventions may be less effective when, as in our study, the strategy is population-based,<sup>18-19</sup> the effect is measured using patient or activity-based outcomes,<sup>20</sup> or when the potential for change in outcome is small.<sup>21</sup> This study was undertaken some time after the publication of the CSAG guidelines and dissemination of the original RCGP guidelines to GPs, and by 1999 secular improvements in primary care management may have

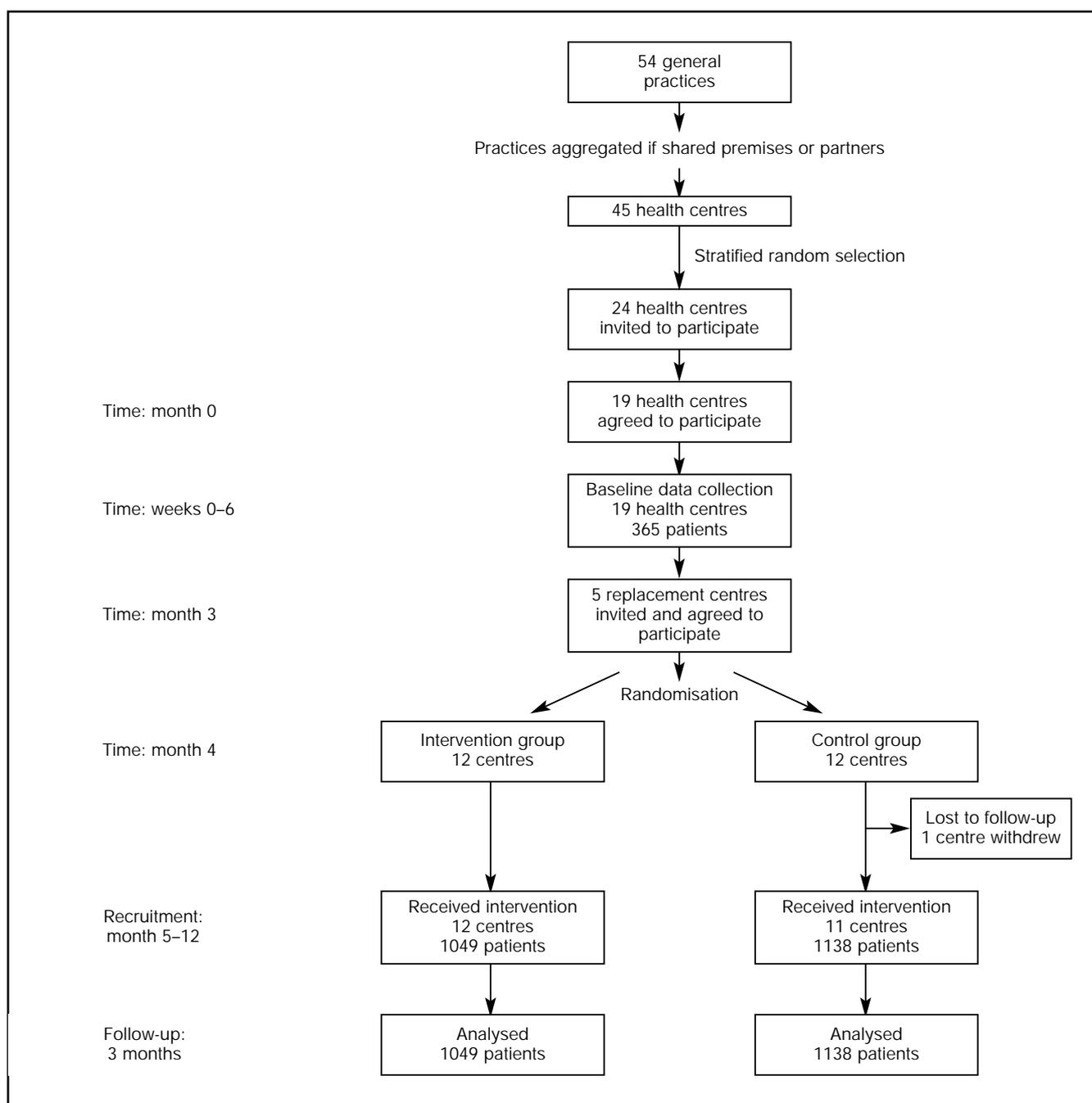


Figure 1. Trial profile.

markedly reduced the likelihood that an outreach education strategy could further change management. However, others have demonstrated some success in further promoting adherence to back pain guidelines through more intensive interventions.<sup>12</sup>

### Limitations

In this study, GPs could not be blinded to their allocated group. Owing to financial constraints, only one research assistant was employed, and blind outcome assessment was not possible. We believe that substantial bias is unlikely because study groups were similar with respect to the

ascertainment of cases. However, study participation may have resulted in greater adherence to best practice in the control group.

The RCGP guidelines emphasise that patients should remain active, and bed rest is not recommended.<sup>3</sup> In this study, 0.6% of patients in both the intervention and control arms were advised to remain on bed rest but, because there was only evidence that 21% of patients had received any form of advice from their GP, this outcome may have been underascertained.

Centres were allocated to the study groups using a minimisation procedure to avoid the potential disadvantages of

Table 3. Comparison of the distribution of outcome measures between the study groups.

	Intervention n = 1049	Control n = 1138	ICC <sup>a</sup>	$\chi^2$
Referred for X-ray (%)	158 (15.1)	156 (13.7)	0.018	0.24; 1 df; P = 0.62
Sickness certificates (%)	186 (17.7)	219 (19.2)	0.048	0.11; 1 df; P = 0.74
Prescribed opioids or muscle relaxants (%)	196 (18.7)	213 (18.7)	0.014	0.00014; 1 df; P = 0.99
Referred to secondary care (%)	36 (3.4)	26 (2.3)	0.001	2.36; 1df; P = 0.12
Referred to physiotherapy or educational programme (%)	273 (26.0)	157 (13.8)	0.056	6.49; 1 df; P = 0.01

<sup>a</sup>Mean cluster size = 95.1. df = degrees of freedom.

pair-matching in cluster randomised controlled trials.<sup>22</sup> Complete data on general practice management of patients with acute low back pain was not available before randomisation. Health centre characteristics that were likely to be associated with either outcome (practice size, PCG) or the ascertainment of patient information (method of record keeping), were therefore used. One centre allocated to the control group withdrew from the trial immediately after randomisation and this contributed to an imbalance in PCGs. However, in the multivariate analysis, adjustment for this factor did not affect the study results.

### Implications for future research

A recent editorial in the *British Journal of General Practice* suggested that future research should consider the contextual barriers to implementing change.<sup>17</sup> National low back pain guidelines are consistent with those published elsewhere,<sup>23</sup> and there is some evidence that adherence to guidelines can improve patient outcome and reduce cost.<sup>12</sup> Most GPs concur with their recommendations, but may feel pressurised to defer to the expectations of patients, real or perceived, for more active management;<sup>13,24,25</sup> it has also been shown that patients may resist simple exercise, at least initially.<sup>26</sup> In this study, GPs may have considered that referral for specialist opinion to a triage service was an active management strategy acceptable to patients, albeit that many were then referred on to physiotherapy, a service readily accessible to practices in the intervention arm. Future attempts to promote adherence with guidelines may need to focus on patient, as well as professional, education.

### References

- Maniadakis N, Gray A. The economic burden of back pain in the UK. *Pain* 2000; **84**: 95-103.
- Borkan J, van Tulder M, Reis S, *et al*. Advances in the field of low back pain in primary care. A report from the 4th International Forum. *Spine* 2002; **27**(5): E128-132.
- Royal College of General Practitioners (RCGP). Clinical guidelines for the management of acute low back pain. <http://www.rcgp.org.uk/rcgp/clinspec/guidelines/backpain/> (accessed 20 Nov 2003).
- Clinical Standards Advisory group (CSAG). *Back pain*. London: HMSO, 1994.
- Thomson O'Brien MA, Ginnan AD, Davies DA, *et al*. Educational outreach visits: effects on professional practice and healthcare outcomes. In: Cochrane Collaboration. *The Cochrane Library*. Issue 1. Oxford: Update Software, 2003.
- Petty RE, Cacioppo JT. The elaboration likelihood model of persuasion. In: Berkowitz L (ed). *Advances in experimental social psychology*. New York: Academic Press, 1986.
- Roland M, Waddell G, Moffat J, *et al*. *The back book*. London: The Stationery Office, 1996.
- Donner A, Klar N. Methods for comparing event rates in intervention studies when the unit of allocation is a cluster. *Am J Epidemiol* 1994; **140**(3): 279-289.

- Donner A, Klar N. Confidence interval construction for effect measures arising from cluster randomisation trials. *J Clin Epidemiol* 1993; **46**(2): 123-131.
- Williams DA. Extra binomial variation in logistic linear models. *Appl Stat* 1982; **31**(2): 144-148.
- RCGP, OPCS (Office of Population, Censuses and Surveys) and Department of Health. *Morbidity statistics for general practice. Fourth national study*. Series MB5 No 3. London: HMSO, 1995.
- McGuirk B, King W, Govind J, *et al*. Safety, efficacy, and cost effectiveness of evidence based guidelines for the management of acute low back pain in primary care. *Spine* 2001; **26**(23): 2615-2622.
- Schers H, Braspenning J, Drijver R, *et al*. Low back pain in general practice: reported management and reasons for not adhering to guidelines in The Netherlands. *Br J Gen Pract* 2000; **50**: 640-644.
- Guitterez B, Bloschichank A, Kurlantzick V. Clinical guidelines for lumbar radiology for patients with low back pain. *JAMA* 1997; **278**(21): 1741-1742.
- Watkins C, Harvey I, Langley C, *et al*. General practitioners' use of guidelines in the consultation and their attitudes to them. *Br J Gen Pract* 1999; **49**: 11-15.
- Fender GRK, Prentice A, Gorst T, *et al*. Randomised controlled trial of educational package on the management of menorrhagia in primary care: the Anglia menorrhagia study. *BMJ* 1999; **318**: 1246-1250.
- Jewell D. How to change clinical behaviour: no answers yet. *Br J Gen Pract* 2003; **53**: 266-267.
- Hall L, Eccles M, Barton R, *et al*. Is untargeted outreach visiting in primary care effective? A pragmatic randomised controlled trial. *J Public Health Med* 2001; **23**: 109-113.
- Premaratne UN, Sterne JAC, Marks GB, *et al*. Clustered randomised trial of an intervention to improve the management of asthma: Greenwich asthma study. *BMJ* 1999; **318**: 1251-1255.
- Searle J, Grover S, Santin A, Weideman P. Randomised trial of an integrated educational strategy to reduce investigation rates in young women with dysfunctional uterine bleeding. *Aust N Z J Obstet Gynaecol* 2002; **42**(4): 395-400.
- Watson M, Gunnell D, Peters T, *et al*. Guidelines and educational outreach visits from community pharmacists to improve prescribing in general practice: a randomised controlled trial. *J Health Serv Res Policy* 2001; **6**(4): 207-213.
- Klar N, Donner A. The merits of matching in community intervention trials: a cautionary tale. *Stat Med* 1997; **16**(15): 1753-1764.
- Koes BW, van Tulder MW, Ostelo R, *et al*. Clinical guidelines for the management of low back pain in primary care. An international comparison. *Spine* 2001; **26**(22): 2504-2514.
- Owen JP, Rutt G, Keir MJ, *et al*. Survey of general practitioners' opinions on the role of radiology patients with low back pain. *Br J Gen Pract* 1990; **40**: 98-101.
- Little P, Cantrell T, Roberts L, *et al*. Why do GPs perform investigations? The medical and social agendas in arranging back X-rays. *Fam Pract* 1998; **15**(3): 264-265.
- Keen S, Dowell AC, Hurst K, *et al*. Individuals with low back pain: how do they view physical activity? *Fam Pract* 1999; **16**: 39-45.

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