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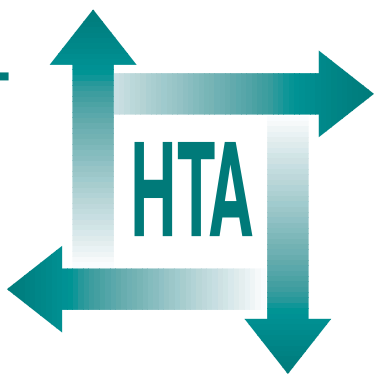
Health Technology Assessment
NHS R&D HTA Programme



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The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial

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NHS R&D HTA Programme

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The editors and publisher have tried to ensure the accuracy of this report but do not accept liability for damages or losses arising from material published in this report. They would like to thank the referees for their constructive comments on the draft document.

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Contents

List of abbreviations

CI	confidence interval
CT	computed tomography
df	degrees of freedom
EQ-5D	EuroQol-5 dimensions
ICER	incremental cost-effectiveness ratio
IQR	interquartile range*
IRMER	Ionizing Radiation (Medical Exposure) Regulations 2000
MRI	magnetic resonance imaging
MWU	Mann–Whitney *U* test*
NSAID	non-steroidal anti-inflammatory drug
OR	odds ratio
QALY	quality-adjusted life-year
SD	standard deviation
SF-36	Short Form with 36 items
SLR	straight leg raising*
TENS	transcutaneous electrical nerve stimulation*
VAS	visual analogue scale

* Used only in tables

Executive summary

Objectives

To test the hypotheses that:

- Lumbar spine radiography in primary care patients with low back pain is not associated with improved patient outcomes, including pain, disability, health status, sickness absence, reassurance, and patient satisfaction or belief in the value of radiography.
- Lumbar spine radiography in primary care patients with low back pain is not associated with changes in patient management, including medication use, and the use of primary and secondary care services, physical therapies and complementary therapies.
- Participants choosing their treatment group (i.e. radiography or no radiography) do not have better outcomes than those randomised to a treatment group.
- Lumbar spine radiography is not cost-effective compared with usual care without lumbar spine radiography.

Design

A randomised unblinded controlled trial.

Setting

Seventy-three general practices in Nottingham, North Nottinghamshire, Southern Derbyshire, North Lincolnshire and North Leicestershire. Fifty-two practices recruited participants to the trial.

Subjects

Randomised arm: 421 participants with low back pain, with median duration of 10 weeks.

Patient preference arm: 55 participants with low back pain, with median duration of 11 weeks.

Intervention

Lumbar spine radiography and usual care versus usual care without radiography.

Main outcome measures

Roland adaptation of the Sickness Impact Profile, visual analogue pain scale, health status scale, EuroQol, use of primary and secondary care services, and physical and complementary therapies, sickness absence, medication use, patient satisfaction, reassurance and belief in value of radiography at 3 and 9 months post-randomisation.

Results

Participants randomised to receive an X-ray were more likely to report low back pain at 3 months (odds ratio (OR) = 1.56; 95% confidence interval (CI), 1.02 to 2.40) and had a lower overall health status score ($p = 0.02$). There were no differences in health or functional status at 9 months. A higher proportion of participants consulted the general practitioner (GP) in the 3 months following an X-ray (OR = 2.72; 95% CI, 1.80 to 4.10). There were no differences in use of any other services, medication use or sickness absence at 3 or 9 months. No serious spinal pathology was identified in either group. The commonest X-ray reports were of discovertebral degeneration and normal findings. Many patients did not perceive their information needs were met within the consultation. Satisfaction with care was greater in the group receiving radiography at 9 months. Participants randomised to receive an X-ray were not less worried, or more reassured about serious disease causing their low back pain. Satisfaction was associated with meeting participants' information needs and reduced belief in the necessity for investigations for low back pain, including X-rays and blood tests. In both groups, at 3 and 9 months 80% of participants would choose to have an X-ray if the choice was available. Participants in the patient preference group achieved marginally better outcomes than those randomised to a treatment group, but the clinical significance of these differences is unclear. Lumbar spine radiography was associated with a net economic loss at 3 and 9 months.

Conclusions

Lumbar spine radiography in primary care patients with low back pain of at least 6 weeks duration is

not associated with improved functioning, severity of pain or overall health status, and is associated with an increase in GP workload. Participants receiving X-rays are more satisfied with their care, but are not less worried or more reassured about serious disease causing their low back pain.

Recommendations for further research

Further work is required to develop and test an educational package that educates patients and GPs about the utility of radiography and provides strategies for identifying and meeting the information needs of patients, and the needs of patients and GPs to be reassured about missing serious disease. Guidelines on the management of low back pain in primary care should be consistent about not recommending lumbar spine radiography in patients with low back pain in the absence of red flags for serious spinal pathology, even if the pain has persisted for at least 6 weeks.

Chapter 1
Introduction

Low back pain in primary care

Low back pain is an extremely common condition in the UK, accounting for 7% of all consultations in primary care.[1] The lifetime incidence of low back pain has been estimated to be as high as 70% for men and 80% for women,[2,3] rates so high that it is now becoming considered as a 'ubiquitous part of human experience', and one that has been overmedicalised.[4] Low back pain is a major international problem, not only from a medical perspective, but also in terms of its economic impact on society, including individuals, families, healthcare services and employers. The direct healthcare cost of back pain in the UK is estimated as £1.6 billion. If indirect costs, such as informal care and production losses, are also considered, the economic impact of back pain on the UK economy may be as high as £10.7 billion, which is approximately 1.3% of GDP.[5] This is in line with findings in other countries. In The Netherlands, the cost of back pain is estimated as 1.7% of GDP (total direct medical costs US $0.4 billion, total indirect costs US $4.6 billion).[6] In Germany the total cost of back pain is estimated as DM 34 billion.[7]

Lumbar spine radiography

Lumbar spine radiography is the most commonly requested investigation in primary care patients with low back pain. In the UK some 5% (£81.6 million) of the direct healthcare cost of back pain is spent on radiology and imaging used for investigation purposes.[5] Two audits of general practitioner (GP) referrals in the UK found that lumbar spine radiographs comprised 15% and 17% of all radiological examinations requested in primary care.[8,9] Each year 15–20% of all primary care attenders with low back pain are referred for lumbar spine radiography.[10] In addition, 40% of new hospital attenders will undergo radiography and many accident and emergency department attenders with low back pain will receive an X-ray.[10] In a population of 100,000 adults, 3000 will receive lumbar spine X-rays each year,[10] at an estimated cost of £90,000. Extrapolating to the level of the GP, each GP will, on average, X-ray 45 adult patients each year, although wide variations in referral rates for X-rays have been noted previously.[10]

Previous work has failed to demonstrate a consistent relationship between symptoms in patients with low back pain and X-ray findings. Several early studies have suggested that degenerative findings on lumbar spine radiography are more likely to be found in patients with low back pain than in asymptomatic patients.[11–13] More recent studies have, however, found degenerative disease arising with similar frequency among those with and those without low back pain.[14–16] Halpin and co-workers[8] reported similar pain scores in patients with significant findings on X-ray compared to those without such findings. Kaplan and co-workers[17] found no difference in the resolution of low back pain over a 4-week period in those with and those without significant findings on X-ray.

Many X-rays in patients with low back pain are reported as normal or as containing incidental findings. Halpin and co-workers[8] found that 37% of patients with low back pain referred for lumbar spine radiography by London GPs had essentially normal X-ray findings. Scavone and co-workers[18] found that 46% of all films in a retrospective review of 1095 lumbar spine examinations of inpatients and outpatients with low back pain had normal or incidental findings. Kaplan and co-workers[17] found that 24% of men with low back pain attending a walk-in clinic in the USA had normal findings on X-ray.

Despite the concerns about the effectiveness and costs of lumbar spine radiology, few economic evaluations have been carried out. Liang and Komaroff[19] concluded that the risks and costs of obtaining lumbar radiographs at the initial visit in patients with acute low back pain do not seem to justify the relatively small associated benefit. It was found that, in order to avert one day of physical suffering in a population of patients, the population would have to be subjected to the additional risk of 3188 mrad of radiation and an additional cost of US $2072. Little evidence exists on the economic efficiency of resources invested in lumbar spine radiography in the UK.

The likelihood of finding serious spinal disease

In addition to many X-rays being reported as normal in patients with low back pain, the chance of finding serious disease when it is not suspected clinically is very low, this being estimated as 1 in 2500.[20] Studies reporting X-ray findings on all patients (including those where serious disease is suspected) only found malignancy, infection or inflammatory spondyloarthropathy in less than 2% of films.[21] However, GPs frequently refer patients for X-rays in order to reassure the patients (88%) and themselves (78%).[22] The exclusion of serious disease is considered of prime importance by GPs.[8] The conclusion, therefore, seems to be that the correlation between symptoms and X-ray findings is poor, and the chance of finding serious disease that is not suspected clinically is extremely low. Despite this, referring for X-rays in order to gain reassurance is commonplace in primary care. Such reassurance may be misplaced, as lumbar spine radiography is relatively insensitive to important diagnoses such as malignancy or infection at an early stage, which would be detected by other imaging techniques such as magnetic resonance imaging (MRI).[23]

The risks of lumbar spine radiography

The dose of radiation from lumbar spine radiography is moderately high, being approximately 120 times that of a chest X-ray. While the risk to an individual patient is extremely low, based on 1973 referral rates (700,000 per year in the UK) it has been estimated that 19 people die each year as a result of this test[8] and that five malignancies per million persons exposed may be induced by lumbar spine radiography.[24] Lumbar spine radiography is therefore not an innocuous test, and the risks of undertaking it must be clearly weighed against the benefits.[8,22] Formal justification of each radiographic exposure is now explicitly required under the Ionizing Radiation (Medical Exposure) Regulations 2000 (IRMER),[25] which came into effect in May 2000. The justification process includes the requirements that the potential benefits of any radiographic exposure are weighed against any detrimental effects and that those alternative diagnostic techniques that involve less or no radiation exposure are considered where available. These alternatives obviously include MRI, although the availability of this imaging modality for GP referrals remains very limited in most of the UK.

Lumbar spine radiography and the management of and outcomes for patients with low back pain

As the incidence of serious spinal disease found on lumbar spine X-rays is very low, it would be expected that radiography reports would have little influence on the management of most patients. One survey of GPs found that GPs perceived that the X-ray results changed patient management in 40% of cases.[26] A second survey found that GPs perceived that X-ray findings were most likely to change patient management in terms of referral to secondary care.[22] Deyo and co-workers,[27] in a small randomised controlled trial of lumbar spine radiography, found no difference in the proportion of participants receiving non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants or narcotics, or requiring hospital admission, specialist referral or physical therapy. Rockey and co-workers,[28] in a non-randomised study, found similar results, with no discernible impact on diagnostic decisions regarding drug treatment, advice on bed rest, exercise or hospitalisation. Indahl and co-workers,[29] in a study of patients off work with low back pain, found those who received an examination, an X-ray, a computed tomography (CT) scan and information about remaining active were more likely to return to work than were those given usual care. In an uncontrolled study, Kaplan and co-workers[17] found that a diagnosis of degenerative joint disease on X-ray was associated with a three-fold increase in the likelihood of being treated with a NSAID. Halpin and co-workers,[8] in an audit of primary care referrals for lumbar spine radiography, found that two out of 30 GPs whose patients had had an X-ray that showed a positive finding said the X-ray result had altered their management. Most said that the investigation had been useful in excluding serious disease. In a survey of GPs in the UK, reassurance of the patient and the GP were frequently reported reasons for requesting lumbar spine radiography: 88% of respondents said they referred to reassure the patient and 78% to reassure themselves.[22]

It therefore appears that radiography reports may reassure the GP and the patient about the absence of serious disease (erroneously in a very small number of cases) and may alter the prescribing of NSAIDs. However, there have only been two randomised controlled trials in this area. The first, a small trial in the USA,[27] which found no effect of radiography, may have been insufficiently powered; in addition, generalising the results

from the USA to the UK may be problematic. The second, which showed reduced sickness absence in the intervention group, recruited patients off work with low back pain for at least 8 weeks and involved a multifaceted intervention that included an X-ray.[29] Here the effect attributable to the X-ray cannot be disentangled from the effect of other aspects of the intervention. The generalisability of these results to all primary care patients with low back pain, the majority of whom have shorter periods of sickness absence, must also be questioned.

Expectations of patients with low back pain

Several studies have assessed patient expectations of radiography. Deyo and Diehl[30] found that 65% of patients with mechanical back pain in a walk-in clinic in the USA believed that everyone with low back pain should have an X-ray. A small trial, by the same authors, of immediate X-ray versus education and delayed X-ray found, at baseline, that 56% of the immediate radiography group and 47% of the delayed radiography group believed all patients with low back pain should receive radiography.[27] Furthermore, at 3 weeks follow-up they found an increase in the proportion holding this belief in the immediate X-ray group to 73%, but no significant decrease in the delayed X-ray group (from 47% to 44%). This suggests that the use of X-rays increases the belief in their value; but not that withholding X-rays reduces belief in their value. The follow-up period for this study was only 3 weeks, and so the applicability of the results to patients whose back pain has continued for longer periods is not clear. It is likely that the longer the back pain continues the greater the importance of having a 'diagnosis' or an explanation for the symptoms.

The explanation of symptoms has been shown to be important in patients with low back pain. Deyo and Diehl[30] found that the most common source of dissatisfaction with care for low back pain, in their study of 140 patients with mechanical back pain in a walk-in clinic in the USA, was failure to receive an adequate explanation of their symptoms. Those who were dissatisfied were also more likely to believe more tests should have been done. Interestingly, in their trial of immediate versus delayed radiography, the proportion receiving an adequate explanation of their problem was not statistically significantly different between those who had received an X-ray and those who had not, suggesting that radiography is not necessary for providing an explanation considered adequate by the patient.[27] Also, the proportion of patients worried that the pain was due to serious illness did not differ between the two groups (54% and 43% in the immediate and delayed radiography groups, respectively), suggesting that radiography does not provide the reassurance for the patient that GPs expect it might,[22] and highlighting the fact that many patients are worried that low back pain may be due to serious disease. It is important, however, to remember that the sample size was small (n = 43 immediate X-ray group, n = 49 delayed X-ray group), and so the study had only limited power to detect differences in these outcomes.

Lumbar spine radiography and patient satisfaction

Patient satisfaction is important as it may correlate with compliance and other outcomes. In a small randomised controlled trial comparing radiography with patient education in patients with low back pain of 2 weeks duration, Deyo and co-workers[27] found a significant correlation between satisfaction and compliance with medication and also between satisfaction and self-rated improvement. Increasing satisfaction was also associated with less desire for more diagnostic tests.

Kaplan and co-workers[17] found that patients given a diagnosis of degenerative joint disease were more satisfied with their care, and were less likely to seek care elsewhere than were those given other non-specific diagnostic labels. Similarly, Rockey and co-workers,[28] in a non-randomised study of patients with low back pain for 1 week or less, found that patients receiving an X-ray were older (on average 5 years), had been symptomatic for longer, and were less likely to be symptom free at 4 weeks but, despite the persistence of their symptoms, were more satisfied with the care they had received.

Deyo and Diehl[30] found that the most frequent source of dissatisfaction was perceived inadequate explanation of what was wrong. Patients who did not receive an adequate explanation were more likely to think more tests should have been done, were more worried about serious illness and were less satisfied with their doctors. Use of X-rays did not account for the difference in the proportion perceiving they had received an adequate explanation, as the proportions having an X-ray were very similar among those who had received an adequate explanation and those who had not.

The conclusion seems to be that patient satisfaction with the consultation for low back pain may be associated with compliance and self-rated improvement. Patient satisfaction appears to be associated with receiving an adequate explanation of what is wrong. Not receiving an adequate explanation is associated with a belief that more tests should be done and with more worry about serious disease. One small trial suggests that the adequacy of the explanation may not be accounted for by having an X-ray. However, to our knowledge, there is at present no other published work that has examined this aspect in the field of low back pain. All the studies relating to patient satisfaction have used patients with a short duration of low back pain. It is likely that the longer the pain continues the greater the need for an adequate explanation, and the greater the potential for patient dissatisfaction and the associated poorer compliance and self-rated improvement. Croft[10] highlights the need to consider consultation behaviour, patient anxiety and perceptions of the importance of X-rays in judging the use of radiography, and acknowledges that there is little or no research evidence in this area.

GP referral patterns

There have been several published studies assessing the implementation of guidelines for GPs on the use of radiology in the UK. It has been estimated that the adoption of guidelines by GPs could reduce referral rates by 30%.[26] Halpin and co-workers[8] found more than 50% of referrals for lumbar spine radiography did not conform to the guidelines of the Royal College of Radiologists, and Oakeshott and co-workers[31] similarly found that 60–65% of GP referrals did not conform to the same guidelines. Several studies have attempted to alter referral behaviour through the implementation of guidelines. All have shown significant, but limited, success. A non-randomised study by the Royal College of Radiologists demonstrated a 17.5% reduction in lumbar spine radiographs, and a non-randomised study by De vos Meiring and Wells[32] found a 26% reduction over a 2-year period following the introduction of guidelines. Oakeshott and co-workers[31] undertook a randomised controlled trial to assess the effect of introducing the Royal College of Radiologists guidelines in 62 practices in London. Following the introduction of the guidelines, they found a significant reduction in the number of requests for lumbar spine radiography, but 45% of requests still did not conform to the guidelines and there was no difference in the proportion conforming in the intervention and control groups. It therefore seems that the introduction of such guidelines has only met with limited success; and that many patients continue to receive lumbar spine X-rays which do not conform to the guidelines. However, the recently introduced IRMER guidelines should lead to a reduction in inappropriate radiographs.

Guidelines on the use of lumbar spine radiography

The guidelines regarding the use of lumbar spine radiography currently make the following recommendations:

- Agency For Healthcare Policy and Research, 1994:[23] "plain X-rays are not recommended for routine evaluation of patients with acute low back problems within the first month of symptoms unless a red flag is noted on clinical examination".
- Clinical Standards Advisory Group, 1994:[33] "X-rays may be performed in simple backache if symptoms and disability are not improving after 6 weeks".
- Royal College of Radiologists, 1998:[34] "radiography is not routinely indicated in acute low back pain with no adverse features".
- Royal College of General Practitioners, 1999:[35] "there is no indication for routine X-rays in acute low back pain of less than 6 weeks in the absence of clinical red flags".

None of the above guidelines have based their recommendations on evidence they have rated as strong. The Royal College of General Practitioners rates the strength of evidence from which their recommendations regarding lumbar spine radiography have been produced as "limited scientific evidence, which does not meet all the criteria of acceptable studies".[35] The Royal College of General Practitioners based their guidelines on those from the Royal College of Radiologists, which are based on consensus, and are not directly linked to evidence.[34] The Agency For Healthcare Policy and Research guidelines rate the strength of the evidence relating to lumbar spine radiography as moderate.[23] It must also be borne in mind that the above guidelines mainly relate to primary care patients with low back pain of between 4 and 6 weeks duration.

The existing guidelines are therefore inconsistent, and mainly relate to primary care patients with low

back pain of 4–6 weeks duration. Although many episodes of low back pain will improve or resolve within 6 weeks; there are still many patients who consult their GP with low back pain that has persisted beyond 6 weeks.[36] The longer an episode of low back pain persists, the greater the concern, both of the GP and the patient, that it may be due to serious spinal pathology, and the greater the likelihood that the GP will refer the patient for radiography. Owen and co-workers,[22] in a survey of GPs, found that less than 10% would always or sometimes refer patients with low back pain of less than 1 month duration for X-ray, but this rose to 70% once the pain had lasted for more than 1 month. There is, therefore, a need for evidence on which to base guidelines regarding radiography in patients with low back pain of more than 6 weeks duration.

Summary

The available evidence suggests that lumbar spine radiography is a commonly requested examination in primary care, but is not particularly useful in distinguishing the cause of the low back pain, and in a few cases may provide false reassurance when serious spinal pathology does exist. In addition, one small trial has failed to demonstrate an effect of X-rays on patient outcomes, and one trial of a multifaceted intervention, which included an X-ray, has shown a reduction in sickness absence. At present, therefore, there is insufficient evidence to assess the impact of radiography on patient outcomes. However, many patients do worry that their low back pain may be caused by serious disease, and believe that patients with low back pain require X-rays. Dissatisfaction with care is most commonly associated with failure to receive an adequate explanation for the pain, and dissatisfied patients are more likely to believe more tests should have been done. One small trial has suggested that radiography is not associated with receiving an adequate explanation, or decreasing worry about serious disease, but may increase belief in the value of X-rays among patients. GPs frequently refer for radiography to reassure patients and themselves, and the longer the duration of pain the greater the likelihood of the GP referring the patient for X-ray. Several studies have attempted to reduce the number of GP referrals for lumbar spine radiography by means of the implementation of guidelines, and have demonstrated limited success, with many referrals still failing to conform to the guidelines. The existing guidelines for patients with low back pain of at least 6 weeks duration give conflicting advice about the use of radiography, and are not based on strong evidence.

Randomisation is important to eliminate selection bias, whereby patients who perceive X-rays as helpful may be more likely to request them, and GPs who perceive that their management of low back pain is affected by the results of radiology or who may themselves be more reassured by a negative X-ray finding may be more likely to refer. Few randomised studies have been undertaken to assess the impact of radiography on patient functioning, patient satisfaction and reassurance and the management of low back pain in primary care. The present trial was undertaken to test the hypothesis that lumbar spine radiography in patients with low back pain for at least 6 weeks is not associated with improved patient functioning, increased patient satisfaction, reassurance or changes in patient management.

Given that resources for healthcare are scarce, decision-makers need information about the relative costs and benefits of lumbar spine radiology from both a health service perspective and, given that indirect costs constitute such a high share of the cost of back pain, from a societal perspective. This study also tested the hypothesis that lumbar spine radiography in primary care patients with low back pain of at least 6 weeks duration is not a cost-effective strategy compared with usual care without radiography.

The results of this study should be used to inform guidelines and other strategies aimed at increasing the appropriateness of lumbar spine radiography in primary care.

Chapter 2
Methods

Objectives

The objectives of the study were to test the following hypotheses:

- Lumbar spine radiography in primary care patients with low back pain is not associated with improved patient outcomes, including pain, disability, health status, sickness absence, reassurance, patient satisfaction or belief in the value of radiography.
- Lumbar spine radiography in primary care patients with low back pain is not associated with changes in patient management, including medication use, use of primary and secondary care services, of physical therapies or of complementary therapies.
- Participants choosing their treatment group (i.e. radiography or no radiography) do not have better outcomes than those randomised to a treatment group.
- Lumbar spine radiography is not cost-effective compared with usual care without lumbar spine radiography.

Practice recruitment

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 in the study, of which 52 recruited participants to the trial.

Study population

The study population comprised patients with low back pain consulting GPs in participating practices between November 1995 and January 1999, and fulfilling the eligibility criteria outlined below.

Identification of patients consulting with low back pain

Patients with low back pain were identified by two methods. In practices recording consultations on computer using a READ code, searches were undertaken using the READ code used by each practice for low back pain. In practices that were not using READ coding on computer for all consultations, patients were identified by the GP flagging the notes of patients seen with low back pain. The computerised searches were conducted by research nurses weekly or fortnightly depending on the size of the practice and the number of patients consulting with low back pain.

Inclusion and exclusion criteria

Patients were included if they had low back pain on the day of randomisation and for at least the preceding 6 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 6 weeks in the preceding 6 months. Exclusion criteria were based on the 'red flags' for potentially serious spinal pathology identified by the Clinical Standards Advisory Group.[33] Patients were excluded if they were under 20 or over 55 years of age, had a history of malignancy, had unexplained weight loss or fever, were taking oral steroids, had a history of tuberculosis, intravenous drug use, a positive HIV test or had symptoms or signs of a cauda equina lesion. Patients were excluded if they had had low back pain for more than 6 months, as the majority of these patients would already have had an X-ray; or if they had had a lumbar spine X-ray in the preceding 12 months. Patients were also excluded if they were pregnant or planning a pregnancy or if the GP considered they were unable to give informed written consent (e.g. patients with a learning disability).

Ascertaining eligibility

The research nurses, prior to sending postal invitations to participate, checked manual and computerised records identified by the searches for eligibility. Patients responding to the invitation to participate were interviewed on the telephone to ascertain other eligibility criteria. Patients appearing eligible at this point 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 prior to randomisation.

Research nurse training

The research nurses were trained in the examination of the lumbar spine and lower limb neurology by the Professor of Orthopaedics at clinics receiving primary care referrals of patients with low back pain at the Queen's Medical Centre, Nottingham. They were taught how to use a goniometer for measuring straight leg raising. To minimise interobserver variation, wherever possible individual research nurses conducted the examinations at all three time points (baseline, 3 months, 9 months) on the same participants.

The intervention

In addition to receiving the usual care provided by the practice for patients with low back pain, the intervention group participants were given an X-ray card to attend for a lumbar spine radiograph at their local hospital by the research nurse at the baseline interview. They were asked to contact their GP for the result of the X-ray, either by telephone, or by consulting with the GP, depending on what the usual procedure was for receiving X-ray results at each participating practice. The control group received the usual care from their GP. The GP was able to refer the patient for an X-ray if they considered it clinically necessary at any time.

Primary and secondary outcome measures

The primary and secondary outcome measures were measured by means of a self-completion questionnaire and a structured face-to-face interview conducted by the research nurse, as indicated for each measure below.

The primary outcome measure was difference in the median Roland score (an adaptation of the Sickness Impact Profile)[37] between treatment groups at 3 and 9 months after randomisation. The Roland score is calculated from a self-completion questionnaire containing 24 questions related to back pain disability as experienced by the person completing the questionnaire on the day of completion. The questions cover self-care, sleeping, walking, household tasks, climbing stairs, resting, bending, appetite and irritability. It is scored from zero to 24. A score of zero indicates no back-related disability and the higher the score the greater the degree of disability. The Roland score has been demonstrated to be reliable, to have construct validity and to be sensitive to clinically meaningful changes in patient functioning.[38–41]

A range of secondary outcome measures were used to reflect the multidimensional nature of the impact of low back pain. These included:

- a visual analogue scale (VAS) for pain
- EuroQol-5 dimensions (EQ-5D), including the health status scale
- satisfaction and expectations of care, reassurance and belief in the value of radiography
- duration of low back pain and of certificated sick leave (obtained from the structured interview)
- use of health and other services (obtained from the structured interview)
- medication use (obtained from the structured interview)
- low back pain as measured by a 2-week self-completion pain dairy.

The self-completion VAS for pain rated pain from 'no pain at all' (scored zero) to 'almost unbearable pain' (scored 5). Participants were asked to rate the degree of back pain they had on the scale on the day of completion. In addition to the VAS for pain a 2-week pain dairy was given to each participant at baseline and at the 3- and 9-month follow-up interviews. The diary contained the same VAS described above, and asked the participant to record the number of hours of pain each day. Participants were asked to complete the diary daily for the 2 weeks subsequent to the baseline and 3- and 9-month follow-up interviews and return it by post. The total number of days with pain, the number of pain-free days, the number of days with pain rated as 'quite bad' or 'worse' (≥ 3 on the pain VAS) and the number of days with more than 4 hours of pain were calculated from the diaries.

States of health may be described using many different instruments (Short Form with 36 items (SF-36), Nottingham Health Profile, Sickness Impact Profile, EQ-5D), which provide a profile of scores in different health domains. EQ-5D, for example, simplifies health into just five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain is given a score from 1 to 3, so the health profile would read 11111 for the best scores in all domains and 33333 for the worst. EQ-5D has 243 possible health profiles,

all of which have been assigned a utility value from general population surveys.[42]

Patients' satisfaction with the care they received for their most recent consultation with the GP regarding their back pain was measured using a self-completion questionnaire containing questions that were designed for, and have been used with, primary care patients with low back pain in the USA.[27,30] The questionnaire comprises nine statements covering perceptions of adequacy of explanation of the problem, understanding of the back problem, feeling that the doctor was concerned and understood patients' concerns, spending enough time with the doctor, their attitude towards seeing the same doctor in the future, seeking help from another professional since their last visit to the doctor, and overall satisfaction with their last contact with the doctor. Participants were asked to 'agree', 'disagree' or enter 'not sure' for each statement. Each statement was scored from 1 to 3. A score of 1 was given for 'agree' responses to negative statements and for 'disagree' responses to positive statements. A score of 2 was given for statements for which the participant entered 'not sure'. A score of 3 was given for 'agree responses' to positive statements and 'disagree' responses to negative statements. The minimum score obtainable was 9 and the maximum 27. A higher score indicates a higher degree of satisfaction. The consistency of the scale has previously been found to be high, with a Cronbach α value of 0.72.[30] Satisfaction as measured with this scale has been shown to be associated with compliance with medication, self-rated improvement and reduced desire for additional diagnostic tests.[30]

Expectations of care were measured by a self-completion questionnaire containing questions taken from an existing questionnaire that had been used with patients attending a rheumatology clinic in the UK.[43] Six statements were used regarding participants' expectations of receiving information on learning to avoid straining their back, on posture, on medication, on other types of treatment for low back pain, on recommendations to rest and on discussion of usual activities. Participants were asked to rate their agreement with each statement on five-point Likert scales, from 'strongly agree' to 'strongly disagree'. In addition, participants were also asked what actually happened at their last consultation with the GP regarding each of the six statements.

Reassurance and belief in the value of radiography were measured using a self-completion questionnaire containing five questions that have previously been used in the same studies as the patient satisfaction questionnaire.[27,30] Participants were asked to rate their agreement on five-point Likert scales, from 'strongly agree' to 'strongly disagree'. The statements covered belief that more tests should have been undertaken, that all patents with low back pain need an X-ray, that all patients with low back pain need a blood test, worry about back pain being due to serious disease, and reassurance that the participant does not have a serious condition causing the back pain.

The research nurse measured primary and secondary outcomes before randomisation and at 3 and 9 months after randomisation by means of a structured face-to-face interview. Interviews were conducted by telephone if the participant was not able to attend for a face-to-face interview at 3 and 9 months. The interview schedules are available on request.

Data were also abstracted from the primary care medical records of the trial participants in order to ascertain the results of lumbar spine radiographs and the diagnosis of serious spinal pathology as the cause of low back pain. Where X-ray reports were not found in the primary care medical records, wherever possible they were obtained from the radiology department at the hospital that undertook the X-ray. The entire primary care records of the trial participants were also searched to ascertain serious spinal pathology as a cause of the low back pain.

Sample size

The original sample-size calculation was based on a baseline mean Roland score of 10.1 (standard deviation (SD) = 5.2) as found by Deyo and Centor[44] in a study of primary care patients with low back pain in the USA. However, after recruiting 88 participants we found that the distribution of the Roland scores among the trial participants had a similar mean but a smaller SD (4.5), so a revised sample size was estimated using this SD. The sample size calculation indicated that 388 participants in total in both arms of the study would allow a difference in a 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). Previous studies using the Roland score in a similar population of patients have found that patients clinically judged to have improved in terms of pain and resumption of usual activities have changes in the Roland score of the order of 3 or more. Consequently, ensuring the study had sufficient power to detect a change in the Roland score of 1.5

meant it was unlikely that the study would miss any clinically important difference.

A *post hoc* sample-size estimation based on detecting equivalence was also undertaken. Using the Roland score as the primary outcome measure and assuming 210 participants per treatment arm, the study had 80% power to show equivalence of the treatment arms, in the sense that the 95% two-sided confidence interval (CI) for the treatment difference falls wholly within the interval from –2 to 2. Assuming 90% power, the study would have shown equivalence based on the 95% two-sided CI for the treatment difference falling wholly within the interval from –2.5 to 2.5.

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 an equal number of participants in each group. A member of the research team (KF) who was not involved in assigning the participants to the treatment groups produced a computer-generated allocation schedule. In addition, the study included a participant preference arm, in which participants who did not consent to randomisation could choose whether to have an X-ray or not.

Blinding

It was not possible to blind the research nurses or participants to the treatment groups. The implications of this are considered in chapter 4.

Ethical committee approval

Ethical committee approval was obtained from: the Queens Medical Centre, Nottingham; Southern Derbyshire Ethics Committee; North Lincolnshire Research Ethics Committee; North Nottinghamshire Health Authority; and Leicestershire Health Authority.

Data preparation and statistical analysis

Data entry and coding

All data were double entered in a relational database (Microsoft ACCESS 97) and, wherever possible, variables were given numeric codes. Data were exported to the statistical package SPSS for Windows (version 8.0) for statistical analysis.

Analysis of the randomised study

The main analysis for primary and secondary outcome measures was based on the intention-to-treat principle. An additional analysis based on the actual 'treatment' received was reported for the Roland score (the primary outcome measure).

Baseline demographic and clinical data were assessed informally to demonstrate the comparability of the intervention and control groups. Continuous measurements were summarised as median and quartile values, and dichotomous variables were summarised as actual numbers and percentages.

The difference in outcomes between treatment groups was assessed at 3 and 9 months after randomisation. The Mann–Whitney *U* test was used to compare non-normally distributed continuous variables. Comparisons between categorical variables were made using χ^2 tests (with Yates' correction and Fisher's exact test where appropriate) and odd ratios (ORs) with 95% CIs were calculated.

Comparison of the randomised study and the patient preference study

Baseline demographic and clinical data were assessed formally to identify any differences between the randomised study groups combined, the patient preference X-ray arm and the patient preference non-X-ray arm.

Differences in outcomes, at 3 and 9 months after entry into the study, between the randomised intervention group and the patient preference X-ray group, and the randomised control group and the patient preference non-X-ray group, were assessed. Clinical outcomes, use of health services and other services, and patient satisfaction and expectations were assessed.

Generalisability

In order to assess the generalisability of our results to the population of patients consulting with low back pain in primary care, we undertook a prospective study in the participating practices. This study was commenced the month after recruitment to the trial was complete. All patients attending with low back pain and aged 20–55 years in February 1999 were identified from the computer records of the practices still

recruiting participants to the trial in January 1999 (16 practices). We were only able to undertake this study after recruitment to the trial had been completed and we could only involve practices still recruiting to the trial as we needed to be able to compare recruited patients with non-recruited patients from the same practices within a short time frame. It is possible that practices still recruiting at the end of the trial may have differed from practices that had stopped recruiting prior to the end of the trial, and so may not be representative of all practices that took part in the study. All patients identified were sent a postal questionnaire to determine their eligibility for inclusion in the trial (socio-demographic characteristics, symptoms, duration of symptoms, pain, disability, satisfaction with previous consultation for low back pain, reassurance and belief in value of radiography, duration of sickness absence from work, use of radiography, primary and secondary care services, use of physical and complementary therapies). Comparisons were then made between participants recruited to the trial from those 16 practices and patients consulting with low back pain. Ethical committee approval for this study was obtained from the same ethics committees as above.

Economic evaluation

Resource-use data were collected prospectively alongside the clinical trial. Eight direct and five indirect cost variables were identified. This is intended to give a societal perspective to the costs of low back pain. Direct costs considered were: intervention costs (resources used in providing radiography for low back pain), inpatient admission, outpatient attendance, GP visits (home or surgery), other community or private services (e.g. osteopathy, physiotherapy, acupuncture), prescribed medication, over-the-counter medications and special equipment purchased (e.g. back supports, transcutaneous electrical nerve stimulation machines, heat packs). Participant and companion travel and work-loss costs were also included in each category, where appropriate. Indirect costs considered were costs of practical help (formal or informal carer), extra expenses incurred (e.g. increased heating bills, paying for gardening/housework), social security payments (e.g. incapacity benefit, income support, family credit), loss of earnings for the participant (due to time off work or change in duties) and loss of productivity for the employer. Quantity and frequency data were abstracted from participants' case notes and from the participant surveys. Unit costs were obtained from a range of sources (*Table 1*). Missing values were excluded from the analysis.

Cost and outcomes were synthesised in cost-effectiveness analyses. These are in the form of the cost per unit change in Roland score and the cost per unit change in satisfaction score at 3 and 9 months after randomisation. These results are reported as point estimates of incremental cost-effectiveness ratios (ICERs) and distributions presented on a cost-effectiveness plane. The origin on the cost-effectiveness plane represents the comparator strategy (control group), while each data point represents the observed change in cost and effect using the intervention strategy (X-ray). This highlights the distribution of cost and effect data. Points in the south-east quadrant (lower costs, higher benefits) dominate the comparator, while points in the north-west quadrant (higher costs, lower benefits) are dominated by the comparator. Points in the remaining two quadrants (north-east and south-west) may or may not be desirable, depending on the decision-maker's values and objectives. ICERs were only calculated for points in these two quadrants. Decision-makers must determine their maximum acceptable ICER.

The valuation of intangible items, such as the reassurance associated with radiography and the costs perceived by participants due to the extra risk of radiation, is a particular problem with economic evaluation in this area. The willingness-to-pay technique was used to estimate these values. Participants were asked directly how much they would (hypothetically) be willing to pay out of their own pocket for an X-ray and how much they would pay for the risk of radiation from the X-rays to be reduced to zero. Open-ended questioning was used for both willingness-to-pay schedules. This then provided values to be used in the cost–benefit analysis. The cost–benefit equation is in the form: change in direct costs + change in indirect costs + value of reassurance from X-ray – perceived value of the loss due to radiation risk.

Cost differences were analysed using a non-parametric statistical test (Mann–Whitney *U* test) due to the positively skewed distribution of the cost data. In addition, to account for possible sampling error and uncertainty around cost-effectiveness ratios, the non-parametric technique of bootstrapping was used. Bootstrapping is a re-sampling technique[45] which can simulate a distribution of ICER estimates from the observed sample. This study used 2000 iterations of re-sampled estimates for pairs of costs and effects in

TABLE 1 *Unit costs*

Variable	Unit cost	Source
Lumbar X-ray	£40	QMC finance
Inpatient stays	£150 per day	Estimate
Outpatient visits	£50 per attendance	QMC finance
GP visits	£15 per consultation	PSSRU
Other services (NHS)	Private care (participant supplied data) NHS care: physiotherapist: £30 per hour of client contact health visitor: £46 per hour of client contact district nurse: £34 per hour spent with a patient	Questionnaire, PSSRU
Carers	Time off work (£4.50 per hour) + participant-supplied data on expenses	Estimate
Prescribed drugs	As BNF	BNF
Over-the-counter drugs	Participant-supplied data	Questionnaire
Equipment	Participant supplied data for own purchases + back support (£18.36) heat pack/lamp (£10.00) TENS machine (£110.00) cushion/pillow (£13.66) massage/oils (£11.15) walking stick (£10.00) McKenzie roll (£9.48) chair/stool (£210.00) car seat (£14.99) trolley (£20.00) shower (£30.00) mattress/board (£62.50) heel raise (£15.00) exercise equipment (£40.00) other (£10.00)	Questionnaire, mean values from baseline dataset
Extra expenses	Participant-supplied data	Questionnaire
Social security payments	Participant-supplied data	Questionnaire
Loss of earnings	Participant-supplied data	Questionnaire (mid-point of income bracket used to proxy wage rates)
Loss of productivity	Derived from loss-of-earnings calculation: if time off was unpaid, assumed no loss in productivity (work covered by other) if time off was fully paid, assumed loss = wage rate if time off was at reduced pay, assumed loss = normal wage rate + reduced rate (e.g. statutory sick pay = £59.55 per week)	Estimate
Travel	Private car: £0.40 per mile Bus: £0.30 per mile Taxi: £5.00 per journey + Participant-supplied data	Estimate, questionnaire

BNF, British National Formulary; PSSRU, Personal Social Services Research Unit; QMC, Queen's Medical Centre; TENS, transcutaneous electrical nerve stimulation

all bootstrap simulations. Since costs may be correlated with effects (more services are more likely to improve effects), only those patients with complete data cost and outcome data were included. The distribution of ICER estimates can be used to plot a so-called 'acceptability curve',[46] which gives an estimate of the proportion of the sampling distribution of costs and effects that lie below a given threshold (the maximum value a decision-maker is prepared to pay for a unit of effect).

Chapter 3
Results

Recruitment of practices

Recruitment of practices took place over an 18-month period. Practices were recruited from Nottingham, South Derbyshire, North Nottinghamshire and Lincolnshire between November 1995 and May 1997. In March 1997 practice recruitment was extended to North Leicestershire and took place over a 2-month period.

All practices in the recruitment areas were sent a postal invitation to take part in the study (n = 321). Each practice was also contacted by telephone. A member of the study team (DK) and a research nurse visited those practices that expressed an interest in the study.

In total, 73 practices were recruited (23% of those invited to participate). Forty practices were recruited from Nottingham, 15 from Southern Derbyshire, ten from Lincolnshire, four from North Nottinghamshire and four from North Leicestershire. The list sizes of the practices ranged from 1750 to 33,200, the mean size being 7011 (SD = 4838). The number of GPs ranged from one to 16. Seventeen practices (23.2%) were single-handed and 31 (42.5%) had four or more GPs. The mean number of GPs per practice was 3.6 (SD = 2.52). Thirty practices (41.1%) had computer records, including READ coded diagnostic data. The median Townsend score did not differ between the practices participating in the trial (median, –0.19; Q1, Q3: –1.67, 2.36) and those not participating in the trial (median –0.23; Q1, Q3: –1.59, 2.34) (Mann–Whitney U = 8815.0, Z = –0.01, p = 0.99).

Participants were recruited into the trial from 52 (71%) of the 73 practices taking part in the study. Non-recruiting practices had a higher median Townsend score, indicating greater deprivation (median 1.55, Q1, Q3: –0.5, 4.03) than recruiting practices (median –0.53; Q1, Q3: –1.9, 1.48) (Mann–Whitney U = 361.5; Z = –2.16; p = 0.03). Eighteen of the 21 practices that did not recruit any participants to the trial did not have computer records. A total of 395 participants were recruited from computerised practices; these comprised 83% of the total participants, including those in the patient preference arm.

Recruitment of trial participants

The process of recruiting trial participants involved five stages:

- identifying patients aged 20–55 years who had attended with low back pain
- excluding those who were ineligible based on record review
- a postal invitation to those appearing eligible
- a telephone interview of responders to the postal invitation to ascertain their eligibility
- a face-to face interview with the patients to recruit them to the trial.

In total, 9453 patients aged 20–55 years were identified as attending participating practices with low back pain during the recruitment period (November 1995 to January 1999). Of these, 3898 (41%) appeared from the case notes search to be eligible for the study and were sent a postal invitation to take part in the study. Of those invited, 2564 (66%) responded to the invitation to take part, 2000 of whom agreed to participate (51.3% of those invited). Of those agreeing to take part 1524 (76%) were ineligible, most commonly because their back pain had resolved. 24% of those agreeing to take part were eligible and were recruited to the trial (n = 476).

Randomised study

Recruitment details

There were 421 participants recruited into the randomised study. Of these, 402 (95.5%) and 394 (93.6%) were available at the 3- and 9-month follow-ups, respectively. *Figure 1* shows the progress of the participants through the trial.

Study population at baseline

The socio-demographic characteristics of participants at baseline, by treatment group, are shown in *Table 2* and the clinical characteristics of participants are shown in *Table 3*. It can be seen

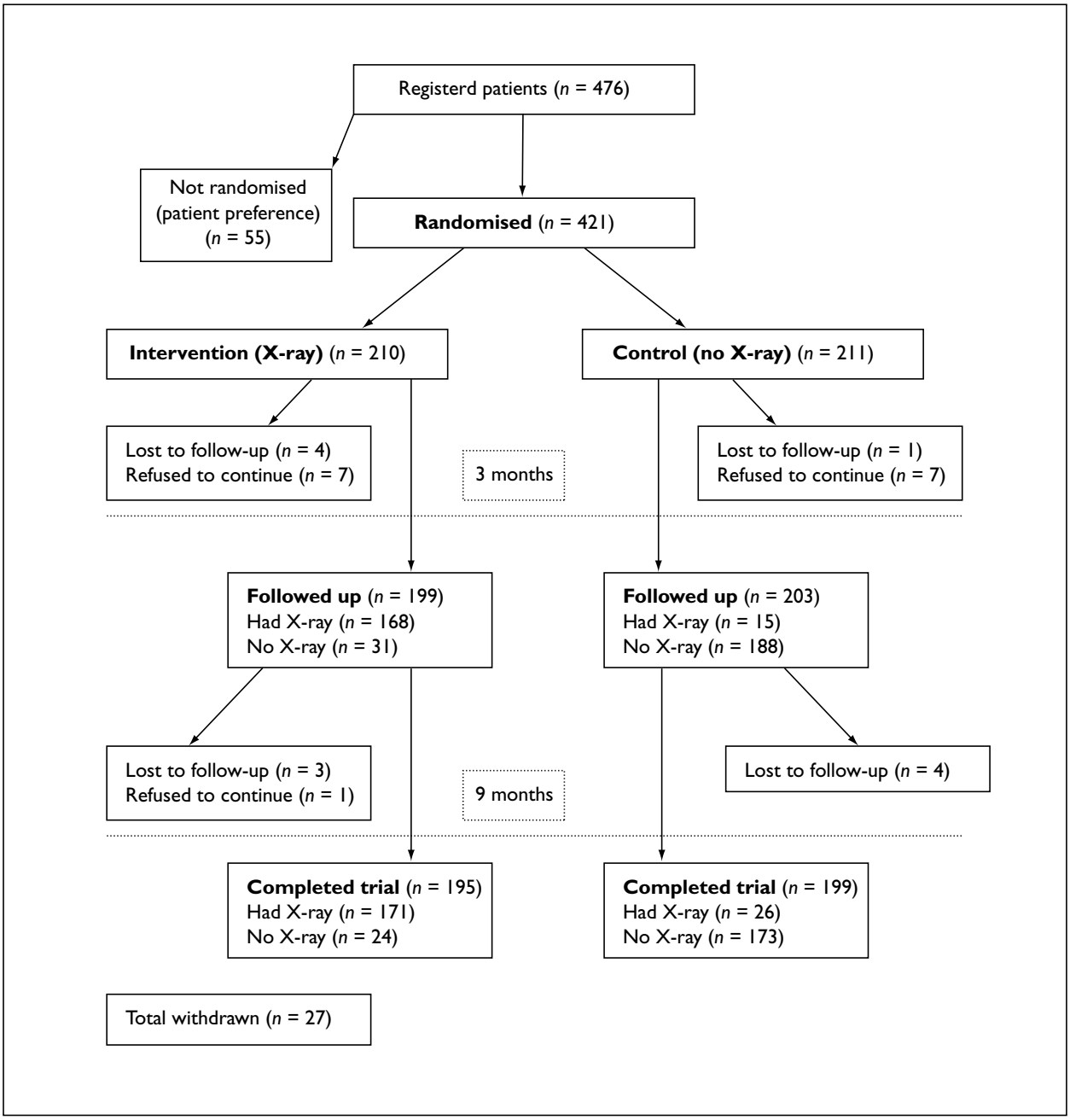

FIGURE 1 *Progress of participants through the trial*

that the treatment groups were similar at baseline. Of the 421 trial participants, 41.3% ($n = 174$) were male, the median age was 39 years (Q1, Q3: 31 years, 45 years) and 65.1% ($n = 274$) were married.

The median length of the present episode of low back pain was 10 weeks (Q1, Q3: 7 weeks, 14 weeks) and approximately 80% of participants reported a previous episode of low back pain. The median baseline Roland score was 8 (Q1, Q3: 4, 12). Approximately 40% of participants had lower limb pain, but abnormal lower limb signs were uncommon.

Pain diary over the 2-week period following randomisation

The information recorded in the pain diary over the 2-week period following randomisation is summarised in *Table 4*. Overall, 90% (189/210) of study participants in the intervention group completed the 2-week pain diary compared with 85% (179/211) in the control group. Comparisons between the treatment groups indicate that the intervention group had a greater number of days with pain ($p = 0.005$), a higher total VAS pain score ($p = 0.003$) and a greater number of days with a VAS pain score

TABLE 2 *Sociodemographic characteristics of the treatment groups at baseline*

Characteristic		Intervention group (*n* = 210)	Control group (*n* = 211)
Sex:	male	90 (42.9%)	84 (39.8%)
	female	120 (57.1%)	127 (60.2%)
Age (median (Q1, Q3))		39 (31, 45)	39 (31, 46)
Ethnic group:	white	206 (98%)	209 (99%)
	non-white	4 (2%)	2 (1%)
Marital status:	married	138 (65.7%)	136 (64.4%)
	single, no partner	27 (12.9%)	24 (11.4%)
	single, partner	25 (11.9%)	26 (12.3%)
	divorced	15 (7.1%)	18 (8.5%)
	separated	4 (1.9%)	5 (2.4%)
	widowed	1 (0.5%)	2 (1.0%)
Resides with dependants:*	yes	121 (57.6%)	122 (57.8%)
	no	89 (42.4%)	89 (42.2%)
Qualifications:	degree or above	25 (11.9%)	19 (9.0%)
	A level	13 (6.2%)	17 (8.1%)
	HND/HNC	8 (3.8%)	6 (2.8%)
	O level/GSCE/CSE	59 (28.1%)	58 (27.5%)
	none of the above	105 (50.0%)	111 (52.6%)
Employment status:	full-time	114 (54.3%)	126 (59.7%)
	part time	49 (23.3%)	43 (20.4%)
	voluntary work	3 (1.4%)	1 (0.5%)
	not employed	44 (21.0%)	41 (19.4%)
In receipt of means-tested benefits:	yes	47 (22.4%)	43 (20.4%)
	no	163 (77.6%)	168 (79.6%)

* *Defined as children or parents*

rated as 'quite bad' or 'worse' (pain score ≥ 3) ($p = 0.024$).

Clinical outcomes at 3 and 9 months after randomisation

Three-month follow-up

The clinical characteristics at 3 months after randomisation are shown in *Table 5*. Telephone interviews were conducted with two intervention group participants and seven control group participants at 3 months; the remainder of participants underwent face-to-face interviews. At the 3-month follow-up, 84% ($n = 168$) and 7% ($n = 15$) of participants in the intervention and control groups, respectively, had had an X-ray. Although the clinical characteristics had improved from those at baseline, more participants in the intervention group were still experiencing back pain (74.4% versus 65.0%, $p = 0.04$) and those in the intervention group perceived their overall health status to be worse (75 versus 80, $p = 0.02$). Participants in the intervention group had a higher Roland score than those in the control group (4 (Q1, Q3: 1, 8) versus 3 (Q1, Q3: 1, 7); $p = 0.05$) and the pain scale score was also higher in the intervention group (1 (Q1, Q3: 1, 2) versus 1 (Q1, Q3: 0, 2); $p = 0.06$). Neither of these differences reached statistical significance. Adjusting the Roland score at 3 months for the baseline Roland score did not alter these results (mean Roland score at 3 months: intervention group 5.11 (SD = 4.58) versus control group 4.37 (SD = 4.48); $p = 0.09$).

The additional analysis based on the 'actual treatment received' showed a significant difference for the Roland score (Mann–Whitney test, $Z = 2.96$; $p = 0.003$). The median Roland score was 4 ($n = 183$; Q1, Q3: 1, 8) and 3 ($n = 219$; Q1, Q3: 1, 7) in the X-ray group and non-X-ray

TABLE 3 *Clinical characteristics of the treatment groups at baseline*[*]

Characteristic	Intervention group (*n* = 210)	Control group (*n* = 211)
Health and functional status		
Roland Disability Questionnaire (median (Q1, Q3))	7 (4, 11.25)	8 (4, 12)
Pain scale (median (Q1, Q3))	2 (1, 2)	2 (1, 2)
EQ-5D score (median (Q1, Q3))	0.69 (0.62, 0.76) [6]	0.69 (0.62, 0.76) [14]
Health status scale (median (Q1, Q3))	70 (50, 80)	70 (50, 80)
Low back pain history		
Length of episode (median (Q1, Q3))	10 (7, 15)	10 (7, 14)
Weeks of low back pain in last 6 months (median (IQR))	12 (9, 16)	12 (8, 15)
Days off work with this episode (median (Q1, Q3))	14 (5.5, 21) [7]	14 (6, 33.25) [7]
Days bed rest with current episode (median (Q1, Q3))	3 (2, 7)	4 (2, 14)
Previous episodes of low back pain	166 (79.0%)	169 (80.1%)
Associated lower limb symptoms		
Pain	95 (45.2%)	90 (42.7%)
Numbness or paraesthesia	35 (16.7%)	42 (19.9%)
Weakness	13 (6.2%)	27 (12.8%)
Associated lower limb signs		
< 90° SLR bilaterally	19 (9.0%)	27 (12.8%)
Absent ankle jerk(s)	12 (5.7%) [1]	10 (4.7%)
Absent knee jerk(s)	8 (3.8%) [1]	12 (5.7%) [1]
Absent light touch sensation	3 (1.4%) [3]	4 (1.9%) [3]
Absent pin prick sensation	3 (1.4%) [3]	4 (1.9%) [3]
Weakness of dorsiflexion of toe	11 (5.3%) [1]	2 (1.0%) [1]
Weakness of dorsiflexion of foot	6 (2.9%) [1]	4 (1.9%) [1]
Thigh wasting > 2 cm either leg	5 (2.4%) [2]	4 (1.9%) [1]
Calf wasting > 2 cm either leg	3 (1.4%) [2]	2 (1.0%) [1]

[*] *Numbers in square brackets are the number of missing values*

IQR, interquartile range; SLR, straight leg raising

TABLE 4 *Two-week pain diary: summary of treatment groups following randomisation*[*]

Characteristic	Intervention group (*n* = 189)	Control group (*n* = 179)	*Z* score from MWU (normal approximation) and significance
Pain and number of hours of pain			
Number of days with pain (median (Q1, Q3))	14 (10, 14) [3]	3 (9, 14) [4]	$Z = -2.28$, $p = 0.005$
Total number of hours with pain (median (Q1, Q3))	58 (31, 118) [4]	46 (25.8, 113) [6]	$Z = -1.55$, $p = 0.12$
Number of days with > 4 hours of pain (median (Q1, Q3))	8 (3, 13) [4]	5 (2, 12) [6]	$Z = -1.40$, $p = 0.16$
VAS pain score			
Total pain score (median (Q1, Q3))	27 (19, 34) [3]	23 (15, 31) [1]	$Z = -3.02$, $p = 0.003$
Number of days with pain of score ≥ 3 (median (Q1, Q3))	4 (1, 7) [3]	2.5 (1, 5) [1]	$Z = -2.26$, $p = 0.024$

[*] *Numbers in square brackets are the number of missing values*

MWU, Mann–Whitney U *test*

TABLE 5 *Clinical characteristics of the treatment groups at 3 months*[*]

Characteristic	Intervention group (*n* = 199)	Control group (*n* = 203)	OR (95% CI) or *Z* score from MWU (normal approximation) and significance
Health and functional status			
Roland Disability Questionnaire (median (Q1, Q3))	4 (1, 8)	3 (1, 7)	$Z = -1.93$, $p = 0.05$
Pain scale (median (Q1, Q3))	1 (1, 2)	1 (0, 2)	$Z = -1.90$, $p = 0.06$
EQ-5D score (median (Q1, Q3))	0.80 (0.69, 0.88) [10]	0.80 (0.69, 0.91) [13]	$Z = -0.92$, $p = 0.36$
Health status scale (median (Q1, Q3))	75 (60, 90) [2]	80 (70, 90) [1]	$Z = -2.32$, $p = 0.02$
Low back pain history over last 3 months			
Still has low back pain	148 (74.4%)	132 (65.0%)	1.56 (1.02 to 2.40), $p = 0.04$
Associated lower limb signs			
< 90° SLR bilaterally	19 (9.5%)	17 (8.4%)	0.87 (0.44 to 1.72), $p = 0.68$
Absent ankle jerk(s)	10 (5.1%) [2]	11 (5.6%) [7]	1.11 (0.46 to 2.68), $p = 0.81$
Absent knee jerk(s)	9 (4.6%) [5]	15 (7.7%) [7]	1.70 (0.73 to 3.99), $p = 0.22$
Absent light touch sensation	0 (0%) [2]	2 (1.0%) [8]	OR undefined, $p = 0.25$
Absent pin prick sensation	1 (0.5%) [2]	0 (0%) [8]	OR undefined, $p = 1.0$
Weakness of dorsiflexion of toe	10 (5.1%) [2]	1 (0.5%) [9]	0.10 (0.01 to 0.76), $p = 0.01$
Weakness of dorsiflexion of foot	8 (4.1%) [2]	0 (0%) [9]	OR undefined, $p = 0.007$
Thigh wasting > 2 cm either leg	2 (1.0%) [4]	2 (1.0%) [11]	0.98 (0.10 to 9.9), $p = 1.0$
Calf wasting > 2 cm either leg	3 (1.5%) [4]	2 (1.0%) [11]	1.48 (0.20 to 12.83), $p = 1.0$

[*] *Numbers in square brackets are the number of missing values*

SLR, striaght leg raising; MWU, Mann–Whitney U test

group, respectively. Despite reaching statistical significance this small difference in the Roland score is unlikely to be clinically important.

Nine-month follow-up

The clinical outcomes at 9 months after randomisation are given in *Table 6*. Telephone interviews were conducted with eight intervention group and 16 control group participants at 9 months; the remainder of the participants had face-to-face interviews. By the 9-month follow-up, 88% ($n = 171$) and 13% ($n = 26$) of participants in the intervention and control groups, respectively, had had an X-ray.

Thus, although more participants in the intervention group still had low back pain (64.6% versus 56.8%), this difference was no longer statistically significant. Participants randomised to the intervention group had a higher Roland score than those in the control group, but the difference did not reach statistical significance (3 (Q1, Q3: 0, 7) versus 2 (Q1, Q3: 0, 6); $p = 0.06$). Adjusting the results for the baseline Roland score gave similar results (mean Roland score at 9 months: intervention group 4.44 (SD = 4.83) versus 3.63 (SD = 4.48) control group; $p = 0.09$).

The additional analysis based on the actual treatment received showed a significant difference for the Roland score ($Z = 3.47$; $p < 0.001$) at the 9-month follow-up. The median Roland score was 3 ($n = 197$, Q1, Q3: 1, 7) and 2 ($n = 197$, Q1, Q3: 0, 5) in the X-ray group and non-X-ray group, respectively. Again this small difference in the Roland score is unlikely to be clinically important.

Table 7 shows the findings on radiography for both treatment groups. No serious spinal pathology was found in either group. Discovertebral degeneration and normal findings were the most commonly reported findings.

Pain diary over the 2-week periods following the 3- and 9-month follow-up visits

The information recorded in the pain diary over the 2-week period following the 3-month follow-up is summarised, by treatment group, in *Table 8*.

TABLE 6 *Clinical characteristics of the treatment groups at 9 months*[*]

Characteristic	Intervention group (*n* = 195)	Control group (*n* = 199)	OR (95% CI) or *Z* score from MWU (normal approximation) and significance
Health and functional status			
Roland Disability Questionnaire (median (Q1, Q3))	3 (0, 7)	2 (0, 6)	$Z = -1.90$, $p = 0.06$
Pain scale (median (Q1, Q3))	1 (0, 2)	1 (0, 2)	$Z = -1.38$, $p = 0.17$
EQ-5D score (median (Q1, Q3))	0.80 (0.69, 1.00) [15]	0.80 (0.73, 1.00) [10]	$Z = -1.07$, $p = 0.28$
Health status scale (median (Q1, Q3))	80 (60, 90) [6]	80 (70, 90) [1]	$Z = -1.04$, $p = 0.30$
Low back pain history over last 6 months			
Still has low back pain	126 (64.6%)	113 (56.8%)	1.39 (0.93 to 2.09), $p = 0.11$
Associated lower limb signs			
< 90° SLR bilaterally	16 (8.2%)	29 (14.6%)	1.91 (1.00 to 3.63), $p = 0.05$
Absent ankle jerk(s)	7 (3.6%) [11]	7 (4.0%) [23]	1.91 (0.36 to 3.05), $p = 0.93$
Absent knee jerk(s)	7 (3.9%) [15]	5 (2.8%) [22]	0.72 (0.22 to 2.31), $p = 0.58$
Absent light touch sensation	0 (0%) [11]	0 (0%) [20]	–
Absent pin prick sensation	0 (0%) [11]	0 (0%) [20]	–
Weakness of dorsiflexion of toe	2 (1.1%) [12]	4 (2.2%) [20]	2.07 (0.37 to 11.44), $p = 0.44$
Weakness of dorsiflexion of foot	4 (2.2%) [12]	2 (1.1%) [20]	0.51 (0.09 to 2.80), $p = 0.68$
Thigh wasting > 2 cm either leg	6 (3.3%) [11]	2 (1.1%) [20]	0.34 (0.07 to 1.68), $p = 0.28$
Calf wasting > 2 cm either leg	5 (2.7%) [11]	1 (0.6%) [20]	0.20 (0.02 to 1.74), $p = 0.22$

[*] *Numbers in square brackets are the number of missing values*

SLR, striaght leg raising; MWU, Mann–Whitney U test

TABLE 7 *Findings on radiography*[*]

Finding	Intervention group (*n* = 170)	Control group (*n* = 22)
Normal X-ray	52 (30.6%)	7 (31.8%)
Abnormal X-ray	118 (69.4%)	15 (68.2%)
Radiography results of abnormal X-rays		
Discovertebral degeneration	116 (68.2%)	12 (54.5%)
Deformity	39 (22.9%)	5 (20.0%)
Minor congenital abnormalities	17 (10.0%)	2 (8.0%)
Facet joint degeneration	8 (4.7%)	3 (12.0%)
Posterior arch defects	6 (3.5%)	1 (4.0%)
Other discovertebral disease	4 (2.4%)	0 (0%)
Alignment abnormalities	3 (1.8%)	0 (0%)
Bone formation	2 (1.2)	0 (0%)
Sacroiliac joint disease	2 (1.2%)	0 (0%)
Alteration of bone density	2 (1.2)	0 (0%)
Total findings reported	251	30

[*] *Reports were unavailable for one intervention and three control subjects; 64 radiography reports had more than one finding recorded*

TABLE 8 *Two-week pain diary: summary of treatment groups at 3 months after randomisation*[*]

Characteristic	Intervention group (*n* = 170)	Control group (*n* = 165)	*Z* score from MWU (normal approximation) and significance
Pain and number of hours of pain			
Number of days with pain (median (Q1, Q3))	12 (5, 14)	10 (5, 14)	$Z = -0.82$, $p = 0.41$
Total number of hours with pain (median (Q1, Q3))	27 (12, 76.5) [4]	29 (8, 60) [2]	$Z = -0.64$, $p = 0.52$
Number of days with > 4 hours of pain (median (Q1, Q3))	2 (0, 10) [4]	2 (0, 8) [2]	$Z = -0.33$, $p = 0.74$
VAS pain score			
Total pain score (median (Q1, Q3))	20 (10, 30)	17 (7, 31)	$Z = -0.93$, $p = 0.35$
Number of days with pain score ≥ 3 (median (Q1, Q3))	2 (0, 5)	1 (0, 5)	$Z = -0.68$, $p = 0.50$

[*] *Numbers in square brackets are the number of missing values*

MWU, Mann–Whitney U test

Compared with the baseline there was an improvement in self-reported pain. There was no significant difference between the intervention and control groups in terms of the number of days reporting pain, the number of hours reporting pain and pain assessed using the VAS at the 3-month follow-up visit.

The 2-week pain diaries for the 2 weeks following the 9-month follow-up visit are summarised in *Table 9*. Compared with the diaries at baseline and the 3-month follow-up visit, participants reported less pain at 9 months. However, at the 9-month follow-up, over the 2 weeks in which the pain diaries were completed, participants in the intervention group reported a greater number of days of pain (median 10 days versus 6 days; $p = 0.004$), a greater total number of hours of pain (median of 28 hours versus 15 hours; $p = 0.006$) and a higher VAS pain score (median 15.5 versus 12.0; $p = 0.014$). However, there was no significant difference between the intervention and control groups for any of these outcomes when the change from baseline was considered (data not reported).

Sickness absence

At baseline

Of those participants in the intervention and control groups, 78% (163/210) and 80% (169/211), respectively, were in paid employment at the time when the baseline questionnaire was administered.

TABLE 9 *Two-week pain diary: summary of treatment groups at 9 months*[*]

Characteristic	Intervention group (*n* = 156)	Control group (*n* = 156)	*Z* score from MWU (normal approximation) and significance
Pain and number of hours of pain			
Number of days with pain (median (Q1, Q3))	10 (4, 14) [2]	6 (0, 14) [1]	$Z = 2.89$, $p = 0.0038$
Total number of hours with pain (median (Q1, Q3))	28 (9, 70) [3]	15 (0, 58) [1]	$Z = 2.77$, $p = 0.0055$
Number of days with > 4 hours of pain (median (Q1, Q3))	2 (0, 9) [3]	0 (0, 7) [1]	$Z = 1.86$, $p = 0.063$
VAS score			
Total pain score (median (Q1, Q3))	15.5 (6, 67) [2]	12.0 (0, 27) [3]	$Z = 2.45$, $p = 0.0143$
Number of days with pain score ≥ 3 (median (Q1, Q3))	0 (0, 4) [2]	0 (0, 4) [3]	$Z = -0.83$, $p = 0.41$

[*] *Numbers in square brackets are the number of missing values*

MWU, Mann–Whitney U test

Table 10 summarises sickness absence for the episode of low back pain current at baseline. At baseline 46.6% of participants in the intervention group had taken time off work compared with 53.8% of participants in the control group. The median length of time taken off work was 2 weeks. Slightly more participants in the control group (25.4%) than the intervention group (18.4%) had certificated sick leave for the current episode of low back pain.

At 3 and 9 months after randomisation

Ninety-six per cent (157/163) of participants in the intervention group and 97% (164/169) of participants in the control group who were in paid employment at baseline completed the 3-month follow-up questionnaire. Ninety-six per cent of participants in the intervention group (156/163) and 96% of participants in the control group (163/169) who were in paid employment at baseline completed the 9-month follow-up questionnaire.

There was no statistical difference between the intervention and control groups in the percentage of participants taking time off work or in the percentage of participants having certificated sickness absence at the 3- and 9-month follow-ups. Furthermore, the number of days off work and number of certificated days of sickness absence were similar in the two groups (*Table 11*).

Use of services

Primary care and hospital services for low back pain

Table 12 shows the number of visits to the GP and outpatient clinic, and day-case and inpatient episodes by treatment group at baseline, up to 3 months after randomisation and between 3 and 9 months after randomisation. At 3 months after randomisation intervention group participants were almost three times more likely to have returned to the GP than were control group participants (OR = 2.72; 95% CI, 1.80 to 4.10;

TABLE 10 *Sickness absence by treatment group at baseline*[*]

	Intervention group (*n* = 163)	**Control group (*n* = 169)**
Sickness absence from work	76 (46.6%)	91 (53.8%)
Number of days off work (median (Q1, Q3))	14 (6,21) [7]	14 (6, 33.25) [7]
Certificated sick leave	30 (18.4%)	43 (25.4%)
Number of days with certificated leave (median (Q1, Q3))	15 (14, 28) [3]	28 (14, 49) [12]

[*] *Numbers in square brackets are the number of missing values*

TABLE 11 *Sickness absence by treatment group at 3 and 9 months after randomisation*[*]

	Intervention group	**Control group**	**OR (95% CI) or *Z* score from MWU (normal approximation) and significance**
3 months	***(n = 157)***	***(n = 164)***	
Sickness absence from work	23 (14.6%)	33 (20.1%)	0.71 (0.38 to 1.32), $p = 0.25$
Number days off work (median (Q1, Q3))	14 (2, 35)	14 (4, 56)	$Z = -0.54$, $p = 0.59$
Certificated sick leave	13 (8.3%)	23 (14.0%)	0.55 (0.25 to 1.20), $p = 0.10$
Number of days with certificated leave (median (Q1, Q3))	28 (14, 84) [2]	45.5 (7, 70) [5]	$Z = -0.14$, $p = 0.89$
9 months	***(n = 156)***	***(n = 163)***	
Sickness absence from work	26 (16.7%)	25 (15.3%)	1.10 (0.61 to 2.01), $p = 0.75$
Number days off work (median (Q1, Q3))	11.5 (4, 56) [2]	8.5 (2, 47.25) [1]	$Z = -0.20$, $p = 0.84$
Certificated sick leave	13 (8.3%)	11 (6.8%)	1.26 (0.55 to 2.90), $p = 0.59$
Number of days with certificated leave (median (Q1,Q3))	35 (14, 70)	42 (14, 56)	$Z = -0.15$, $p = 0.88$

[*] *Numbers in square brackets are the number of missing values*

MWU, Mann–Whitney U test

$p < 0.01$). Some of these attendances will have been to receive the results of the X-ray. However, some practices routinely gave the results of X-rays over the phone, and so the increased consultation rates may not be accounted for entirely by consultations for the results of the X-ray. There was no difference between the groups in outpatient department attendance (OR = 0.87; 95% CI, 0.29 to 2.64; $p = 1.0$). There were no day-case or inpatient episodes in either group. Between 3 and 9 months after randomisation there were no differences in GP attendances (OR = 0.89; 95% CI, 0.55 to 1.42; $p = 0.24$), outpatient attendances (OR = 1.59; 95% CI, 0.74 to 3.39; $p = 0.23$), or day-case (Fisher's exact test, $p = 0.50$) or inpatient episodes (Fisher's exact test, $p = 0.24$) by treatment group.

TABLE 12 *Use of primary care and hospital services for low back pain, by treatment group*

Baseline		
Service used	**Intervention group (*n* = 210)**	**Control group (*n* = 211)**
One GP visit	104 (49.5%)	95 (45.0%)
Two GP visits	62 (29.5%)	62 (29.4%)
Three GP visits	27 (12.9%)	31 (14.7%)
Four GP visits	17 (8.1%)	23 (10.9%)
Outpatient attendance	2 (1.0%)	0 (0%)
Day-case treatment	0 (0%)	0 (0%)
Hospital admission	0 (0%)	0 (0%)
Between baseline and 3 months after randomisation		
Service used	**Intervention group (*n* = 199)**	**Control group (*n* = 203)**
One GP visit	83 (41.7%)	42 (20.7%)
Two GP visits	17 (8.5%)	7 (3.4%)
Three or more GP visits	6 (3.0%)	11 (5.4%)
Outpatient attendance	6 (3.0%)	7 (3.4%)
Day-case treatment	0 (0%)	0 (0%)
Hospital admission	0 (0%)	0 (0%)
Between 3 and 9 months after randomisation		
Service used	**Intervention group (*n* = 195%)**	**Control group (*n* = 199%)**
One GP visit	21 (10.8%)	32 (16.1%)
Two GP visits	12 (6.2%)	6 (3.0%)
Three or more GP visits	9 (4.6%)	9 (4.5%)
Outpatient attendance	18 (9.2%)	12 (6.0%)
Day-case treatment	1 (0.5%)	0 (0%)
Hospital admission	2 (1.0%)	0 (0%)

Use of other services for low back pain

Table 13 shows the use of other services, by treatment group, at baseline, up to 3 months after randomisation and between 3 and 9 months after

TABLE 13 *Use of other services for low back pain, by treatment group*[*]

Baseline		
Service used	**Intervention group (*n* = 210)**	**Control group (*n* = 211)**
Acupuncture	5 (2.5%) [9]	7 (3.4%) [6]
Aromatherapy	6 (3.0%) [9]	2 (1.0%) [6]
Chiropractic	6 (3.0%) [9]	6 (2.9%) [6]
Counselling	4 (2.0%) [9]	1 (0.5%) [6]
District or practice nursing	2 (1.0%) [9]	3 (1.5%) [6]
Health visiting	2 (1.0%) [9]	3 (1.5%) [6]
Osteopathy	22 (10.5%) [9]	14 (6.8%) [6]
Physiotherapy	54 (26.9%) [9]	64 (31.2%) [6]
Other[†]	9 (4.3%)	9 (4.3%)
Between baseline and 3 months after randomisation		
Service used	**Intervention group (*n* = 199)**	**Control group (*n* = 203)**
Acupuncture	3 (1.5%)	7 (3.4%)
Aromatherapy	4 (2.0%)	3 (1.5%)
Chiropractic	4 (2.0%)	6 (3.0%)
Osteopathy	7 (3.5%)	9 (4.4%)
Physiotherapy	67 (33.7%)	59 (29.1%)
Other[†]	7 (3.5%)	6 (3.0%)
Between 3 and 9 months after randomisation		
Service used	**Intervention group (*n* = 195)**	**Control group (*n* = 199)**
Acupuncture	1 (0.5%)	2 (1.0%)
Aromatherapy	5 (2.6%)	1 (0.5%)
Chiropractic	6 (3.1%)	5 (2.5%)
Osteopathy	6 (3.1%)	7 (3.5%)
Physiotherapy	31 (15.9%)	27 (13.6%)
Social services	3 (1.5%)	0 (0%)

[*] *Numbers in square brackets are the number of missing values*
[†] *Includes social services, reflexology and massage*

randomisation. Physiotherapy was the service most commonly used by both treatment groups at all time points. Osteopathy was the second most commonly used service, but this was used by < 10% of the trial participants at baseline and by < 5% thereafter. All the other services were used by < 5% of participants at all time points. There were no differences between treatment groups in terms of the receipt of physiotherapy up to 3 months after randomisation (OR = 1.24; 95% CI, 0.81 to 1.89; $p = 0.32$) or between 3 and 9 months after randomisation (OR = 1.20; 95% CI, 0.69 to 2.12; $p = 0.51$).

Use of special equipment for low back pain

The use of special equipment for low back pain at baseline, up to 3 months after randomisation and between 3 and 9 months after randomisation is shown by treatment group in *Table 14*. Fewer than one in five participants used any special equipment for their low back pain at any of the time points. Back supports and heat lamps or heat packs were the most commonly used equipment at all time points. There was no difference in the proportion using special equipment up to 3 months after randomisation (OR = 0.93; 95% CI, 0.50 to 1.76; $\chi^2 = 0.05$, 1 degree of freedom (df); $p = 0.82$) or between 3 and 9 months after randomisation (OR = 0.82; 95% CI, 0.44 to 1.53; $\chi^2 = 0.43$, 1 df; $p = 0.51$).

Medication use

Prescribed medication

In the intervention group, 135 (64.3%) participants had been prescribed some medication by the time of the baseline interview, as had 146 (69.2%) of the control group participants. Forty-six (21.9%) of the intervention group had had two drugs prescribed, 12 (5.7%) had had three drugs and two (1%) had had four drugs prescribed. In the control group 54 (25.6%) had had two drugs prescribed and ten (4.7%) had had three drugs prescribed. The classes of drugs prescribed for the intervention and control groups at baseline are shown in *Table 15*, and a comparison of the most commonly prescribed drugs, by class, is given in *Table 16*. NSAIDs were the most commonly prescribed medication in both groups, followed by compound analgesics. In both groups ibuprofen was the most commonly prescribed NSAID, having been prescribed for 23.3% and 27.0% of the intervention and control groups, respectively. Diclofenac was the second most commonly prescribed NSAID, being prescribed for 20.0% and 22.3% of the intervention and control groups, respectively. Co-proxamol was the most commonly prescribed compound

TABLE 14 *Use of special equipment for low back pain at baseline, by treatment group*

Baseline		
Equipment used	**Intervention group (*n* = 210)**	**Control group (*n* = 211)**
Used special equipment	38 (18.1%)	39 (18.5%)
Back support	14 (6.7%)	15 (7.1%)
Heat lamp or pack	9 (4.3%)	12 (5.7%)
TENS machine	3 (1.4%)	1 (0.5%)
Cushion or pillow	3 (1.4%)	3 (1.4%)
Massage equipment	3 (1.4%)	5 (2.4%)
Walking stick	2 (1.0%)	0 (0%)
Lumbar roll	5 (2.4%)	3 (1.4%)
Chair	3 (1.4%)	3 (1.4%)
Other*	6 (2.9%)	3 (1.4%)
Between baseline and 3 months after randomisation		
Equipment used	**Intervention group (*n* = 199)**	**Control group (*n* = 203)**
Used special equipment	24 (12.1%)	26 (12.8%)
Back support	4 (2.0%)	8 (3.9%)
Heat lamp or pack	5 (2.5%)	4 (1.8%)
Exercise equipment	3 (1.5%)	2 (1.0%)
Lumbar roll	2 (1.0%)	5 (2.5%)
Chair	3 (1.5%)	2 (1.0%)
Other*	9 (4.5%)	7 (3.4%)
Total items used	26	28
Between 3 and 9 months after randomisation		
Equipment used	**Intervention group (*n* = 195)**	**Control group (*n* = 199)**
Used special equipment	24 (12.3%)	29 (14.6%)
Back support	11 (5.6%)	12 (6.0%)
Heat lamp or pack	3 (1.5%)	2 (1.0%)
TENS machine	2 (1.0%)	3 (1.5%)
Lumbar roll	2 (1.0%)	4 (2.0%)
Chair	2 (1.0%)	8 (4.0%)
Other*	5 (2.6%)	5 (2.5%)
Total items used	25	34

TENS, transcutaneous electrical nerve stimulation

* *Includes car seat, trolley, mattress, cushion or pillow, massage oils and equipment, walking stick, heel raise, TENS machine and exercise equipment*

analgesic, having been prescribed for 10% and 12.3% of the intervention and control groups, respectively. Co-codamol was the second most commonly prescribed drug (11.4% and 7.1% of the intervention and control groups, respectively). Seven different oral NSAIDs were prescribed in the intervention group and eight in the control group.

Fewer participants received prescribed medication in the 3 months between baseline and the 3-month follow-up interview (63 (31.7%) and 59 (29.1%) in the intervention and control groups, respectively). Very few participants in either group received more than two prescribed medications during the 3-month period. The classes of drugs prescribed for the intervention and control groups between baseline and the 3-month follow-up interview are shown in *Table 17*. A comparison of the most commonly prescribed classes of drugs is given in *Table 18*. Again NSAIDs and compound analgesics were the most commonly prescribed drugs in each group, and no difference was found in the proportion of participants receiving prescriptions for NSAIDS or analgesics. The pattern of the most commonly prescribed drugs within each class was similar to that at baseline.

Between 3 and 9 months after randomisation the proportion of participants receiving prescribed drugs fell to 28.7% ($n = 56$) and 24.6% ($n = 49$) in the intervention and control groups, respectively. NSAIDs and compound analgesics were still the most commonly prescribed drugs (*Table 19*). Again there was no difference in the classes of drugs prescribed in the two treatment groups (*Table 20*). The pattern of drugs prescribed in the period 3–9 months after randomisation was again similar to that at baseline.

Over-the-counter medication

Over-the-counter medication had been purchased for low back pain by a similar proportion of participants in both groups as were receiving prescribed medication (135 (64.3%) intervention group, 154 (73.0%) control group). The most commonly purchased over-the-counter medications are shown in *Tables 21* and *22*. It can be seen that ibuprofen and paracetamol were the most commonly purchased medications in both groups.

Fewer participants purchased over the counter medications between baseline and 3 months after randomisation (68 (34.2%) intervention group, 67 (33.0%) control group). The types of medication purchased during this period are shown in *Tables 23* and *24* and are similar to those purchased at baseline. There was no difference

TABLE 15 *Medication prescribed at baseline*

Drug type	Intervention group (*n* = 210)	Control group (*n* = 211)
NSAID	101 (48.1%)	111 (52.6%)
Compound analgesic	49 (23.3%)	54 (25.6%)
Benzodiazepine	10 (4.8%)	8 (3.8%)
Opioid analgesic	8 (3.8%)	8 (3.8%)
Non-opioid analgesic	3 (1.4%)	3 (1.4%)
Muscle relaxant	1 (0.5%)	1 (0.5%)
Antidepressant	2 (1.0%)	1 (0.5%)
Counter-irritant	1 (0.5%)	1 (0.5%)

TABLE 16 *Most commonly prescribed medication at baseline*

Drug type	Intervention group (*n* = 210)	Control group (*n* = 211)
NSAID	81 (38.5%)	82 (38.9%)
Compound analgesic	29 (13.8%)	25 (11.8%)
Both	20 (9.5%)	29 (13.7%)
Neither	80 (38.1%)	75 (35.5%)

TABLE 17 *Medication prescribed between baseline and 3 months after randomisation*

Drug type	Intervention group (*n* = 199)	Control group (*n* = 203)
NSAID	42 (21.1%)	35 (17.2%)
Compound analgesic	21 (10.6%)	22 (10.8%)
Benzodiazepine	2 (1.0%)	1 (0.5%)
Opioid analgesic	4 (2.0%)	3 (1.5%)
Non-opioid analgesic	1 (0.5%)	1 (0.5%)
Compound analgesic with NSAID	0 (0%)	1 (0.5%)
Antidepressant	2 (1.0%)	3 (1.5%)
Counter-irritant	0 (0)	1 (0.5%)

TABLE 18 *Most commonly prescribed medication between baseline and 3 months after randomisation*

Drug type	Intervention group (*n* = 199)	Control group (*n* = 203)	Significance
NSAID	38 (19.1%)	30 (14.8%)	$\chi^2 = 1.43$, 3 df; $p = 0.70$
Compound analgesic	17 (8.5%)	17 (8.4%)	
Both	4 (2.0%)	5 (2.5%)	
Neither	140 (70.4%)	151 (74.4%)	

TABLE 19 *Medication prescribed between 3 and 9 months after randomisation*

Drug type	Intervention group (*n* = 195)	Control group (*n* = 199)
NSAID	38 (19.5%)	23 (11.6%)
Compound analgesic	20 (10.3%)	24 (12.1%)
Benzodiazepine	1 (0.5%)	0 (0)
Opioid analgesic	4 (2.1%)	3 (1.5%)
Non-opioid analgesic	0 (0)	1 (0.5%)
Muscle relaxant	0 (0)	2 (1.0%)
Antidepressant	2 (1.0%)	1 (0.5%)
Counter-irritant	0 (0)	1 (0.5%)

TABLE 20 *Most commonly prescribed medication between 3 and 9 months after randomisation*

Drug type	Intervention group (*n* = 195)	Control group (*n* = 199)	Significance
NSAID	31 (15.9%)	16 (8.0%)	χ^2 = 6.02, 3 df; p = 0.11
Compound analgesic	13 (6.7%)	17 (8.5%)	
Both	7 (3.8%)	7 (3.5%)	
Neither	144 (73.8%)	159 (79.9%)	

TABLE 21 *The most commonly purchased over-the-counter drugs at baseline*

Drug	Intervention group (*n* = 210)	Control group (*n* = 211)
Ibuprofen	70 (33.3%)	72 (34.1%)
Co-codamol	10 (4.8%)	13 (6.2%)
Paracetamol	52 (24.8%)	54 (25.6%)
Ibuprofen gel	9 (4.3%)	17 (8.1%)
Aspirin	10 (4.8%)	11 (5.2%)
Deep heat	25 (11.9%)	30 (14.2%)

TABLE 22 *The number of participants who purchased ibuprofen or paracetamol over the counter at baseline*

Drug	Intervention group (*n* = 210)	Control group (*n* = 211)
Ibuprofen	57 (27.1%)	57 (27.0%)
Paracetamol	39 (18.6%)	39 (18.5%)
Both	13 (6.2%)	15 (7.1%)
Neither	101 (48.1%)	100 (47.4%)

TABLE 23 *The most commonly purchased over-the-counter drugs between baseline and 3 months after randomisation*

Drug	Intervention group (*n* = 199)	Control group (*n* = 203)
Ibuprofen	24 (12.1%)	32 (15.8%)
Co-codamol	6 (3.0%)	2 (1.0%)
Paracetamol	24 (12.1%)	24 (11.8%)
Ibuprofen gel	2 (1.0%)	4 (2.0%)
Aspirin	8 (4.0%)	4 (2.0%)
Deep heat	7 (3.5%)	4 (2.0%)

TABLE 24 *The number of participants who purchased ibuprofen or paracetamol over the counter between baseline and 3 months after randomisation*

Drug	Intervention group (*n* = 199)	Control group (*n* = 203)	Significance
Ibuprofen	22 (11.1%)	17 (8.4%)	χ^2 = 1.98, 3 df; p = 0.58
Paracetamol	22 (11.1%)	19 (9.4%)	
Both	2 (1.0%)	5 (2.5%)	
Neither	153 (76.9%)	152 (74.9%)	

between the two groups in the proportion of participants purchasing ibuprofen or paracetamol.

Between 3 and 9 months after randomisation over-the-counter medications had been purchased for low back pain by 69 (35.3%) of the intervention group and 57 (28.6%) of the control group. Ibuprofen and paracetamol were still the two most commonly purchased medications in both groups, as shown in *Tables 25* and *26*. There was no difference between the groups in the proportion of participants purchasing these two medications.

Expectations of care and satisfaction with consultations for low back pain

At baseline

Participants' expectations of their consultation about low back pain are shown in *Table 27*, along with their perceptions of the care they actually received. It indicates that participants' expectations regarding information and advice about various aspects of low back pain were high, and in most cases they did not perceive that these information needs were met.

Table 28 indicates that half the participants believed more tests should have been done, slightly less than one-third believed that all patients with low

TABLE 25 *The most commonly purchased over-the-counter drugs between 3 and 9 months after randomisation*

Drug	Intervention group (*n* = 195)	Control group (*n* = 199)
Ibuprofen	30 (15.4%)	22 (11.1%)
Co-codamol	5 (2.6%)	3 (1.5%)
Paracetamol	22 (11.3%)	25 (12.6%)
Ibuprofen gel	3 (1.5%)	1 (0.5%)
Aspirin	6 (3.1%)	5 (2.5%)
Deep heat	5 (2.6%)	5 (2.5%)

TABLE 26 *The number of participants who purchased ibuprofen or paracetamol over the counter between 3 and 9 months after randomisation*

Drug	Intervention group (*n* = 195)	Control group (*n* = 199)	Significance
Ibuprofen	29 (14.9%)	19 (9.5%)	$\chi^2 = 3.47$, 3 df; $p = 0.32$
Paracetamol	21 (10.8%)	22 (11.1%)	
Both	1 (0.5%)	3 (1.5%)	
Neither	144 (73.8%)	155 (77.9%)	

TABLE 27 *Number of participants agreeing with statements on expectations about care and perceptions of the care and information given at the baseline GP visit*[*]

Statement	Expected		Question	Received	
	Intervention group (*n* = 210)	Control group (*n* = 211)		Intervention group (*n* = 210)	Control group (*n* = 211)
I expected to receive information on learning to avoid straining my back	143 (69.1%) [3]	135 (64.9%) [3]	Did you receive information on learning to avoid straining your back?	63 (30.3%) [2]	67 (31.9%) [1]
I expected to learn about posture	109 (56.7%) [3]	112 (53.8%) [3]	Did you learn about posture?	45 (21.7%) [3]	39 (18.7%) [2]
I expected to discuss problems with my usual daily activities	134 (65.4%) [5]	148 (71.8%) [5]	Did you discuss whether you were having any problems with daily activities?	105 (50.7%) [3]	110 (52.4%) [1]
I expected to be recommended to rest	95 (46.3%) [5]	96 (46.8%) [6]	Were you recommended to rest?	72 (34.8%) [3]	80 (38.1%) [1]
I expected to receive information on medicine for low back pain	120 (58.0%) [3]	130 (62.2%) [2]	Did you receive information on medicine for low back pain?	76 (36.4%) [1]	86 (41.1%) [2]
I expected to receive information on other types of treatment for low back pain	110 (52.9%) [2]	120 (57.4%) [2]	Did you receive information on other types of treatment for low back pain?	40 (21.5%) [24]	34 (18.0%) [22]

[*] *Numbers in square brackets are the number of missing values*

TABLE 28 *Number of participants agreeing with statements on beliefs and concerns about low back pain at baseline*[*]

Statement	Intervention group (*n* = 210)	Control group (*n* = 211)
I think more tests should have been done	107 (51.2%) [1]	100 (49.8%) [1]
I am worried about serious disease due to my back pain	69 (33.5%) [4]	83 (39.7%) [2]
I believe that everyone with low back pain needs an X-ray	60 (28.6%)	65 (30.8%)
I believe that everyone with low back pain needs a blood test	34 (16.6%) [5]	38 (18.4%) [4]
I feel reassured that I do not have any serious conditions causing my back pain	91 (43.8%) [2]	98 (46.4%)

[*] *Numbers in square brackets are the number of missing values*

back pain needed an X-ray and one-sixth that they needed a blood test. One-third of participants were worried that their back pain was due to serious disease and less than half were reassured that they did not have a serious condition causing their low back pain.

Table 29 gives details of participants' satisfaction with their most recent visit to their GP for low back pain. It illustrates that levels of satisfaction with the consultation were relatively low. Not feeling the GP was concerned about them, not feeling the GP understood what was bothering them, not understanding what was wrong with their back and not having an adequate explanation of their problem were all sources of dissatisfaction.

There was no association between the Roland score (Spearman's correlation coefficient = –0.03; $p = 0.58$), EQ-5D (Spearman's correlation coefficient = 0.04; $p = 0.42$) or health status scale (Spearman's correlation coefficient = 0.07; $p = 0.20$) and satisfaction. Those experiencing greater pain had lower levels of satisfaction (Spearman's correlation coefficient = –0.13; $p = 0.05$).

Satisfaction with the GP consultation for low back pain was significantly associated with being given advice about avoiding straining the back, posture ($Z = –5.19$; $p < 0.001$), usual activities ($Z = –5.72$; $p < 0.001$), medication ($Z = –4.61$; $p < 0.001$) and other treatments ($Z = –2.05$; $p = 0.04$).

Those believing more tests should be done (Spearman's correlation coefficient = 0.35; $p = 0.01$), those worrying that their low back pain was due to serious disease (Spearman's correlation coefficient = 0.20; $p = 0.01$), and those believing everyone with low back pain needs an X-ray (Spearman's correlation coefficient = 0.18; $p = 0.01$) or blood test (Spearman's correlation coefficient = 0.14; $p = 0.01$) were significantly less satisfied. Those feeling reassured that they did not have serious disease were significantly more satisfied with the consultation (Spearman's correlation coefficient = –0.19; $p = 0.01$).

At the 3- and 9-month follow-ups

At the 3-month follow-up visit all participants who had had a consultation with the GP about low back pain since randomisation (106 intervention and 60 control group participants) completed the questionnaire about patient expectations about care and actual care and information given at the most recent GP visit (*Table 30*). There were few differences in expectations of care or perceptions of actual care at 3 months after randomisation. Control group participants were more likely to expect, and to perceive, they had been given advice about rest, and were more likely to perceive they had been given information about medication for low back pain.

At 3 months after randomisation intervention group participants were less likely to believe more tests should have been done (*Table 31*). They were not more reassured or less worried about their low back pain. A higher proportion of participants were worried that their back pain was due to serious disease and more than at

TABLE 29 *Number of participants agreeing with statements on satisfaction with their most recent GP consultation for low back pain at baseline*[*]

Statement	Intervention group (*n* = 210)	Control group (*n* = 211)
I was satisfied with my most recent contact with the GP	122 (58.4%) [1]	127 (60.2%)
I did not have an adequate explanation of my problem	64 (30.8%) [2]	45 (21.4%) [1]
I felt that my GP was concerned about me	122 (58.1%)	133 (63.3%) [1]
I felt that my GP understood what was bothering me	139 (66.2%)	146 (69.9%) [2]
I felt that I understood what was wrong with my back	60 (29.3%) [5]	86 (41.1%) [2]
My GP did not spend enough time with me	37 (17.8%) [2]	46 (22.4%) [6]
I would not like to see the same doctor the next time I visit my GP's surgery	59 (28.5%) [3]	50 (24.2%) [4]
I have sought help from another doctor, health professional, or hospital after my last visit to the GP's surgery	21 (10.1%) [2]	20 (9.9%) [8]
My medical care for this back problem is better than most of my visits to my GP	29 (14.1%) [4]	35 (17.0%) [5]
Overall satisfaction score (median (Q1, Q3))	19 (17, 22) [14]	20 (17.75, 22) [21]

[*] *Numbers in square brackets are the number of missing values*

TABLE 30 *Number of participants agreeing with statements on expectations about care and perceptions of care and information given at their most recent GP visit 3 months after randomisation*[*]

Statement	Expected			Question	Received		
	Intervention group (*n* = 106)	Control group (*n* = 60)	OR (95% CI); significance		Intervention group (*n* = 106)	Control group (*n* = 60)	OR (95% CI); significance
I expected to receive information on learning to avoid straining my back	70 (68.0%) [3]	33 (57.9%) [3]	1.54 (0.75 to 3.18); $p = 0.20$	Did you receive information on earning to avoid straining your back?	26 (25.0%) [2]	15 (25.8%) [2]	0.96 (0.43 to 2.13); $p = 0.90$
I expected to learn about posture	62 (60.2%) [3]	34 (59.6%) [3]	1.02 (0.50 to 2.08); $p = 0.95$	Did you learn about posture?	23 (22.1%) [2]	15 (25.9%) [2]	0.81 (0.36 to 1.84); $p = 0.59$
I expected to discuss problems with my usual daily activities	78 (75.7%) [3]	43 (75.4%) [3]	1.02 (0.45 to 2.29); $p = 0.97$	Did you discuss whether you were having any problems with daily activities?	46 (44.2%) [2]	27 (46.6%) [2]	0.91 (0.45 to 1.83); $p = 0.78$
I expected to be recommended to rest	22 (21.4%) [3]	21 (36.2%) [2]	0.48 (0.22 to 1.04); $p = 0.04$	Were you recommended to rest?	11 (10.6%) [2]	20 (34.5%) [2]	0.22 (0.10 to 0.55); $p < 0.001$
I expected to receive information on medicine for low back pain	58 (55.8%) [2]	36 (62.1%) [2]	0.77 (0.38 to 1.56); $p = 0.44$	Did you receive information on medicine for low back pain?	28 (26.9%) [2]	26 (44.8%) [2]	0.45 (0.22 to 0.94); $p = 0.02$
I expected to receive information on other types of treatment for low back pain	60 (58.3%) [3]	36 (62.1%) [2]	0.85 (0.42 to 1.74); $p = 0.64$	Did you receive information on other types of treatment for low back pain?	23 (23.0%) [6]	13 (23.6%) [5]	0.97 (0.42 to 2.26); $p = 0.93$

[*] *Numbers in square brackets are the number of missing values*

TABLE 31 *Number of participants agreeing with statements on beliefs and concerns about low back pain 3 months after randomisation*[*]

Statement	Intervention group (*n* = 106)	Control group (*n* = 60)	OR (95% CI); significance
I think more tests should have been done	33 (31.4%) [1]	28 (48.3%) [2]	0.49 (0.24 to 1.00); *p* = 0.03
I am worried about serious disease due to my back pain	39 (37.5%) [2]	26 (44.8%) [2]	0.74 (0.37 to 1.49); *p* = 0.36
I believe that everyone with low back pain needs an X-ray	46 (44.2%) [2]	19 (32.8%) [2]	1.63 (0.79 to 3.37); *p* = 0.15
I believe that everyone with low back pain needs a blood test	25 (24.8%) [5]	14 (24.1%) [2]	1.03 (0.46 to 2.35); *p* = 0.93
I feel reassured that I do not have any serious conditions causing my back pain	53 (52.0%) [4]	28 (48.3%) [2]	1.16 (0.58 to 2.32); *p* = 0.65

[*] *Numbers in square brackets are the number of missing values*

baseline believed that all patients with low back pain needed an X-ray and a blood test. It must be remembered that the figures for 3 months after randomisation relate only to participants who had consulted their GP with their low back pain since randomisation, and hence they relate to those whose low back pain was taking longer to resolve.

At 3 months after randomisation control group participants were more likely to be satisfied with their most recent GP consultation and were more likely to feel their GP was concerned about them (*Table 32*). The overall satisfaction score was higher in the control group, but this did not reach statistical significance.

At the 9-month follow-up visit all 42 participants from the intervention group and 47 participants from the control group who had consulted their GP about low back pain between the 3- and 9-month follow-up visits completed the questionnaire about patient expectations and the information given at their most recent GP visit. There were no differences between treatment groups. As at both baseline and 3 months after randomisation, substantially more participants expected information and advice than perceived they had been given it (*Table 33*).

At 9 months after randomisation, as at 3 months, fewer intervention group participants believed

TABLE 32 *Number of participants agreeing with statements on satisfaction with their most recent GP consultation for low back pain at 3 months after randomisation*[*]

Statement	Intervention group (*n* = 106)	Control group (*n* = 60)	OR (95% CI); significance
I was satisfied with my most recent contact with the GP	58 (55.8%) [2]	47 (81.0%) [2]	0.30 (0.13 to 0.67); *p* = 0.001
I did not have an adequate explanation of my problem	30 (38.8%) [2]	14 (25.0%) [4]	1.22 (0.55 to 2.72); *p* = 0.60
I felt that my GP was concerned about me	56 (53.8%) [2]	42 (72.4%) [2]	0.44 (0.21 to 0.94); *p* = 0.02
I felt that my GP understood what was bothering me	61 (58.7%) [2]	42 (72.4%) [2]	0.54 (0.25 to 1.14); *p* = 0.08
I felt that I understood what was wrong with my back	45 (43.7%) [3]	29 (50.9%) [3]	0.75 (0.37 to 1.51); *p* = 0.38
My GP did not spend enough time with me	16 (15.5%) [3]	14 (24.1%) [2]	0.58 (0.24 to 1.39); *p* = 0.18
I would not like to see the same doctor the next time I visit my GP's surgery	18 (17.6%) [4]	17 (30.4%) [4]	0.49 (0.21 to 1.13); *p* = 0.07
I have sought help from another doctor, health professional, or hospital after my last visit to the GP's surgery	10 (9.6%) [2]	7 (12.1%) [2]	0.78 (0.25 to 2.42); *p* = 0.82
My medical care for this back problem is better than most of my visits to my GP	6 (5.8%) [2]	3 (5.2%) [2]	1.12 (0.23 to 7.20); *p* = 1.00
Overall satisfaction score (median (Q1, Q3))	20 (17, 23) [6]	21 (19, 23) [5]	*Z* = –1.50; *p* = 0.13

[*] *Numbers in square brackets are the number of missing values*

TABLE 33 *Number of participants agreeing with statements on expectations about care and perceptions of the care and information given at their most recent GP visit 9 months after randomisation*[*]

Statement	Expected			Question	Received		
	Intervention group (*n* = 42)	Control group (*n* = 47)	OR (95% CI); significance		Intervention group (*n* = 42)	Control group (*n* = 47)	OR (95% CI); significance
I expected to receive information on learning to avoid straining my back	22 (66.7%) [9]	25 (55.6%) [3]	1.52 (0.54, 4.33); *p* = 0.38	Did you receive information on learning to avoid straining your back?	13 (33.3%) [3]	12 (26.1%) [1]	1.42 (0.50,4.01); *p* = 0.47
I expected to learn about posture	22 (55.0%) [2]	24 (53.3%) [2]	1.07 (0.42, 2.75); *p* = 0.88	Did you learn about posture?	12 (30.0%) [2]	10 (21.7%) [1]	1.54 (0.53, 4.56); *p* = 0.38
I expected to discuss problems with my usual daily activities	31 (77.5%) [2]	31 (67.4%) [1]	1.67 (0.58, 4.89); *p* = 0.42	Did you discuss whether you were having any problems with daily activities?	19 (47.5%) [2]	22 (48.9%) [2]	0.95 (0.37, 2.42); *p* = 0.90
I expected to be recommended to rest	18 (45.0%) [2]	14 (30.4%) [1]	1.87 (0.71, 4.99); *p* = 0.16	Were you recommended to rest?	15 (37.5%) [2]	14 (31.1%) [2]	1.33 (0.49, 3.60); *p* = 0.54
I expected to receive information on medicine for low back pain	25 (62.5%) [2]	23 (51.1%) [2]	1.59 (0.61, 4.17); *p* = 0.29	Did you receive information on medicine for low back pain?	17 (42.5%) [2]	12 (26.1%) [1]	2.09 (0.77, 5.76); *p* = 0.11
I expected to receive information on other types of treatment for low back pain	25 (62.5%) [2]	29 (63.0%) [1]	0.98 (0.37, 2.57); *p* = 0.96	Did you receive information on other types of treatment for low back pain?	5 (13.9%) [6]	14 (33.3%) [5]	0.32 (0.08, 1.12); *p* = 0.08

[*] *Numbers in square brackets are the number of missing values*

TABLE 34 *Number of participants agreeing with statements on beliefs and concerns about low back pain 9 months after randomisation*[*]

Statement	Intervention group (*n* = 42)	Control group (*n* = 47)	OR (95% CI); significance
I think more tests should have been done	15 (37.5%) [2]	25 (54.3%) [1]	0.50 (0.19 to 1.30); *p* = 0.12
I am worried about serious disease due to my back pain	17 (42.5%) [2]	17 (37.8%) [3]	1.17 (0.45 to 3.08); *p* = 0.72
I believe that everyone with low back pain needs an X-ray	19 (48.7%) [3]	22 (48.9%) [2]	0.99 (0.39 to 2.56); *p* = 0.99
I believe that everyone with low back pain needs a blood test	16 (40.0%) [2]	20 (44.4%) [2]	0.83 (0.32 to 2.16); *p* = 0.68
I feel reassured that I do not have any serious conditions causing my back pain	23 (57.5%) [2]	22 (47.8%) [1]	1.48 (0.58 to 3.79); *p* = 0.37

[*] *Numbers in square brackets are the number of missing values*

TABLE 35 *Number of participants agreeing with statements on satisfaction with the most recent GP consultation for low back pain 9 months after randomisation*[*]

Statement	Intervention group (*n* = 42)	Control group (*n* = 47)	OR (95% CI); significance
I was satisfied with my most recent contact with the GP	31 (77.5%) [2]	29 (63.0%) [1]	2.02 (0.71 to 5.86); *p* = 0.22
I did not have an adequate explanation of my problem	11 (28.1%) [3]	17 (40.0%) [3]	0.67 (0.24 to 1.85); *p* = 0.39
I felt that my GP was concerned about me	27 (67.5%) [2]	25 (54.3%) [1]	1.74 (0.66 to 4.63); *p* = 0.21
I felt that my GP understood what was bothering me	31 (77.5%) [2]	25 (55.6%) [2]	2.76 (0.97 to 7.95); *p* = 0.06
I felt that I understood what was wrong with my back	25 (62.5%) [2]	14 (31.1%) [2]	3.69 (1.37 to 10.08); *p* = 0.004
My GP did not spend enough time with me	5 (12.8%) [3]	15 (34.1%) [3]	0.28 (0.07 to 0.97); *p* = 0.02
I would not like to see the same doctor the next time I visit my GP's surgery	10 (26.3%) [4]	14 (31.1%) [2]	0.79 (0.27 to 2.28); *p* = 0.63
I have sought help from another doctor, health professional, or hospital after my last visit to the GP's surgery	7 (17.5%) [2]	7 (15.6%) [2]	1.15 (0.32 to 4.16); *p* = 0.96
My medical care for this back problem is better than most of my visits to my GP	9 (22.5%) [2]	11 (23.9%) [1]	0.92 (0.30 to 2.81); *p* = 0.92
Overall satisfaction score (median (Q1, Q3))	21 (19, 23) [4]	19 (16, 21) [6]	*Z* = –2.69; *p* < 0.01

[*] *Numbers in square brackets are the number of missing values*

that more tests should have been done, but this did not reach statistical significance. A higher proportion of participants than at baseline, in both groups, believed that all patients with low back pain needed an X-ray and a blood test. It must be remembered that the figures for 9 months after randomisation relate only to participants who had consulted their GP with low back pain since randomisation, and hence they relate to those whose low back pain was taking longer to resolve (*Table 34*).

Table 35 shows participants' satisfaction with their most recent GP consultation for low back pain 9 months after randomisation. Those in the intervention group were significantly more satisfied with their consultation than were those in the control group, as shown by the overall satisfaction score. They were more likely to feel their GP understood what was bothering them, that they understood what was wrong with their back, and that their GP had spent enough time with them.

Economic evaluation

Cost of illness

Tables 36 to *41* show all the cost data. At baseline the overall observed cost for the existing episode of low back pain (median duration 10 weeks) for all randomised patients (both groups) was

TABLE 36 *Comparison of direct costs at baseline*[*]

Resource variable	Intervention group (*n* = 210)	Control group (*n* = 211)
Inpatient visits		
Total	£0	£0
Mean, median (Q1, Q3)	–	–
Quantity	No admissions	No admissions
Outpatient visits		
Total	£100	£0
Mean, median (Q1, Q3)	< £1, £0 (£0, £0)	£0 (£0, £0)
Quantity	2 attendances	No attendances
GP visits		
Total	£6463	£6753
Mean, median (Q1, Q3)	£31, £30 (£17, £34) [1]	£32, £30 (£17, £45)
Quantity	210 people	211 people
Other services		
Total	£6987	£5985
Mean, median (Q1, Q3)	£35, £0 (£0, £43) [10]	£29, £0 (£0, £35) [7]
Quantity	76 people	83 people
Prescribed drugs		
Total	£860	£956
Mean, median (Q1, Q3)	£5, £2 (£0, £5) [21]	£5, £2 (£0, £6) [15]
Quantity	126 people	125 people
Over-the-counter drugs		
Total	£708	£1012
Mean, median (Q1, Q3)	£4, £2 (£0, £6) [22]	£5, £3 (£0, £7) [16]
Quantity	110 people	136 people
Equipment		
Total	£2,072	£713
Mean, median (Q1, Q3)	£10, £0 (£0, £0) [2]	£3, £0 (£0, £0)
Quantity	40 people	31 people
Total direct costs		
Total	£14,935	£14,354
Mean, median (Q1, Q3)	£92, £50 (£26, £102) [48]	£82, £52 (£31, £95) [36]

[*] *Numbers in square brackets are the number of missing values*

£141,957. The overall observed cost of low back pain at 3 months after randomisation was £98,642 and at 9 months after randomisation was £171,892.

Direct costs accounted for 20–25% of total resource use among the intervention group and 15–20% in the control group. At baseline the two groups were broadly similar with respect to all economic variables considered (see *Tables 36* and *37*).

TABLE 37 *Comparison of indirect costs at baseline*[*]

Resource variable	Intervention group (*n* = 210)	Control group (*n* = 211)
Carers		
Total	£328	£839
Mean, median (Q1, Q3)	£2, £0 (£0, £0) [1]	£4, £0 (£0, £0)
Quantity	4 people	5 people
Extra expenses		
Total	£1200	£887
Mean, median (Q1, Q3)	£6, £0 (£0, £0) [7]	£4, £0 (£0, £0) [8]
Quantity	14 people	10 people
Social Security payments (per week _10)		
Total	£31,211	£28,148
Mean, median (Q1, Q3)	£150, £0 (£0, £0) [2]	£137, £0 (£0, £0) [5]
Quantity	45 people	38 people
Loss of earnings (employee)		
Total	£4449	£15,521
Mean, median (Q1, Q3)	£22, £0 (£0, £0) [8]	£76, £0 (£0, £0) [6]
Quantity	21 people	29 people
Loss of productivity (employer)		
Total	£28,721	£48,039
Mean, median (Q1, Q3)	£139, £0 (£0, £39) [4]	£233, £0 (£0, £82) [5]
Quantity	54 people	65 people
Total indirect costs		
Total	£60,215	£80,802
Mean, median (Q1, Q3)	£315, £82 (£0, £530) [19]	£425, £77 (£0, £636) [21]
Quantity	107 people	110 people
All resource use (direct + indirect)		
Total	£61,542	£80,415
Mean, median (Q1, Q3)	£410, £182 (£43, £554) [60]	£509, £143 (£45, £673) [53]

[*] *Numbers in square brackets are the number of missing values*

At 3 months after randomisation the intervention group had higher direct costs ($p < 0.001$). The components of direct cost accounting for this difference were intervention costs ($p < 0.001$) and GP consultation costs ($p < 0.001$) (see *Table 38*).

At 9 months after randomisation the intervention group had higher direct costs than did the control group ($p < 0.001$), and this was still due to the intervention and GP costs. There were no differences in any other direct cost variables (see *Table 39*).

Indirect costs accounted for the majority of total resource use in both groups. No significant differences in any indirect cost variables were found at 3 and 9 months after randomisation. Overall resource use (direct plus indirect costs) was higher among intervention group patients ($p < 0.001$) at both time points (see *Tables 40* and *41*).

Most patients (80%) would choose to have an X-ray if the choice was available, and place a median monetary value of £30 (see *Table 44*) on the benefit in terms of reassurance derived from it. Patients would be willing to pay a median of around £40 to avoid the risk of radiation.

Cost–benefit analysis

Simple cost comparisons between the intervention and control groups considering the impact on direct and indirect costs indicates that lumbar spine radiography is associated with economic loss at both time points (*Table 42*). Cost–benefit analysis (*Table 43*) incorporating willingness-to-pay valuations for the reassurance gained from an X-ray and the perceived risk of radiation also indicates that lumbar spine radiography is associated with net economic loss at the 3- and 9-month follow-ups (*Tables 43* and *44*).

Cost-effectiveness analysis

It was intended that cost-effectiveness ratios in the form of cost per unit of change in the primary outcome measure (Roland score) be performed to compare the two groups at the different time points. However, at both time points the overall resource use was actually higher in the intervention group and no significant difference in health or functional outcomes was found. These results suggest that standard practice is a dominant strategy over lumbar spine radiography, and cost-effectiveness ratios are therefore redundant. Similarly, cost–utility analysis in the form of cost

TABLE 38 *Comparison of direct costs up to 3 months after randomisation*[*]

Resource variable	Intervention group (*n* = 199)	Control group (*n* = 203)
Intervention		
Total	£7328	£640
Mean, median (Q1, Q3)	£37, £42 (£40, £46)	£3, £0 (£0, £0) [1]
Quantity	168 X-rays	15 X-rays
Inpatient visits		
Total	£0	£0
Mean, median (Q1, Q3)	–	– [1]
Quantity	No admissions	No admissions
Outpatient visits		
Total	£496	£624
Mean, median (Q1, Q3)	£2, £0 (£0, £0)	£3, £0 (£0, £0) [1]
Quantity	6 attendances	7 attendances
GP visits		
Total	£2121	£1469
Mean, median (Q1, Q3)	£11, £15 (£0, £17)	£7, £0 (£0, £15) [1]
Quantity	104 people	59 people
Other services		
Total	£7750	£7627
Mean, median (Q1, Q3)	£40, £0 (£0, £61) [4]	£38, £0 (£0, £39) [4]
Quantity	74 people	73 people
Prescribed drugs		
Total	£689	£617
Mean, median (Q1, Q3)	£3, £0 (£0, £3)	£3, £0 (£0, £1) [2]
Quantity	63 people	58 people
Over-the-counter drugs		
Total	£370	£359
Mean, median (Q1, Q3)	£2, £0 (£0, £2)	£2, £0 (£0, £2) [1]
Quantity	68 people	67 people
Equipment		
Total	£979	£878
Mean, median (Q1, Q3)	£5, £0 (£0, £0)	£4, £0 (£0, £0) [1]
Quantity	24 people	26 people
Total direct costs[†]		
Total	£19,386	£12,111
Mean, median (Q1, Q3)	£97, £67 (£45, £136) [4]	£61, £20 (£0, £73) [6]

[*] *Numbers in square brackets are the number of missing values*
[†] *Z = –7262;* p < *0.001*

TABLE 39 *Comparison of direct costs up to 9 months after randomisation*[*]

Resource variable	Intervention group (*n* = 195)	Control group (*n* = 199)
Intervention		
Total	£8196	£1080
Mean, median (Q1, Q3)	£42, £42 (£40, £46)	£5, £0 (£0, £0)
Quantity	171 X-rays	26 X-rays
Inpatient visits		
Total	£550	£0
Mean, median (Q1, Q3)	£3, £0 (£0, £0)	–
Quantity	2 admissions	–
Outpatient visits		
Total	£1977	£1351
Mean, median (Q1, Q3)	£10, £0 (£0, £0)	£7, £0 (£0, £0) [1]
Quantity	22 attendances	19 attendances
GP visits		
Total	£3311	£2597
Mean, median (Q1, Q3)	£17, £15 (£0, £30)	£13, £0 (£0, £17) [1]
Quantity	120 people	79 people
Other services		
Total	£11,978	£11,603
Mean, median (Q1, Q3)	£63, £0 (£0, £98) [5]	£59, £0 (£0, £70) [1]
Quantity	93 people	95 people
Prescribed drugs		
Total	£1221	£1137
Mean, median (Q1, Q3)	£6, £0 (£0, £5) [5]	£6, £0 (£0, £5) [1]
Quantity	78 people	76 people
Over-the-counter drugs		
Total	£984	£718
Mean, median (Q1, Q3)	£5, £0 (£0, £6) [1]	£4, £0 (£0, £4)
Quantity	89 people	90 people
Equipment		
Total	£1440	£2931
Mean, median (Q1, Q3)	£7, £0 (£0, £0)	£15, £0 (£0, £0)
Quantity	35 people	44 people
Total direct costs[†]		
Total	£27,608	£20,602
Mean, median (Q1, Q3)	£150, £97 (£60, £202) [11]	£109, £44 (£5, £142) [10]

[*] *Numbers in square brackets are the number of missing values*
[†] *Z = –5.408;* p *< 0.001*

TABLE 40 *Comparison of indirect costs up to 3 months after randomisation*[*]

Resource variable	Intervention group (*n* = 199)	Control group (*n* = 203)
Carers		
Total	£11	£1046
Mean, median (Q1, Q3)	< £1, £0 (£0, £0) [11]	£5, £0 (£0, £0) [11]
Quantity	1 person	4 people
Extra expenses		
Total	£115	£1436
Mean, median (Q1, Q3)	< £1, £0 (£0, £0)	£7, £0 (£0, £0) [6]
Quantity	6 people	14 people
Social security payments (per week x 12)		
Total	£21,202	£18,685
Mean, median (Q1, Q3)	£112, £0 (£0, £0) [10]	£96, £0 (£0, £0) [8]
Quantity	25 people	20 people
Loss of earnings (employee)		
Total	£2717	£5634
Mean, median (Q1, Q3)	£14, £0 (£0, £0) [9]	£29, £0 (£0, £0) [8]
Quantity	8 people	9 people
Loss of productivity (employer)		
Total	£10,937	£22,448
Mean, median (Q1, Q3)	£58, £0 (£0, £0) [9]	£115, £0 (£0, £0) [8]
Quantity	16 people	23 people
Total indirect costs[†]		
Total	£30,161	£41,248
Mean, median (Q1, Q3)	£178, £0 (£0, £0) [30]	£236, £0 (£0, £0) [28]
Quantity	39 people	42 people
All resource use (direct + indirect)[‡]		
Total	£45,532	£49,110
Mean, median (Q1, Q3)	£269, £81 (£49, £248) [30]	£298, £28 (£2, £148) [38]

[*] *Numbers in square brackets are the number of missing values*
[†] *Z = –0.216;* p *= 0.829*
[‡] *Z = –5.071;* p *< 0.001*

TABLE 41 *Comparison of indirect costs up to 9 months after randomisation*[*]

Resource variable	Intervention group (*n* = 195)	Control group (*n* = 199)
Carers		
Total	£56	£1262
Mean, median (Q1, Q3)	< £1, £0 (£0, £0) [11]	£7, £0 (£0, £0) [9]
Quantity	2 people	5 people
Extra expenses		
Total	£1795	£2085
Mean, median (Q1, Q3)	£9, £0 (£0, £0) [1]	£11, £0 (£0, £0) [1]
Quantity	12 people	24 people
Social security payments		
Total	£53,413	£51,008
Mean, median (Q1, Q3)	£292, £0 (£0, £0) [12]	£260, £0 (£0, £0) [3]
Quantity	42 people	19 people
Loss of earnings (employee)		
Total	£6928	£14,505
Mean, median (Q1, Q3)	£38, £0 (£0, £0) [12]	£78, £0 (£0, £0) [13]
Quantity	14 people	12 people
Loss of productivity (employer)		
Total	£27,649	£33,803
Mean, median (Q1, Q3)	£151, £0 (£0, £0) [12]	£182, £0 (£0, £0) [13]
Quantity	27 people	32 people
Total indirect costs[†]		
Total	£71,819	£65,820
Mean, median (Q1, Q3)	£449, £0 (£0, £221) [35]	£392, £0 (£0, £95) [31]
All resource use[‡]		
Total	£90,319	£81,573
Mean, median (Q1, Q3)	£590, £160 (£65, £452) [42]	£507, £88 (£12, £272) [38]

[*] *Numbers in square brackets are the number of missing values*
[†] $Z = 0.891$; $p = 0.373$
[‡] $Z = -3.805$; $p < 0.001$

per quality-adjusted life-year (QALY) gained is redundant, and no significant difference between the EQ-5D scores for the groups was found. Additional QALYs cannot be gained at any cost using lumbar spine radiography.

Figure 2 shows the distribution of ICERs after bootstrapping the cost and Roland score pairs for the 3-month data. Nearly all the 2000 data points (94%) lay in the dominant quadrant (control superior to X-ray group). *Figure 3* shows the results of bootstrapping the cost and Roland score pairs for the 9-month data. These results are similar, with 89% of the data points lying in the dominant quadrant.

Satisfaction with care was observed to be greater in the group receiving radiography, and so cost-effectiveness analysis can be used to examine the change in cost and change in satisfaction associated with radiography. *Figure 4* shows the bootstrapped cost and satisfaction score pairs for the 3-month data; 89% of data points lay in the dominated quadrant.

Table 45 shows cost-effectiveness analysis using the satisfaction score as the primary outcome at 9 months. The X-ray intervention generates additional units of satisfaction at additional cost (£20). *Figure 5* shows the bootstrapped cost and satisfaction score data at 9 months. Some data points lay in the dominant quadrant (X-ray superior) and many lay in the north-east quadrant (greater satisfaction at greater cost), where decisions need to be made.

The cost-effectiveness acceptability curve for the 9-month cost and satisfaction data (*Figure 6*) shows that radiography is only likely to be defined as cost-effective where satisfaction is valued relatively highly. For example, there is around a 90% chance of radiography being cost-effective if a unit of satisfaction is valued at £30 (when an X-ray costs £40). *Figure 6* also illustrates the difference that changing the cost of an X-ray between £20 and £80 makes to the results.

TABLE 42 *Cost comparisons: median values*

	3-month follow-up (intervention – control)	9-month follow-up (intervention – control)
Difference in direct costs	(£67 – £20) = £47 loss per patient	(£97 – £44) = £53 loss per patient
Difference in indirect costs	£0 (no significant difference)	£0 (no significant difference)
Difference in all resource use (direct + indirect)	(£81 – £28) = £53 loss per patient	(£160 – £88) = £72 loss per patient

TABLE 43 *Simple cost–benefit analysis: median values*

	3-month follow-up	9-month follow-up
Cost 1: change in overall resource use due to X-ray	+ £53	+ £72
Cost 2: risks of radiation	£40	£43
Benefit 1: reassurance from radiography	£29	£30
Net economic impact	(–£53 + £40) – £29 = £42 loss	(–£72 + £43) – £30 = £59 loss

TABLE 44 *Willingness to pay*[*]

Variable	Baseline (*n* = 421)	3 months (*n* = 401)	9 months (*n* = 394)
Willingness to pay for reassurance from an X-ray (median (Q1, Q3))	£30 (£16, £50) [41]	£29 (£15, £50) [47]	£30 (£15, £50) [47]
Willingness to pay for no risk from radiation (median (Q1, Q3))	£40 (£20, £100) [45]	£40 (£20,£90) [50]	£43 (£20, £98) [54]

[*] *Numbers in square brackets are the number of missing values*

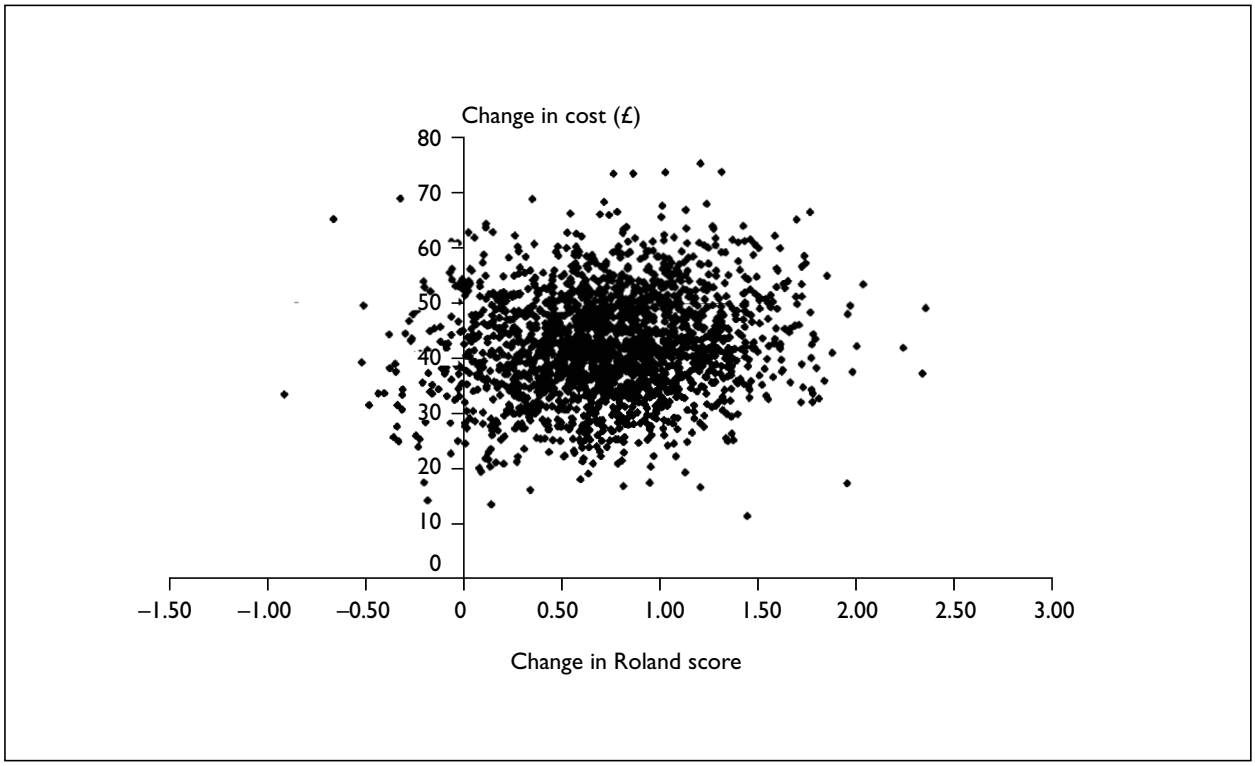

FIGURE 2 *Distribution of the ICERs after bootstrapping the cost and Roland score pairs for the 3-month data*

Patient preference study versus randomised study

At baseline

Fifty-five participants took part in the patient preference arm of the study. Thirty-two (58.1%) chose to have an X-ray and 23 (41.2%) chose not to have an X-ray. *Table 46* shows the baseline socio-demographic characteristics of both the patient preference groups compared with the randomised participants. The only difference between the groups was that a higher proportion of the patient preference X-ray group was male.

Table 47 shows the clinical characteristics of the patient preference study and randomised study participants at baseline. The only significant difference between the groups was that the

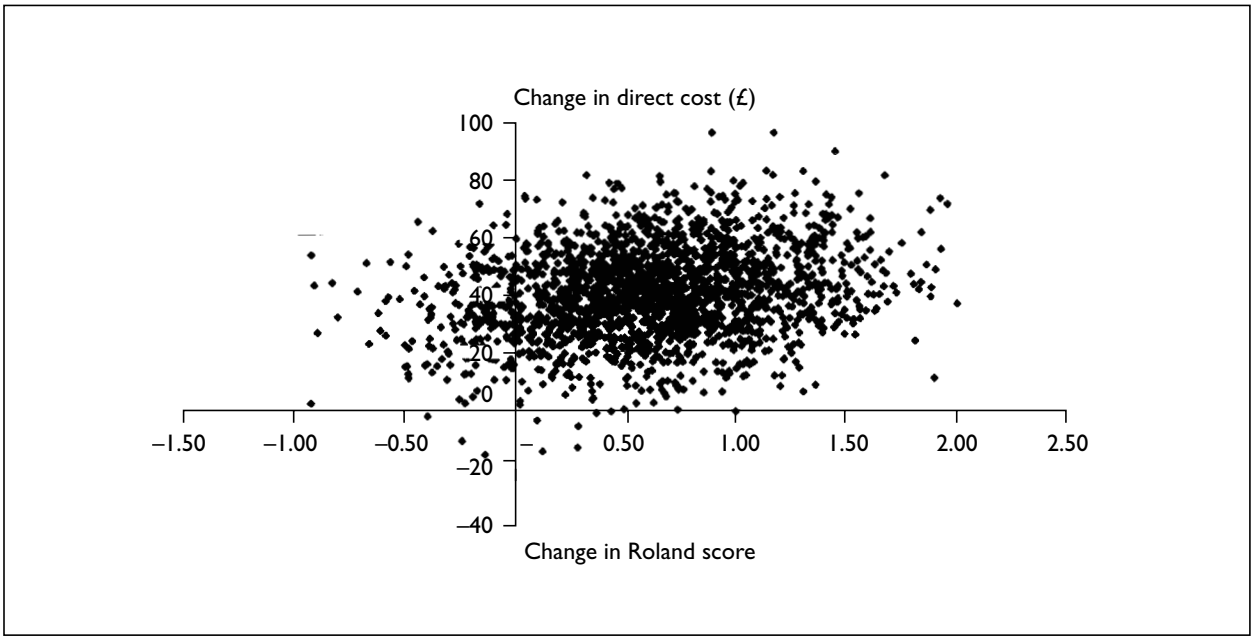

FIGURE 3 *Distribution of the ICERs after bootstrapping the cost and Roland score pairs for the 9-month data*

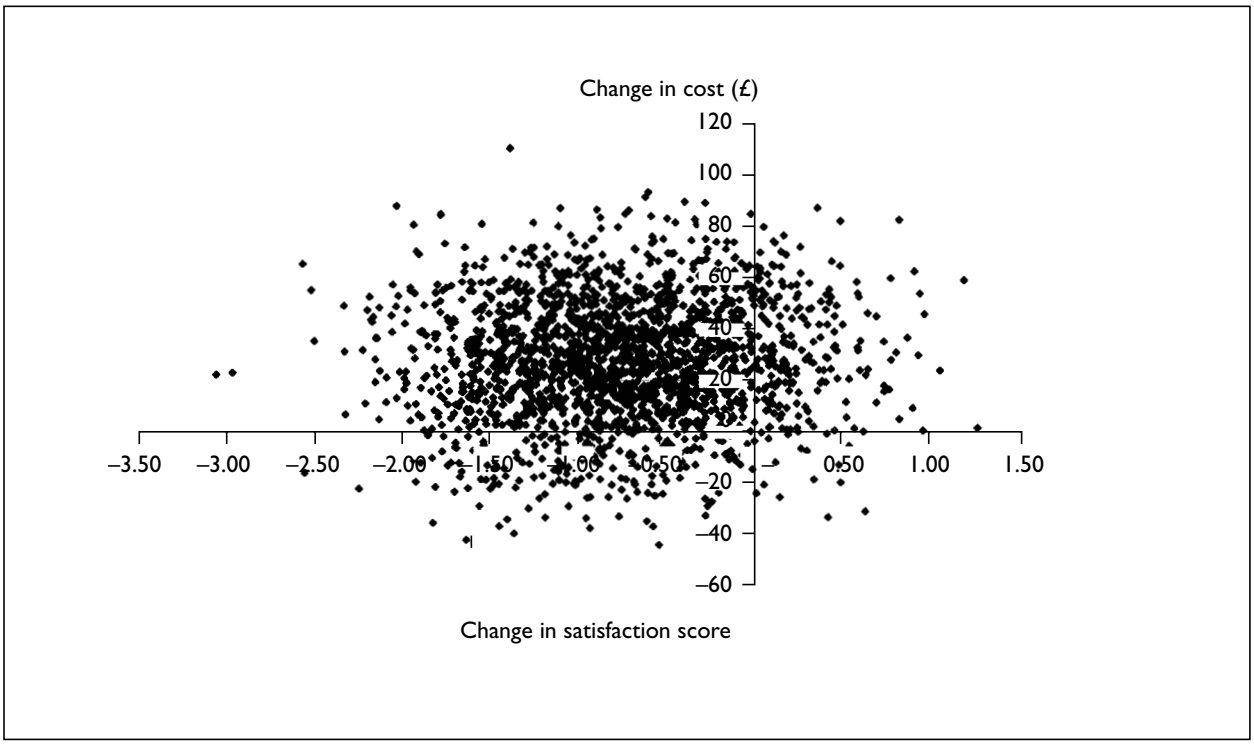

FIGURE 4 *Distribution of the ICERs after bootstrapping the cost and satisfaction score pairs for the 3-month data*

TABLE 45 *Cost-effectiveness analysis: 9 months after randomisation*

Resource variable	Intervention group (*n* = 195)	Control group (*n* = 199)	Difference
Mean direct cost	£150.04 (*n* = 195)	£109.00 (*n* = 199)	£41.04
Mean effect (satisfaction score)	20.71 (*n* = 42)	18.61 (*n* = 47)	2.1
Additional cost for additional unit of satisfaction	–	–	£19.54

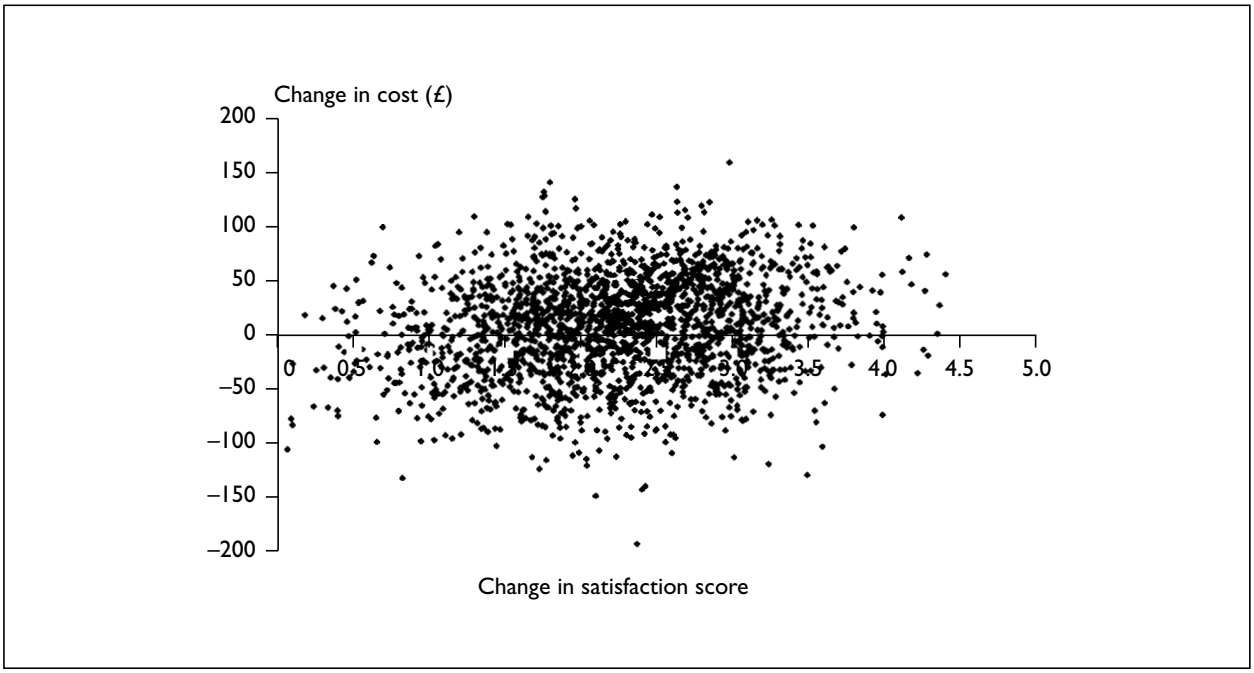

FIGURE 5 *Distribution of the ICERs after bootstrapping the cost and satisfaction score pairs for the 9-month data*

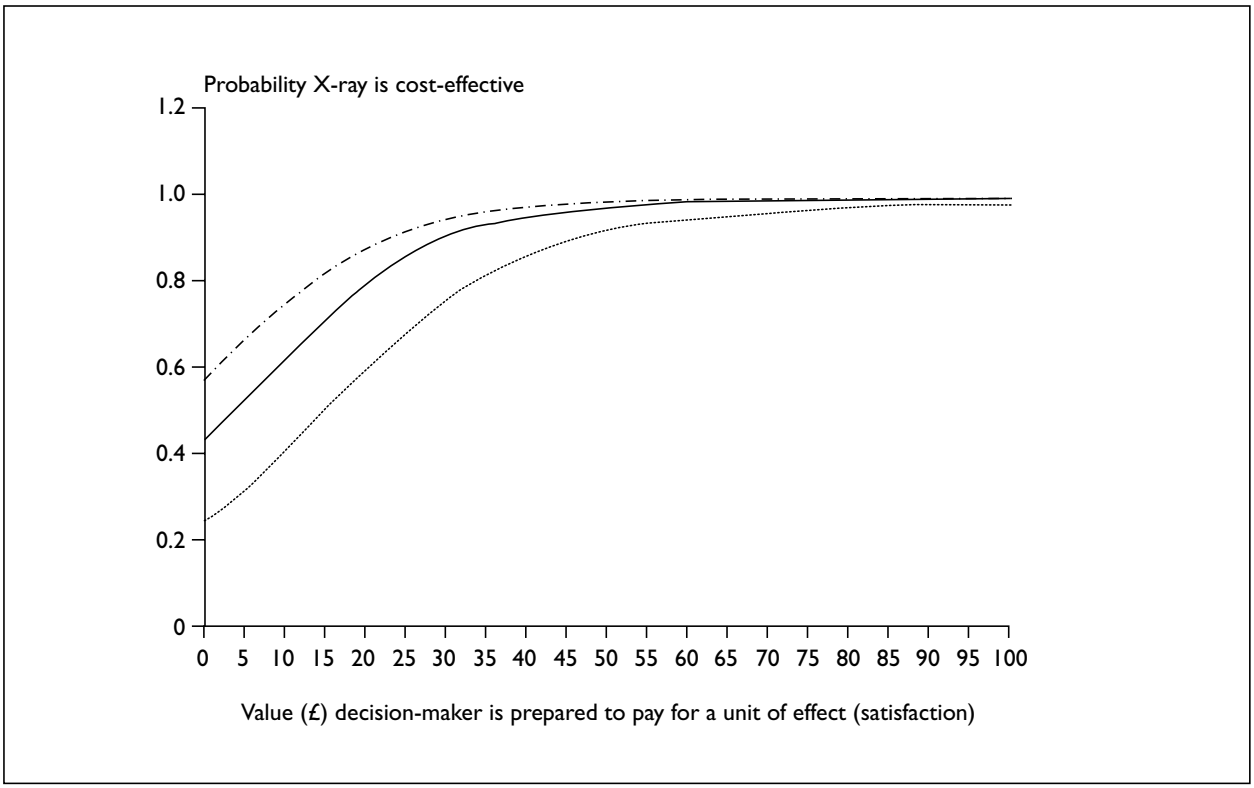

FIGURE 6 *The cost-effectiveness acceptability curves*

patient preference X-ray group reported a higher Roland score than did the other two groups.

Three months after randomisation

At both 3 and 9 months after randomisation, comparisons were made between the groups receiving an X-ray and the groups not receiving an X-ray. At 3 months, participants choosing an X-ray were more likely to have taken time off work and to report a higher Roland score. There were no significant differences between those choosing not to have an X-ray or who were randomised to the control group (*Tables 48* and *49*).

TABLE 46 *Socio-demographic characteristics of the patient preference and randomised participant groups at baseline*

Characteristic	Patient preference study		Randomised study (*n* = 421)	Significance (χ^2 test, df = 2)
	X-ray group (*n* = 32)	Non-X-ray group (*n* = 23)		
Male	22 (68.8%)	12 (52.2%)	174 (41.3%)	9.79; *p* = 0.007
Age (median (Q1, Q3))	38 (33.25, 47)	39 (31, 46)	39 (31, 45)	0.214; *p* = 0.898
Ethnic group white	30 (93.8%)	22 (95.7%)	415 (98.6%)	4.52; *p* = 0.104
Married/living with partner	24 (75.0%)	18 (78.3%)	325 (77.2%)	0.10; *p* = 0.95
Resides with dependants	12 (37.5%)	12 (52.2%)	243 (57.7%)	5.09; *p* = 0.079
Educational level above O level	22 (68.8%)	13 (78.3%)	304 (72.2%)	0.611; *p* = 0.737
Employment status:				
full-time employment	21 (65.6%)	14 (60.9%)	240 (57.0%)	1.00; *p* = 0.606
in receipt of means-tested benefits	5 (15.6%)	5 (21.7%)	90 (21.4%)	0.601; *p* = 0.741

TABLE 47 *Clinical characteristics of the patient preference and randomised participant groups at baseline*[*]

Characteristic	Patient preference study		Randomised study (*n* = 421)	Significance (χ^2 test, df = 2)
	X-ray group (*n* = 32)	Non-X-ray group (*n* = 23)		
Low back pain history				
Length of episode (median (Q1, Q3))	10.5 (7.25, 14)	12 (8, 14)	10 (7, 14)	0.141; *p* = 0.932
Weeks of low back pain in last 6 months (median (Q1, Q3))	12 (9.25, 14.75)	10 (8, 12)	12 (9, 16)	1.403; *p* = 0.496
Days off work with this episode (median (Q1, Q3))[†]	14 (5.75, 22.75) [4]	10.5 (4, 28) [3]	14 (6, 28)	0.452; *p* = 0.798
Days rested in bed with this episode (median (Q1, Q3))[‡]	6 (3.5, 12.25) [7]	7 (1.5, 59.5) [5]	4 (2, 7)	1.039; *p* = 0.595
Previous episodes of low back pain	25 (78.1%)	19 (82.6%)	335 (79.6%)	0.171; *p* = 0.918
Health and functional status				
Roland Disability Questionnaire (median (Q1, Q3))	12.5 (7.25, 16.0)	7 (4, 11)	8 (4, 12)	13.9; *p* = 0.001
Pain scale (median (Q1, Q3))	2 (1, 3)	2 (2, 2)	2 (1, 2)	1.586; *p* = 0.452
EQ-5D score (median (Q1, Q3))	0.69 (0.52, 0.73)	0.69 (0.62, 0.76)	0.69 (0.62, 0.76)	2.947; *p* = 0.229
Health status scale (median (Q1, Q3))	70 (50, 78.75)	80 (60, 85)	70 (50, 80)	5.532; *p* = 0.063
Satisfaction (median (Q1, Q3))	19 (17.75, 21)	20 (19, 23.5)	20 (17, 22)	3.375; *p* = 0.185

[*] *Numbers in square brackets are the number of missing values*
[†] *Number of participants taking time off work: patient preference X-ray group* n = *14, patient preference non-X-ray group* n = *10, randomised* n = *167*
[‡] *Number of participants told to rest in bed: patient preference X-ray group* n = *13, patient preference non-X-ray group* n = *10, randomised* n = *165*

TABLE 48 *Clinical characteristics of the X-ray groups 3 months after randomisation*[*]

Characteristic	Randomised X-ray group (*n* = 199)	Patient preference X-ray group (*n* = 30)	OR (95% CI) or *Z* score from MWU (normal approximation) and significance
Low back pain history over last 3 months			
Still has low back pain	148 (74.4%)	23 (76.7%)	1.13 (0.46 to 2.80); $p = 0.788$
Taken time off work	23 (12.0%) [7]	9 (30.0%)	3.15 (1.29 to 7.70); $p = 0.009$
Days off work (median (Q1, Q3))[†]	14 (2, 35)	21 (2, 84)	$Z = -0.494$; $p = 0.621$
Health and functional status			
Roland Disability Questionnaire (median (Q1, Q3))	4 (1, 8)	6.5 (3, 14.75)	$Z = -2.38$; $p = 0.018$
Pain scale (median (Q1, Q3))	1 (1, 2)	1 (0, 2)	$Z = -0.352$; $p = 0.725$
EQ-5D score (median (Q1, Q3))	0.80 (0.69, 0.88) [10]	0.80 (0.64, 0.84) [2]	$Z = 0.428$; $p = 0.669$
Health status scale (median (Q1, Q3))	75 (60, 90) [2]	77.5 (48.8, 90)	$Z = 0.222$; $p = 0.824$
Satisfaction with consultation[‡] (median (Q1, Q3))	20 (17, 23) [63]	18 (16.5, 21) [10]	$Z = -0.718$; $p = 0.473$

[*] *Numbers in square brackets are the number of missing values*
[†] *Participants having days off work: randomised X-ray group* n = *23, patient preference X-ray group* n = *9*
[‡] *Participants who had a GP consultation: randomised X-ray group* n = *106, patient preference X-ray group* n = *19*
MWU, Mann–Whitney U *test*

TABLE 49 *Clinical characteristics of the non-X-ray groups 3 months after randomisation*[*]

Characteristic	Randomised non-X-ray group (*n* = 203)	Patient preference non-X-ray group (*n* = 22)	OR (95% CI) or *Z* score from MWU (normal approximation) and significance
Low back pain history over last 6 months			
Still has low back pain	132 (65.0%)	16 (72.7%)	1.43 (0.54 to 3.83); $p = 0.470$
Taken time off work	33 (16.4%) [2]	4 (18.2%) [1]	Fisher's; $p = 0.759$
Days off work (median (Q1, Q3))[†]	14 (3.5, 56)	10.25 (1.50, 25.4)	$Z = -0.982$; $p = 0.326$
Health and functional status			
Roland Disability Questionnaire (median (Q1, Q3))	3 (1, 7)	3 (2, 7.25)	$Z = -0.683$; $p = 0.495$
Pain scale (median (Q1, Q3))	1 (0, 2)	1 (1, 2)	$Z = -1.135$; $p = 0.256$
EQ-5D score (median (Q1, Q3))	0.80 (0.69, 0.91) [13]	0.76 (0.72, 0.91)	$Z = -0.624$; $p = 0.532$
Health status scale (median (Q1, Q3))	80 (70, 90) [1]	77.5 (57.5, 90)	$Z = -0.750$; $p = 0.453$
Satisfaction with consultation[‡] (median (Q1, Q3))	20 (18, 23) [13]	21 (21, 24) [2]	$Z = -1.070$; $p = 0.285$
Use of health and other services over last 6 months			
Had X-ray	15 (7.4%)	2 (9.1%)	Fisher's; $p = 0.675$

[*] *Numbers in square brackets are the number of missing values*
[†] *Participants having days off work: randomised non-X-ray group* n = *33, patient preference non-X-ray group* n = *4*
[‡] *Participants having a consultation with GP: randomised non-X-ray group* n = *60, patient preference non-X-ray group* n = *5*
MWU, Mann–Whitney U *test*

Nine months after randomisation

Nine months after randomisation participants who chose to have an X-ray were less likely to report that they still had back pain compared with those randomised to the X-ray group, but there were no other differences (*Table 50*).

Participants who chose not to have an X-ray reported a higher health status score than did those randomised to the non-X-ray group, otherwise there were no differences between the randomised and patient preference non-X-ray groups (*Table 51*).

Table 52 shows the findings on radiography for the randomised and patient preference X-ray groups. Discovertebral degeneration was the main finding in both groups. However, there was no significant difference between the two groups ($\chi^2 = 1.71$, df = 1; $p = 0.19$).

Table 53 shows the findings on radiography for the randomised and patient preference non-X-ray groups. No statistical tests were undertaken due to the extremely small numbers.

Expectations of care and satisfaction with consultations for low back pain

Table 54 shows participants' beliefs and concerns about low back pain, both for those randomised and those choosing whether or not to have an X-ray. It indicates that those choosing to have an X-ray were more likely to believe that more tests should have been done and that everyone with low back pain needs an X-ray and blood test, and that were more worried and less reassured about the cause of their low back pain.

There were no differences in the overall satisfaction score for the most recent GP consultation between the randomised and patient preference X-ray groups at baseline, at 3 months or at 9 months after randomisation (see Tables *47, 48* and *50*). There was no difference in overall satisfaction with the consultation between the randomised and patient preference non-X-ray groups at baseline or at 3 months. Comparisons were not been made for these two groups at 9 months due to the small numbers (see *Tables 47, 49* and *51*).

Prospective study

The prospective study participants were recruited from 16 practices. Of those in the randomised study, 65% (273/421) of trial participants were recruited from these 16 practices.

Tables 55 to *57* compare the results for the prospective study participants with those for the randomised trial participants from the same

TABLE 50 *Clinical characteristics of the X-ray groups 9 months after randomisation*[*]

Characteristic	Randomised X-ray group (*n* = 195)	Patient preference X-ray group (*n* = 29)	OR (95% CI) or *Z* score from MWU (normal approximation) and significance
Low back pain history over last 6 months			
Still has low back pain	126 (64.6%)	13 (44.8%)	0.45 (0.20 to 0.98); $p = 0.040$
Taken time off work	26 (13.3%) [1]	2 (6.9%)	Fisher's; $p = 0.546$
Days off work (median (Q1, Q3))[†]	11.5 (4, 56) [2]	21 (7, 35)	$Z = -0.242$; $p = 0.809$
Health and functional status			
Roland Disability Questionnaire (median (Q1, Q3))	3 (0, 7)	3 (0.5, 6.5)	$Z = -0.299$; $p = 0.765$
Pain scale (median (Q1, Q3))	1 (0, 2)	1 (0, 2)	$Z = -1.092$; $p = 0.275$
EQ-5D score (median (Q1, Q3))	0.80 (0.69,1.00) [15]	0.80 (0.76, 1.00) [2]	$Z = -0.426$; $p = 0.670$
Health status scale (median (Q1, Q3))	80 (60, 90) [6]	80 (62.5, 93.75) [1]	$Z = -0.541$; $p = 0.588$
Satisfaction with consultation[‡] (median (Q1, Q3))	21 (19, 23) [4]	19 (17, 21) [1]	$Z = -1.526$; $p = 0.127$
Use of health and other services over last 6 months			
Had X-ray[§]	171 (87.7%)	27 (93.1%)	0.53 (0.12 to 2.36); $p = 0.396$

[*] *Numbers in square brackets are the number of missing values*
[†] *Participants having days off work: randomised X-ray group* n = *26, patient preference X-ray group* n = *2*
[‡] *Participants having a consultation with the GP: randomised X-ray group* n = *42, patient preference X-ray group* n = *6*
[§] *Participants not attending for X-ray: randomised X-ray group* n = *24, patient preference X-ray group* n = *2*
MWU, Mann–Whitney U *test*

TABLE 51 *Clinical characteristics of the non-X-ray groups at 9 months*[*]

Characteristic	Randomised non-X-ray group (*n* = 199)	Patient preference non-X-ray group (*n* = 21)	OR (95% CI) or *Z* score from MWU (normal approximation) and significance
Low back pain history over last 6 months			
Still has low back pain	113 (56.8%)	8 (38.1%)	0.47 (0.19 to 1.18); *p* = 0.102
Taken time off work[†]	25 (12.6%) [4]	0 (0%)	
Days off work (median (Q1, Q3))[†]	8.5 (2, 45.5) [1]	0 (0%)	
Health and functional status			
Roland Disability Questionnaire (median (Q1, Q3))	2 (0, 6)	1 (0, 4)	*Z* = –1.259; *p* = 0.208
Pain scale (median (Q1, Q3))	1 (0, 2)	0 (0, 1)	*Z* = –1.392; *p* = 0.164
EQ-5D score (median (Q1, Q3))	0.80 (0.73, 1.00) [10]	0.83 (0.76, 1.00) [1]	*Z* = –0.650; *p* = 0.516
Health status scale (median (Q1, Q3))	80 (70, 90) [1]	90 (75.5, 95)	*Z* = –2.019; *p* = 0.043
Use of health and other services over last 6 months			
Had X-ray	26 (13.1%)	3 (14.3%)	Fisher's; *p* = 0.745

[*] *Numbers in square brackets are the number of missing values. Satisfaction scores are not presented because only one patient preference non-X-ray group participant had consulted their GP, while 47 randomised non-X-ray group participants had consulted their GP*
[†] *Participants having days off work: randomised non-X-ray group n = 25, patient preference non-X-ray group* n = *0*
MWU, Mann–Whitney U *test*

TABLE 52 *Findings on radiography for the randomised X-ray and patient preference X-ray groups*

Radiography result	Randomised X-ray group (*n* = 170)[*]	Patient preference X-ray group (*n* = 27)[*]
Discovertebral degeneration	84 (49.4%)	17 (63.0%)
No abnormality detected	52 (30.6%)	6 (22.2%)
Deformity	39 (22.9%)	6 (22.2%)
Minor congenital abnormalities	17 (10.0%)	0 (0%)
Facet joint degeneration	8 (4.7%)	3 (11.1%)
Posterior arch defects	6 (3.5%)	1 (3.7%)
Other discovertebral disease	4 (2.4%)	1 (3.7%)
Alignment abnormalities	3 (1.8%)	1 (3.7%)
Bone formation	2 (1.2%)	1 (3.7%)
Sacroiliac joint disease	2 (1.2%)	0 (0%)
Alteration of bone density	2 (1.2%)	0 (0%)
Total findings reported	219	36

[*] *In the randomised group 49 reports had more than one finding; in the patient preference group nine reports had more than one finding*

TABLE 53 *Findings on radiography for the randomised and patient preference non-X-ray groups*

Radiography result	Randomised non-X-ray group[*] (*n* = 22)	Patient preference non-X-ray group (*n* = 3)
Discovertebral degeneration	9 (40.9%)	2 (66.7%)
No abnormality detected	7 (31.8%)	–
Deformity	5 (22.7%)	–
Minor congenital abnormalities	2 (9.1%)	1 (33.3%)
Facet joint degeneration	3 (13.6%)	–
Posterior arch defects	1 (4.5%)	–
Total findings reported	27	3

[*] *In the randomised group five reports had more than one finding. Three partcicipants in this group reported having an X-ray, but no X-ray reports were found in the GP records; nor was any record found of serious spinal pathology*

TABLE 54 *Number of participants agreeing with statements on beliefs and concerns about low back pain at baseline*[*]

Statement	Patient preference X-ray group (*n* = 32)	Patient preference non-X-ray group (*n* = 23)	Randomised group (*n* = 421)	Significance (χ^2 test, df = 2)
I think more tests should have been done	24 (75.0)	8 (34.8)	207 (49.4) [2]	$p = 0.006$
I am worried about serious disease due to my back pain	20 (64.5) [1]	5 (22.7) [1]	152 (36.6) [6]	$p = 0.003$
I believe that everyone with low back pain needs an X-ray	20 (62.5)	2 (8.7)	125 (29.7)	$p < 0.001$
I believe that everyone with low back pain needs a blood test	10 (32.3) [1]	1 (4.5) [1]	72 (17.5) [9]	$p = 0.03$
I feel reassured that I do not have any serious conditions causing my back pain	10 (31.3)	14 (63.6) [1]	189 (45.1) [2]	$p = 0.06$

[*] *Numbers in square brackets are the number of missing values*

TABLE 55 *Socio-demographic characteristics of trial and prospective study participants*

Characteristic	Trial participants (*n* = 273)	Prospective study participants (*n* = 75)	Significance
Male	117 (42.9%)	36 (48.0%)	$\chi^2 = 0.63$, df = 1; $p = 0.43$
Married	187 (68.5%)	53 (70.7%)	$\chi^2 = 0.13$, df = 1; $p = 0.72$
Ethnic group categorised as white	270 (99.3%)	75 (100%)	Fisher's exact test, two-tailed; $p = 1.00$
Employed	223 (81.7%)	60 (80.0%)	$\chi^2 = 0.11$, df = 1; $p = 0.74$
No formal qualifications	133 (48.7%)	28 (42.4%)	$\chi^2 = 0.84$, df = 1; $p = 0.36$
Age (mean ± SD)	38.8 ± 9.11	42.5 ± 9.99	$t = 3.00$, df = 345; $p = 0.003$

TABLE 56 *Characteristics of low back pain among the trial and prospective study participants*[*]

Characteristic	Trial participants (*n* = 273)	Prospective study participants (*n* = 75)	Significance
Had previous episode of low back pain	219 (80.2%)	16 (21.3%)	$\chi^2 = 93.0$, df = 1; $p < 0.001$
Length of this episode of low back pain (weeks)	10 [7, 14]	8 [5.5, 12] (*n* = 69)	MWU = –2.88; $p = 0.004$
Days rested in bed this episode	4 [2, 7] (*n* = 29)	3 [2,7.25] (*n* = 14)	MWU = –0.55; $p = 0.58$
Sickness absence from work (days)	14 [5, 21] (*n* = 105)	21 [7,35] (*n* = 39)	MWU = 1.56; $p = 0.12$
Roland score	7 [4, 11]	7 [3, 13]	MWU = –0.59; $p = 0.56$
VAS pain score	2 [1, 2]	2 [1, 3]	MWU = –0.18; $p = 0.86$
Satisfaction with last GP consultation for low back pain	19 [17, 22]	18 [17, 19] (*n* = 68)	MWU = –3.38; $p < 0.001$

MWU, Mann-Whitney U *test*

[*] *Numbers in square brackets are the interquartile range*

TABLE 57 *Use of services among the trial and prospective study participants*

Characteristic	Trial participants (*n* = 273)	Prospective study participants (*n* = 75)	Significance
Number of GP visits for current episode of low back pain:			χ^2 = 2.01, df = 2; *p* = 0.37
1	130 (47.6%)	23 (37.7%)	
2	85 (31.1%)	22 (36.1%)	
≥ 3	58 (21.2%)	16 (26.2%)	
Outpatient attendance for current episode of low back pain	1 (0.4%)	5 (6.7%)	Fisher's exact test, two-tailed; *p* = 0.002
Hospital admission for current episode of low back pain	0 (0%)	0 (0%)	–
Had prescribed drugs	175 (64.1%)	48 (64.0%)	χ^2 = 0.0, df = 1; *p* = 0.99
Had over-the-counter drugs	189 (69.2%)	46 (61.3%)	χ^2 = 1.67, df = 1; *p* = 0.20
Had acupuncture	10 (3.8%) (*n* = 263)	2 (2.9%) (*n* = 68)	Fisher's exact test, two-tailed; *p* = 1.00
Had physiotherapy	77 (29.3%) (*n* = 263)	30 (44.1%) (*n* = 68)	χ^2 = 5.44, df = 1; *p* = 0.002
Had osteopathy	26 (9.9%) (*n* = 263)	12 (17.6%) (*n* = 68)	χ^2 = 3.20, df = 1; *p* = 0.074
Had chiropractic	10 (3.8) (*n* = 263)	7 (10.3%) (*n* = 68)	Fisher's exact test, two-tailed; *p* = 0.06

practices. They indicate that the trial participants were slightly younger than were the prospective study participants, they had had back pain for longer and were more likely to have had a previous episode of low back pain. In addition, they were more satisfied with the care given by their GP for their most recent consultation for low back pain. They were also less likely to have made an outpatient department attendance for their low back pain or to have received physiotherapy than were prospective study participants.

Summary of results

At baseline

Treatment groups were similar at baseline in terms of socio-demographic and clinical characteristics. The median duration of low back pain was 10 weeks. Eighty per cent of participants had had previous episodes of low back pain.

Treatment groups were similar in terms of use of primary and secondary care, physical therapies and complementary therapies. The majority of care took place in primary care. The median number of GP visits prior to randomisation was two. Very few participants had used secondary care services. Physiotherapy was the most commonly used physical therapy, but this was used by less than one-third of participants.

Two-thirds of participants had been prescribed medication, most commonly NSAIDs and compound analgesics. A similar proportion had purchased over-the-counter medication, most commonly ibuprofen and paracetamol.

Participants had high expectations regarding information and advice about low back pain, but these information needs were frequently not met.

Half the participants believed that more tests should have been done, slightly less than one-third believed all patients with low back pain needed an X-ray, and one-sixth believed that they needed a blood test. One-third of participants were worried that their back pain was due to serious disease, and less than half were reassured that they did not have a serious condition causing their low back pain.

Levels of satisfaction with the consultation were relatively low. Not feeling the GP was concerned about them, not feeling the GP understood what was bothering them, not understanding what was wrong with their back and not having an adequate explanation of their problem were the most common sources of dissatisfaction.

There was no association between Roland score, EQ-5D or health status scale and satisfaction. Those experiencing greater pain had lower levels of satisfaction.

Satisfaction with the GP consultation for low back pain was significantly associated with meeting the information needs of participants. Those being given advice about avoiding straining the

back, posture, usual activities, medication and other treatments were significantly more satisfied with their GP consultation.

Satisfaction was significantly lower among those who believed that more tests should be done, those who were worried that their low back pain was due to serious disease, and those who believed that everyone with low back pain should have an X-ray or blood test. Those feeling reassured that they did not have serious disease were significantly more satisfied with their consultation.

Three months after randomisation

A greater proportion of intervention group participants still had low back pain at 3 months (74% versus 65%; OR 1.56; 95% CI, 1.02 to 2.40; $p = 0.04$). The intervention group had a significantly lower health status scale score.

There was no difference in the Roland score, the VAS for pain, satisfaction or EQ-5D scores between treatment groups.

There was no difference between the intervention and control groups in the proportion of participants who had taken time off work, or in the number of days of sickness absence.

Fifty-three per cent of the intervention group consulted their GP between randomisation and the 3-month follow-up interview about their low back pain, compared with 30% of the control group (OR = 2.72; 95% CI, 1.80 to 4.10; $p < 0.01$).

There was no difference in outpatient department attendances by treatment group; and there were no day-case or hospital admissions in either group.

Thirty per cent of participants had used physiotherapy between randomisation and the 3-month follow-up interview. Other physical therapies were used by less than 5% of participants in both groups. There was no difference between the groups in the proportion of participants using any of the physical or complementary therapies.

Twelve per cent of participants used special equipment for their back between randomisation and the 3-month follow-up interview, most commonly a back support. There was no difference between the groups in the proportion of participants using special equipment.

NSAIDs and compound analgesics were the most commonly prescribed drugs in both treatment groups. There was no significant difference between groups in the proportion of participants prescribed these drugs.

Ibuprofen and paracetamol were the most commonly purchased over-the-counter medications in both groups. There was no difference between groups in the proportion of participants purchasing these drugs.

Eighty-seven per cent of participants would have chosen to have an X-ray if they had been given a choice. There was no difference between groups in the proportion of participants expressing a preference to have an X-ray.

Nine months after randomisation

There was no difference between groups in the proportion of participants still experiencing low back pain at 9 months.

There was no difference in the Roland score, the VAS pain score, the health status score or the EQ-5D.

Intervention group participants were significantly more satisfied with the care they had received for their low back pain. They were more likely to believe that their GP understood what was bothering them, that the GP understood what was wrong with their back and that the GP spent enough time with them.

There was no difference between groups in the proportion of participants who had taken time off work, or in the number of days of sickness absence. Twenty-two per cent of participants in the intervention group and 24% of the control group had consulted their GP about their low back pain between the 3- and 9-month follow-up interviews. There was no difference between groups in GP or outpatient department attendances or in day-case or hospital admissions.

Fifteen per cent of participants had used physiotherapy between the 3- and 9-month follow-up interviews. There was no difference between groups in the proportion of participants using any of the physical or complementary therapies.

Thirteen per cent of participants used special equipment for their back between randomisation and the 3-month follow-up interview, most commonly a back support. There was no difference between groups in the proportion of participants using special equipment.

NSAIDs and compound analgesics were the most commonly prescribed drugs in both treatment

groups. There was no significant difference between groups in the proportion of participants prescribed these drugs.

Ibuprofen and paracetamol were the most commonly purchased over-the-counter medications in both groups. There was no difference between groups in the proportion of participants purchasing these drugs.

Eighty-three per cent of participants would have chosen to have an X-ray if they had been given a choice. The intervention group participants were less likely to choose an X-ray than were the control group participants. This difference was of borderline significance (OR = 0.60; 95% CI, 0.33 to 1.05; $p = 0.07$).

No serious spinal pathology was found in either group. Discovertebral degeneration was the most commonly reported X-ray finding, followed by no abnormalities detected.

Economic evaluation

The overall resource use (direct plus indirect costs) was higher among intervention group patients at 3 and 9 months after randomisation.

Cost–benefit analysis incorporating willingness-to-pay valuations for the reassurance gained from having an X-ray and the perceived risk of radiation also indicates that routine referral for lumbar spine radiology is associated with net economic loss at 3 and 9 months after randomisation.

The X-ray intervention generates additional units of satisfaction at additional cost (£20). Radiography is only likely to be defined as cost-effective where satisfaction is valued relatively highly.

These results suggest that the standard practice is a better strategy than is referral for lumbar spine radiography.

Patient preference study

Fifty-five participants chose to enter the patient preference arm of the study, and of these 58% chose to have an X-ray. The patient preference X-ray group differed from the randomised X-ray group in that participants were more likely to be male and had a higher Roland score.

Those choosing to have an X-ray were more likely to believe that more tests should be done and that all patients with low back pain needed an X-ray or blood test, and were more worried and less reassured about their low back pain than those randomised to X-ray.

There was no difference in satisfaction with the consultation between the randomised and patient preference groups, either at baseline or at the 3- and 9-month follow-ups.

At the 3-month follow-up the patient preference X-ray group had a higher Roland score and were more likely to have taken time off work. By the 9-month follow-up patients in the patient preference X-ray group were less likely to have low back pain, but did not differ in any other way from the participants randomised to have an X-ray. The patient preference non-X-ray group had a higher health status score than the randomised non-X-ray group, but no other differences were found.

Prospective study

Sixteen practices took part in the prospective study to compare the characteristics of trial participants with those of patients with low back pain consulting in primary care. Trial participants were slightly younger. As was expected due to the inclusion criteria, trial participants had had back pain for longer and were more likely to have had previous episodes of low back pain. They were also more satisfied with their most recent GP consultation for low back pain.

Chapter 4
Discussion

Limitations of the study

Lack of blinding of participants and outcome assessors to treatment group

Blinding of participants to treatment group in a study of lumbar spine radiography could only be achieved by the use of placebo X-rays. One such study has been funded by the HTA Programme, but it failed to recruit sufficient participants. It is possible that, while placebo X-rays may be acceptable to researchers, they may not be to patients or GPs.

Participants' knowledge of their group allocation may have impacted on their self-assessed outcome measures such as the Roland score, the VAS for pain, the health status scale and the EQ-5D. If participants believed that X-rays are beneficial in some way they may have been less likely to report pain and disability. If they believed X-rays to be harmful in some way they have been more likely to report symptoms. Interestingly, the VAS pain score completed at baseline prior to group allocation was very similar in the two groups. However, the pain diaries completed for the 2-week period subsequent to randomisation indicated that the X-ray group experienced more days of pain and more severe pain than did the control group. This suggests that participants who were referred for an X-ray reported more pain than those who were not referred. It is possible that referring for an X-ray is a way of acknowledging and legitimising a patient's symptoms, and this may heighten their perception of pain or their willingness to report it. Similarly, the slightly poorer outcomes at 3 and 9 months in terms of the Roland score, the VAS pain score and the health status score may reflect greater willingness to report symptoms or heightened perception of symptoms as a result of being referred for and having received the results of the X-ray. Had we been able to use placebo X-rays we would have been able to disentangle the effect of having a real X-ray (and a result) compared with a placebo X-ray, which would have provided information on the effect of having an X-ray. However, in usual practice, patients have X-rays and get their results, and so our intervention was as similar as possible to usual practice in primary care. Hence, if in this trial referring patients for X-rays led to heightened perceptions of symptoms or a heightened reporting of symptoms, this is also likely to happen when patients in primary care are referred for radiography.

Blinding the research nurses (who collected the outcome data) to treatment group was also not possible within this trial for several reasons. First, the research nurses randomised participants at the baseline interview, and in order to reduce interobserver variation we tried to use the same research nurse to follow up the participants they had recruited to the trial. Second, even if the nurses had been blinded to treatment group, we felt it was possible that participants would inform them of the group they were in at follow-up interviews. As the primary and most of the secondary outcome measures were assessed by self-completion questionnaires by the participants, the nurses' knowledge of the treatment group should have had little effect on the measurement of these outcomes.

How 'safe' is it not to X-ray patients with low back pain?

This study was not designed to answer the question of how safe it is not to X-ray patients with low back pain in primary care. Although we found no serious pathology in any of the trial participants we followed up for 9 months, the study was not adequately powered to detect a difference in the detection rate for serious pathology. Nachemson[20] has estimated that only 1 in 2500 lumbar spine X-rays in patients not clinically suspected of having serious pathology will find such disease. Given such a low incidence, a clinical trial is not the appropriate methodology for detecting the increased risk of missing serious disease by not undertaking an X-ray. This can only be achieved by the long-term surveillance of those with low back pain who do not receive an X-ray. The results of the present study cannot, therefore, be used to infer that it is 'safe' not to X-ray patients with low back pain in primary care, but only that the giving of X-rays was not associated with improved clinical outcomes, changes in patient management, reduction in sickness absence or greater patient reassurance. Practitioners must continue to use their clinical judgement based on diagnostic triage, as recommended in current guidelines on the management of low back pain, in order to decide which patients to refer for radiography.[33,35]

Generalisability

The results of this prospective study suggest that trial participants are similar to patients consulting with low back pain in primary care in terms of socio-demographic characteristics. The mean age of participants was slightly younger than that of patients consulting with low back pain in primary care, but the difference between the mean ages of 39 and 43 years is unlikely to be large enough to have a major impact on prognosis. Trial participants had experienced back pain for longer than those consulting in primary care, but these findings are to be expected due to the inclusion criteria for the trial, which specified a minimum duration of the current episode of low back pain of 6 weeks. In addition trial participants were more likely to have had a prior episode of low back pain. As a history of low back pain is associated with a poorer prognosis for the current episode of low back pain, this is also to be expected as a result of the study inclusion criteria.[10,35,36,47] The similarity of the Roland score and the VAS pain score suggests that trial participants did not differ in terms of their degree of disability or the severity of their symptoms from those routinely consulting in primary care. Trial participants were less likely to have received physiotherapy or to have attended an outpatient department. This may relate to the development of services following the report on low back pain by the Clinical Standards Advisory Group[33] rather than to differences in pain and disability. Trial participants were more satisfied with their most recent GP consultation than were patients routinely consulting in primary care, which is to be expected, as dissatisfied patients are probably less likely to participate in a trial. While it would have been preferable to have data from every practice on clinical and functional status of patients not recruited, rather than just from those still recruiting at the end of the trial, the results of the prospective study do suggest that recruited patients did not differ in terms of pain or disability from those consulting with low back pain in primary care. However, the present trial results may overestimate the degree of satisfaction of patients with low back pain routinely consulting in primary care.

The primary care management of patients with low back pain

Our results clearly show that the vast majority of the care provided for patients with low back pain is given in primary care. Very few patients had made any secondary care attendances. Less than one-third had received any physiotherapy; and very few had received any other physical therapy. Similar findings were made in another UK study,[48] and together these results indicate that adherence to the Clinical Standards Advisory Group guidelines[33] with respect to physical therapy has been incomplete. Prescribing patterns were in line with current guidelines, with ibuprofen being the most commonly prescribed drug and diclofenac the second most commonly prescribed drug. Compound analgesics were prescribed less often than NSAIDS, and prescribing of benzodiazepines and opioid analgesics was uncommon, again in line with current guidelines.[35] Advice to purchase over-the-counter simple analgesics was not ascertained, so we were unable to assess concurrence with the guidelines in this area.

Patients had high expectations of their care regarding their low back pain, based on the questionnaire designed by Fitzpatrick and coworkers.[43] Many more participants at baseline expected, than received, advice about avoiding straining their back, posture, medication and other treatments. Part of the explanation for this mismatch between expectations of care and actual care may be that, although participants were given advice, they may have been unable to recall this as having happened. Alternatively, participants may not have been given the advice, or not given it in an accessible way. Previous work suggests many GPs, both in the UK[49,50] and the USA,[51] do not give advice about daily activities or exercise. If participants cannot recall being given advice they are unlikely to have acted upon that advice, or to do so in the future. Hence, even if such advice is being given in primary care, in its current format it is unlikely to have the impact it is intended to, and alternative, more effective methods of providing this information are required. The effect of meeting patients' information needs has received relatively little attention in relation to low back pain.[51,52] Previous work has suggested that meeting inpatients' needs for information is associated both with greater levels of satisfaction and with improved patient outcomes in terms of quality of life.[53] One small trial of a physician education programme aimed at helping family physicians become more knowledgeable, confident, positive, reassuring and informative in their low back pain consultations failed to demonstrate any effect on patient satisfaction or any other patient outcomes.[51] Further work is needed in this area to confirm or refute this finding.

Half the participants at baseline believed that more tests should have been done; almost one-third believed everyone with low back pain needs an X-ray and one-sixth believed that they needed a blood test. One-third of participants were worried about serious disease due to their low back pain, and only 40% were reassured that they did not have a serious condition causing their low back pain. This suggests that patient education regarding the utility of investigations in low back pain is required, and that more attention should be paid in the consultation to reassuring patients that their back pain is unlikely to be due to serious disease. Interestingly, having an X-ray did not increase reassurance or reduce worry about serious disease; despite reassurance (both of the patient and of themselves) being a reason commonly cited by GPs for undertaking X-rays.[22,54] The study findings suggest that having an X-ray does not reassure patients. GPs need to be made aware of this and alternative strategies found for reassuring both patients and GPs.

Only 60% of participants were satisfied with their most recent GP consultation at baseline. Previous work has found lower levels of satisfaction with consultations for low back pain than for other conditions.[30,49] The most common reasons for dissatisfaction were not having an adequate explanation of their problem, not feeling that their GP was concerned about them or understood what was bothering them, and not feeling that they understood what was wrong with their back. Previous research among primary care patients with low back pain in the UK has found similar results.[49] These studies clearly indicate how to improve patient satisfaction with consultations for low back pain. Previous work,[27,30] which is confirmed by the present findings, indicates that those who are more satisfied are less likely to believe that more tests should have been done, less likely to believe that everyone needs an X-ray or blood test, and are more reassured and less worried about serious disease. Improving patient satisfaction with consultations for low back pain may, therefore, reduce patients' desire and expectation for investigations, including radiography. Further research is needed to assess the effectiveness of this approach in increasing satisfaction and reducing the use of radiography in primary care patients with low back pain.

Comparisons with previous studies

Study design

Three previous studies have examined patient outcomes among those receiving and those not receiving lumbar spine radiography: a randomised controlled trial by Deyo and co-workers,[27] a randomised controlled trial by Indahl and co-workers[29] and a non-randomised prospective controlled study by Rockey and co-workers.[28]

The study most comparable to the present one is that by Deyo and co-workers,[27] which was set in a walk-in clinic in the USA, with participants whose main complaint was low back pain. A total of 101 participants were randomised to receive lumbar spine X-rays at the index visit (X-ray group), or to receive an educational intervention at the index visit and lumbar spine X-rays only if their pain had not improved after 3 weeks of conservative treatment (education group). The mean duration of low back pain was 12.6 and 16.1 days in the X-ray and education groups, respectively. Consequently, they had suffered low back pain for a much shorter period of time than the participants in the present trial. In addition, a greater proportion of the participants in the present study had had previous episodes of low back pain. These two factors suggest that the participants in the present study might have a poorer prognosis than those in the trial of Deyo and co-workers.[27] The participants in the present study were older (median age 39 years versus 33 years), more were married (65% versus 48%), more were employed (80% versus 45%) and a higher proportion were women (59% versus 52%).

Indahl and co-workers[29] undertook a randomised controlled trial in Norway and recruited participants who had been off work due to low back pain for at least 8 weeks. Participants were randomised to a multifaceted intervention comprising an examination, an X-ray, a CT scan and information to stay active and to mobilise the lumbar spine. The only outcome reported in this trial was sickness absence from work.

Rockey and co-workers[28] undertook the only other prospective controlled study. They followed up 440 patients with back pain who attended a walk-in acute minor illness clinic at an army teaching medical centre in Texas, USA, between December 1975 and July 1976. Patients were given lumbar spine X-rays in accordance with a clinical algorithm. This resulted in those patients taking corticosteroids, those aged 60 years and over, those with a history of malignancy, those with spinal tenderness as a result of trauma and those seeking compensation receiving an X-ray. Physicians, using clinical judgement, were also able to order radiographs on patients who did not fulfil the criteria for radiography in the

algorithm. This group therefore comprised patients with some of the red flags for spinal pathology as described by the Clinical Standards Advisory Group.[33] The control group, who did not receive an X-ray, did not have these red flags. The majority of patients (72%) had had low back pain for 1 week or less. Similarly to the present trial, 47% of both groups were male. The mean age was 45 years in the X-ray group and 40 years in the control group, this being slightly older than the participants in the present trial. No other data were provided on factors that may influence prognosis, such as employment, previous episodes of low back pain, duration of low back pain and severity of pain.

Functional status, pain and sickness absence

Deyo and co-workers[27] found no significant differences in functional status (measured by the Sickness Impact Profile), days lost from work, self-rated improvement, clinician-rated improvement or duration of pain at 3 weeks or 3 months follow-up. The mean number of physician visits per patient is reported as being similar in the two groups at the 3-month follow-up, but was not specified. Indahl and co-workers[29] found that their intervention group had a highly significant reduction in sickness leave compared with their control group, with 50% fewer participants still on sick leave 200 days after randomisation. Rockey and co-workers[28] found no difference in symptom status or in sickness absence from work between their X-ray and non-X-ray groups.

How do these results compare with those found in the present trial? We found that intervention group participants were more likely to have low back pain 3 months after randomisation and had had a lower health status score. These findings cannot be explained by differences at baseline between the two groups. They suggest that radiography may have an effect such that those who had an X-ray perceived themselves to be less well than those who have not had an X-ray, although the differences may be too small to be clinically important. Our findings are therefore similar to those of Deyo and co-workers[27] with respect to pain and functional status, but as they did not measure health status we cannot compare our results for this outcome. It is difficult to know the extent to which the large treatment effect found by Indahl and co-workers[29] can be attributed to the X-ray, when the intervention was multifaceted. In addition, the participants in the study by Indahl and co-workers[29] had been off work with low back pain for much longer than had the participants in the present trial (8 versus 2 weeks), and so comparisons with those from the present study are limited.

Use of services and medication

Deyo and co-workers[27] found no difference between study groups in medication use, specialist referral, hospital admission or physical therapy. Similarly, Rockey and co-workers[28] found no differences in the management of those receiving and those not receiving X-rays. These findings are all confirmed by those from the present larger trial.

Patient satisfaction, beliefs and expectations of care

Deyo and co-workers[27] found no difference in the overall satisfaction score at either the 3-week or 3-month follow-up. At the 3-week follow-up the X-ray group was more likely to believe that everyone with low back pain should have an X-ray than was the education group, but were no more likely to feel they had had an adequate explanation of their problem and were no less likely to believe that their pain was due to a serious problem. The authors concluded that their educational intervention had reassuring effects similar to those of obtaining an X-ray and that at the 3-month follow-up there had been no compensatory increase in physician visits, use of laboratory tests or X-rays in the education group. They also concluded that physicians can avoid lumbar spine X-rays for low-risk patients without antagonising them or producing adverse psychological outcomes. Rockey and co-workers[28] found that their non-X-ray group was significantly more likely to be dissatisfied with their care or to see another physician about their low back pain than was the X-ray group.

Unlike Deyo and co-workers,[27] but similar to the findings of Rockey and co-workers,[28] we found higher levels of satisfaction in the intervention group at 9 months after randomisation. Caution must be exercised in interpreting the results of the patient satisfaction questionnaire at the 9-month follow-up interview as the numbers are small in both treatment groups (42 and 47 in intervention and control groups, respectively). The components of the satisfaction score that differed were: a higher proportion in the X-ray group believed that their GP understood what was bothering them, a higher proportion believed that they understood what was wrong with their back, and a higher proportion believed that the GP had spent enough time with them. More of the X-ray group participants than the control

group felt they had had an adequate explanation of their problem, but this did not reach statistical significance; and still fewer than three-quarters of participants considered they had had an adequate explanation. Sixty per cent of the control group felt they had had an adequate explanation without having an X-ray. The majority of patients will not have had an X-ray result that explained their symptoms, as 'degenerative disease' or 'normal' findings were the most often reported. However, as the patient may have perceived that the X-ray 'ruled out' serious disease, they may have felt that they had a better understanding of what was wrong with their back, not because they knew what was causing the pain, but because they knew what was not causing the pain. Little work has so far been undertaken to explore patients' perceptions of the possible causes of low back pain,[55] and the potential for diagnosing these conditions by means of radiography would be useful. This would help elucidate the perceived utility of X-rays for patients. This information could then be used to design patient education that enables patients to understand what is wrong, without the need for recourse to X-rays.

We found no difference between treatment groups in the proportion who were worried about serious disease or were reassured that serious disease was not the cause of their back pain. This confirms the findings of Deyo and co-workers,[27] and suggests that X-rays do not reassure patients or reduce their worry about serious disease being the cause of their low back pain. As reassurance of the patient is a reason frequently given by GPs for undertaking X-rays[22] it is important to educate GPs that the X-ray findings do not reassure patients. If it is the GPs that need reassuring, further training may be required in this area. However, attention must be paid to the process and content of such training, as one small trial of physician education aimed at increasing physician reassurance failed to impact on the patients' level of worry about their low back pain.[51]

At 9 months after randomisation a higher proportion of the control group believed that more tests should have been done. Half the participants believed that all patients with low back pain need an X-ray, and two-fifths that all patients with low back pain need a blood test. This suggests that having an X-ray satisfies, to some extent, patients' beliefs regarding the need for investigations in low back pain.[49] However, one-third of the intervention group still believed that more tests should have been done. In addition, the proportion of participants believing that every patient with low back pain needs an X-ray and a blood test increased in both the intervention and control groups over the 9-month period. This may reflect the finding that the participants who completed the satisfaction questionnaire were still experiencing pain at the 9-month follow-up, and the belief in investigations may be related to the duration of symptoms. Similarly, previous work suggests that the longer the duration of symptoms the more likely the GP is to undertake an X-ray; indicating that perhaps the GP also values investigations more highly when the symptoms have persisted for longer.[22,54] This highlights the high potential for both patient and GP education in this area.

Rockey and co-workers[28] have identified five possible explanations for increased satisfaction among patients receiving an X-ray:

- Patients may trust technology such as a ray, and will expect that an X-ray will be used to evaluate their problem. However, we found no evidence to suggest that the X-ray findings altered patient management. Patient education is needed to address the expectation that an X-ray will contribute to decisions about their management, as for the majority of patients it does not.
- A normal X-ray may reassure an anxious patient and may contribute to symptom resolution. We have found no evidence in either the short or longer term that having an X-ray is associated with less worry about serious disease or with greater patient reassurance.
- By ordering an X-ray the GP may communicate to the patient that he or she is concerned about the patient's health. At the 9-month follow-up more participants in the X-ray group felt their GP was concerned about them, but this was not significant (OR = 1.74; 95% CI, 0.66 to 4.63). However, the lack of significance may have been due to insufficient power resulting from small numbers.
- Patients who are X-rayed may receive more attention with regard to their low back pain. Participants in our trial received a greater number of GP consultations in the first 3 months after randomisation, and in addition they received attention from the radiologist. Consequently, the increased attention could contribute to patient satisfaction.
- Patients who receive an X-ray are more likely to get a 'diagnosis'. If this is the case, the GP may feel more comfortable treating a patient with a diagnosis. Having a diagnosis may acknowledge and legitimise the patient's symptoms, and

through this may encourage illness behaviour. There was some support for this in our trial, with X-ray group participants feeling they had a better understanding of their back pain problem, which may have been related to getting a 'diagnosis'. It is also possible that the slightly poorer functional and symptomatic outcomes of the intervention group patients may have been a result of encouraging illness behaviour by giving a 'diagnosis'. We do not know how the X-ray results were explained to trial participants, or what the participants' understanding of the results was, so it is difficult to draw any further conclusions regarding this.

The conclusion from our findings is that, although X-rays are associated with increased patient satisfaction at 9 months after randomisation, this is not accounted for by the provision of better explanations of their problems and patients are not more reassured about the possibility of serious illness. They do feel that they have a better understanding of what is wrong with their back and that the GP had a greater understanding of what was bothering them. The challenges are to explore the factors that are important in helping the patient to understand what is wrong with their back and to develop patient and GP education to increase patients' understanding without recourse to X-rays.

The effect of patient choice of treatment group on outcome

The results of this patient preference study indicate that patients who choose to have an X-ray report a greater degree of back-pain-related disability than those agreeing to be randomised. We also found that those choosing an X-ray were more worried and less reassured about serious disease and were more likely to believe that patients with low back pain needed more tests, and that all patients needed X-rays and blood tests. In terms of outcomes, due to the small number of participants caution must be exercised in interpreting the results, but there was some evidence that those choosing whether or not to have an X-ray had marginally better outcomes than those randomised to a treatment group. The patient preference X-ray group had poorer Roland scores at baseline but similar Roland scores at the 9-month follow-up, suggesting they may have shown more improvement than those randomised to X-ray. Similarly, the patient preference non-X-ray group had a higher health status score at the 9-month follow-up than those randomised to the control group. As there were no differences in any other outcomes between the randomised and patient preference groups the clinical significance of these improvements is unclear. Although we have not demonstrated any large benefit related to choice of treatment group, the small number in the patient preference arm of the study means we are unable to rule out differences in other outcomes that may be clinically important. However, even if clinically important differences in outcomes could be demonstrated, these would have to be weighed against the risks of radiography.

Economic evaluation of lumbar spine radiography

This study has shown that lumbar spine radiography in primary care patients with low back pain of at least 6 weeks duration is not associated with improvement in health outcome as measured by Roland and pain scores after 3 or 9 months. Health status scores were lower in the X-ray group at 3 months, indicating a poorer health status, but showed no difference at 9 months. However, lumbar spine radiography in these patients is associated with higher direct costs at 3 and 9 months and higher total resource use at 9 months. These findings indicate that this intervention is not cost-effective.

Patient satisfaction with the management of their episode of back pain by their GP was shown to be higher at 9 months for those who had an X-ray. There is also significant patient demand for lumbar X-rays; some 80% would choose to have one if offered. In addition, patients placed a positive value on the reassurance derived from having an X-ray (median £30), so ruling out serious spinal pathology is a tangible benefit to the patient. These results are perhaps unsurprising, as patients have the possibility to derive some kind of benefit from an X-ray, but they of course would not incur the direct cost of receiving it. At a zero price at the point of consumption demand is likely to be high for most commodities.

The increased satisfaction is achieved at considerable cost and radiography is only likely to be cost-effective where satisfaction is valued highly. Exactly how much decision-makers might choose to pay for additional units of satisfaction for patients with low back pain using lumbar X-rays is unknown, but we can make some inferences from observed behaviour. We know that X-rays, which currently cost around £40, are frequently used in the management of low back pain. We observed in

this study that this generated, on average, two units of patient satisfaction, and consequently we might infer from this that £20 per unit of satisfaction is acceptable to decision-makers. An alternative way of looking at this is that 80% of patients in this study said that, if given the choice, they would choose to have a lumbar X-ray, and that they would be willing to pay, on average, £30 for the benefit they perceived they would obtain from an X-ray. Hence, we might infer that patients value a unit of satisfaction at around £15. When satisfaction is valued at these levels there is a 70–80% chance that X-rays will be cost-effective compared to routine practice. In addition, it must be remembered that we were unable to demonstrate any improvement in health or functional outcomes associated with having an X-ray.

However, patients do also perceive a real risk from X-ray radiation and place a negative value (median £43) on this aspect, which is greater than the gain from reassurance. Thus, when asked to quantify the value of the benefits and the risks of X-ray, it is found that risks in fact outweigh the benefits at the patient level.

Usual care without radiography is a cost-effective strategy compared with lumbar spine radiography. Cost–benefit analysis indicates that lumbar spine radiography is associated with a net economic loss and is cost-ineffective from the perspective of the health service provider, the patient and thus society.

Ways of reducing GP referrals for X-rays

Several studies assessing the impact of guidelines on referral rates for lumbar spine radiography have met with limited success.[9,31,32] Although all have demonstrated overall reductions in referral rates, a large proportion of the referrals still do not conform to the guidelines. This suggests that guidelines about the appropriate use of radiography are not the complete answer to reducing X-ray use among patients with low back pain in primary care. In addition, an assessment of the impact of implementing the Agency for Healthcare Policy and Research guidelines in Canada reached the conclusion that implementing the guidelines would result in increased utilisation of lumbar spine radiography.[56] The authors called for further evaluation and modification of the guidelines. The new regulations on ionising radiation may help reduce inappropriate use of lumbar spine radiography, but the effect of these regulations awaits evaluation.[25]

The majority of GPs say they undertake X-rays to reassure the patient and themselves. Yet, the present study failed to demonstrate that X-rays are associated with increased patient reassurance, or reduced worry about serious disease. In addition, we found that patients having an X-ray were not more likely to consider they had received an adequate explanation of their problem. As the correlation between X-ray findings and patients' symptoms is poor; it is not surprising that X-ray results may not help the GP to provide an adequate explanation of a patient's symptoms. This suggests that other methods need to be found for explaining the likely causes of low back pain and for reassuring patients that they are unlikely to have serious disease, without recourse to X-rays.

The majority of participants would like an X-ray for their low back pain, even those in the intervention group who had an X-ray which did not impact on their management and did not aid resolution of their symptoms. Anecdotally, GPs perceive that patients want, and expect, X-rays when they have low back pain. Previous research supports the importance attached by patients to investigations.[49] Part of any strategy to try to reduce unnecessary radiography must therefore comprise patient education regarding the risks and utility of X-rays and GP education regarding exploring the patient's expectations and concerns and meeting the needs that patients perceive X-rays meet in other ways. As discussed above, further research is needed to explore patients' beliefs concerning X-rays and the needs they perceive they will meet, in order to develop, and test, an educational package that can be used in primary care to address these needs. In addition, a primary care educational package must address the needs of patients and GPs for reassurance about the risk of serious pathology, as well as provide strategies for GPs to address patients' expectations and concerns within consultations for low back pain.

Chapter 5

Conclusions and recommendations for further research

The conclusions from our trial are that lumbar spine radiography is not associated with improvements in patient functioning, duration or severity of pain, or health status. In addition, the use of radiography is not associated with changes in patient management or sickness absence from work. It is associated with increased GP consultation rates within the first 3 months after receiving the X-ray, some of which will be accounted for by consultations to receive the results of the X-ray. Lumbar spine radiography is associated with increased patient satisfaction, but not with increased reassurance or reduced worry about the cause of back pain. Many patients did not have their information needs met within the consultation. Meeting these needs was associated with satisfaction. Increased satisfaction was associated with a reduced desire for investigations, including X-rays, and with increased reassurance and reduced worry. Most patients would choose to have an X-ray if the choice was available. Meeting information needs and increasing satisfaction may therefore be a useful strategy for reducing the desire for and expectation of X-rays among patients. Lumbar spine radiography was associated with a net economic loss.

Recommendations for further research

Based on the evidence obtained in this study we make the following recommendations relating to research:

- Further research is needed to elucidate patients' understanding of the utility of X-rays.

Further research is required to design educational packages aimed at:

- educating patients about the utility, and the risks of X-rays
- providing GPs with strategies, skills and resources to identify and meet patients' information needs
- reassuring patients and GPs about the small chance of missing serious spinal pathology in the absence of red flags for serious spinal pathology.
- The effectiveness of the educational package described above must be tested in primary care, using a randomised design and incorporating outcome measures that include patient satisfaction, patient expectations for information and advice, patient and GP reassurance, and referral rates for radiography.

Based on the evidence obtained the implications for healthcare are:

- Guidelines on the use of radiography in primary care patients with low back pain should be consistent about not recommending lumbar spine radiography in patients with low back pain of at least 6 weeks duration without red flags for serious spinal pathology.

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We look forward to hearing from you.

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