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Abstract

Does early imaging influence management and improve outcome in patients with low back pain? A pragmatic randomised controlled trial

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Objectives: To establish whether the early use of sophisticated imaging techniques influences the clinical management and outcome of patients with low back pain (LBP) and whether it is cost-effective.
Design: A pragmatic multicentre randomised controlled trial using a standard two parallel group approach incorporating an economic evaluation. For a subgroup of trial participants, a controlled 'before and after' approach was used to assess the impact of 'early imaging' on clinicians' diagnostic and therapeutic confidence.
Setting and participants: A total of 782 participants who had been referred by their general practitioner to a consultant orthopaedic specialist or neurosurgeon because of symptomatic lumbar spine disorders. The study included 14 hospitals in Scotland and one in England over a 24-month period.
Results: Participants in both groups reported an improvement in health status at 8 and 24 months with the 'early imaging' group having statistically significantly better outcome. Other than the proportion of participants receiving imaging (90% versus 30%), there were few differences between the groups in the management received throughout the 24-month follow-up. The total number of outpatient consultations in the two groups was similar although more people in the 'early imaging' group had return outpatient appointments during the 8-month follow-up. Clinicians' diagnostic confidence, between trial entry and follow-up, increased significantly for both groups with a greater increase in the 'early imaging' group. The cost of imaging was the main determinant of the difference in total costs between the groups and it was estimated that 'early imaging' could provide an additional 0.07 quality-adjusted life-years (QALYs), at an additional average cost of £61 over the 24-month follow-up. Using non-imputed costs and QALYs but adjusted for baseline differences in EQ-5D score, the mean incremental cost per QALY of 'early imaging' was £870. The results were sensitive to the costs of imaging and the confidence intervals surrounding estimates of average costs and QALYs.
Conclusions: The early use of sophisticated imaging does not appear to affect management overall but does result in a slight improvement in clinical outcome at an estimated cost of £870 per QALY. Imaging was associated with an increase in clinicians' diagnostic confidence, particularly for non-specialists. Further research is required to determine if more rapid referral to sophisticated imaging and secondary care is important in the acute episode and whether the use of imaging would be more beneficial for particular categories of LBP.

Contents

List of abbreviations

ALBP	Aberdeen Low Back Pain
BNF	British National Formulary
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
CSAG	Clinical Standards Advisory Group
CT	computed tomography
DA	data abstraction of patients' medical notes
EQ-5D	EuroQol-5 dimensions
GP	general practitioner
ICER	incremental cost-effectiveness ratio
IP	inpatient
IQR	interquartile range
LBP	low back pain
MRI	magnetic resonance imaging
OP	outpatient
PQ	patient questionnaire
PTTQ	patient time and travel questionnaire
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SE	standard error
SF-36	Short Form with 36 Items
SHSC	Scottish Health Service costs

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Objectives

To establish whether the early use of sophisticated imaging techniques such as magnetic resonance imaging (MRI) or computed tomography (CT) influences the clinical management and outcome of patients with low back pain (LBP) and whether it is cost-effective.

Design

A pragmatic multicentre randomised controlled trial using a standard two parallel group approach incorporating an economic evaluation. For a subgroup of trial participants, a controlled 'before and after' approach was used to assess the impact of 'early imaging' on clinicians' diagnostic and therapeutic confidence.

Setting

A total of 14 hospitals in Scotland and one in England over a 24-month period (seven teaching hospitals and eight district general hospitals).

Subjects

The 782 participants had been referred by their general practitioner to a consultant orthopaedic specialist or neurosurgeon because of symptomatic lumbar spine disorders, and the specialist was clinically uncertain about the need for imaging.

Intervention

Of the eligible patients who consented to participate, 393 were randomly allocated to 'early imaging' (MRI or CT as soon as practicable) and 389 to 'delayed, selective imaging' (no imaging unless a clear clinical indication developed). Choice of imaging modality and patient management plans was at the discretion of the referring clinician.

Main outcome measures

Participants completed a baseline questionnaire containing the Short Form with 36 Items (SF-36), Aberdeen Low Back Pain score (ALBP score) and the EuroQol (EQ-5D). Postal questionnaires were completed after 8 and 24 months. Patient management was determined retrospectively by case note abstraction and from patient questionnaires. In the study of diagnostic impact, clinicians completed assessment forms at the time of trial entry and at follow-up appointment.

Results

Participants in both groups reported an improvement in health status at 8 and 24 months with the 'early imaging' group having statistically significantly better outcome. After adjustment for baseline score and other factors, the mean differences at 24 months were 3.62 points [95% confidence interval (CI) –5.92 to –1.32; $p = 0.002$] for the ALBP score and 0.057 (95% CI 0.013 to 0.101; $p = 0.01$) for the EQ-5D. The 'early imaging' group also had significantly greater improvement in most subscales of the SF-36 at 8 months, but only for the Bodily Pain subscale at 24 months.

Other than the proportion of participants receiving imaging (90% versus 30%), there were few differences between the groups in the management received throughout the 24-month follow-up. The total number of outpatient consultations in the two groups was similar although more people in the 'early imaging' group had return outpatient appointments during the 8-month follow-up ($p < 0.001$).

Clinicians' diagnostic confidence, between trial entry and follow-up, increased significantly for both groups with a greater increase in the 'early imaging' group ($p = 0.01$).

The cost of imaging was the main determinant of the difference in total costs between the groups and it was estimated that 'early imaging' could

provide an additional 0.07 quality-adjusted life-years (QALYs), at an additional average cost of £61 over the 24-month follow-up. Using non-imputed costs and QALYs but adjusted for baseline differences in EQ-5D score, the mean incremental cost per QALY of 'early imaging' was £870. The results were sensitive to the costs of imaging and the confidence intervals surrounding estimates of average costs and QALYs.

Conclusions

The early use of sophisticated imaging does not appear to affect management overall but does result in a slight improvement in clinical outcome at an estimated cost of £870 per QALY. Imaging was associated with an increase in clinicians' diagnostic confidence, particularly for non-specialists.

Implications for health care

The main resource implication is the cost of imaging. Decisions about the use of sophisticated imaging in this context will depend upon judgements about the value of the observed differences in outcome and whether these justify the extra costs.

Recommendations for research

Further research is required to determine if more rapid referral to sophisticated imaging and secondary care is important in the acute episode and whether the use of imaging would be more beneficial for particular categories of LBP.

Chapter 1
Introduction

In the mid-1990s, the place of sophisticated imaging in the clinical management of low back pain (LBP) was identified as a research priority by the NHS R&D Health Technology Assessment Programme. This report describes work commissioned to address this issue.

Low back pain

LBP is one of the most common reasons for general practice consultations in the UK.[1–3] The associated disability has major implications for the sufferers, the health service and society in general through work incapacity, sickness and invalidity benefit payments.[4] Furthermore, the burden that this represents has been increasing. As reported by the Clinical Standards Advisory Group (CSAG),[2] in the decade to 1993 outpatient attendances for back pain rose fivefold and the number of days of incapacity for which social security benefits were paid more than doubled.[5]

Although most episodes of back pain are self-limiting, 10–20% of patients are referred to secondary care for a specialist opinion[6] and the associated costs consume large amounts of NHS resources. Estimates of the cost of back pain to the NHS ranging from £300 to 500 million have been reported.[7,8] More recently, Maniadakis and Gray[4] suggested that the total direct cost including private services could be of the order of £1632 million, with additional informal care and employment-related costs of as much as £5018–10,668 million.

Imaging and LBP

Prior to the development of sophisticated imaging techniques such as magnetic resonance imaging (MRI) and computed tomography (CT), plain film radiography was the primary imaging modality for the investigation of lumbar spinal dysfunction. Lumbar spine X-rays account for approximately 5% of all NHS radiographic examinations and remain the most common investigation for LBP requested by general practitioners (GPs).[9–11] This is despite the fact that lumbar spine radiography contributes little to the clinical management of most patients.[11–14] MRI and CT are sophisticated, non-invasive imaging technologies that produce high-quality cross-sectional images of the lumbar spine. MRI has largely replaced CT as the 'gold standard' for lumbar spine imaging. It produces detailed images of both bone and soft tissue structures, with no radiation exposure. However, MRI is an expensive imaging technique with high capital costs and maintenance, staff and operational costs. Access to MRI is more limited than CT and most MRI scanners are located in teaching hospitals with some hospitals dependent on mobile scanners. CT is widely available throughout the UK, with most district general hospitals having access to a scanner. It is superior to MRI in the detection of degenerative changes; its main disadvantage is exposure to large doses of radiation.

The controversy about the place of imaging in the management of LBP

While MRI and CT provide greatly enhanced images in comparison with plain film radiography, the putative link between abnormalities and back pain is controversial. Studies in asymptomatic subjects have shown a high prevalence of imaging abnormalities for both MRI[15–17] and CT.[18] Furthermore, studies amongst people with back pain have shown poor correlation between imaging appearance and LBP symptoms.[15] The value of imaging for clinical decision making has therefore been questioned and the need for careful interpretation in conjunction with the clinical history and physical examination emphasised.

The Royal College of Radiologists guidelines[9] recommend that MR or CT imaging of the lumbar spine should be restricted to LBP patients with signs of potentially serious underlying pathology which may indicate the presence of infectious, neoplastic or inflammatory disease ('red flags'), or those with progressive neurological deficit. Within the NHS there is general agreement that no imaging is indicated when LBP is likely to resolve with conservative management and conversely that

imaging is a prerequisite for patients requiring surgical intervention. However, spinal surgery rates in the UK are lower than in many other countries.[19,20] Most patients referred to secondary care continue to receive conservative management and it is the role of sophisticated imaging in the management of these patients that is uncertain, poorly defined and variable.[19,21,22] Some clinicians routinely request imaging to confirm their diagnosis, provide reassurance and assist in treatment selection.[23,24] Others limit their use of imaging to patients for whom a decision has been made to perform some form of interventional treatment, arguing that wider use of imaging could provide misleading information, generate unnecessary anxiety and lead to inappropriate management.[25,26] In addition to any clinical uncertainties of the value of imaging for these patients, concerns have been expressed by radiologists and healthcare providers[27] that resource-intensive technologies have diffused into clinical practice with little evidence of benefit to patient health or quality of life[28] and that unselective overuse is a waste of scarce resources.

Health technology assessment evaluative hierarchy

In the 1970s, the introduction of CT stimulated much debate on the evaluation of imaging and new diagnostic technologies in general. It was recognised that there are difficulties of assessing how such health technology might directly affect the physical health of the patient in view of the chain of events between application of the technology and any potential influence on patient health.[29] Fineberg and co-workers[30] suggested that diagnostic imaging should be evaluated at four separate 'levels of efficacy' – technical output, diagnostic information, therapeutic impact and patient outcome. This conceptual framework evolved into a five-level hierarchy,[31,32] which clearly differentiated between the technical attributes (technical and diagnostic performance) and the influence on patient diagnosis, management and health outcome (diagnostic impact, therapeutic impact and impact on health[33] (*Figure 1*). Historically, most published studies on the clinical efficacy of imaging have focused on technical and diagnostic accuracy. While a few studies have attempted to assess diagnostic and therapeutic impact,[30,34–42] there is little evidence that the use of sophisticated imaging significantly improves patient health or quality of life.[36,39,42–46] More recently, the evaluative framework has been extended to include a sixth level (impact on society) to include cost-effectiveness[27,32,47] in recognition of the need to evaluate the impact of new technologies on the associated costs to both service users and service providers.

In health technology assessment, it is generally accepted that the randomised controlled trial (RCT) is the gold standard for deriving evidence of clinical and cost-effectiveness since it minimises bias.[48] Although a few randomised comparisons have been made between MRI and other diagnostic procedures,[49–52] this study design has rarely been applied to assessments of diagnostic imaging because of the perceived ethical problems of denying patients access to imaging.[53–55] Two randomised trials of lumbar spine radiography in primary care patients with LBP have recently been conducted. Kendrick and co-workers[11] observed that the intervention group reported more LBP and had poorer overall health status after 9 months of follow-up, but there was no statistically significant difference in outcome between the intervention (radiography) group and the control group. However, patients referred for radiography reported greater satisfaction with care. Similarly, Kerry and co-workers[56] reported no significant difference in physical outcome at 12 months

FIGURE 1 *Evaluative hierarchy[30,33] applied to the assessment of imaging. A sixth level has been included to allow cost–benefit and cost-effectiveness analyses.[28,32] Each level depends on the demonstration of a favourable influence at the preceding level.*

between those referred and those not referred for radiography, but suggested a small improvement in psychological well-being in those referred for radiography. An earlier study of 101 participants, randomised to receive either lumbar spine radiography or a brief educational intervention,[57] reported no significant difference in functional status between the groups after 3 months. A randomised comparison of plain radiography and rapid MRI for patients with LBP[51,58] showed a slightly better outcome in the MRI group, but the difference was not statistically significant.

Rationale for study

Since LBP places huge demands on healthcare and associated services, it is important for both service providers and commissioners in the NHS that the uncertainty in the role of imaging for LBP patients is clarified. Current expansion of the use of imaging should only be encouraged if it is known to be effective and cost-effective. Restricting the use of imaging to clear clinical indications would greatly reduce demand. On the other hand, more liberal use of imaging amongst patients with LBP could be beneficial and thus could be a potentially cost-effective use of resources. Sound evidence is also required to assist GPs in selecting appropriate referrals for specialist opinion and to inform decisions about open access to imaging services.

The objectives of this study were therefore to compare the package of care associated with two policies for the use of imaging for patients with LBP as might be applied within the current health service: a policy of 'early imaging', implying more liberal use of imaging as opposed to 'delayed and selective imaging', which implies restrictive use limited to patients for whom a clear clinical need later develops, for example a decision to perform surgery. Although imaging might have a directly beneficial effect (as, for example, has been shown for prenatal ultrasound examination) by providing reassurance, the greatest impact seems likely to result from changes in management prompted by its results. Relating the resources expended to any health gain (or loss) as a result of a policy of 'early imaging' should provide a basis for deciding whether or not this is an efficient investment for the health service.

The aim of the study was therefore to establish whether the early use of sophisticated imaging techniques such as MRI or CT influences the clinical management and outcome of patients with LBP and whether it is cost-effective. The two imaging policies were compared in relation to diagnostic impact, therapeutic impact, impact on health and impact on society[33] (*Figure 1*).

Chapter 2
Method

Study design

The basic design of the study was a multicentre pragmatic RCT using a standard two parallel group approach. Outcome was measured at fixed time points to assess the impact on health and on society. In the study of diagnostic and therapeutic impact, a controlled 'before and after' approach was used to assess changes due to 'early imaging'. This part of the study was restricted to a subgroup of participants in the trial.

Patients who consented to participate in the trial were randomly allocated to either 'early imaging' (MRI or CT as soon as practicable) or 'delayed, selective imaging' (no MRI or CT unless a clear clinical indication developed, for example a decision to perform surgery or an alteration in a patient's clinical condition). The choice of imaging modality and patient management plans was at the discretion of the referring clinician. Clinical history at trial entry was recorded on trial entry forms (Appendix 1) and participants completed health status questionnaires at the time of recruitment into the study (Appendix 4).

The principal comparison of outcome was made at 2 years after trial entry since the overriding interest was to determine any sustained differences. However, shorter term differences are also important, particularly in terms of health, and an intermediate outcome measurement at 8 months was included to assess any differential effects of the two policies that could be maximal within the first few months.

Ethical approval for this study was obtained from the Scottish Multicentre Research Ethics Committee and the appropriate Local Research Ethics Committees.

Clinical centres

Centres were eligible if there was access to MRI and/or CT scanning, with a doctor(s) responsible for the care of patients with back pain who wished to collaborate. The original plan had been that patient recruitment would be by orthopaedic specialists and neurosurgeons who had a particular interest in LBP, working in the four major Scottish teaching hospitals. However, it was later felt that a mixture of teaching and district general hospitals and the involvement of other doctors (such as orthopaedic physicians) responsible for care of such patients would be more representative of the UK healthcare system.

Study population

Participating consultants were asked to assess all new patients presenting with symptomatic lumbar spine disorders (LBP and/or sciatica) for the trial. Eligible patients were those for whom there was clinical uncertainty about the need for imaging. This excluded patients requiring immediate referral for imaging (such as those for whom surgical intervention was judged necessary; those with 'red flags'); patients who had had imaging (MRI or CT) in the previous 12 months; patients for whom there was no need to consider imaging, such as those discharged to primary care; and patients with pain of non-spinal origin. Based on clinical criteria, patients were categorised into one of the following five diagnostic categories: (1) symptomatic lumbar disc protrusion, (2) root entrapment secondary to degenerative disease, (3) neurogenic claudication, (4) chronic LBP not covered by (1)–(3), and (5) other [not covered by (1)–(4)] (Appendix 1).

Research nurses in the clinics explained the trial to eligible patients, obtained written informed consent (Appendix 2), formally recruited participants to the study and ascertained the randomised allocation (Appendix 3).

Randomisation

Randomisation was organised centrally at the Health Services Research Unit, Aberdeen, and was independent of all clinical collaborators. The first 66 patients were randomised by hand using a table of random numbers. From then onwards, a fully automated telephone randomisation service was used. Assignment to the 'early imaging' or 'delayed, selective imaging' group was made by

minimisation stratified by consultant and with age (using five age bands), sex and clinical category (using the above five categories) as minimisation factors.

Data collection

Data to describe subsequent clinical management and later outcome were assembled in two principal ways: patient questionnaires (Appendix 4) and case note review. Standardised questionnaires were sent to all participants together with pre-paid envelopes at 8 and 24 months after trial entry for self-completion at home and return by post. Data from case notes were extracted retrospectively 8 and 24 months after trial entry.

Initially during the 8-month follow-up, non-responders received up to two reminder telephone calls or letters. This increased the response rate from 50% to approximately 75%. Additional strategies were later introduced to contact non-responders and encourage return of the postal questionnaires, for example verification of non-responders' addresses via their general practitioner, postal reminders and a more formal reminder letter which stressed the importance of participants' responses to the results of the study. These measures increased the response rate to approximately 90% and were applied throughout the 24-month follow-up.[59]

Structured data abstraction (Appendix 5) was performed at 8 and 24 months by trained researchers from hospital case notes. This allowed verification of self-completed questionnaires and estimates of management and resource use.

Outcome measures

The comparison of outcome of the two imaging policies was in relation to four perspectives of the health technology framework:[33]

- Diagnostic impact: the extent to which a policy of 'early imaging' changed a clinician's diagnostic confidence; whether such change resulted in changes in diagnostic category.
- Therapeutic impact: the extent to which 'early imaging' changed management and treatment in terms of hospital and GP visits, the use of hospital-based treatment (e.g. physiotherapy, surgery), the use of non-NHS treatments (e.g. private physiotherapy, osteopathy, chiropractic), use of home-based treatment (e.g. drugs, lumbar supports) and the costs of these changes.
- Impact on health: the extent to which 'early imaging' changed the patient's health status in terms of pain, disability and social function.
- Resource use in relation to any health gain: the cost-effectiveness to the NHS of the two policies.

As discussed in more detail later, the main measures for assessing the effects on health were the Aberdeen Low Back Pain[60] (ALBP) score, the SF-36 (Short Form with 36 Items) and the EQ-5D (EuroQol-5 dimensions) (note: the ALBP score was used in preference to the originally chosen back pain specific outcome measure, the Oswestry Disability Scale,[61] because it was thought more likely to be responsive to change in this patient group).

Statistical methods

For the assessment of diagnostic impact, univariate comparisons of categorical data were made using the chi-squared test. The Wilcoxon signed-rank test was used to test for change in diagnostic and therapeutic confidence between trial entry and follow-up for each group separately. The Mann–Whitney test was used to test differences in non-normally distributed continuous data. Non-parametric data were presented as medians with interquartile ranges (IQRs). In the assessment of therapeutic impact, dichotomous outcomes were analysed using the chi-squared test.

For the ALBP score, EQ-5D utility score and six of the SF-36 subscales, the primary analysis was analysis of covariance adjusting for the factors used in the minimisation (i.e. age, sex, clinical category and consultant) and the score at baseline. 'Consultant' was considered as a random factor in the model and interaction terms were not included. Adjusted mean scores in each group with 95% confidence intervals (CIs) for the difference in means are reported. The three SF-36 subscales with six or fewer possible responses (i.e. role–physical functioning, role–emotional functioning and reported health transition) were regarded not as continuous but as ordinal outcomes, and ordinal logistic regression adjusting for the minimisation factors and the score at baseline was used. In each case, adjustment was made for the minimisation factors as failure to account for them in the analysis may result in p-values that are too conservative.[62] In the event, adjustment was also made for an imbalance in the

baseline score at trial entry. There has been considerable debate in the statistical literature as to the most appropriate methods for analysing data in which there has been baseline imbalance and a number of methods have been suggested, including analysis of change scores and analysis of covariance. However, there is now consensus that analysis of covariance is the most robust analysis and the only analysis that will be truly unbiased.[63–65]

Secondary analyses were also conducted, their main role being to confirm the robustness of the primary results. These involved the use of *t*-tests on the raw score, multiple regression and the inclusion of duration of current episode as a covariate in the model. In addition, subgroup analyses were conducted to examine the differential effects of the 'early imaging' policy for specific categories of participants. These were those in each clinical category, groups defined by duration of episode, and groups characterised by whether or not there was sciatica (referred pain to the leg). To detect differential effects for different categories of patients, the presence of significant interaction effects between each of these variables and the randomisation variable was tested using a multiple regression model. A conservative level of significance ($p < 0.01$) was again used. The results of the subgroup analyses were treated conservatively and 99% CIs shown where appropriate.

All analyses were performed on an intention-to-treat basis.

Sample sizes

The original aim was to recruit 1200 participants to give 90% power to identify a difference of 3.0 percentage points on the ALBP score and 80% power to detect a 2.5 percentage point difference. A trial of this size would also have been able to identify moderate differences (4 points) in the SF-36 subscales with reasonable confidence. Because recruitment to the trial was slower than expected, this was revised to 800 at the time of the Data Monitoring Committee meeting (see below) in September 1998. A trial of this size had 90% power to detect a difference of 3.70 points in the ALBP score and 80% power to detect a difference of 3.19 points. All calculations were based on a two-sided significance level of 0.05.

The sample size for the substudy on diagnostic impact was based on the results of a pilot study involving 27 patients. This suggested that diagnostic confidence was increased after imaging in 21 (78%) of 27 patients. Adopting a more conservative estimate (reflecting the small numbers on which the pilot study was based), we aimed to detect whether imaging was associated with increased diagnostic confidence in at least 70% of patients. Accepting that a number of those randomly assigned to the 'delayed, selective' imaging group would actually undergo imaging, and accepting that clinicians' diagnostic confidence may have increased anyway by the time of the second assessment, the trial was sized to detect a difference in the proportion who had increased their confidence from 40% in the 'delayed, selective' imaging group to at least 70% in the imaging group by the time of the second assessment. To detect this difference with 90% power and at the 5% significance level required approximately 130 participants. To allow for the potential loss to follow-up because of patient non-attendance at the second visit, we aimed to recruit at least a further 20% of patients.

Data monitoring

In September 1998, an independent data monitoring committee met to review the overall conduct of the trial, patient accrual, data collection and an interim analysis of follow-up data. They considered data available up to 31 July 1998. At that time, 442 participants had been recruited, 219 allocated to the 'early imaging' group and 223 to the 'delayed selective imaging' group. On the basis of the data available to them, they saw no reason to recommend any change to the protocol or to the length of recruitment.

The study of diagnostic impact

The subgroup of patients involved in the study of diagnostic impact were enrolled during the final year of recruitment to the trial.[66] Using standardised questionnaires (Appendix 6), the recruiting clinicians made paired assessments at trial entry and follow-up appointments recording a diagnostic category, their diagnostic confidence (0–100%), the proposed management plan and confidence (0–100%) in the choice of management, and the expectations of imaging (establish or confirm diagnosis, assess extent or location of disease, exclude pathology, plan treatment). The second assessment was at the follow-up appointment after the time of imaging, if allocated, but without reference to the first assessment. For patients in the 'imaging' group,

clinicians assessed the contribution of imaging and stated their opinion on the scale of the contribution. Management plans were ordered by increasing degrees of intervention as follows: (1) discharge with reassurance; (2) further investigations only, for example, blood tests to exclude inflammatory or infectious disorders, bone scans or further lumbar spine imaging; (3) conservative treatment (including physiotherapy, manual therapy, lumbar support or medication); (4) injection therapy, for example epidural, facet; and (5) surgery or chemonucleolysis. In assessing changes from trial entry to follow-up, differences between the paired assessments were rated as more or less interventionist. For example, if the proposed treatment was changed from discharge to physiotherapy, this was classified as a change to 'more interventionist', whereas a change from surgery to injection therapy would be classified as a change to 'less interventionist'.

The study was conducted in both teaching and district general hospitals, and involved specialist spinal surgeons, general orthopaedic surgeons, a specialist orthopaedic physician and orthopaedic junior staff in the assessment of patients. Some patients were assessed by a different clinician at the follow-up appointment. Although limited by sample size, additional analyses were performed to assess the potential impact of these factors.

The study of therapeutic impact

Healthcare resource use is generally estimated by either data abstraction from medical records or by patient self-reported questionnaires or interviews, but neither method is entirely satisfactory.[67,68] The decision to use either patient-completed questionnaires or hospital case notes was informed by a small substudy (reported in detail in Appendix 7), which compared the data describing management of the first 116 patients over an 8-month period. The data were abstracted from questionnaires, hospital notes and the best available third source. Agreement was assessed using pairwise comparisons and discrepancies were investigated. The results showed that fewer data were available from questionnaires than from other sources. Where data were available from questionnaires, pairwise comparisons were made of data from all three sources and agreement between the data sources ranged from 73 to 96% with no method performing consistently better. However, questionnaires may be the only feasible method to collect some types of data (e.g. use of medications and consultations in primary care). As a general rule, therefore, data from case notes were used to provide estimates of care in secondary care and questionnaires were used as the source of data on primary care.

Details of healthcare within the NHS related to LBP, such as imaging, outpatient appointments and inpatient/outpatient procedures including surgery and injections, during the 2-year period after trial entry were collected retrospectively from hospital case notes. Information on physiotherapy was taken primarily from the patient self-report questionnaire and only taken from case notes if this was missing. Information on GP consultations, purchase of prescription and non-prescription medicines and lumbar supports, non-NHS treatment, for example, private physiotherapy, osteopathy and time off work/usual activities due to LBP, was obtained from patient questionnaires.

Impact on health

A wide variety of measures are available for outcome assessment in LBP research.[69–71] The validity, reliability and clinical utility of physical measures are uncertain[72–74] and have been shown to be only weakly associated with outcomes more pertinent to patients and society such as pain, function and work status.[75] For these reasons, after discussion with orthopaedic collaborators, we decided not to proceed with our original plan to include clinical assessment of patients at trial entry and follow-up to assess measures such as straight leg raising and lumbar spine mobility.

In order to assess the biopsychosocial complexity of LBP disorders,[71,73,74] well-validated and reliable multidimensional instruments are necessary. There is general consensus that the combination of a generic health status measure, to provide a summary of overall health, and a more sensitive condition-specific measure is required.[76–78] The ALBP score was chosen as it was considered to have greater sensitivity to change.[77] The ALBP score is a condition-specific questionnaire developed through review of the clinical literature and consultation with clinicians.[60] It assesses the health status of patients with LBP across several dimensions, including pain, physical impairment and functional disability. Responses to the 19 questions are summed and converted to a percentage score from 0 (least disabled) to 100 (most severely disabled). It has been rigorously validated against the SF-36 and is more responsive to clinical change.[77]

The SF-36 was included as a measure of general health status. It is a 36–item generic multidimensional health status questionnaire, which has been shown to be a reliable and valid instrument in assessing functional status and is widely used.[80–84] It assesses health on eight subscales each scored from 0 (worst health) to 100 (best health): physical functioning; social functioning; role–physical; role–emotional; mental health; vitality; bodily pain; and general health. Patients with LBP have been shown to have lower scores than normal on all eight subscales.[70,83,85] An additional unscaled item – reported health transition – assesses health change over the past year.

The EQ-5D is a generic measure of health status that was specifically developed for the derivation of quality-adjusted life-years (QALYs)[75,86] and it has been used successfully in studies of LBP.[87,88] This is discussed further in the section on economic evaluation in Chapter 3.

Chapter 3
Results

Recruitment

The trial involved 22 orthopaedic surgeons, two orthopaedic physicians and one neurosurgeon, working in seven teaching hospitals and eight district general hospitals.

Between November 1996 and June 1999, eligibility assessment forms were completed for 2657 patients, 782 (29%) of whom were recruited into the randomised comparison. Patient recruitment at each centre started in a rolling programme over a period of 18 months as shown in *Figure 2*. Patient recruitment from each centre to the RCT is shown in *Figure 3* and overall recruitment in *Figure 4*.

Changes in the funding of non-commercial research and development in the NHS[89] and in the procedure for applications to research ethics committees[90] delayed the start of recruitment at some centres.[91] These delays led to discussions with the NCCHTA and resulted in the study being extended overall for an additional 6 months. In common with many RCTs, the initial rate of recruitment was less than the rate expected. In Aberdeen it had been estimated that approximately seven patients per week would be eligible for the study, but in the first 3 months only 22 patients had been recruited into the trial. This led to modification of the patient assessment form, provision of a trial information pack for junior staff and the appointment of a trial research assistant to facilitate patient assessment as a standard practice in the outpatient clinic. This led to improved rates of recruitment. As a consequence, research nurses were funded on a sessional or pro rata basis to assist with patient recruitment at all collaborating centres.

Figure 5 summarises the reasons for non-recruitment. Of the 1875 not recruited into the trial, 1772 (95%) were found to be ineligible: 613 (33%) were judged to require 'immediate' referral for imaging, for 78 (4%) imaging was considered clearly not indicated, a further 214 (11%) had had previous imaging and so were also not eligible, 687 (37%) were discharged back to primary care with no further outpatient care and 104 (6%) had pain that was thought not to be spinal in origin. Of 885 eligible patients, 103 were not recruited: 74 declined and 29 were not formally approached. *Table 1* compares the clinical categories of those referred for imaging with those recruited. Symptomatic disc herniation predominates in the former and chronic LBP in the latter.

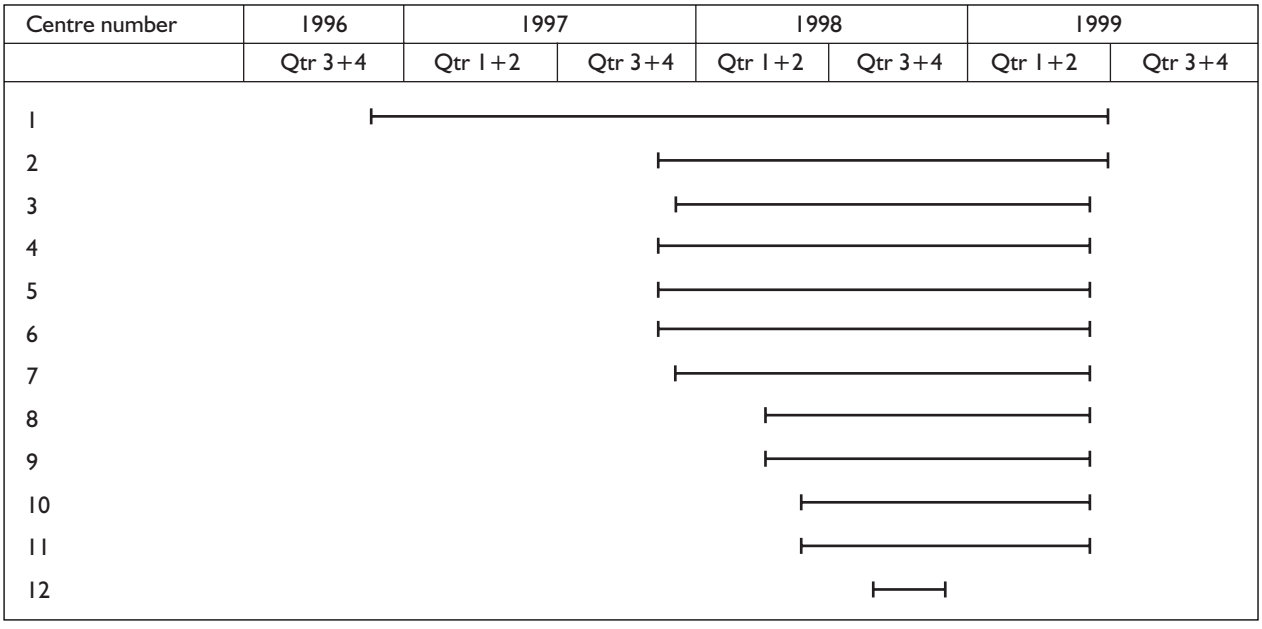

FIGURE 2 *Timescale of patient recruitment at each centre*

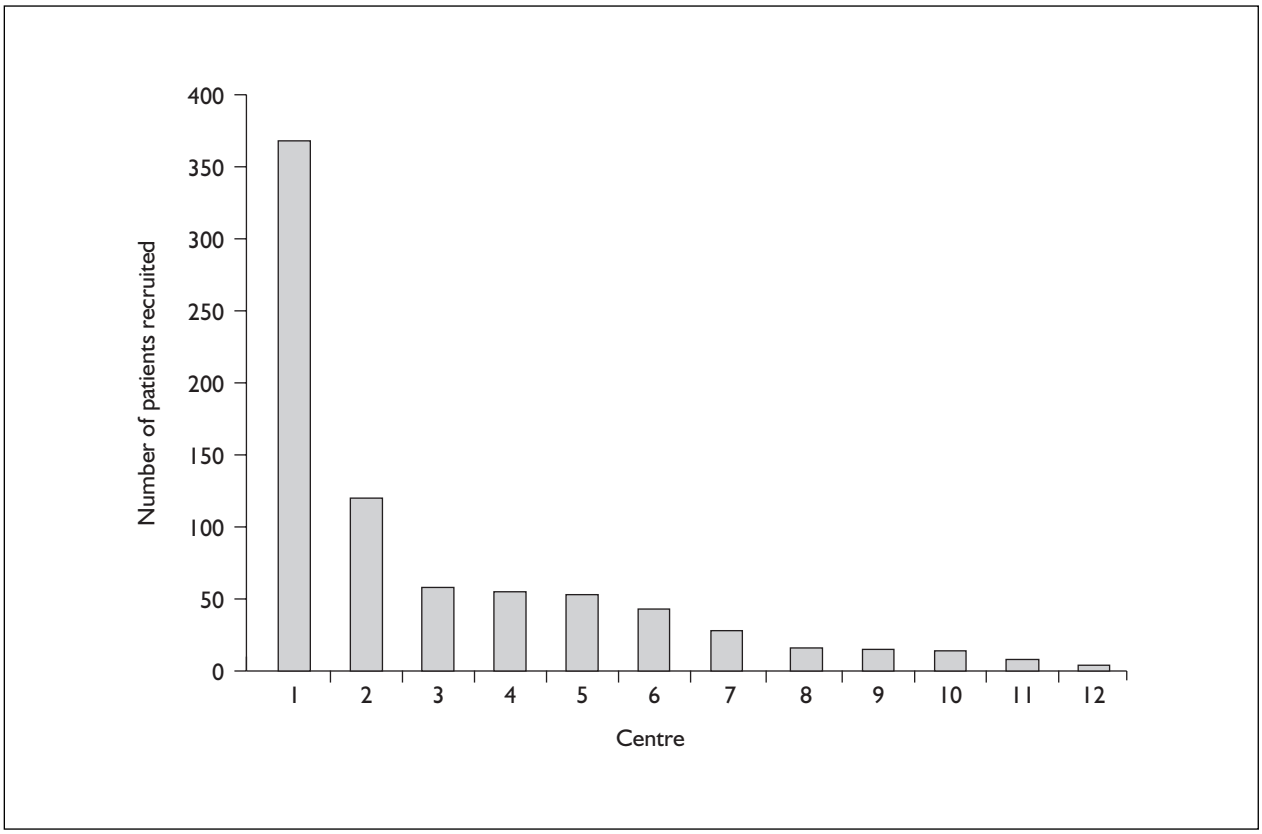

FIGURE 3 *Patient recruitment at each centre*

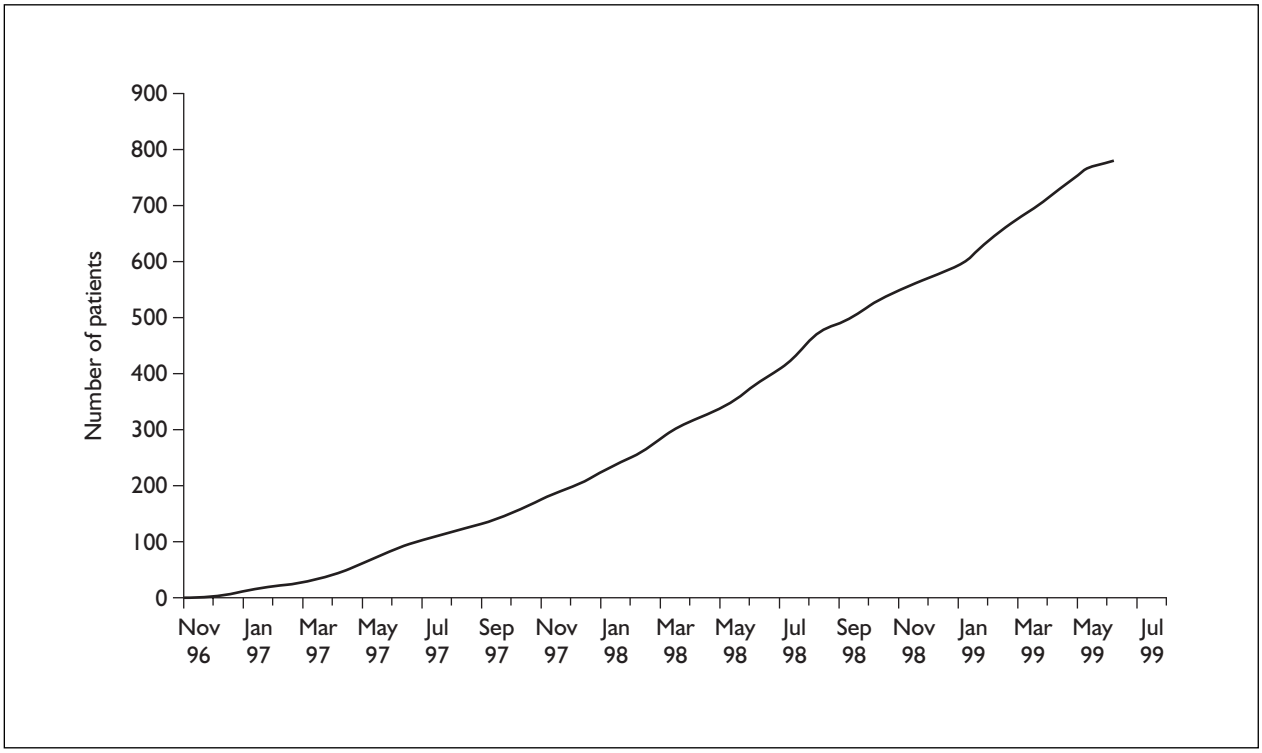

FIGURE 4 *Patient recruitment*

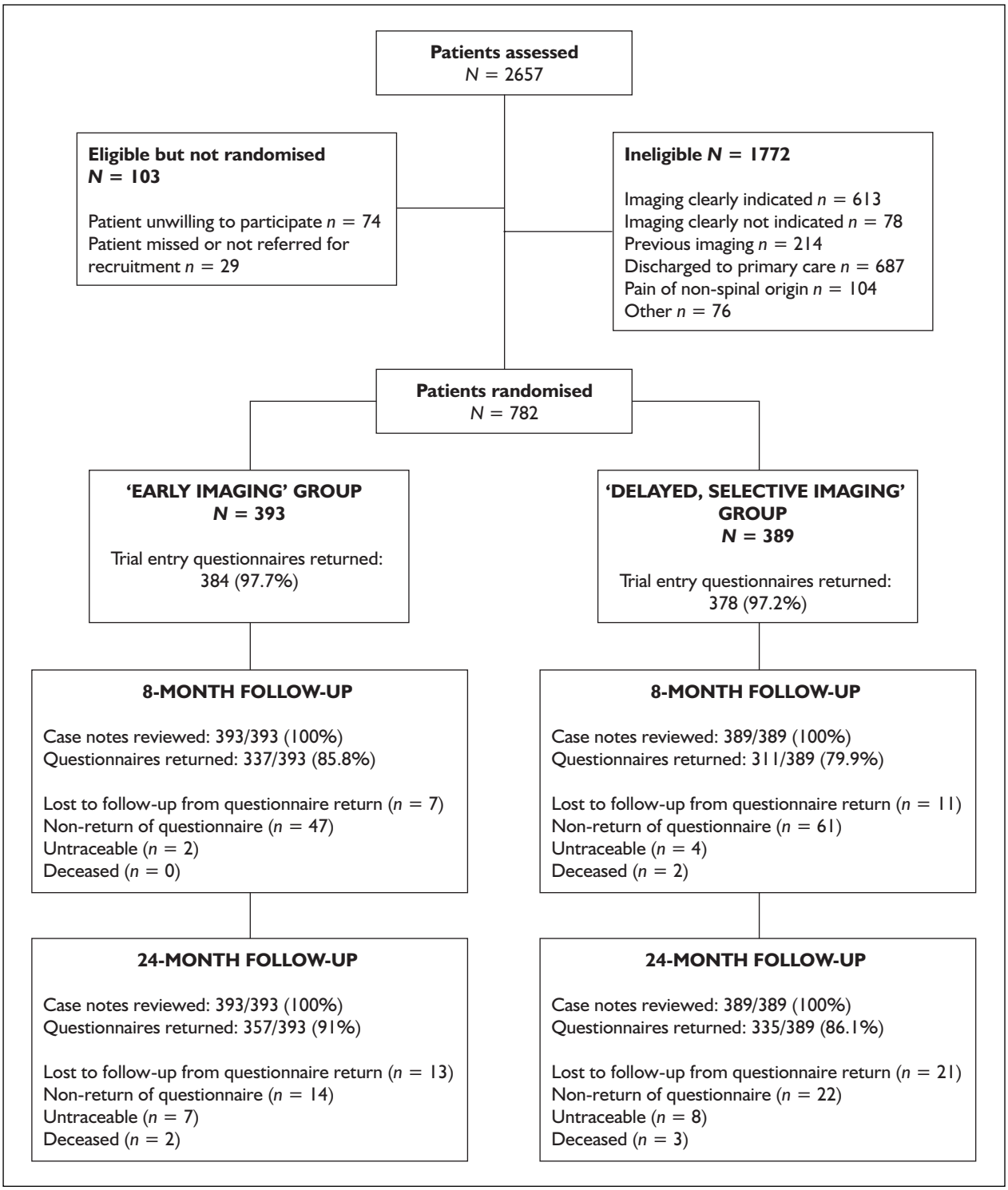

FIGURE 5 *Participant progress through trial*

Recruitment and characteristics of the trial groups at entry

The number of patients formally recruited was 782 (88% of those eligible), 393 randomly allocated 'early imaging' and 389 'delayed, selective imaging'. The demographic and clinical characteristics of the participants in the two trial groups were similar at entry with respect to age, sex and diagnostic category (*Table 2*). The duration of the current episode of LBP tended to be shorter in the 'early imaging' group. There was also a baseline imbalance in health status with patients in the 'early imaging' group

TABLE 1 *Clinical categories of patients ineligible for the randomised trial and referred for MR or CT imaging compared with trial patients*

Clinical category	Ineligible patients referred for imaging *N* = 613 (%)	RCT patients *N* = 782 (%)
Symptomatic disc protrusion	204 (33)	147 (19)
Root entrapment secondary to degenerative disease	82 (13)	92 (12)
Neurogenic claudication	33 (5)	12 (2)
Chronic LBP	108 (18)	481 (62)
Other LBP	52 (8)	50 (6)
Not known	134 (22)	0
Total	613	782

TABLE 2 *Description of groups at trial entry*

	Randomised treatment	
	Early	Delayed, selective
Total no. of patients recruited	393	389
Age[a]: mean (SD)[b] (years)	43.9 (13.3)	42.8 (12.9)
Sex[a]: *n* (%)		
Male	193 (49.1)	190 (48.8)
Female	200 (50.9)	199 (51.2)
Occupation: *n* (%)		
Manual	147 (37.4)	134 (34.4)
Non-manual	85 (21.6)	75 (19.3)
Not working/unemployed	135 (34.4)	152 (39.1)
Retired	24 (6.1)	24 (6.2)
Not known	2 (0.5)	4 (1.0)
Diagnostic category[a]: *n* (%)		
(1) Symptomatic lumbar disc protrusion	73 (18.6)	74 (19.0)
(2) Root entrapment secondary to degenerative disease	50 (12.7)	43 (11.1)
(3) Neurogenic claudication	3 (0.8)	8 (2.1)
(4) Chronic LBP not covered by the above categories	242 (61.6)	239 (61.4)
(5) Other, not covered by the above categories	25 (6.4)	25 (6.4)
Duration of current episode: *n* (%)		
<3 months	83 (21.1)	56 (14.4)
3–12 months	158 (40.2)	167 (42.9)
>12 months	149 (37.9)	163 (41.9)
Not known	3 (0.8)	3 (0.8)
History of back pain: *n* (%)		
Yes	364 (92.6)	369 (94.9)
No	22 (5.6)	13 (3.3)
Variable	4 (1.0)	5 (1.3)
Not known	3 (0.8)	2 (0.5)
Previous lumbar spine X-ray		
Yes	343 (87.3)	331 (85.1)
No	47 (12.0)	52 (13.4)
Not known	3 (0.8)	6 (1.5)

continued

TABLE 2 *Description of groups at trial entry (cont'd)*

	Randomised treatment	
	Early	**Delayed, selective**
Previous treatment this episode: *n* (%)		
Physiotherapy	253 (64.4)	271 (69.7)
Osteopathy	87 (22.1)	89 (22.9)
Other	64 (16.3)	87 (22.4)
No. returning baseline questionnaire: *n* (%)	384 (97.7)	378 (97.2)
ALBP score: mean (SD)[c]	38.33 (15.0)	40.94 (16.0)
EQ-5D: mean (SD)[d]	0.48 (0.3)	0.44 (0.3)
SF-36 score: mean (SD)[e]		
Physical Functioning	49.13 (26.1)	45.28 (26.4)
Social Functioning	57.25 (27.7)	53.37 (28.8)
Mental Health	64.85 (19.1)	61.97 (20.9)
Vitality	46.64 (20.8)	42.14 (22.3)
Bodily Pain	31.60 (19.7)	29.67 (18.8)
General Health Perception	61.48 (20.2)	58.41 (22.5)
Role–Physical Functioning	25.29 (37.2)	23.00 (36.8)
Role–Emotional Functioning	58.86 (44.6)	49.68 (45.9)
Reported Health Transition[f]	38.97 (21.2)	35.90 (21.1)

[a] Allocation by minimisation using these factors. Minimisation was stratified by consultant surgeon.
[b] SD = standard deviation.
[c] A lower value for this score indicates less pain (scored from 0 to 100).
[d] A higher value for this score indicates better health (scored from –0.59 to 1).
[e] A higher value for this score indicates better health (scored from 0 to 100).
[f] Each questionnaire compares health today with 1 year ago.

having on average better scores on each of the nine SF-36 subscales, the ALBP score and the EQ-5D.

Data collection and completeness of follow-up

Data collection and follow-up rates are also shown in *Figure 5*. Although the majority of participants completed their trial entry questionnaire in the outpatient clinic at the time of recruitment, some requested to complete the questionnaire at home and return it in a pre-paid reply envelope. Twenty patients (3%) failed to return these. Hospital case notes were successfully retrieved for all 782 participants. All relevant available information was extracted, distinguishing between events before 8 months and events between 8 and 24 months after trial entry. Overall, 648/782 (83%) participants completed follow-up questionnaires at 8 months and 692/782 (88%) at 24 months. By 24 months, 34 had formally withdrawn, 15 were untraceable and five had died. Only 36 other participants did not return their follow-up questionnaire. Response analysis showed no clear differences in the clinical characteristics (age, sex, diagnostic category) at trial entry between those patients who returned follow-up questionnaires at 8 and 24 months and those who did not.

Use of MRI and CT imaging in the trial groups

Review of case notes and radiology department records showed that by 24 months after trial entry 353 (90%) participants in the 'early imaging' group and 115 (30%) in the 'delayed, selective imaging' group had received imaging (*Table 3*). The ratio of MRI to CT was 11:1 in the 'early imaging' group and 5:1 in the 'delayed, selective imaging' group. In the 'early imaging' group, 19 patients had no record of a request for imaging in the case notes or in radiology department records, 12 patients cancelled or did not attend their imaging appointment, two were pregnant, two suffered from claustrophobia and the radiologist

TABLE 3 *Actual use of imaging to 24 months after trial entry*

	Early ***N* = 393**	**Delayed, selective** ***N* = 389**
No. with case notes reviewed at 8 months: *n* (%)	393 (100.0)	389 (100.0)
No. with case notes reviewed at 24 months: *n* (%)	393 (100.0)	389 (100.0)
No. imaged at least once: *n* (%)[a]	353 (89.8)	115 (29.6)
MRI imaging: *n* (%)	324 (82.4)	95 (24.4)
CT imaging: *n* (%)	29 (7.4)	20 (5.1)
Time to first imaging: median (IQR) (weeks)[a,b]	4.14 (2.57–9.61)	20.14 (10.43–34.57)

[a] Only MRI and CT count as imaging.
[b] Includes only those having imaging.

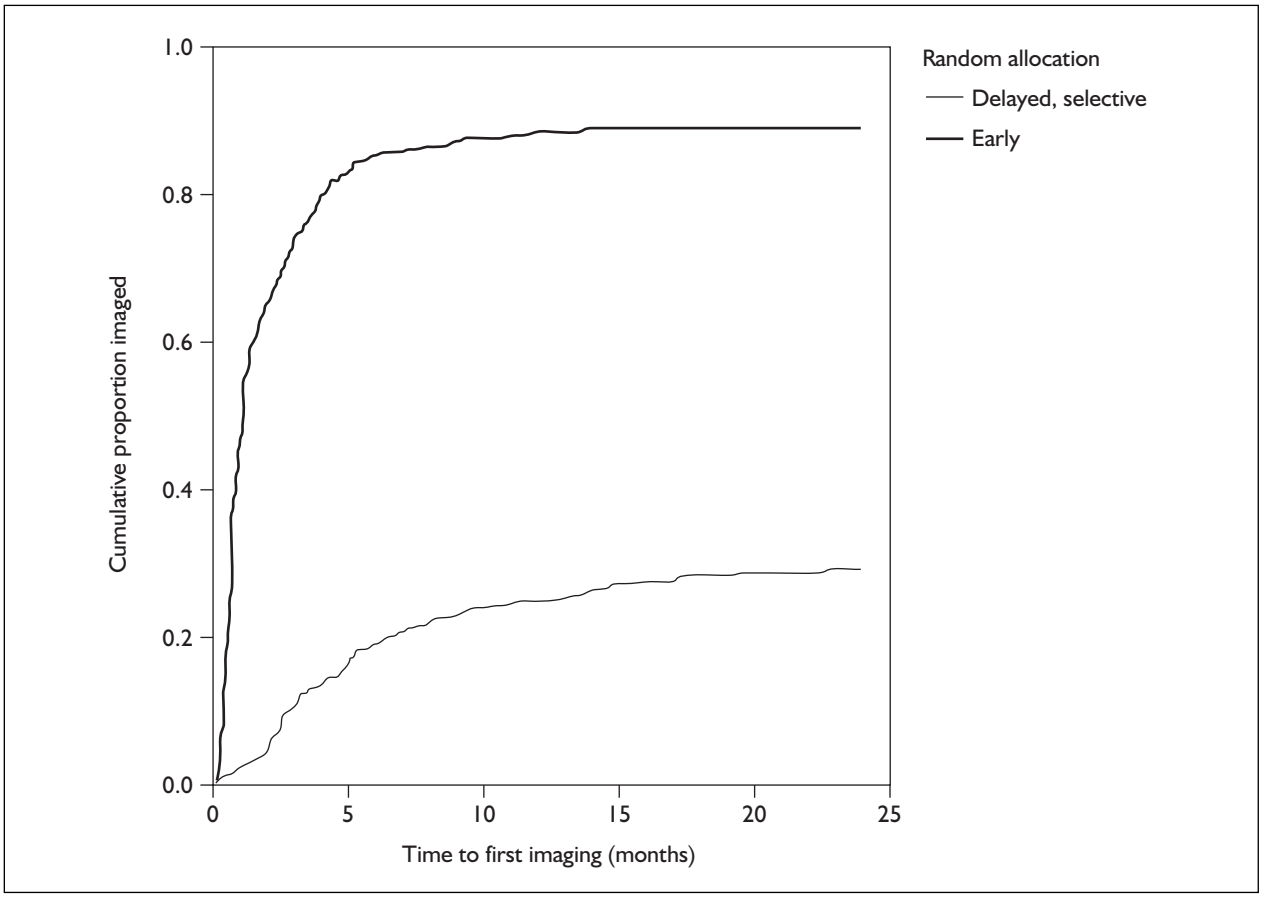

FIGURE 6 *Time to first imaging*

cancelled imaging requests for two patients. The median time to first imaging (including only those imaged) in the two trial groups was 4.14 weeks in the 'early imaging' group and 20.14 weeks in the 'delayed, selective imaging' group. *Figure 6* describes graphically the timing of the first imaging in the two trial groups. The majority of those allocated 'early imaging' received imaging within 3 months of trial entry, whereas it was later amongst those imaged in the 'delayed, selective imaging' group. By 8 months, 88% in the imaged group and 24% in the delayed group had received imaging. The numbers imaged for the first time after 8 months were 2 and 6%, respectively.

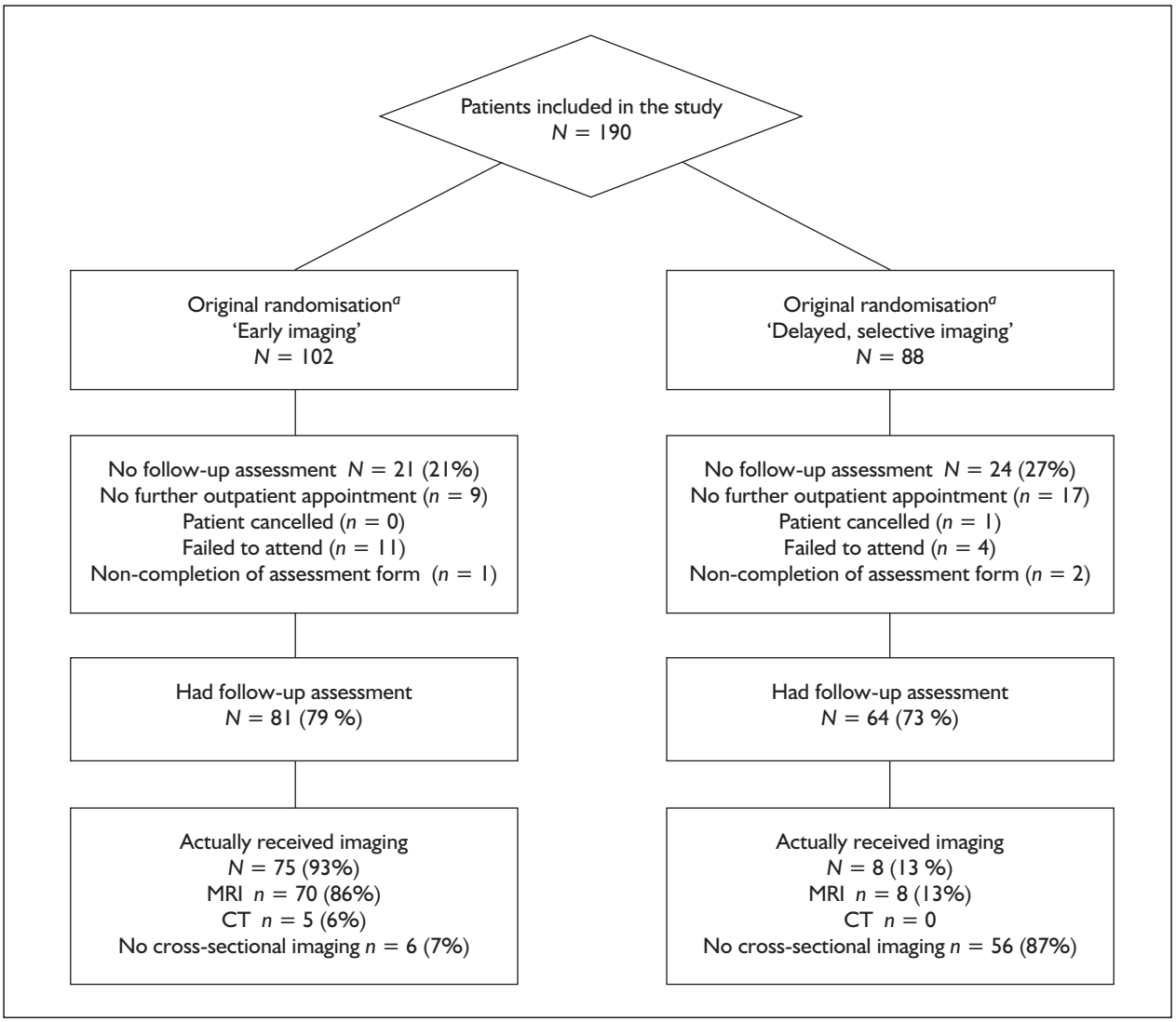

FIGURE 7 *Flowchart describing patients' progress through the diagnostic impact study. ([a]Only a subgroup of the clinicians in the RCT participated in this study. The randomisation incorporated stratification and minimisation; this ensured balance in respect of a number of prognostic variables. The difference in the total numbers in the two groups reflects small differences within the strata, characterised by surgeon.)*

Diagnostic impact

The diagnostic impact study conducted during the final 12 months of recruitment involved clinicians at nine of the participating centres and 190 participants who had been recruited into the RCT.

Both trial entry and follow-up diagnostic impact assessment forms were available for 145 out of the original 190 participants. The progress of participants through this study is shown in *Figure 7*. The clinical characteristics of the 190 participants recruited, the 45 lost to follow-up and the 145 for whom completed follow-up assessment forms were available are shown in *Table 4*. Response analysis showed no statistically significant differences in the clinical characteristics (age, sex, diagnostic category) at trial entry between those participants who completed the study and those lost to follow-up. Of those with follow-up assessments, 81 (56%) were from the 'early imaging' arm of the trial and 64 (44%) from the 'delayed, selective imaging' arm. Some forms were incomplete, usually owing to omission of diagnostic confidence scores, and the numbers in each of the data tables vary accordingly. There was no significant difference in the median time interval between trial entry and follow-up appointments for the two study groups. Similarly, there were no differences in whether it was the same or a different person who did the assessment or in whether or not the form was completed at the time of the second assessment.

TABLE 4 *Characteristics of participants in the diagnostic impact study*

	Randomised and follow-up assessment			
	All randomised (*N* = 190)	**Lost to follow-up (*N* = 45)**	**'Early imaging' (*N* = 81)**	**'Delayed, selective imaging' (*N* = 64)**
Age: mean (SD) (years)	43.6 (12.9)	41.9 (13.8)	43.84 (13.0)	44.39 (12.0)
Sex: *n* (%)				
Male	97 (51.1)	20 (44.4)	44 (54.3)	33 (51.6)
Female	93 (48.9)	25 (55.6)	37 (45.7)	31 (48.4)
Diagnostic category: *n* (%)				
Symptomatic lumbar disc protrusion	40 (21.1)	9 (20.0)	18 (22.2)	13 (20.3)
Root entrapment	25 (13.2)	5 (11.1)	11 (13.6)	9 (14.1)
Neurogenic claudication	4 (2.1)	0	2 (2.5)	2 (3.1)
Chronic LBT	101 (53.2)	29 (64.4)	38 (46.9)	34 (53.1)
Other[a]	20 (10.5)	2 (4.4)	12 (14.8)	6 (9.4)
Time interval between assessments: median (IQR) (days)			87 (54, 126)	70 (42, 98)
Assessor of two assessments: *n* (%)				
Same			63 (77.8)	53 (82.8)
Different			18 (22.2)	11 (17.2)
Time form completed: *n* (%)				
At time of second assessment			50 (61.7)	37 (57.8)
Retrospective			31 (38.3)	27 (42.2)

[a] Other categories of LBP include spondylosis, spondylolisthesis, spinal stenosis, sacroiliitis, pathological fracture and osteoporosis.

TABLE 5 *Changes in diagnosis and diagnostic confidence between trial entry and follow-up assessments*

	Original randomisation		
	'Early imaging' (max. *N* = 81)	**'Delayed, selective imaging' (max. *N* = 63)**	**Chi-squared between-groups *p*-value**
Diagnosis altered: *n* (%)			
Yes	35 (43.2)	34 (54.0)	0.27
No	46 (56.8)	29 (46.0)	
Change in diagnostic confidence: *n* (%)			
Increased confidence	57 (73.1)	27 (47.4)	0.01
No impact	13 (16.7)	18 (31.6)	
Decreased confidence	8 (10.3)	12 (21.1)	
Median % change in diagnostic confidence between trial entry and follow-up assessments (IQR)	10 (0, 20)	0 (0, 11.3)	
p-Value[a]	<0.001	0.017	

[a] Wilcoxon signed rank test for within-group change in diagnostic confidence between trial entry and follow-up assessments.

At follow-up, changes in diagnostic category were reported for 35/81 (43%) in the 'early imaging' group and 34/63 (54%) in the 'no imaging' group ($p = 0.265$; *Table 5*) (difference = –11%; 95% CI difference for = –27 to 6%, $\chi^2 = 1.24$. Although there was an overall increase in diagnostic confidence between trial entry and follow-up in both groups, this was significantly greater in the 'early imaging' group (73% versus 47%; difference = 26%, 95% CI for difference = 9 to 41%, $\chi^2 = 9.28$, $p = 0.01$) (*Table 5*).

TABLE 6 *Changes in treatment and therapeutic confidence between trial entry and follow-up assessments*

	Original randomisation		
	'Early imaging' (max. *N* = 77)	**'Delayed, selective imaging' (max. *N* = 62)**	**Chi-squared between-groups *p*-value**
Treatment altered: *n* (%)			
Yes	39 (50.6)	29 (46.8)	0.73
No	38 (49.4)	33 (53.2)	
Change in proposed treatment: *n* (%)[a]			
Change to less invasive	27 (35.1)	18 (29.0)	0.75
No change	38 (49.4)	33 (53.2)	
Change to more invasive	12 (15.6)	11 (17.7)	
Change in therapeutic confidence: *n* (%)			
Increased confidence	30 (56.6)	23 (65.7)	0.65
No impact	13 (24.5)	6 (17.1)	
Decreased confidence	10 (18.9)	6 (17.1)	
Median % change in therapeutic confidence between trial entry and follow-up assessments (IQR)	10 (0, 20)	10 (0, 30)	
p-Value[b]	0.001	0.001	

[a] Classified as described in Chapter 2: 1 = discharge (least invasive); 2 = further investigations; 3 = conservative therapy; 4 = injection therapy; 5 = surgical therapy (most invasive).
[b] Wilcoxon signed rank test for within-group change in therapeutic confidence between trial entry and follow-up assessments.

There was no significant difference between the groups in relation to changes in management plans (*Table 6*). Management plans were unchanged for approximately 50% of patients in both groups and where treatment plans were altered, approximately one-third of patients in each group had their management changed to a less interventionist treatment. There was a statistically significant increase in therapeutic confidence between trial entry and follow-up in both groups ($p = 0.001$) but no significant difference between the groups in this respect.

Contribution of imaging to management

The expected contribution of imaging was most frequently confirmation of diagnosis (33%), with establishment of a diagnosis, assessment of the extent or location of the disease and exclusion of pathology all expected with similar frequencies (each approximately 20%). In contrast, imaging was expected to contribute to the planning of treatment in less than 5% of participants. Amongst those allocated imaging, the actual contribution to the management plan was rated as considerable for more than one-third of participants, moderate for 25% and minor 27%, with no contribution for 10% of participants. The actual contributions cited were confirmation of diagnosis 37%, exclusion of pathology 35%, establishment of diagnoses 12%, assessment of disease location/extent 7% and planning of treatment 9%.

The influence of clinician experience on diagnostic impact

A secondary analysis comparing specialist and non-specialist spinal surgeons revealed a statistically significant difference in changes in diagnosis for participants in the 'no imaging' group. Diagnostic category was altered in 6/21 (29%) cases assessed by a spinal specialist compared with 28/42 (67%) cases assessed by non-specialists ($\chi^2 = 6.72$, $p = 0.007$). In the 'early imaging' group, diagnostic category was similarly altered, but this was not statistically significant ($\chi^2 = 1.99$, $p = 0.16$). Trial analyses stratified by whether or not the surgeon was a specialist showed no statistically significant difference between the trial groups in changes in diagnostic category, diagnostic confidence or management plan between trial entry and follow-up, emphasising the value of the control group. A similar analysis stratified according to whether or not the same clinician, regardless of level of experience or expertise, had performed both assessments also

TABLE 7 *Management received in 0–24 months (based on case note review and patient questionnaires)*

	Early (*N* = 393)	Delayed, selective (*N* = 389)
Outpatient consultations: *n* (%)		
Yes	328 (83.5)	264 (67.9)
No	49 (12.5)	95 (24.4)
Did not attend	16 (4.1)	30 (7.7)
No. of consultations[a] (those who consulted): mean (SD)	2.29 (1.8)	2.77 (3.2)
No. of consultations[a] (all patients): mean (SD)	1.91 (1.9)	1.88 (3.0)
Physiotherapy: *n* (%)[b]		
Yes	248 (63.1)	233 (59.9)
No	134 (34.1)	144 (37.0)
Referred	5 (1.3)	6 (1.5)
Did not attend	6 (1.5)	6 (1.5)
No. of sessions[a] (those who consulted): mean (SD)	6.56 (9.1)	5.52 (9.5)
No. of sessions[a] (all patients): mean (SD)	4.13 (7.9)	3.31 (7.8)
Admitted to hospital: *n* (%)		
No	362 (92.1)	363 (93.3)
Yes	31 (7.9)	26 (6.7)
No. of visits: *n* (%)		
1	28 (90.3)	20 (76.9)
2	2 (6.5)	6 (23.1)
3	0	0
4	1 (3.2)	0
Length of hospital stay (days) (for those who were admitted): mean (SD)	7.32 (4.1)	9.13 (5.9)
Surgery: *n* (%)		
Yes	27 (6.9)	20 (5.1)
No	364 (92.6)	363 (93.3)
Waiting list/referred	1 (0.3)	3 (0.8)
Referred but patient declined	1 (0.3)	2 (0.5)
Referred but no evidence in notes	0	1 (0.3)
Injections: *n* (%)		
Yes	70 (17.8)	76 (19.5)
No	320 (81.4)	313 (80.5)
Referred but no evidence in notes	1 (0.3)	0
Did not attend	2 (0.5)	0

continued

showed no statistically significant difference between the trial groups in respect of changes in diagnostic category, management plans or diagnostic and therapeutic confidence.[66]

Therapeutic impact

The clinical management received by the full 782 participants in the 24 months following trial entry is shown in *Table 7*. Based on case note review, a larger proportion of participants in the 'early imaging' group had a subsequent outpatient appointment (difference 15.6%; 95% CI for difference = 9.7 to 21.5%, $p < 0.001$).

However, consultation was less frequent in the early group and hence the mean number of consultations in each group was similar (mean 1.91 versus 1.88).

About 60% of both groups had NHS-provided physiotherapy. There was no detectable difference in hospital admission (7.9 versus 6.7%; difference 1.2%; 95% CI –2.4 to 4.9%, $p = 0.52$) in surgery (6.9 versus 5.1%; difference 1.7%; 95% CI –1.6 to 5.1%, $p = 0.31$) or use of injections (17.8 versus 19.3%; 95% CI –7.2 to 3.7%, $p = 0.54$).

Based on responses to questionnaires, there was also no difference detected in privately arranged

TABLE 7 *Management received in 0–24 months (based on case note review and patient questionnaires) (cont'd)*

	Early (*N* = 393)	Delayed, selective (*N* = 389)
Private physiotherapist/osteopath/chiropractor: *n* (%)		
Yes	81 (22.0)	94 (26.9)
No	288 (78.0)	255 (73.1)
No. of sessions: mean (SD)	1.51 (4.9)	1.23 (3.1)
Back support/corset/brace: *n* (%)		
Yes	111 (30.2)	102 (29.1)
No	257 (69.8)	248 (70.9)
GP consultations: *n* (%)		
Yes	261 (70.7)	244 (70.1)
No	108 (29.3)	104 (29.9)
No. of consultations (those who consulted): mean (SD)	8.36 (11.0)	9.65 (13.9)
No. of consultations (all patients): mean (SD)	5.70 (9.9)	6.52 (12.2)
Prescription medicines: *n* (%)		
Yes	261 (70.9)	240 (69.0)
No	107 (29.1)	108 (31.0)
Bought medicines: *n* (%)		
Yes	150 (40.8)	146 (42.2)
No	218 (59.2)	200 (57.8)
Taken time off work: *n* (%)		
Yes	156 (46.0)	142 (44.9)
No	183 (54.0)	174 (55.1)

[a] Imputation used where number missing for 0–8 or 9–24 months.
[b] Response taken from questionnaires and only taken from case notes if missing on patient questionnaire.

physical therapy, the use of back support, GP consultations, medicine prescription, medicines bought over the counter and the proportion who had taken time off work.

Table 8 gives information about the timing of treatments. It shows management in the first phase of follow-up at 8 months, and then during the second phase of follow-up at 9–24 months. In contrast to the first 8 months when there were significantly more consultations in the 'early group', there were somewhat fewer in the 'early group' during the 9–24 month period. In both trial groups, the more conservative managements, such as NHS physiotherapy and injections, were concentrated in the first 8 months. In contrast, hospital admission, surgery, non-NHS physical therapy, use of a back support, GP consultations, prescription medicines and over-the-counter medicines were equally common in the two time periods. There were no differences between the trial groups in these respects.

Impact on health

Table 9 shows the results for the principal measures of outcome – ALBP score, SF-36 score and EQ-5D – first at 8 months and then at 24 months. Overall, the changes in scores from baseline show improvement at 8 months in both trial groups with further improvement between 8 and 24 months.

The actual scores were generally 'better' (higher EQ-5D and SF-36 scores and lower ALBP score) in the 'early imaging' group at both 8 and 24 months. However, some of this difference reflected differences at baseline (which favoured the 'early imaging' group). Also, these comparisons do not take into account the effects of minimisation at trial entry (for age, sex, clinical category and consultant responsible for care). Analyses adjusted for all these factors are presented in *Table 10*. The adjusted difference in the mean ALBP score was –3.05 (95% CI –5.16 to –0.95, $p = 0.005$) at 8 months and –3.62 (95% CI –5.92 to –1.32,

TABLE 8 *Management received in 0–8 and 9–24 months (based on case note review)*

	0–8 months		9–24 months	
	Early (*N* = 393)	**Delayed, selective (*N* = 389)**	**Early (*N* = 393)**	**Delayed, selective (*N* = 389)**
No. with case notes reviewed: *n* (%)	393 (100.0)	389 (100.0)	393 (100.0)	389 (100.0)
Outpatient consultations: *n* (%)				
Yes	319 (81.2)	254 (65.3)	94 (23.9)	104 (26.7)
No	58 (14.8)	103 (26.5)	293 (74.6)	277 (71.2)
Did not attend	16 (4.1)	32 (8.2)	6 (1.5)	8 (2.1)
No. of consultations (those who consulted): mean (SD)	1.71 (1.0)	1.89 (1.4)	2.20 (1.6)	2.41 (2.9)
No. of consultations (all patients): mean (SD)	1.39 (1.1)	1.23 (1.5)	0.53 (1.2)	0.65 (1.8)
Physiotherapy: *n* (%)[a]				
Yes	228 (58.0)	201 (51.7)	95 (24.2)	89 (22.9)
No	153 (38.9)	174 (44.7)	296 (75.3)	300 (77.1)
Referred	5 (1.3)	8 (2.1)	2 (0.5)	0
Did not attend	7 (1.8)	6 (1.5)	0	0
No. of sessions (those having physiotherapy): mean (SD)	6.03 (7.7)	5.20 (7.0)	9.04 (8.0)	9.71 (13.2)
No. of sessions (all patients): mean (SD)	3.42 (6.5)	2.57 (5.6)	1.19 (4.2)	1.27 (5.8)
Admitted to hospital: *n* (%)				
No	374 (95.2)	374 (96.1)	378 (96.2)	377 (96.9)
Yes	19 (4.8)	15 (3.9)	15 (3.8)	12 (3.1)
No. of admissions: *n* (%)				
1	18 (94.7)	11 (73.3)	14 (93.3)	11 (91.7)
2	1 (5.3)	4 (26.7)	1 (6.7)	1 (8.3)
Length of hospital stay (days) (for those who were admitted): mean (SD)	5.79 (3.0)	9.50 (6.9)	7.80 (3.38)	7.92 (3.96)
Surgery: *n* (%)				
Yes	14 (3.6)	9 (2.3)	14 (3.6)	11 (2.8)
No	379 (96.4)	378 (97.2)	377 (95.9)	373 (95.9)
Referred but patient declined	0	1 (0.3)	1 (0.3)	4 (1.0)
Referred but no evidence in notes	0	1 (0.3)	1 (0.3)	1 (0.3)
Injections: *n* (%)				
Yes	55 (14.0)	63 (16.2)	30 (7.6)	33 (8.5)
No	337 (85.8)	324 (83.5)	361 (91.9)	355 (91.3)
Referred but no evidence in notes	0	1 (0.3)	1 (0.3)	1 (0.3)
Did not attend	1 (0.3)	0	1 (0.3)	0
Missing data	0	1	0	0
No. returning 8-month questionnaires: *n* (%)	337 (85.8)	311 (79.9)	357 (90.8)	335 (86.1)
Private physiotherapist/osteopath/chiropractor: *n* (%)				
Yes	49 (14.5)	57 (18.3)	61 (17.1)	66 (19.7)
No	283 (84.0)	252 (81.0)	286 (80.1)	266 (79.4)
Not known	5 (1.5)	2 (0.6)	10 (2.8)	3 (0.9)
No. of sessions: mean (SD)	0.83 (3.6)	0.71 (2.3)	0.84 (2.9)	0.65 (1.9)
Back support/corset/brace: *n* (%)				
Yes	83 (24.6)	70 (22.5)	71 (19.9)	75 (22.4)
No	252 (74.8)	236 (75.9)	275 (77.0)	258 (77.0)
Not known	2 (0.6)	5 (1.6)	11 (3.1)	2 (0.6)
GP consultations: *n* (%)				
Yes	199 (59.1)	177 (56.9)	192 (53.8)	182 (54.3)
No	133 (39.5)	128 (41.2)	152 (42.6)	148 (44.2)
Not known	5 (1.5)	6 (1.9)	13 (3.6)	5 (1.5)

continued

TABLE 8 *Management received in 0–8 and 9–24 months (based on case note review) (cont'd)*

	0–8 months		9–24 months	
	Early (*N* = 393)	**Delayed, selective (*N* = 389)**	**Early (*N* = 393)**	**Delayed, selective (*N* = 389)**
No. of consultations (those who consulted): mean (SD)	4.97 (6.2)	5.10 (4.7)	7.40 (10.2)	9.41 (14.3)
No. of consultations (all patients): mean (SD)	2.77 (5.3)	2.71 (4.2)	3.66 (8.0)	4.64 (11.1)
Prescription medicines: *n* (%)				
Yes	216 (64.1)	197 (63.3)	192 (53.8)	189 (56.4)
No	115 (34.1)	110 (35.4)	154 (43.1)	142 (42.4)
Not known	6 (1.8)	4 (1.3)	11 (3.1)	4 (1.2)
Bought medicines: *n* (%)				
Yes	101 (30.0)	105 (33.8)	105 (29.4)	93 (27.8)
No	223 (66.2)	196 (63.0)	235 (65.8)	229 (68.4)
Not known	13 (3.9)	10 (3.2)	17 (4.7)	13 (3.9)
Taken time off work: *n* (%)				
Yes	130 (38.6)	121 (38.9)	53 (14.8)	61 (18.2)
No	181 (53.7)	158 (50.8)	161 (45.1)	155 (46.3)
Not known	26 (7.7)	32 (10.3)	143 (40.1)	119 (35.5)

[a] Primary data source was questionnaire: response only taken from case notes if missing on patient-answered questionnaire.

TABLE 9 *ALBP, SF-36 and EQ-5D scores at 8 and 24 months*

	8 months Randomised treatment		24 months Randomised treatment	
	Early (*N* = 393)	**Delayed, selective (*N* = 389)**	**Early (*N* = 393)**	**Delayed, selective (*N* = 389)**
No. returning questionnaires: *n* (%)	337 (85.8)	311 (79.9)	357 (90.8)	335 (86.1)
No. withdrawn: *n* (%)	9 (2.3)	17 (4.4)	22 (5.6)	32 (8.2)
ALBP score: mean (SD)[a]	32.67 (17.4)	36.98 (19.8)	31.63 (19.0)	35.75 (20.8)
EQ-5D: mean (SD)[b]	0.56 (0.3)	0.53 (0.3)	0.60 (0.3)	0.54 (0.3)
SF-36 score: mean (SD)[c]				
Physical Functioning	54.08 (27.5)	50.38 (29.7)	56.38 (28.5)	52.84 (29.9)
Social Functioning	64.50 (28.1)	58.47 (31.1)	66.36 (28.9)	61.83 (30.0)
Mental Health	65.52 (19.3)	62.26 (21.3)	64.30 (20.6)	62.95 (22.1)
Vitality	46.48 (21.2)	40.60 (23.4)	46.22 (22.2)	42.66 (23.9)
Bodily Pain	44.76 (22.8)	40.53 (24.6)	47.80 (25.3)	43.19 (26.8)
General Health Perception	56.82 (23.0)	53.21 (23.8)	55.30 (23.7)	53.60 (25.2)
Role–Physical Functioning	37.42 (41.2)	32.89 (41.8)	43.97 (44.2)	38.16 (43.2)
Role–Emotional Functioning	60.69 (44.5)	55.25 (45.0)	61.68 (44.9)	55.78 (45.2)
Reported Health Transition	55.12 (25.6)	48.47 (25.5)	51.70 (25.26)	49.77 (24.0)

[a] A lower value for this score indicates less pain (scored from 0 to 100).
[b] A higher value for this score indicates better health (scored from –0.59 to 1).
[c] A higher value for this score indicates better health (scored from 0 to 100).

TABLE 10 *Results of primary analyses of ALBP, SF-36 and EQ-5D scores at 8 and 24 months*

	8 months			24 months		
	Adjusted difference in means	**95% CI for difference in means**	***p*-Value**	**Adjusted difference in means**	**95% CI for difference in means**	***p*-Value**
ALBP score[a]	–3.05	(–5.16 to –0.95)	0.005	–3.62	(–5.92 to –1.32)	0.002
EQ-5D[a]	0.022	(–0.023 to 0.067)	0.33	0.057	(0.013 to 0.101)	0.01
SF-36 score						
Physical Functioning[a]	1.53	(–1.75 to 4.80)	0.36	2.95	(–0.48 to 6.39)	0.09
Social Functioning[a]	4.92	(1.07 to 8.77)	0.01	3.69	(–0.27 to 7.64)	0.07
Mental Health[a]	1.76	(–0.72 to 4.24)	0.17	–0.16	(–2.80 to 2.48)	0.91
Vitality[a]	4.28	(1.52 to 7.05)	0.002	2.43	(–0.50 to 5.37)	0.10
Bodily Pain[a]	4.54	(1.23 to 7.86)	0.007	5.14	(1.61 to 8.67)	0.004
General Health Perception[a]	1.56	(–1.37 to 4.50)	0.30	0.69	(–2.46 to 3.84)	0.67
	Odds ratio	**95% CI for odds ratio**	***p*-Value**	**Odds ratio**	**95% CI for odds ratio**	***p*-Value**
Role–Physical Functioning[b]	1.30	(0.95 to 1.78)	0.10	1.30	(0.97 to 1.76)	0.08
Role–Emotional Functioning[b]	1.19	(0.86 to 1.64)	0.30	1.24	(0.91 to 1.70)	0.18
Reported Health Transition[b]	1.64	(1.23 to 2.19)	0.001	1.15	(0.87 to 1.53)	0.33

[a] Analysis of covariance adjusting for age, sex, clinical category, consultant and baseline score.
[b] Ordinal logistic regression adjusting for age, sex, clinical category and baseline score.

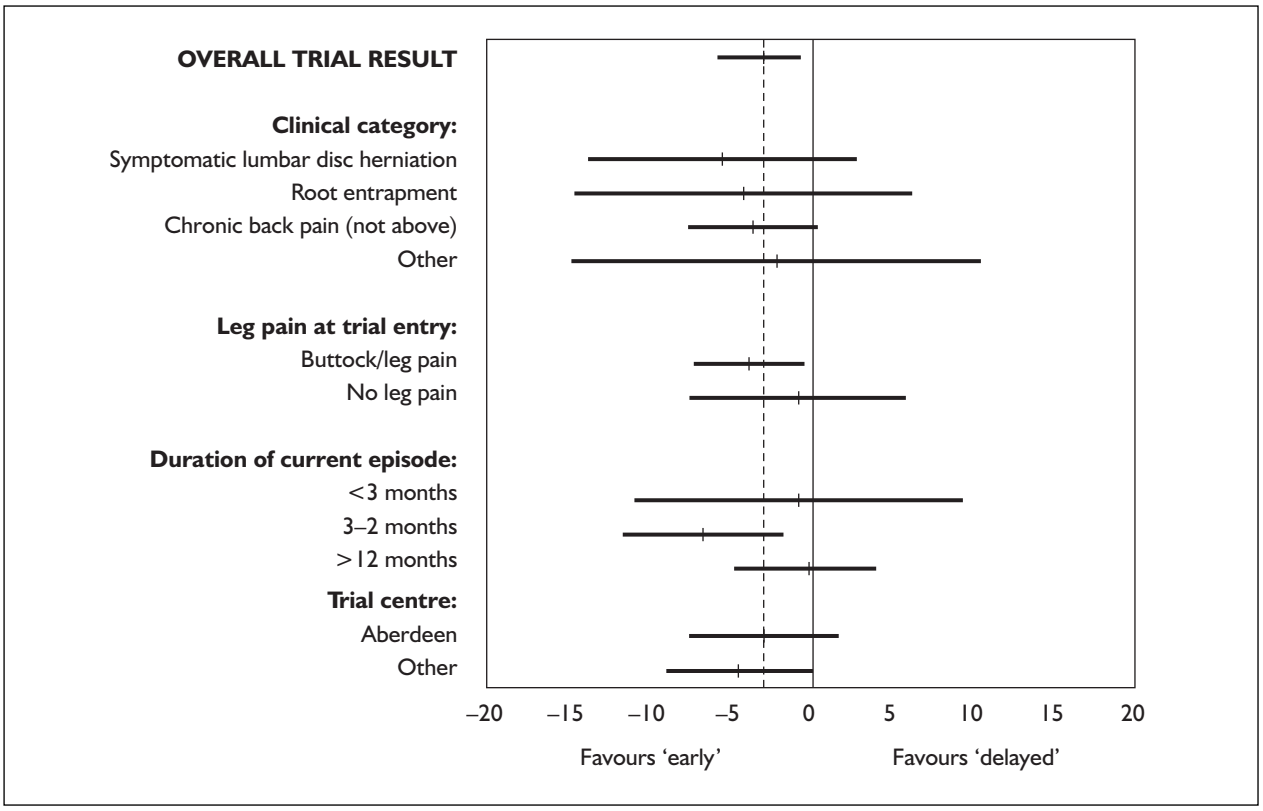

FIGURE 8 *Subgroup analysis of ALBP score at 24 months after trial entry. Adjusted difference in ALBP score at 24 months (95% CI for overall trial result and 99% CIs for subgroups)*

$p = 0.002$) at 24 months. The clearest difference in the SF-36 was in Bodily Pain, for which the adjusted mean difference was 4.54 (95% CI 1.23 to 7.86, $p = 0.007$) at 8 months and 5.14 (95% CI 1.65 to 8.67, $p = 0.004$) at 24 months. The adjusted scores in other subscales favoured the 'early imaging' group (except Mental Health, which showed little difference between the groups), statistically significantly so for Social Functioning, Vitality and Reported Health Transition, all at 8 months. The EQ-5D score also favoured the 'early imaging' group, significantly so at 24 months (adjusted difference in means 0.057; 95% CI 0.013 to 0.101, $p = 0.01$).

Secondary analyses explored whether any treatment effects were modified by the diagnostic category, the recruiting clinical centre or the duration of current episode. The results of these analyses in respect of the ALBP score at 24 months are shown in *Figure 8*. The adjusted differences in means in all four clinical categories and the two strata based on recruiting centre were all close to, and consistent with, the difference observed for all patients. Although the observed difference was larger in the stratum with buttock or leg pain at trial entry, there was no statistically significant difference between the subgroups, and mean ALBP scores in both strata were compatible with the overall result. In the analyses stratified by differing lengths of current episode of pain, the difference in mean ALBP score was largest in the middle group (3–12 months), but the confidence intervals were all wide and overlapping, and hence consistent with the analysis based on all participants. No statistically significant interaction effects were observed.

Economic evaluation

As the resources available to society for healthcare are scarce, decisions must be made as to whether the benefits that could be obtained from using the limited resources in one way are greater than could have been obtained had the resources been used for other desirable purposes. The cost of using resources in one way is that the opportunity to obtain the benefits from other alternative uses of those resources is given up. This is the economic notion of 'opportunity cost'. Economic evaluation is a method of providing decision-makers with information about the opportunity cost of the decisions that could be made. It

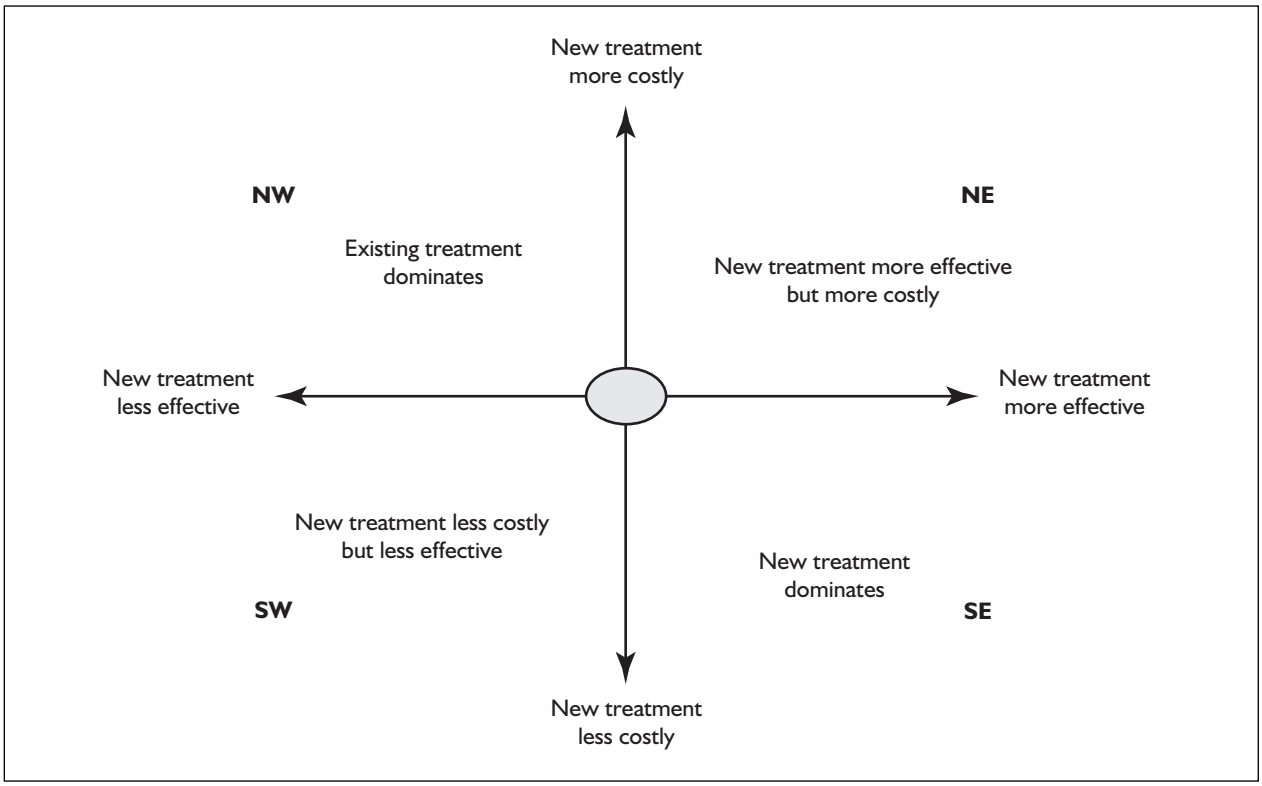

FIGURE 9 *Relationship between difference in cost and effects between a new (experimental) treatment and standard (control) treatment*

involves the comparative analysis of alternative policies in terms of both their cost (resource use) and benefits (health). How an economic evaluation brings together information on costs and effects is illustrated in *Figure 9*.

The vertical axis in *Figure 9* represents the difference in costs between an experimental and control treatment, and the horizontal axis represents differences in benefits between an experimental and control treatment. In the NW and SE quadrants of the figure a clear decision about which treatment should be preferred is provided because one or other treatment 'dominates'. In the NW quadrant the experimental treatment is more costly and provides less benefit and therefore the control treatment is more efficient. In the SE quadrant the opposite situation occurs and the experimental treatment is more efficient as it is less costly and provides more benefit. The circle in the centre of the figure represents the possibility that no meaningful differences in costs or benefits exist between the treatments and for practical purposes the two interventions are equally efficient. In the two remaining areas of the figure, the NE and SW quadrants, a judgement is required as to whether the more effective treatment is worth the extra cost. To aid these judgements, information can be provided in terms of an incremental cost-effectiveness ratio (ICER). The higher the ICER of an experimental treatment compared with a control treatment, the less likely it is that the experimental treatment will be considered efficient. In the economic evaluation described in this section, the difference between the trial groups in terms of mean costs per patient has been derived and equated against the difference in mean QALYs. These data have been used to calculate an ICER.

Derivation of NHS costs

Data describing the management of patients were used to estimate costs for each area of resource use and hence the total average costs for both 'early imaging' and 'delayed selective imaging' policies. A summary of the method used to estimate costs for each area where resource use occurred is detailed in *Table 11*. For some areas of resource use only one source of data (participant completed questionnaires or case notes) was appropriate. However, for other areas of resource use the choice was informed on by the results of a small study that investigated the concordance between different methods of data collection (Appendix 7). Also shown in *Table 11* are the source of data and

TABLE 11 *Economic evaluation: methods of data collection and outcomes*

Costs	Relevant variables	No. of events	Method of costing	Reported outcome
Patient management	Imaging	DA	Bottom-up costing for each method of imaging	Cost per event/patient
	Outpatient appointments	DA	SHSC less procedure costs	Cost per event/patient
	Inpatient stay	DA	SHSC less theatre/radiology	Cost per event/patient
	Tests and investigations	DA	Bottom-up costing	Cost per event/patient
	Injections	DA	Bottom-up costing	Cost per event/patient
	GP consultations	PQ	Netten and Curtis[93]	Cost per event/patient
	Medication usage (prescribed/non-prescribed)	PQ	BNF	Cost per event/patient
	Operation costs	DA	Bottom-up costs and discussions with orthopaedic surgeons involved	Cost per event/patient
	Physiotherapy/osteopathy/ chiropractic	PQ & DA	SHSC	Cost per event/patient
Patient costs	Time and travel costs	PTTQ[a]	Not applicable	Natural outcomes
	Complementary therapy costs	PQ	Not applicable	Natural outcomes
	Medication usage (non-prescribed)	PQ	BNF	Cost per event/patient
	Days off work	PQ	Not applicable	Natural outcomes

[a] This questionnaire was sent to trial participants 16 months after recruitment.
BNF, British National Formulary;[94] DA, data abstraction of patients' medical notes; PQ, patient questionnaire; PTTQ, patient time and travel questionnaire; SHSC, Scottish Health Service Costs.[92]

the method of costing. For events such as outpatient appointments and inpatient stay, standard published sources[92–94] were used to provide a cost per event. The cost per patient was simply the cost per event multiplied by the number of events. In some situations existing sources of cost data did not provide sufficient detail to allow an event, for example an operation, to be costed. In these situations, a 'bottom-up' costing exercise was conducted. 'Bottom-up' costing involved identifying the staff, materials (both disposable and reusable) and relevant overheads (e.g. heat, power, light, building costs) required to provide a procedure or test. Details of these resources were identified from a subsample of six of the hospitals involved in the trial. This subsample was chosen on the basis that the majority of the participants in the trial were recruited from these hospitals. The business managers for directorates with responsibility for radiology and orthopaedics were contacted and asked to provide details of the resources required to provide specific procedures and tests including information on the unit costs (prices) of reusable and disposable equipment. Staff costs were based on national salary scales plus additions for national insurance and superannuation. If reusable equipment was expected to last longer than 1 year, information on expected lifespan was also requested and its purchase cost was converted into an equivalent annual cost. A cost per patient was estimated by dividing the equivalent annual cost by the number of people who would be expected to use the equipment in a year.

The data on costs are presented in two ways. First, the mean (and median) difference is presented for the costs of each area of resource use. A 95% CI is presented for these differences. The differences in means for each area of resource use were then summed to provide the total difference in cost per patient. This approach was adopted because complete information for all patients over each area of resource use was not obtainable. However, it also meant that a confidence interval around the estimated difference in total costs between 'early imaging' and 'delayed, selective imaging' could not be readily obtained. For this reason, costs are presented in a second way. Missing data for

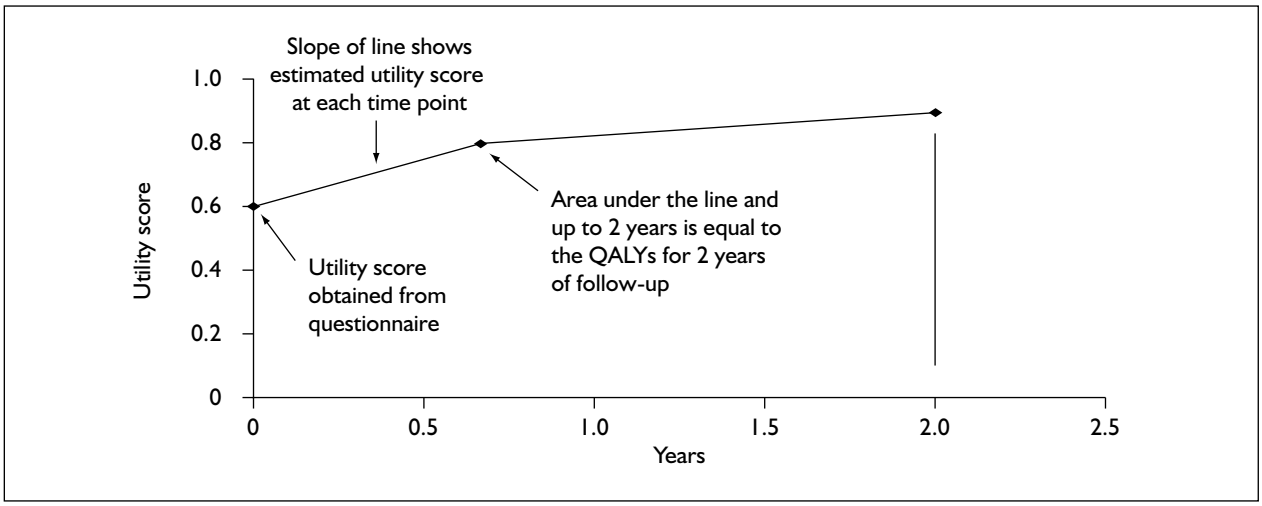

FIGURE 10 *Hypothetical example of QALY estimation*

patients were imputed using regression methods for the main determinants of the difference in cost and the mean value of the existing data for the other cost-generating events. The mean and median difference in cost between 'early imaging' and 'delayed, selective imaging' were recalculated this time with CIs.

Cost data are often positively skewed, as there are frequently a small number of patients who incur very high costs. Although the median cost per patient provides useful information, especially when considered along with mean cost per patient, it is the mean cost that is still the most useful in a cost analysis. The reason for this is that when the total budget for health care is fixed, it is the cost per patient and the total cost of adopting the intervention that are of interest. This is because there is a clear relationship between mean cost per patient and the total cost to the health service, whereas no such relationship exists between median costs and total costs.
All costs are presented in 1999/2000 pounds sterling. Costs incurred in the second year of follow-up have been discounted at a 6% discount rate and equivalent annual costs were also calculated using the same discount rate.

Derivation of QALYs

The QALYs were derived using the EQ-5D. The EQ-5D defines health in terms of five dimensions, namely mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of these dimensions has three levels. By combining the levels and categories, 343 health states can be defined. Each of these health states can be given a utility score. In this evaluation, the utility score was taken from the EQ-5D UK tariff which had been derived from a sample of the UK general public. The response to the EQ-5D that each trial participant provided was used to calculate the health state tariff for that person using a standard SPSS syntax developed by the EuroQol group (Kind P, University of York: personal communication, 2000). The utility scores obtained at baseline, 8 months and 24 months for each participant were used to estimate QALYs. This was done by estimating the area under the lines that link the utility scores, obtained at the three time points (*Figure 10*). The QALYs were estimated in two ways. In the first approach, the mean number of QALYs was estimated using information from those trial participants who had utility scores at all three time points. The drawback of this approach is that a participant would be excluded if data for that participant were only available for two or less time points. A second approach was therefore also adopted. With this approach, missing EQ-5D scores were extrapolated from an individual's other EQ-5D scores when observations were available from two time points. If an individual was missing two or more EQ-5D scores, then the missing data at each time point were imputed from the mean scores of those who did provide a response. The concern about this latter approach is that it may artificially improve the precision of estimates. Also, both estimates may be biased if the data are not missing at random and non-responders differ from responders in some way.

Using a method described by Manca and colleagues (Manca A, University of York: personal communication, 2002), the difference in mean QALY values between groups was based on an analysis of covariance adjusting for the factors used in the minimisation (i.e. age, sex, clinical

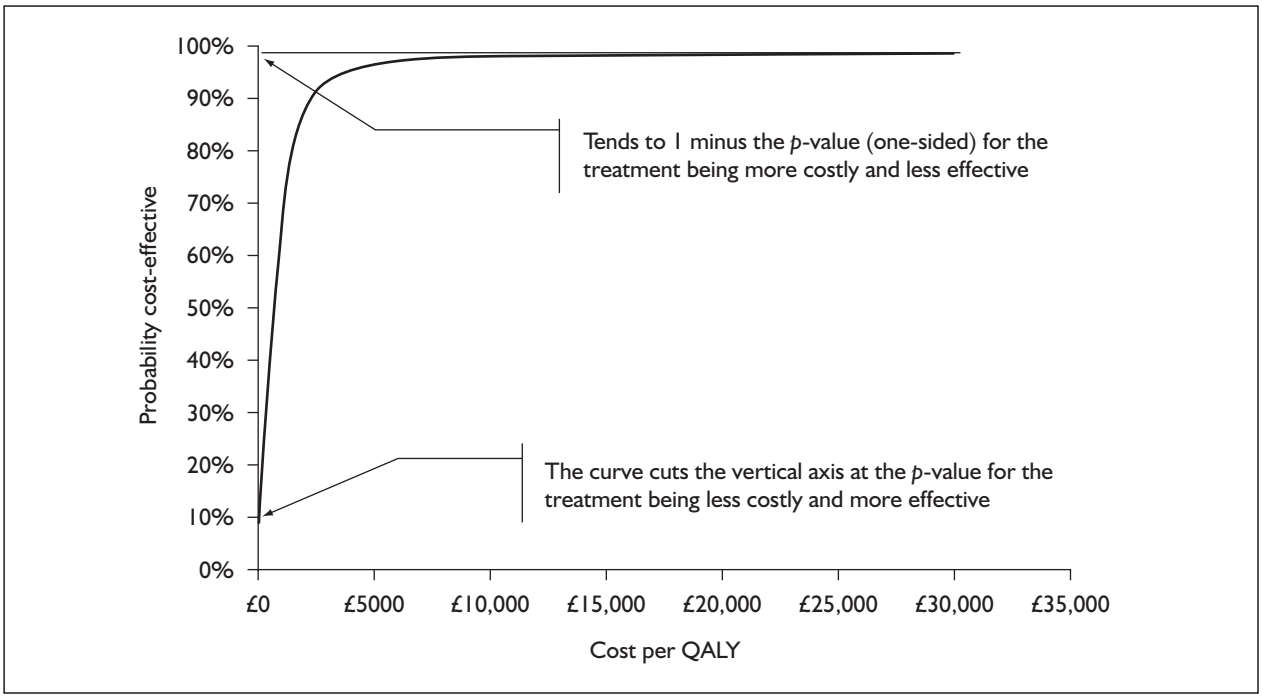

FIGURE 11 *Example of a cost-effectiveness acceptability curve*

category and consultant) and the EQ-5D score at baseline. As with the analysis of data on effectiveness described above, 'consultant' was considered as a random factor in the model and interaction terms were not included.

Assessment of cost–utility

The incremental cost per QALY was first estimated from the difference in mean costs and the differences in effectiveness between 'early imaging' and 'delayed, selective imaging' when missing data had not been imputed. Confidence intervals could not be calculated, because complete data on costs and QALYs were available for very few patients.

However, when missing data on costs and QALYs were imputed, it was possible to make statistical inferences. Bootstrap methods were used for statistical inference on costs, QALYs and cost per QALY because of skewed distributions.[95] The bootstrapped estimates of cost per QALY are presented in terms of a cost-effectiveness acceptability curve (CEAC). The rationale behind the CEAC is that what a decision-maker really needs to know is whether the intervention is cost-effective in relation to some value they think is the maximum worth paying for a QALY. An example is shown in *Figure 11*. At each ceiling value for society's willingness to pay for a QALY, the CEAC shows the probability that the treatment would be cost-effective. In the example, at a ceiling value of £5000 per QALY, the experimental treatment has approximately a 95% chance of being cost-effective.

Sensitivity analysis

The main determinant of the differences in cost between 'early imaging' and 'delayed, selective imaging' was the cost of an image provided by an MRI or CT scanner. The 'baseline' estimated cost of an MRI scanner may not accurately reflect the costs to a hospital of any increase in the provision of sophisticated imaging that would be a consequence of adopting a policy of 'early imaging'. Therefore, the analysis was repeated with the cost of a sophisticated image varied between baseline costs and £500. The cost of £500 was chosen as this was felt to be the extreme of the plausible range of MRI when all building and overhead costs are included.[92]

Derivation of costs to patients and their families

Although the main perspective of the analysis was costs to the NHS, information on costs borne by patients and their families was also elicited. While actual costs of, for example, complementary therapy can be derived, the estimation of costs of time spent travelling and receiving care and also time away from usual activities is problematic. The principal problem is that it is difficult to identify a reliable opportunity cost for such time. Therefore, such time losses have been presented in natural

units so that a subjective assessment of their importance can be made by a decision-maker.

A questionnaire was sent to all trial participants 16 months after their entry to the trial to identify the costs that they had incurred (Appendix 8). The questionnaire sought information with which to elicit the monetary cost and time costs of participants' most recent experience of different types of healthcare (GP consultations, outpatient visits and hospital admissions). Travel costs for each type of contact were based on fares paid when bus, rail or taxis were used and AA mileage rates[96] multiplied by miles travelled for those who travelled by private transport. Also included in travelling costs were any parking fees or other relevant costs. For each type of healthcare contact, data on other costs such as additional childcare costs were elicited. However, income lost as a result of a healthcare contact was not included. The times spent travelling to and from a healthcare contact and also the time the contact took (including waiting) were also sought. A monetary cost was not estimated for this cost but rather data are presented in terms of hours of time.

For each healthcare contact, a mean monetary cost and time cost per patient were estimated. These costs represented the unit cost of each individual healthcare contact. These unit costs were combined with the estimated frequency of each type of contact with health services. The costs per patient for each type of healthcare contact were summed for both monetary and time costs. Monte Carlo analysis was used to construct a 95% CI for the difference between early and delayed imaging for both the monetary and time costs of patients.

Results

Analysis of NHS costs

Table 12 details the unit costs used in the analyses and also shows the data that underpin these. The unit cost information, once combined with the resource use information reported in detail in the therapeutic impact section above, provided the estimate of total cost per patient (*Tables 13* and *14*).

Table 13 shows for 0–8 and 9–24 months, the estimates of total mean cost per patient for both 'early imaging' and 'delayed, selective imaging' and the difference in mean costs when missing data were not imputed. These tables demonstrate that the majority of the cost for participants in both the 'early imaging' and the 'delayed, selective imaging' groups is incurred during the first few months following trial entry (roughly three-fifths of the total cost being incurred during the first 8 months). The main determinant of the difference in total cost between the two imaging policies is, as would be expected, the cost of imaging, which accounts for 92% of the difference in cost observed over the follow-up period. The CIs that are reported in *Table 13* should be interpreted with caution as cost data are frequently positively skewed. However, these do serve to illustrate the extent of the uncertainty surrounding estimates of cost for many of the areas of resource use.

The data reported in *Table 13* provide only very limited information on the statistical uncertainty surrounding the estimate of the net difference in cost per patient of the two imaging strategies. When the missing data were imputed, a total cost for each trial participant could be calculated and hence standard deviation and confidence intervals derived (*Table 14*). This table shows the cost per patient of each imaging strategy and the estimated extra cost per person of 'early imaging'. As can be seen from *Tables 13* and *14*, the estimated extra cost per person is similar regardless of whether or not data were imputed. In *Table 14* the cost data for each of the modalities are positively skewed (the median total cost per person is less than the mean total cost per person). Therefore, the confidence interval for the cost difference should be treated with caution.

Estimation of QALYs

Using the actual scores, 'early imaging' was estimated to provide 0.09 QALY more on average than 'delayed, selective imaging' over the 2-year follow-up when missing data were not imputed. When data were imputed, the mean difference was 0.08 QALY (*Table 15b*). The medians are higher than the means, indicating that the data are negatively skewed. Therefore, the CIs provide only an approximation of the difference in QALYs. Adjusting for the differences in baseline EQ-5D scores led to an estimated mean additional QALY of 0.07 when missing data were not imputed and 0.04 (–0.015 to 0.10) when missing data were imputed (*Table 15b*). CIs were based on the 2.5 and 97.5 percentile bootstrap iterations.

Incremental cost per QALY of 'early imaging' compared with 'delayed selective imaging'

The cost-effectiveness of 'early imaging' compared with 'delayed, selective imaging' is dependent on whether the differences in QALYs are considered to be important clinically and to people with LBP. On the one hand, such differences are judged to

TABLE 12 *Unit costs of primary and secondary NHS care*

Area	Resource use	Average costs (£)		Unit
		Months 1–12	Months 12–24[a]	
Imaging	X-ray	42.46	37.79	Per item
	MRI	89.79	84.60	Per item
	CT	70.49	65.24	Per item
	Stress discogram	21.92	19.51	Per item
	Myelogram	188.44	177.52	Per item
	Bone scan	84.44	75.16	Per item
	Ultrasound	84.44	75.16	Per item
Hospital visits	Physiotherapy	8.55	7.61	Per session
	Occupational therapy	9.50	8.45	Per session
	Outpatient visits	37.00	32.93	Per session
Injections	Facet OP	27.96	24.88	Per injection
	Epidural IP	72.52	65.22	Per injection
	Epidural OP	55.67	50.56	Per injection
	Nerve root OP	21.63	19.25	Per injection
	Sclerosant OP	22.27	19.82	Per injection
	Trigger OP	21.63	19.25	Per injection
Supports	Lumbar	15.00	13.35	Per item
	Corset	22.92	20.40	Per item
	Brace	70.27	62.54	Per item
	Insoles	40.00	35.60	Per item
Other tests	TENS	11.17	9.94	Per test
	Blood	4.66	4.15	Per test
	Urine	6.04	5.38	Per test
	Manipulation (chiropractic/osteopathy)	12.00	9.51	Per test
Hospitalisation	Bed day (IP)	135.61	120.70	Per day
	Day case	222.82	198.31	Per day
Surgery	Chemonucleolysis	54.91	48.87	Per procedure
	Discectomy	545.20	494.70	Per procedure
	Bone fusion	585.82	522.69	Per procedure
	Ligament stabilisation	502.48	456.20	Per procedure
	Percutaneous discectomy	561.83	509.53	Per procedure
	Decompression	502.48	456.20	Per procedure
	Type unknown	539.56	487.86	Per procedure
Medication	In-hospital range	0.21–9.70	0.19–8.63	Per week
	Prescription range			
Primary care	GP visits	16.00	14.24	Per visit

[a] Discounted at 6%.
IP, inpatient; OP, outpatient.

be immaterial, then, relative to 'delayed selective imaging', 'early imaging' provides no more benefits and is more costly ('early imaging' lies in the NW quadrant of *Figure 9* where 'delayed, selective imaging' dominates because it is the most cost-effective). On the other hand, if the difference in QALYs is taken to be of importance to patients with LBP, then 'early imaging' is likely to be both more costly and more effective than 'delayed, selective imaging' (represented by the NE quadrant of *Figure 9*). Taking the mean difference in costs from *Table 13* and mean difference in the non-imputed estimates of QALYs after adjustment for baseline differences in EQ-5D scores from *Table 15(a)*, the mean incremental cost per QALY is £870. This estimate, however, is subject to uncertainty.

This result is of limited value to decision-makers. More useful data can be obtained by using the patient level costs and QALYs summarised in *Tables 14* and *15*. These data were used to provide bootstrapped estimates of the incremental cost per QALY of 'early imaging' compared with 'delayed, selective imaging'. These data were then presented in the form of a CEAC for analyses using both the adjusted and unadjusted QALY estimates (*Figure 12*).

TABLE 13 *Cost per patient in total and for each area of resource use for each imaging policy*

Area of resource use	Early (*N* = 393): mean cost (SD) (£) [*n*]	Delayed, selective (*N* = 389): mean cost (SD) (£) [*n*]	Difference in means (£)	95% CI for difference (£)
0–8 months				
Outpatient consultations	53.48 (40) [377]	49.75 (54) [357]	3.73	–3.19 to 10.68
Imaging	83.58 (38) [393]	26.75 (60) [389]	56.83	50.54 to 63.12
Physiotherapy	34.31 (53) [373]	24.75 (46) [369]	9.56	2.41 to 16.70
Admissions to hospital	41.06 (217) [393]	63.80 (407) [389]	–22.73	–68.67 to 23.20
Surgery	20.03 (117) [393]	14.24 (102) [389]	5.78	–9.64 to 21.21
Injections	13.61 (44) [393]	11.64 (34) [388]	1.96	–3.54 to 7.46
Back support/corset/brace	5.44 (10) [337]	4.94 (9) [311]	0.50	–0.95 to 1.94
GP consultations	44.27 (84) [300]	43.31 (68) [273]	0.96	–11.67 to 13.58
Prescription medicines	4.87 (10) [253]	6.04 (25) [240]	–1.17	–4.51 to 2.18
Non-prescription medicines	0.07 (1) [393]	0.09 (1) [389]	–0.02	–0.14 to 0.10
Special tests	1.12 (3) [393]	1.17 (3) [389]	–0.05	–0.43 to 0.33
Total (0–8 months)	301.84	246.48	55.36	Extreme values –39.94; 160.50
9–24 months				
Outpatient consultations	17.60 (40) [393]	21.25 (60) [389]	–3.65	–10.80 to 3.50
Imaging	10.65 (49) [393]	13.52 (46) [389]	–2.87	–9.53 to 3.78
Physiotherapy	9.46 (31) [380]	9.95 (43) [381]	–0.49	–5.83 to 4.84
Admissions to hospital	59.80 (172) [393]	37.50 (98) [389]	22.29	2.68 to 41.91
Surgery	23.14 (128) [393]	16.67 (113) [389]	6.47	–10.50 to 23.44
Injections	6.35 (25) [392]	6.83 (28) [388]	–0.48	–4.17 to 3.22
Back support/corset/brace	4.05 (8) [357]	4.25 (8) [335]	–0.19	–1.39 to 1.01
GP consultations	52.13 (114) [301]	66.08 (157) [292]	–13.95	–36.08 to 8.19
Prescription medicines	4.06 (10) [257]	5.73 (14) [249]	–1.68	–3.80 to 0.44
Non-prescription medicines	0.14 (1) [393]	0.13 (1) [389]	0.01	–0.17 to 0.19
Special tests	0.24 (1) [393]	0.16 (1) [389]	0.08	–0.10 to 0.25
Total 9–24 months	187.62	182.07	5.54	Extreme values –79.19; 90.77
Total 0–24 months	489.46	428.55	60.91	Extreme value –119.13; 251.27

TABLE 14 *Estimate of total mean cost per patient for each intervention and difference in mean cost per patient when data were imputed*

Area of resource use	Early (*N* = 393): mean cost (SD) (£)	Delayed, selective (*N* = 389): mean cost (SD) (£)	Difference in means (£)	95% CI for difference (£)
Outpatient consultations	71.09 (63.3)	70.98 (100.9)	0.11	
Imaging	94.22 (61.7)	40.26 (75.1)	53.96	
Physiotherapy	43.41 (63.7)	34.43 (63.7)	8.98	
Admissions to hospital	100.86 (309.0)	101.30 (417.7)	–0.44	
Surgery	43.16 (175.1)	30.91 (150.4)	12.25	
Injections	19.96 (56.6)	18.47 (47.9)	1.49	
Back support/corset/brace	8.67 (14.3)	8.15 (13.6)	0.52	
GP consultations	96.40 (138.4)	109.39 (164.2)	–12.99	
Prescription medicines	8.93 (12.3)	11.77 (23.0)	–2.84	
Non-prescription medicines	0.22 (1.5)	0.23 (1.6)	–0.01	
Special tests	1.36 (3.3)	1.32 (2.8)	0.04	
Total	**488.28 (580.6) [median 305.99]**	**427.21 (647.3) [median 231.88]**	**61.07**	**(–25.24 to 147.36) [Mann–Whitney test $p < 0.001$]**

TABLE 15 *Mean total QALYs up to 24 months and difference in means for the two imaging policies when missing data (a) were not imputed and (b) were imputed*

Adjustment for difference in baseline EQ-5D scores	Early imaging (SD) [median]	Delayed, selective imaging (SD) [median]	Difference in means	95% CI for difference
(a) Data not imputed				
No	1.14 (0.51) [1.31]	1.05 (0.58) [1.24]	0.09	(–0.003 to 0.18)
Yes[b]	1.12	1.05	0.07	(0.00 to 0.13)[a]
(b) Data imputed				
No	1.12 (0.47) [1.24]	1.03 (0.52) [1.12]	0.08	(0.01 to 0.15) [Mann–Whitney test $p = 0.01$]
Yes[b]	1.07	1.03	0.04	(–0.015 to 0.10)[a]

[a] Based on the 2.5% and 97.5 percentile bootstraps.
[b] Adjustment for baseline imbalance.

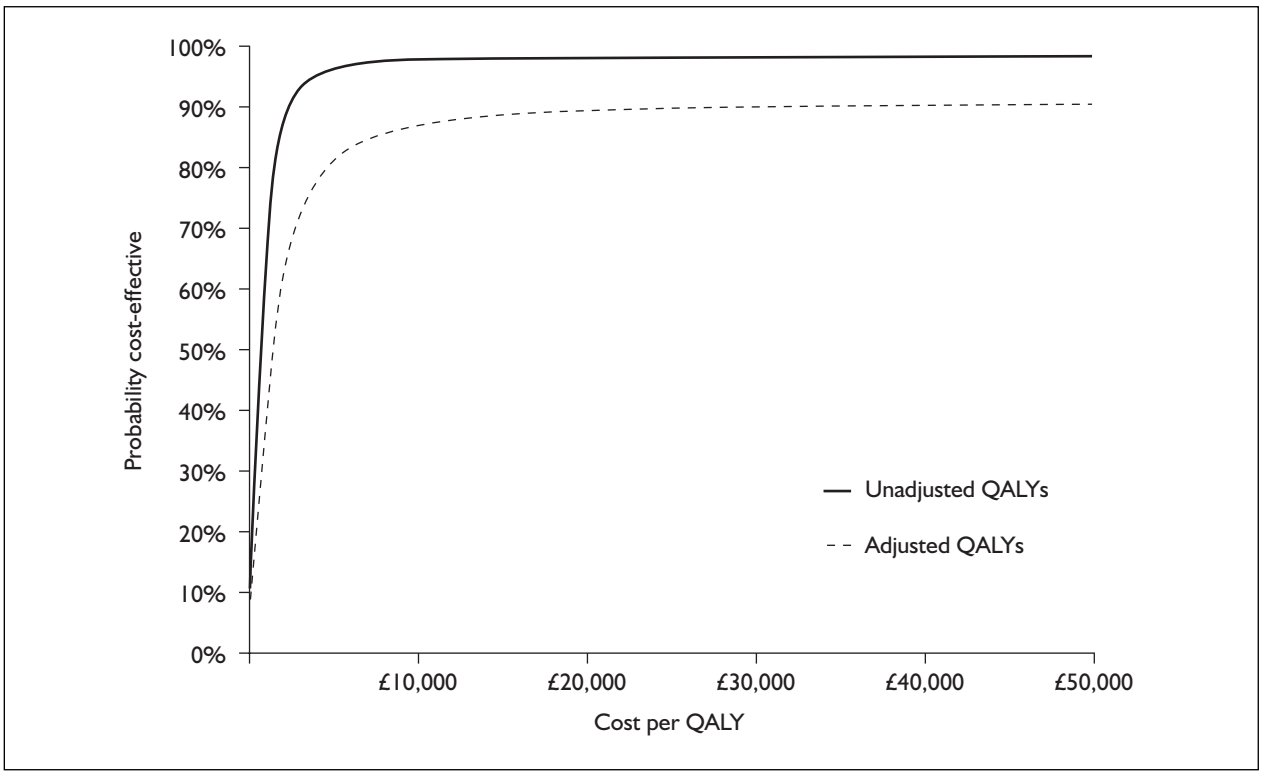

FIGURE 12 *Cost-effectiveness acceptability curve for the incremental cost per QALY of 'early imaging' compared with 'delayed, selective imaging' for both an analysis 'adjusted' or 'unadjusted' for differences in baseline EQ-5D scores*

In the baseline analysis there is approximately a 10% chance that 'early imaging' is more effective and less costly than 'delayed, selective imaging' (the intercept with the vertical axis in *Figure 12*). The CEAC rises sharply, indicating that even at low estimates of society's willingness to pay for an extra QALY, 'early imaging' is likely to be considered cost-effective. At a probability of 97.5% (analogous to the probability commonly used in one-sided statistical tests for detecting a difference when one exists), the incremental cost per QALY will be less than £7300. This finding should be contrasted with the results based on QALY estimates after adjustments are made for the imbalance in baseline EQ-5D scores. In this analysis there is approximately a 9% chance that 'early imaging' is more costly and less effective than 'delayed, selective imaging'. There is approximately a 90% likelihood that 'early imaging' is less costly and more effective or would provide an additional QALY at less than £30,000. To aid interpretation, the probability that 'early

TABLE 16 *Probability that the cost per QALY is less than society's willingness to pay (WTP) for a QALY for different unit costs of sophisticated imaging (based on adjusted QALYs)*

Society's WTP for a QALY (£)	Unit cost of sophisticated imaging (%)				
	Baseline	200	300	400	500
0[a]	9.0	0.3	0	0	0
1000	37.2	23.0	0.6	0.1	>0.1
5000	81.0	92.8	52.2	37.8	24.8
10,000	96.9	96.7	75.1	68.9	61.1
15,000	88.8	97.6	82.4	78.5	74.2
20,000	89.7	98.0	84.8	82.6	79.7
25,000	90.1	98.2	86.3	84.6	82.9
30,000	90.3	98.3	87.2	85.8	84.4

[a] 'Early imaging' less costly and more effective. Note: there is a probability of 8.3% that 'delayed, selective imaging' is less costly and more effective.

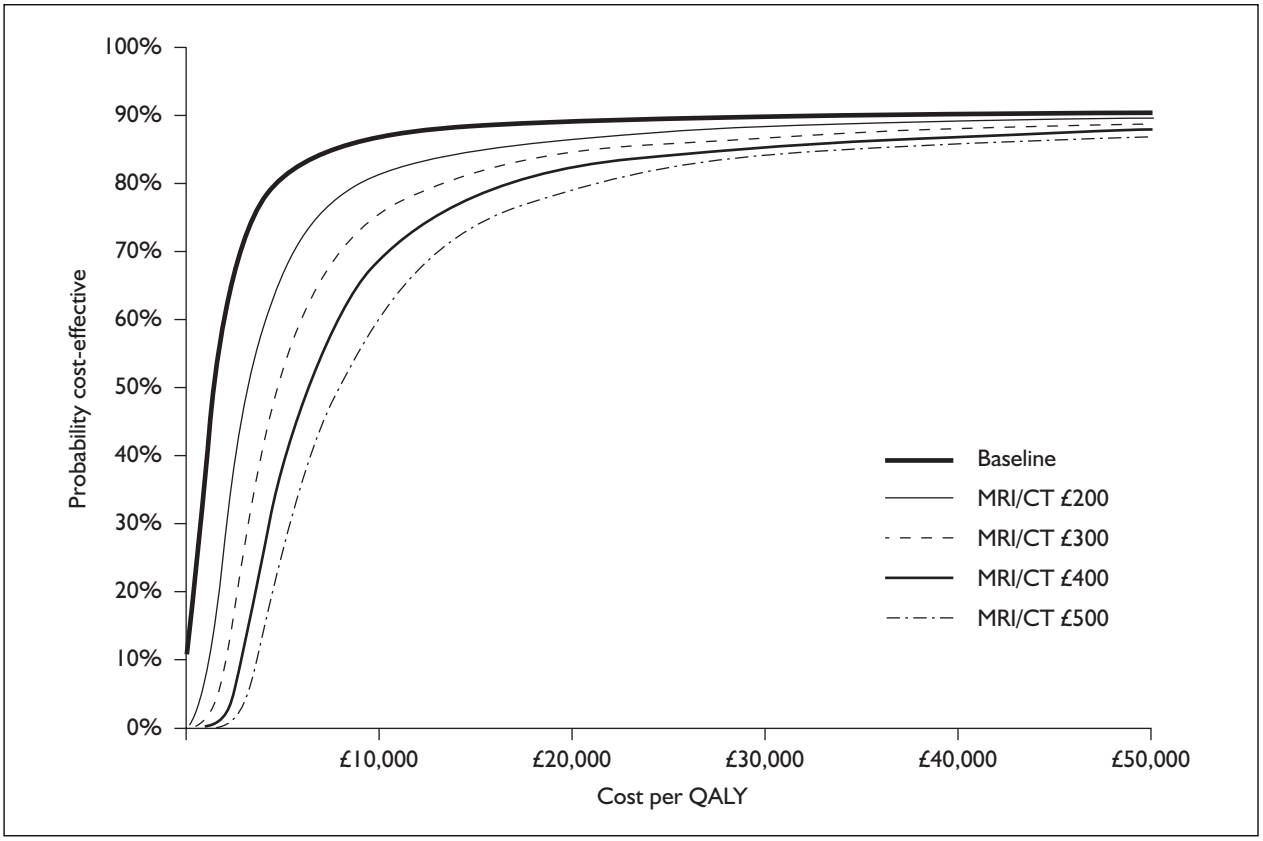

FIGURE 13 *Cost-effectiveness acceptability curve for the incremental cost per QALY of 'early imaging' compared with 'delayed, selective imaging' for different costs for MR and CT imaging*

imaging' would be considered cost-effective is also presented for different selected values for society's willingness to pay for a QALY in *Table 16* for the adjusted analysis.

Sensitivity analysis

Figure 13 and *Table 16* show the effect on cost per QALY after adjustment for the differences in baseline EQ-5D scores of changing the estimated cost of sophisticated imaging. As can be seen from *Table 16* and *Figure 13*, as the cost of sophisticated imaging increases, the likelihood that 'early imaging' would represent an efficient use of resources decreases. For example, if society were willing to pay £1000 for each QALY gained by 'early imaging', then using the baseline cost of

TABLE 17 *Cost to the patient and their families/carer of a single visit or admission*

		Imaging policy	
		Early	Delayed, selective
Area of resource use	**Time or monetary cost**	**Mean (SE)**	**Mean (SE)**
GP visit, physiotherapy	Time spent in making a GP visit (minutes)	38.96 (2.64)	48.79 (4.66)
	Cost of travelling to a GP[a] (£)	2.98 (0.34)	3.58 (0.44)
	Other costs arising from a GP visit[a] (£)	12.39 (2.52)	16.66 (5.99)
Outpatient visit	Time spent attending an OP visit (minutes)	104.48 (7.96)	104.8 (7.21)
	Cost of travelling[a] (£)	10.21 (0.98)	9.93 (1.02)
	Other costs[a] (£)	32.21 (23.75)	23.55 (9.87)
Hospitalisation	Time spent travelling to hospital (minutes)	152.06 (17.80)	172.57 (22.61)
	Cost of travelling to hospital[a] (£)	15.22 (2.48)	16.64 (2.78)
	Other costs of hospital stay[a] (£)	132.4 (92.25)	101.25 (72.04)

TABLE 18 *Average monetary costs (£) to patients of the two imaging policies and the difference in cost between policies*

	Imaging policy		
	Early	**Delayed, selective**	**Difference**
At 8 months			
Cost of GP visits	42.58	54.98	–12.40
Cost of NHS physiotherapy visits	52.57	52.14	0.43
Cost of private physiotherapy	29.36	28.60	0.75
Cost of outpatient visits	60.23	41.459	18.77
Cost of travelling for hospitalisations	7.33	4.94	2.39
Sub-total	192.07	182.12	9.94
From 8 to 24 months			
Cost of GP visits	53.08	88.81	–35.73
Cost of NHS physiotherapy visits	17.26	24.31	–7.05
Cost of private physiotherapy	27.13	25.44	1.69
Cost of outpatient visits	21.66	20.67	0.99
Cost of travelling for hospitalisations	5.46	3.733	1.73
Sub-total	124.59	162.95	–38.36
Total (95% CI)	**317 (142 to 565)**	**345 (142 to 616)**	**–28 (-352 to 284)**

sophisticated imaging there would be a 37% chance that 'early imaging' would be cost-effective. However, if the cost of imaging were £500, then 'early imaging' would have less than a 0.02% chance of being cost-effective if each QALY cost £1000.

Costs to patients

The average costs to a patient and their families/carers of a single contact with either a GP, physiotherapy (private or NHS), an outpatient consultation or an inpatient admission are reported in *Table 17*. The data contained in *Table 17* were combined with information on the number of contacts (GP visits, etc.) that trial participants had (reported in the therapeutic impact section above) to estimate a monetary cost per patient and a time cost per patient for both 'early imaging' and 'delayed, selective imaging' (*Table 18* monetary costs and *Table 19* time costs). As both *Tables 18* and *19* show, LBP results in a considerable financial burden to patients and their families (excluding any time away from usual activities due to ill-health). However, as would be expected, owing to the lack of differences in therapeutic impact, the differences in costs to patients between the two imaging policies are small and the CIs around the differences in both the monetary and the time costs are very wide and include zero.

TABLE 19 *Average time costs (hours) to patients of the different imaging policies and the difference in cost between policies*

	Imaging policy		
	Early	**Delayed, selective**	**Difference**
At 8 months			
GP visits	1.80	2.20	–0.41
Physiotherapy visits	2.22	2.09	0.13
Private physiotherapy	0.54	0.58	–0.04
Outpatient visits	2.42	2.15	0.27
Hospitalisation travelling	0.12	0.11	0.01
Time in hospital	13.44	22.37	–8.93
Sub-total	20.54	29.50	–8.96
From 8 to 24 months			
GP visits	2.38	3.77	–1.40
Physiotherapy visits	0.77	1.03	–0.26
Private physiotherapy	0.55	0.53	0.02
Outpatient visits	0.92	1.14	–0.21
Hospitalisation travelling	0.10	0.09	0.01
Time in hospital	7.20	6.05	1.14
Sub-total	11.91	12.61	–0.70
Total (95% CI)	**32 (19 to 47)**	**42 (19.32 to 70.25)**	**–9.66 (–40.33 to 17.77)**

Chapter 4
Discussion

To our knowledge, this is the first multicentre randomised trial of sophisticated imaging (MRI or CT) in the management of LBP. The use of early sophisticated imaging was associated with a 3.62-point greater improvement in the ALBP score, sustained 24 months after entry, and statistically significantly lower SF-36 Bodily Pain subscale and higher EQ-5D scores. Overall, 'early imaging' provided more QALYs (after adjusting for differences in baseline EQ-5D scores) at an additional average cost of £61. The estimated mean incremental cost per QALY of 'early imaging' is £870 (based on non-imputed costs and non-imputed QALYs after adjustment for baseline differences in EQ-5D). As discussed below, these do not represent large improvements in patients' symptoms and well-being and the interpretation of the findings is not straightforward.

The possibility of selection bias

Despite random allocation, there were imbalances at trial entry in the ALBP score, the SF-36 score and EQ-5D in favour of the 'early imaging' group. There was also a small difference in the duration of the presenting episode of back pain, tending to be longer in the 'delayed, selective' group. Patients with a shorter duration of back pain do have a better prognosis and so would be expected to have a better outcome.[97,98] Nevertheless, differences in outcome persisted after adjustment for baseline differences and the values quoted above are after adjustment.

There is no obvious explanation for these imbalances. Randomisation was arranged remotely by telephoning an automated service and hence the allocation was securely concealed until formal entry had occurred. The balance, as would be expected, was good for those prognostic features included as minimisation factors in the allocation procedure. The questionnaires used to generate the baseline scores were completed at the time of randomisation. The intention was for these to be completed before the allocation was known. It is possible, however, that if some participants had notification of their allocation to imaging or no imaging while completing the questionnaire, this might have affected their self-reporting of health status, perhaps feeling better knowing that an imaging test was to be ordered.

Protection against other sources of bias

Other possible sources of bias would not affect baseline scores but might influence later comparisons. The primary outcome measures were derived from participants completing questionnaires. In a pragmatic trial such as this one, any influence of knowing that a test has been performed and being notified of its result is seen as part of the test's effectiveness, and so this does not represent bias. The number and characteristics of losses to follow-up were similar in the two groups and so again this did not appear to have introduced bias. By 24 months, 30% of those allocated 'delayed, selective imaging' had received imaging compared with 90% of those in the 'early imaging' group. This would, however, be expected to reduce rather than increase any differences between the trial groups' outcomes.

Precision of estimates of effect

Interpretation should also take into account that the estimates of effects may also be prone to random errors. Based on 95% CIs, the true difference (after baseline adjustment) in ALBP score at 24 months is likely to lie between –1.32 and –5.95 and in EQ-5D between 0.013 and 0.101. As discussed further below, a decision as to whether or not any effect is clinically and economically significant may be importantly influenced by whether or not the true effect is at the upper or lower end of these ranges.

The clinical significance of the observed differences in outcome

Interpretation also depends on what the observed changes in outcome are likely to mean for people receiving care for LBP – whether they are clinically important differences.[75,77,99,100,101] At the outset we did not expect any effects of 'early imaging' to be large because of the chain of events between

imaging and the time of follow-up assessment of health status.[102] The final sample size sought (800) was chosen to provide a reasonable chance (80% power) of a statistically significant result if the true effect was a 3.2-point difference in the ALBP score. The actual result suggests a 64% likelihood that the true difference is of this magnitude or greater.

The ALBP score was the primary measure of outcome. It was chosen because condition-specific measures are more discriminating and sensitive to change.[103] In the York back pain trial, Garratt and co-workers[77] compared the discriminatory power and responsiveness of the ALBP score with another condition-specific instrument, the Roland Disability questionnaire, and with the EQ-5D, in relation to self-reported back pain transition. They reported that the ALBP score was more responsive with a score change of approximately 7.5 points for patients in the control group who said they were 'better' at 1-year. Similarly, these patients recorded a score change of 0.14 points on the EQ-5D. In this context, our observed score difference of 3.62 points on the ALBP score and 0.057 on the EQ-5D (and thus the difference in QALYs) in favour of the 'early imaging' group would not equate to a shift of the distribution to 'better'. If such a shift were to be judged to be the minimum required for clinical significance, 'early imaging' would not be cost-effective since it is most likely to be more costly and does not provide meaningful additional benefits.

We did, however, explore further whether differences in the ALBP score of the size observed were indeed clinically significant. We did this in a number of other ways. Garratt and co-workers,[77] using data from the UKBEAM feasibility study (Garratt AM, University of Oxford: personal communication, 2001) were able to compare the estimates of effect derived from different instruments. *Table 20* shows the association between a self-assessed global rating of change in back pain[104] and the ALBP score at 1 month. Most of the data applied to people who reported 'no change', 'slightly improved' or 'much improved'. The differences between these ratings represented by the ALBP scores were –5.29 and –3.25, respectively.

We then looked internally at our data and correlated the Reported Health Transition state in the SF-36 with the ALBP score. *Table 21* shows this for the data at 24 months. The differences in the mean ALBP scores between the strata vary between –4.23 and –10.38.

We also considered the likely clinical significance of our finding of a 4.54 (95% CI 1.23 to 7.86) difference in the Bodily Pain subscale of the SF-36. A comparison of SF-36 score changes with patients' subjective reports of improvement in a group of patients with sciatica[70] suggested that a seven-point difference in the SF-36 Physical Functioning and Bodily Pain subscales was consistent with a clinically important difference. Although this suggests that our observed difference may not be clinically significant, caution is required in generalising results to all categories of LBP for which the prognosis and natural history may differ.[100,101]

The EQ-5D also included a 'thermometer' asking respondents to rate their health that day between 100 (best imaginable health state) and 0 (worst imaginable health state). The mean scores at 24 months were 65.75 in the 'early imaging' group and 62.57 in the 'delayed, selective imaging' group, a difference of 3.18 ($p = 0.028$). This finding is consistent with the observed small differences in the ALBP and SF-36 scores. Exploring the five component questions of the EQ-5D showed a 4% difference in the number who reported no difficulty in walking (29 versus 25%), 7% difference in the number with no difficulty with self-care (72 versus 65%), 4% difference in the number with no problem with usual activities (16 versus 12%), no difference in the number reporting no pain (3 versus 3%) and 9% difference in the number not anxious (58 versus 49%) ('early imaging' versus 'delayed, selective imaging' respectively).

The generalisability of the findings

The majority of trial participants were recruited from orthopaedic clinics and this specialty receives the majority of GP referrals,[20] and by the time of trial entry 87% of participants had already had a lumbar spine X-ray. Although the incidence of LBP is similar across the UK, there is wide variation in referral rates and access to secondary care specialists.[7] Although our study was primarily Scotland-wide, waiting times and access to secondary care and imaging services are variable and this is likely to be generalisable to the rest of the UK since the organisation of the NHS is similar.

Despite being a multicentre trial, 47% of participants were recruited from one centre (Aberdeen). This centre provides care to

TABLE 20 *Relationship between Beurskens categories and mean ALBP scores (1-month data, unpublished data from Garratt* et al., *2001*[77]*)*

Beurskens category[a]	*N*	ALBP score: mean (SD)	ALBP score differences between categories
Completely recovered	2	–12.87 (7.11)	–1.90
Much improved	43	–10.97 (10.64)	–3.25
Slightly improved	59	–7.74 (11.52)	–5.29
No change	58	–2.45 (9.53)	–3.96
Slightly worsened	11	1.51 (6.27)	–6.02
Much worsened	10	7.53 (8.44)	–20.25
Vastly worsened	1	27.78 (–)	

[a] Self-assessed global rating of change in back pain over 1-month on a seven-point scale on which 'completely recovered' and 'much improved' were defined as clinically important changes (Beurskens *et al.*, 1996[104]).

TABLE 21 *Relationships between reported health transition and change in mean ALBP score at 24 months*

Reported health transition[a]	*N*	ALBP score: mean (SD)	ALBP score differences between categories
Much worse	44	8.87 (12.29)	8.76
Somewhat worse	118	0.11 (13.83)	4.24
About the same	338	–4.13 (14.62)	10.38
Somewhat better	107	–14.51 (14.56)	4.84
Much better	59	–19.35 (14.48)	

[a] Reported health transition question in the SF-36 in which patients rate their general health compared with 1 year ago.

approximately 500,000 people with roughly 50% in one urban area and the remainder spread over a large, remote and predominantly rural geographic region. Secondary analyses stratified by centre showed that results from Aberdeen were not different from those from other centres. At most centres, patients were generally recruited from only one clinic and/or by one consultant, many of whom had a special interest in back pain, and the patient population approached for recruitment reflects this.[105] Although every effort was made to recruit all eligible patients from all of the centres, some eligible patients were overlooked, for example, as a result of local variation in interpretation of the eligibility criteria, if junior staff were unfamiliar with trial eligibility criteria or if the research nurse was unavailable at the time of the clinic.

Since the patients in this study had baseline scores for SF-36 and EQ-5D which were lower (i.e. poorer health) than scores reported in two recent studies of LBP patients referred by GPs for plain film radiography,[11,56] our data may only be generalisable to the patients with more severe disability who are referred to secondary care specialists. Hence the improvement in outcome scores might not have been so apparent if this study had been conducted solely with primary care patients.

The secondary stratified analyses did not provide any clear evidence of a larger or smaller effect in any subgroup of participants. Estimates of effect were similar in the various clinical categories and consistent with the overall trial results. In relation to duration of symptoms, the pattern of changes in outcome scores did not follow the expectation that the improvement would be greatest amongst those with pain for <3 months. Instead, the largest difference in the mean score was in the 3–12-month group. The CIs around all these estimates were wide, however, but once again each is compatible with the overall result.

Possible explanations for the findings

A study of diagnostic impact[66] was built into the larger randomised controlled trial. This provided possible insights into how the differences seen in

the trial might have been mediated. Changes were observed in both groups (highlighting the value of the randomised control design and showing that previous non-randomised studies assessing the impact of imaging on diagnosis and management are likely to have overestimated the contribution of imaging to clinical decision-making).[34,38,39,45] However, the only difference observed was greater clinician confidence in the diagnosis in the 'early imaging' group, with no apparent difference in diagnosis or management plan. In this context, there was some evidence[66] that imaging was more helpful to the non-back specialist, where there was considerably more doubt over the diagnosis.

One effect of 'early imaging' was increased return visits to the hospital clinic. However, those in the 'early imaging' group subsequently had fewer visits and over the full 2-year follow-up the total numbers of consultations were similar in the two groups. In other words, while more in the 'early imaging' group had a further consultation, those in the 'delayed, selective imaging' group who consulted did so more frequently. There was no detectable difference in other types of management. In particular, surgery was reported in 6.9% in the 'early imaging' group compared with 5.1% in the 'delayed, selective imaging' group (95% CI for difference –1.6 to 5.1%). The pattern of management did not therefore suggest that the difference observed between the trial groups reflected more intensive management in a small minority of participants in the 'early imaging' group. Furthermore, the pattern of individuals' changes in the ALBP scores was more consistent with a small, added improvement in a larger number of participants than a large improvement in a few participants. These considerations point towards a direct effect of imaging, perhaps through reassurance, rather than an indirect effect through changes in active management.

The two recently reported trials of X-rays for LBP provide some, albeit limited, support for this suggestion. In the trial by Kerry and co-workers,[56] there was some evidence of improved psychological well-being in the group referred for X-ray. However, this was principally in respect of the Mental Health subscale of the SF-36, and a range of other indices such as the HAD scores were not significantly different between the two groups. Kendrick and co-workers[11] reported a larger number of GP consultations and greater satisfaction with care in the group allocated X-ray, but with no evidence that this group was less worried or more reassured. Both of these trials were smaller than that reported here and the relatively less precise estimates of effect may possibly obscure real differences. Also, follow-up was for only 12 and 9 months, respectively, and so differences in longer term patterns of care, as observed in our trial particularly in respect of consultations, were not studied.

Cost-effectiveness

Biases specific to the economic evaluation may have arisen owing to difficulties in the collection of resource use. Specifically, as we were interested in collecting resource use over a 2-year period, there were concerns that participants would have difficulty in recalling their contacts with the health service. In order to address this concern, a substudy was conducted (Appendix 7) investigating the concordance between different methods of data collection. As a result of this substudy, we chose to make more use of hospital records. This had the bonuses of reducing biases caused by participant recall and the amount of missing data that existed. Where data were missing from patient completed questionnaires, the substudy was able to identify no differences between responders and non-responders. Although problems relating to missing data were minimised for part of the economic evaluation, any missing data had to be imputed. The method chosen to do this was, for costs, by imputing missing data using regression methods for both imaging and physiotherapy. Other outcomes were imputed using means of the data that were available. Mean imputation will artificially improve the precision of estimates of cost-per QALY by narrowing the confidence intervals. However, as *Table 15* demonstrates, the effect of this is likely to be minor. Furthermore, provided that the data were missing at random (a particular group of patients were not more or less likely to have missing data), the central estimates of costs, QALYs and incremental cost per QALY would not be changed.

The principal resource implication is the cost of imaging, as there appear to be few differences in management over the 2-year follow-up period. The cost-effectiveness analysis is subject to the same statistical uncertainties as discussed above. On the one hand, there is a 10% possibility that imaging is both less costly and more effective and an approximately 90% possibility that the incremental cost per QALY is less than £30,000. On the other hand, there is a 10% possibility that 'early imaging' is more costly and equally or less effective.

Chapter 5
Conclusions

Decisions about the use of sophisticated imaging will therefore depend to an important extent on judgements about the value of the observed differences in outcome and whether they are worth the extra costs of 'early imaging'. Although the early use of MRI does not appear to affect management overall, the benefit that it delivers is of questionable clinical significance. Whereas some may argue that any improvement is worthwhile given that the other costs of management/therapy do not appear to be increased, others may say that the cost of providing a small, questionable improvement in patients' overall well-being is not justifiable, especially when there are many competing demands for MRI resources.

Chapter 6

Future research

Information from the subgroup analysis, although the differences were not statistically significant, suggests that MRI may have more impact on patients with sciatica and those with symptoms of 3–12 months' duration. Further work may be justified concentrating on this group and examining whether the early use of MRI impacts on patient outcome. Patients could be recruited from either a primary care setting or from a 'fast-track' secondary care setting to avoid lengthy NHS waiting times. In the more common, chronic LBP group of patients, MRI does not appear to contribute to an understanding of the cause of the pain. However, a trial of patient reassurance, comparing the effect of MRI with clinician or other healthcare worker explanation, may be justified. However, there is some evidence that MRI may be more clinically useful than a plain radiograph.[106,107] A large-scale randomised trial is justified to compare MRI with plain radiography to establish if this results in improved patient outcome.

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Contributions of the authors

FJ Gilbert was the principal grant applicant, contributed to the development of the trial protocol and the preparation of the report and was overall responsible for the conduct of the trial.

AM Grant contributed to the development of the trial design, commented on all aspects of the conduct of the trial and contributed to the preparation of the report.

MGC Gillan was responsible for the day-to-day management of the trial, monitored data collection and assisted in the preparation of the report.

L Vale and E McIntosh were responsible for the protocol for the economic evaluation and L Vale conducted the economic data collection and analysis and prepared the economic evaluation for the report.

MK Campbell and NW Scott contributed to the trial design, conducted the statistical analysis, assisted L Vale in the analysis of the data for the economic evaluation and commented on the report.

D Wardlaw and D Knight advised on clinical aspects of the trial design and the conduct of the trial and commented on the draft report.

RW Porter contributed to the grant application and the trial design, advising on clinical aspects, and commented on the development of the trial protocol.

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Appendix 1

Patient eligibility assessment form

SECTION 1 **THE SCOTTISH BACK TRIAL**
SURGEON'S INITIAL ASSESSMENT

	Surname	**Firstname**
or	**Date of Birth**	/ / dd mm yy
	Sex **Male** ☐	**Female** ☐

Once assessed clinically, please consider this patient for the 'THE SCOTTISH BACK TRIAL'

○ RING THE APPROPRIATE DIAGNOSTIC CATEGORY (*one only):*

1 Symptomatic lumbar disc protrusion
2 Root entrapment secondary to degenerative disease
3 Neurogenic claudication
4 Chronic low back pain not covered by the above categories
5 Other, not covered by the above categories, *please specify*

Do you think the patient requires IMMEDIATE imaging?

☐ No ☐ Yes → Ineligible

Reason:

Are you discharging the patient without further inpatient or outpatient treatment or follow up?

☐ No ☐ Yes → Ineligible → Return this form to the trial research nurse

THE PATIENT IS ELIGIBLE
Is there any reason why the patient should not be recruited into the Scottish Back Trial?

☐ No ☐ Yes, Reason …….

Complete the following questions

Further appointment planned (unless allocated early imaging) ☐ No ☐ Yes ☐☐☐ weeks

If allocated early imaging which modality would you order?

☐ MRI ☐ CT ☐ MYELOGRAPHY

If there had been no trial would you have ordered early imaging? ☐ No ☐ Yes

Name of person completing form _____

Grade: (*tick one*)	Consultant	☐	Senior registrar	☐
	Associate specialist	☐	SHO	☐
	Staff grade	☐	Orthopaedic physician	☐
	Specialist registrar	☐	Specialist physiotherapist	☐

NOW PASS THIS FORM (AND THE PATIENT!) TO THE RESEARCH NURSE

Appendix 2

Patient information leaflet, consent form and GP letter

If you need further information, please contact Maureen Gillan on:

01224 681818 ext 51170

The Scottish Back Trial is a multi centre study funded by a grant from the NHS Research and Development Programme

Departments of
Radiology
Orthopaedics
Neurosurgery
and
Health Services Research Unit
University of Aberdeen
ABERDEEN
AB25 2ZD

Your doctor has arranged for you to see a specialist in this hospital because of your back problems. We shall do all that we can to help you. However, we are always trying to improve the care we give and this leaflet describes a research study being conducted by the University of Aberdeen to assess how useful imaging tests (pictures of your back) are for people with back problems like yours. If your back specialist considers that you would be suitable for our study we would like you to read this leaflet and consider taking part in the study.

The need for further investigation of the back by special scans (pictures) is not absolutely clear. There are several types of scans:

1. CT - a body scan using a computer and X-rays
2. MRI - using computerised magnets or
3. Myelograms - where dye is injected into the back.

These scans are time consuming and very expensive. Some doctors might advise this type of imaging early whereas others only book the scan later if the symptoms do not settle.

Your back specialist will do a thorough assessment and discuss your treatment plan with you. In addition, if your specialist considers that you would be suitable for our research study you will be invited to join the study.

Your specialist with others across Scotland is taking part in a study which will find out how useful (or not) early imaging tests are for people with back problems. In this research study some patients are randomly allocated to have early imaging (scans) and others to have imaging only if and when their doctor thinks it is definitely necessary. In a randomised study like this one neither your doctor nor you are able to choose which group you go into.

If you do agree to join the study please be reassured that if at any time your specialist decides imaging is clearly needed then this will be arranged. If you decide not to take part this will not affect the care you receive and if you decide to take part now you can withdraw at any time in the future.

You will be asked to complete a questionnaire to assess your health status and how your back problems affect your everyday life. Similar questionnaires will be sent to you after 6 months and 2 years. All information will be dealt with in the strictest confidence.

Your specialist or the trial nurse/therapist will discuss the study and answer any of your questions.

CONSENT FORM FOR PATIENTS

Have you read the patient information sheet? [YES] [NO]

Have you discussed the study and received satisfactory answers to any questions? [YES] [NO]

Have you received enough information about the study? [YES] [NO]

Who have you spoken to: Dr/Mr/Mrs/Ms……..

Do you want to join the study? [YES] [NO]

Do you understand:-
that you are free to withdraw from the trial at any time? [YES] [NO]

that if you do withdraw, you do not have to give any reason? [YES] [NO}

and that if you do withdraw, this will not affect your care? [YES] [NO]

that if you are pregnant you will not be scanned? [YES] [NO]

Telephone number where patient can be contacted:

……..(Home) ……..(Work)

Please sign here: ……Date: ……/……/……

and write your name here in block letters ……..

The Grampian Research Ethics Committee of Grampian Health Board and the University of Aberdeen has approved this study and may wish to inspect the data collected at any time as part of its monitoring activities.

THE SCOTTISH BACK TRIAL

DEPARTMENT OF RADIOLOGY
UNIVERSITY OF ABERDEEN
WEST BLOCK POLWARTH BUILDING FORESTERHILL ABERDEEN AB25 2ZD
Telephone 01224 681818 Ext 51170 Fax 01224 403032
Email: m.g.gillan@abdn.ac.uk

Professor FJ Gilbert
Professor of Radiology
Dr MGC Gillan
Trial Coordinator

Date:

Dear Dr

Patient:
Address:

I am writing to advise you that this patient has given informed consent to participate in a research study being conducted by the University of Aberdeen. The study has the approval of the Multi Centre Research Ethics Committee for Scotland and the local research ethics committee.

The study is a randomised controlled trial to establish whether early use of sophisticated imaging (MRI or CT scanning) influences the clinical management and outcome of patients with low back pain and whether it is cost effective. All patients with symptomatic lumbar spine disorders referred to orthopaedic or neurosurgeons for whom there is clinical uncertainty about whether to perform imaging are eligible for the trial. However, patients in whom imaging is clearly indicated e.g. need for surgery or for whom there is no clinical reason to consider imaging, such as those discharged from the clinic, will be excluded.

Having given informed consent, patients are randomised to either:

a. *'early imaging'* i.e. MRI or CT (or myelography) as soon as possible or
b. *'delayed, selective'* imaging i.e. patients will only have imaging if a clear clinical indication develops.

Patients complete a health status questionnaire on entry to the trial and postal questionnaires will be sent after 8 and 24 months.

Your patient was allocated EARLY/DELAYED SELECTIVE IMAGING

NB If you consider that a trial patient allocated DELAYED/SELECTIVE imaging *may* require imaging, *please do not request a scan* but refer the patient for an urgent outpatient review appointment.

If you require further information please contact Maureen Gillan on 01224 681818 ext551170.

Yours sincerely

Maureen G C Gillan (Trial Coordinator)

The Scottish Back Trial, a multi centre study funded by the NHS Research & Development Programme, is being conducted by the Departments of Radiology, Orthopaedics, Neurosurgery and the Health Services Research Unit, University of Aberdeen.

Appendix 3

Trial entry form

TRIAL ENTRY FORM

(to be completed by the research nurse)

	Surname	**Firstname**

or

Check that the patient is eligible and is fully informed about the trial; then seek consent.

Consent given

Consent not given

Reason: _____

_____

Just return this form along with the surgeon's form to the coordinating centre

Duration of current episode: ☐☐☐ days

History of back pain: ☐☐☐ months

Number of previous episodes? ☐☐

Previous treatment this episode? No ☐ Yes ☐

GP ☐ 1 Physiotherapy ☐ 2 Osteopath ☐ 3 Other (*details*) ☐ 4 _____

Has the patient ever had a lumbar spine x-ray? No ☐ Yes ☐ Date: / /
dd mm yy

Has the patient ever had previous back imaging? No ☐ Yes ☐

If YES: Type	Date	Place
(1)	/ /	
(2)	/ /	

In paid employment? No ☐ Yes, manual ☐ Yes, non-manual ☐

Occupation: _____

Taken time off work/normal activities because of this episode of back pain? No ☐ Yes ☐

If so, work-related back pain? No ☐ Yes ☐

Is litigation, because of back injury, pending? No ☐ Yes ☐

ADDITIONAL IDENTIFYING DETAILS

Patient's telephone number:

hospital number:

GP's name: _____

Address: _____

_____

Postcode: _____

Now ask the patient to complete the trial entry questionnaire. Once this is underway, telephone for the trial allocation. Be ready to give:

The consultant surgeon's code (from the list) | | | | | |

The patient's:

Surname _____ Firstname _____

Date of birth | | | | | | |

Sex Male | | 1 Female | | 2

(and from the surgeon's form)
The number of the diagnostic category | |

Then phone 0800 387 444

You will be given in return: **The study number:** | | | | |

(write it here)

The allocation: EARLY DELAYED, SELECTIVE

(Please circle)

If the allocation is to early imaging:

- tell the patient (a) that an appointment for imaging will be sent through the post; and (b) to arrange an outpatient appointment two/three weeks after the imaging examination appointment
- have the imaging request form completed, signed and passed to the radiology department.
- ask the patient to complete the patient diary to assist answering the questionnaire which will be sent in eight months' time.

If the allocation is to delayed, selective imaging:

- tell the patient to make an appointment as requested (if at all) on the surgeon's form.
- ask the patient to complete the patient diary to assist in answering the questionnaire which will be sent in eight months' time.

Appendix 4

Baseline questionnaire, 8-month follow-up questionnaire and 24-month follow-up questionnaire

TRIAL ENTRY QUESTIONNAIRE Study No ☐☐☐☐☐

Dear Patient

Thank you for agreeing to participate in The Scottish Back Trial.

This questionnaire is designed to give us information about how your back trouble has affected your ability to manage in everyday life. Each question will help us evaluate your back pain problem. We would therefore ask you to answer all the questions (even those that seem very alike).

Departments of Radiology, Orthopaedics, Neurosurgery and Health Services Research Unit,
University of Aberdeen

Section 1

The following questions ask for your views about how well you are able to do your usual activities. If you are unsure about how to answer any question, please give the best answer you can and make any of your own comments if you like.

1. In general, would you say your health is:
(please tick one box only)

Excellent	☐ 1
Very Good	☐ 2
Good	☐ 3
Fair	☐ 4
Poor	☐ 5

2. Compared to one year ago, how would you rate your health in general now?
(please tick one box only)

Much better than one year ago	☐ 1
Somewhat better than one year ago	☐ 2
About the same	☐ 3
Somewhat worse than one year ago	☐ 4
Much worse than one year ago	☐ 5

The following questions are about activities you might do during a typical day.
Please tick ☑ **one** box on **each** line.

3. Does your health limit you in these activities? If so, how much?
(*please tick one box for each question)*

	Yes, limited a lot 1	**Yes, limited a little** 2	**No, not limited at all** 3
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
Lifting or carrying groceries	☐	☐	☐
Climbing **several** flights of stairs	☐	☐	☐
Climbing **one** flight of stairs	☐	☐	☐
Bending, kneeling or stooping	☐	☐	☐
Walking **more than a mile** (1.6 km)	☐	☐	☐
Walking **half a mile** (500 metres)	☐	☐	☐
Walking **100 yards** (100 metres)	☐	☐	☐
Bathing and dressing yourself	☐	☐	☐

4. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?
(please tick either **Yes** or **No** to each question)

	Yes 1	**No** 2
Cut down on the **amount of time** you spent on work or other activities	☐	☐
Accomplished less than you would like	☐	☐
Were limited in the **kind** of work or other activities	☐	☐
Had **difficulty** performing the work or other activities	☐	☐

5. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?
(please tick either **Yes** or **No** to each question)

	Yes 1	**No** 2
Cut down on the **amount of time** you spent on work or other activities	☐	☐
Accomplished less than you would like	☐	☐
Didn't do work or other activities as **carefully** as usual	☐	☐

6. During the *past 4 weeks*, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?
(please tick one box)

Not at all	☐ 1
Slightly	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

7. How much *bodily* pain have you had during the *past 4 weeks*?
(please tick one box only)

None	☐ 1
Very Mild	☐ 2
Mild	☐ 3
Moderate	☐ 4
Severe	☐ 5
Very Severe	☐ 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work including work both outside the home and housework?
(please tick one box only)

None at all	☐ 1
A little	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

These questions are about how you feel and how things have been with you during the past month. (For each question, please indicate the one answer that comes closest to the way you have been feeling)

9. How much time during *the past month*: (please tick **one** box on **each** line)

	All of the time 1	**Most of the time** 2	**A good bit of the time** 3	**Some of the time** 4	**A little of the time** 5	**None of the time** 6
Did you feel full of life	☐	☐	☐	☐	☐	☐
Have you been a very nervous person	☐	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up	☐	☐	☐	☐	☐	☐
Have you felt calm and peaceful	☐	☐	☐	☐	☐	☐
Did you have a lot of energy	☐	☐	☐	☐	☐	☐
Have you felt downhearted and low	☐	☐	☐	☐	☐	☐
Did you feel worn out	☐	☐	☐	☐	☐	☐
Have you been a happy person	☐	☐	☐	☐	☐	☐
Did you feel tired	☐	☐	☐	☐	☐	☐

10. During the *past 4 weeks*, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? *(please tick one box)*

All of the time	☐ 1
Most of the time	☐ 2
Some of the time	☐ 3
A little of the time	☐ 4
None of the time	☐ 5

11. Please choose the answer that best describes how true or false each of the following statements is for you. *(please tick one box on each line)*

	Definitely true 1	**Mostly True** 2	**Not sure** 3	**Mostly false** 4	**Definitely false** 5
I seem to get ill more easily than other people	☐	☐	☐	☐	☐
I am as healthy as anybody I know	☐	☐	☐	☐	☐
I expect my health to get worse	☐	☐	☐	☐	☐
My health is excellent	☐	☐	☐	☐	☐

Section 2

Please indicate which statement describes your own health state **today**. Please answer all by placing a tick ☑ in **one** of the three options for each question.

1. Mobility

I have no problems in walking about	1
I have some problems walking about	2
I am confined to my bed	3

2. Self-care

I have no problems with self-care	1
I have some problems washing or dressing myself	2
I am unable to dress myself	3

3. Usual activities

I have no problems with performing my usual activities e.g. work, study, housework, family or leisure	1
I have some problems performing my usual activities	2
I am unable to perform my usual activities	3

4. Pain/discomfort

I have no pain or discomfort	1
I have moderate pain or discomfort	2
I have extreme pain or discomfort	3

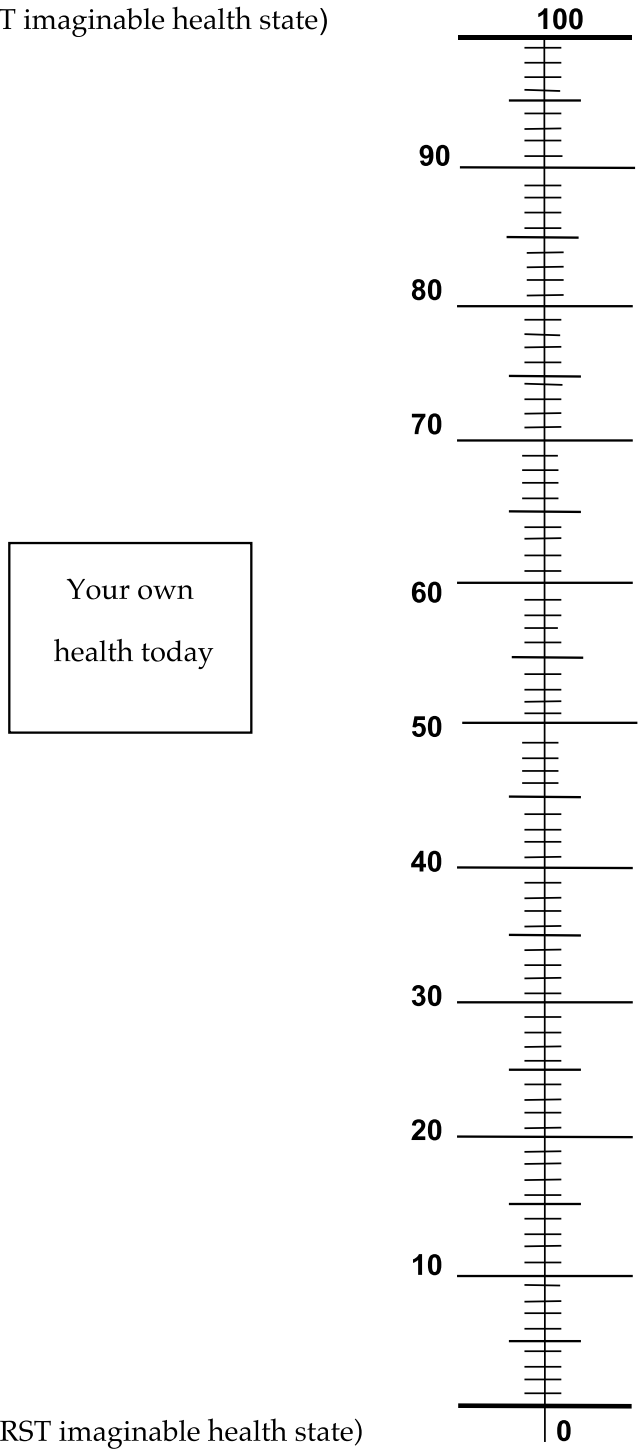
5. Anxiety/depression

I am not anxious or depressed	1
I am moderately anxious or depressed	2
I am extremely anxious or depressed	3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state is marked by 0.

We would like you to indicate on this scale how good or bad your own health is, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale best indicates how good or bad your health state is.

(BEST imaginable health state)



Your own health today

(WORST imaginable health state)

Section 3

YOUR BACK

1. In the last two weeks, for how many days did you suffer pain in the back or leg(s)?
(Please tick one box)

None at all	1
Between 1 and 5 days	2
Between 6 and 10 days	3
For more than 10 days	4

2. On the worst day during the last two weeks, how many painkilling tablets did you take?
(Please tick one box)

None at all	1
Less than 4 tablets	2
Between 4 and 8 tablets	3
Between 9 and 12 tablets	4
More than 12 tablets	5

3. Is the pain made worse by any of the following?
(Please tick all boxes that apply to you)

Coughing	1
Sneezing	2
Sitting	3
Standing	4
Bending	5
Walking	6

4. Does lying down ease the pain?
(Please tick one box)

Yes	1
No	2

5. In your right leg, do you have any pain in the following areas?
(Please tick all boxes that apply to you)

Pain in the buttock	1
Pain in the thigh	2
Pain in the shin/calf	3
Pain in the foot/ankle	4

6. In your left leg, do you have any pain in the following areas?
(Please tick all boxes that apply to you)

Pain in the buttock	☐ 1
Pain in the thigh	☐ 2
Pain in the shin/calf	☐ 3
Pain in the foot/ankle	☐ 4

7. Do you have any loss of feeling in your legs?
(Please tick one box)

No	☐ 1
Yes, just one leg	☐ 2
Yes, both legs	☐ 3

8. In your right leg, do you have any weakness or loss of power in the following areas?
(Please tick all boxes that apply to you)

The hip	☐ 1
The knee	☐ 2
The ankle	☐ 3
The foot	☐ 4

9. In your left leg, do you have any weakness or loss of power in the following areas?
(Please tick all boxes that apply to you)

The hip	☐ 1
The knee	☐ 2
The ankle	☐ 3
The foot	☐ 4

10. If you were to try and bend forwards without bending your knees, how far down do you think you could bend before the pain stopped you?
(Please tick one box)

I could touch the floor	☐ 1
I could touch my ankles with the tips of my fingers	☐ 2
I could touch my knees with the tips of my fingers	☐ 3
I could touch my mid-thighs with the tips of my fingers	☐ 4
I couldn't bend forwards at all	☐ 5

11. On the worst night during the last two weeks, how badly was your sleep affected by the pain?
(Please tick one box)

Not affected at all	☐ 1
I didn't lose any sleep but needed tablets	☐ 2
It prevented me from sleeping but I slept for more than four hours	☐ 3
I had only 2-4 hours sleep	☐ 4
I had less than two hours sleep	☐ 5

12. On the worst day during the last two weeks, did the pain interfere with your ability to sit down?

(Please tick one box)

I was able to sit in any chair as long as I liked	1
I could only sit in my favourite chair as long as I liked	2
Pain prevented me from sitting more than 1 hour	3
Pain prevented me from sitting more than 30 minutes	4
Pain prevented me from sitting more than 15 minutes	5
Pain prevented me from sitting at all	6

13. On the worst day during the last two weeks, did the pain interfere with your ability to stand?

(Please tick one box)

I could stand as long as I wanted without extra pain	1
I could stand as long as I wanted but it gave me extra pain	2
Pain prevented me from standing for more than 1 hour	3
Pain prevented me from standing for more than 30 minutes	4
Pain prevented me from standing for more than 15 minutes	5
Pain prevented me from standing at all	6

14. On the worst day during the last two weeks, did the pain interfere with your ability to walk?

(Please tick one box)

Pain did not prevent me walking any distance	1
Pain prevented me walking more than 1 mile	2
Pain prevented me walking more than 1/2 mile	3
Pain prevented me walking more than 1/4 mile	4
I can walk but less than 1/4 mile	5
I was unable to walk at all	6

15. In the last two weeks, did the pain prevent you from carrying out your work/housework and other daily activities?

(Please tick one box)

No, not at all	1
I could continue with my work, but my work suffered	2
Yes, for one day	3
Yes, for 2-6 days	4
Yes, for more than 7 days	5

16. In the last two weeks, for how many days have you had to stay in bed because of the pain?

(Please tick one box)

None at all	1
Between 1 and 5 days	2
Between 6 and 10 days	3
For more than 10 days	4

17. In the last two weeks, has your sex life been affected by your pain?
(Please tick one box)

Not affected by the pain	☐ 1
Mildly affected by the pain	☐ 2
Moderately affected by the pain	☐ 3
Pain prevents any sex life at all	☐ 4
Does not apply	☐ 5

18. In the last two weeks, have your leisure activities been affected by your pain (including sports, hobbies and social life)?
(Please tick one box)

Not affected by the pain	☐ 1
Mildly affected by the pain	☐ 2
Moderately affected by the pain	☐ 3
Severely affected by the pain	☐ 4
Pain prevents any social life at all	☐ 5

19. In the last two weeks, has the pain interfered with your ability to look after yourself e.g. washing, dressing etc.?
(Please tick one box)

Not at all	☐ 1
Because of pain, I needed some help looking after myself	☐ 2
Because of pain, I needed a lot of help looking after myself	☐ 3
Because of pain, I could not look after myself at all	☐ 4

Thank you for your cooperation in completing this questionnaire.
This information is completely confidential and will only be seen by the research team.

Please return the questionnaire in the enclosed pre-paid envelope

THANK YOU FOR PARTICIPATING IN THE SCOTTISH BACK TRIAL

The Scottish Back Trial is a multi centre study funded by the NHS Research & Development Programme

Study No. | | | | | |

8 MONTH FOLLOW-UP PATIENT QUESTIONNAIRE

Dear Participant

Thank you again for agreeing to take part in The Scottish Back Trial.
We would be very grateful if you would fill in this questionnaire so that we know how you are now.

The Scottish Back Trial is a multi centre study funded by the NHS Research & Development Programme

First, we would like to ask you some questions about hospital visits and other treatments for your back problem. We are asking about the eight months since you joined the study. Please tick a 'YES' or 'NO' box and give extra details if you tick 'YES'.

During the time since you joined the study about eight months ago have you ***because of your back troubles:***

Had further outpatient consultations?	☐ NO	☐ YES	How many?	_____
Had imaging (e.g. MRI, X-ray)?	☐ NO	☐ YES	Where?	_____
Had physiotherapy?	☐ NO	☐ YES	Where?	_____
			How often?	_____
Seen a private physiotherapist/osteopath/ chiropractor?	☐ NO	☐ YES	How often?	_____
Had a back support/corset/brace?	☐ NO	☐ YES	Details?	_____
Been admitted to hospital?	☐ NO	☐ YES	How often?	_____
			Which hospital?	_____
Had surgery?	☐ NO	☐ YES	Which hospital?	_____
Had injections for your back?	☐ NO	☐ YES	How many?	_____
			Which hospital?	_____
Had any other special tests or procedures for your back?	☐ NO	☐ YES	Details?	_____
Seen your GP about your back?	☐ NO	☐ YES	How often?	_____
Had prescription medicines for your back?	☐ NO	☐ YES	How many?	_____
Bought any medicines for your back?	☐ NO	☐ YES	Details:	_____
Had days off work?	☐ NO	☐ YES	Number?	_____

Now please turn to the next page and complete the questionnaire.

This questionnaire is similar to the one you completed at trial entry and is designed to give us information about how your back trouble has affected your ability to manage everyday life. Please answer all the questions (even those that seem very alike).

Section 1

The following questions ask for your views about how well you are able to do your usual activities. If you are unsure about how to answer any question, please give the best answer you can and make any of your own comments if you like.

1. In general, would you say your health is:
(please tick one box only)

Excellent	☐ 1
Very Good	☐ 2
Good	☐ 3
Fair	☐ 4
Poor	☐ 5

2. Compared to one year ago, how would you rate your health in general now?
(please tick one box only)

Much better than one year ago	☐ 1
Somewhat better than one year ago	☐ 2
About the same	☐ 3
Somewhat worse than one year ago	☐ 4
Much worse than one year ago	☐ 5

The following questions are about activities you might do during a typical day.
Please tick ☑ **one** box on **each** line.

3. Does your health limit you in these activities? If so, how much?
(please tick one box only)

	Yes, limited a lot 1	Yes, limited a little 2	No, not limited at all 3
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
Lifting or carrying groceries	☐	☐	☐
Climbing **several** flights of stairs	☐	☐	☐
Climbing **one** flight of stairs	☐	☐	☐
Bending, kneeling or stooping	☐	☐	☐
Walking **more than a mile** (1.6 km)	☐	☐	☐
Walking **half a mile** (500 metres)	☐	☐	☐
Walking **100 yards** (100 metres)	☐	☐	☐
Bathing and dressing yourself	☐	☐	☐

4. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?
(please tick either **Yes** or **No** to each question)

	Yes 1	No 2
Cut down on the **amount of time** you spent on work or other activities	☐	☐
Accomplished less than you would like	☐	☐
Were limited in the **kind** of work or other activities	☐	☐
Had **difficulty** performing the work or other activities	☐	☐

5. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

(please tick either **Yes** or **No** to each question)

	Yes 1	No 2
Cut down on the **amount of time** you spent on work or other activities	☐	☐
Accomplished less than you would like	☐	☐
Didn't do work or other activities as **carefully** as usual	☐	☐

6. During the *past 4 weeks*, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?
(please tick one box)

Not at all	☐ 1
Slightly	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

7. How much *bodily* pain have you had during the *past 4 weeks*?
(please tick one box only)

None	☐ 1
Very Mild	☐ 2
Mild	☐ 3
Moderate	☐ 4
Severe	☐ 5
Very Severe	☐ 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work including work both outside the home and housework?

(please tick one box only)

None at all	☐ 1
A little	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

These questions are about how you feel and how things have been with you during the past month. (For each question, please indicate the one answer that comes closest to the way you have been feeling)

9. How much time during *the past month*: (please tick **one** box on **each** line)

	All of the time 1	**Most of the time** 2	**A good bit of the time** 3	**Some of the time** 4	**A little of the time** 5	**None of the time** 6
Did you feel full of life	☐	☐	☐	☐	☐	☐
Have you been a very nervous person	☐	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up	☐	☐	☐	☐	☐	☐
Have you felt calm and peaceful	☐	☐	☐	☐	☐	☐
Did you have a lot of energy	☐	☐	☐	☐	☐	☐
Have you felt downhearted and low	☐	☐	☐	☐	☐	☐
Did you feel worn out	☐	☐	☐	☐	☐	☐
Have you been a happy person	☐	☐	☐	☐	☐	☐
Did you feel tired	☐	☐	☐	☐	☐	☐

10. During the *past 4 weeks,* how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? *(please tick one box)*

All of the time	☐ 1
Most of the time	☐ 2
Some of the time	☐ 3
A little of the time	☐ 4
None of the time	☐ 5

11. Please choose the answer that best describes how true or false each of the following statements is for you. (please tick one box on each line)

	Definitely true 1	Mostly True 2	Not sure 3	Mostly false 4	Definitely false 5
I seem to get ill more easily than other people	☐	☐	☐	☐	☐
I am as healthy as anybody I know	☐	☐	☐	☐	☐
I expect my health to get worse	☐	☐	☐	☐	☐
My health is excellent	☐	☐	☐	☐	☐

Section 2

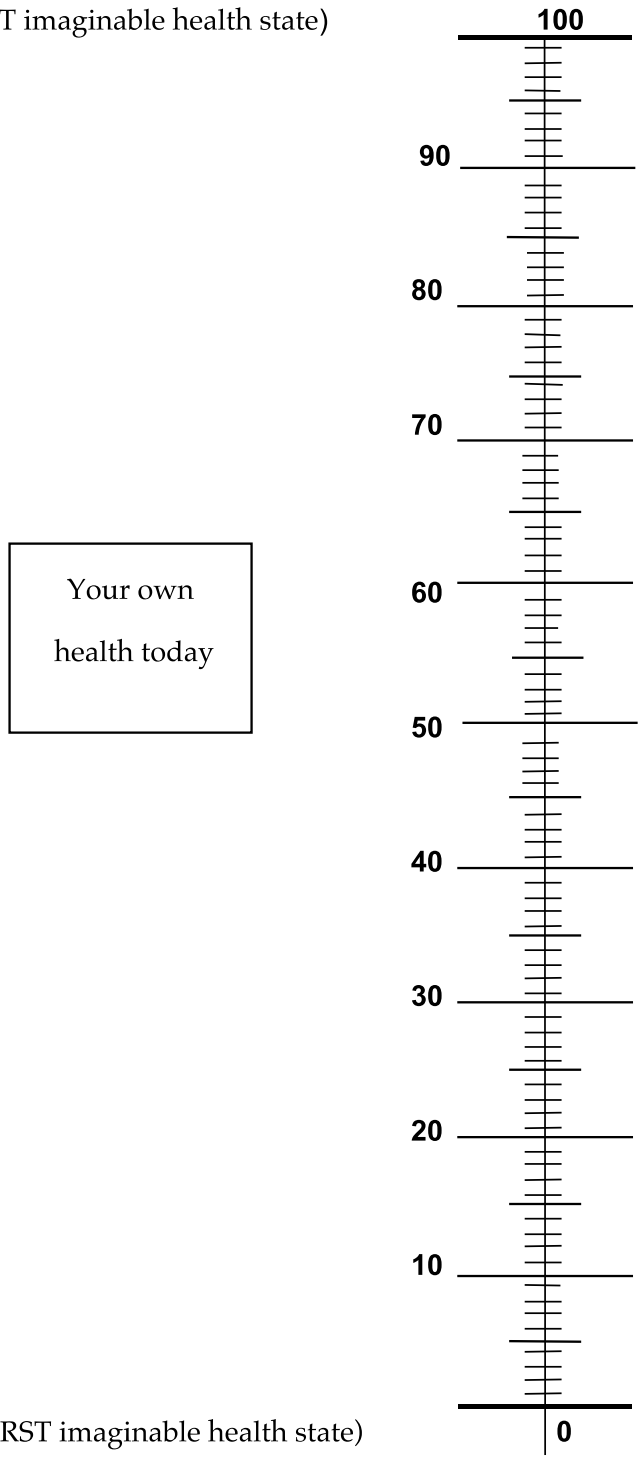
Please indicate which statement describes your own health state **today**. Please answer all by placing a tick ☑ in **one** of the three options for each question.

1.	**Mobility**	I have no problems in walking about	☐ 1
		I have some problems walking about	☐ 2
		I am confined to my bed	☐ 3
2.	**Self-care**	I have no problems with self-care	☐ 1
		I have some problems washing or dressing myself	☐ 2
		I am unable to dress myself	☐ 3
3.	**Usual activities**	I have no problems with performing my usual activities e.g. work, study, housework, family or leisure	☐ 1
		I have some problems performing my usual activities	☐ 2
		I am unable to perform my usual activities	☐ 3
4.	**Pain/discomfort**	I have no pain or discomfort	☐ 1
		I have moderate pain or discomfort	☐ 2
		I have extreme pain or discomfort	☐ 3
5.	**Anxiety/depression**	I am not anxious or depressed	☐ 1
		I am moderately anxious or depressed	☐ 2
		I am extremely anxious or depressed	☐ 3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state is marked by 0.

We would like you to indicate on this scale how good or bad your own health is, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale best indicates how good or bad your health state is.

(BEST imaginable health state)



Your own health today

(WORST imaginable health state)

Section 3

YOUR BACK

1. In the last two weeks, for how many days did you suffer pain in the back or leg(s)?
(Please tick one box)

None at all	1
Between 1 and 5 days	2
Between 6 and 10 days	3
For more than 10 days	4

2. On the worst day during the last two weeks, how many painkilling tablets did you take?
(Please tick one box)

None at all	1
Less than 4 tablets	2
Between 4 and 8 tablets	3
Between 9 and 12 tablets	4
More than 12 tablets	5

3. Is the pain made worse by any of the following?
(Please tick all boxes that apply to you)

Coughing	1
Sneezing	2
Sitting	3
Standing	4
Bending	5
Walking	6

4. Does lying down ease the pain?

Yes	1
No	2

5. In your right leg, do you have any pain in the following areas?
(Please tick all boxes that apply to you)

Pain in the buttock	1
Pain in the thigh	2
Pain in the shin/calf	3
Pain in the foot/ankle	4

6. In your left leg, do you have any pain in the following areas?
(Please tick all boxes that apply to you)

Pain in the buttock	☐	1
Pain in the thigh	☐	2
Pain in the shin/calf	☐	3
Pain in the foot/ankle	☐	4

7. Do you have any loss of feeling in your legs?
(Please tick one box)

No	☐	1
Yes, just one leg	☐	2
Yes, both legs	☐	3

8. In your right leg, do you have any weakness or loss of power in the following areas?
(Please tick all boxes that apply to you)

The hip	☐	1
The knee	☐	2
The ankle	☐	3
The foot	☐	4

9. In your left leg, do you have any weakness or loss of power in the following areas?
(Please tick all boxes that apply to you)

The hip	☐	1
The knee	☐	2
The ankle	☐	3
The foot	☐	4

10. If you were to try and bend forwards without bending your knees, how far down do you think you could bend before the pain stopped you?
(Please tick one box)

I could touch the floor	☐	1
I could touch my ankles with the tips of my fingers	☐	2
I could touch my knees with the tips of my fingers	☐	3
I could touch my mid-thighs with the tips of my fingers	☐	4
I couldn't bend forwards at all	☐	5

11. On the worst night during the last two weeks, how badly was your sleep affected by the pain?
(Please tick one box)

Not affected at all	☐	1
I didn't lose any sleep but needed tablets	☐	2
It prevented me from sleeping but I slept for more than four hours	☐	3
I had only 2-4 hours sleep	☐	4
I had less than two hours sleep	☐	5

12. On the worst day during the last two weeks, did the pain interfere with your ability to sit down?

(Please tick one box)

I was able to sit in any chair as long as I liked	1
I could only sit in my favourite chair as long as I liked	2
Pain prevented me from sitting more than 1 hour	3
Pain prevented me from sitting more than 30 minutes	4
Pain prevented me from sitting more than 15 minutes	5
Pain prevented me from sitting at all	6

13. On the worst day during the last two weeks, did the pain interfere with your ability to stand?

(Please tick one box)

I could stand as long as I wanted without extra pain	1
I could stand as long as I wanted but it gave me extra pain	2
Pain prevented me from standing for more than 1 hour	3
Pain prevented me from standing for more than 30 minutes	4
Pain prevented me from standing for more than 15 minutes	5
Pain prevented me from standing at all	6

14. On the worst day during the last two weeks, did the pain interfere with your ability to walk?

(Please tick one box)

Pain did not prevent me walking any distance	1
Pain prevented me walking more than 1 mile	2
Pain prevented me walking more than ½ mile	3
Pain prevented me walking more than ¼ mile	4
I can walk but less than ¼ mile	5
I was unable to walk at all	6

15. In the last two weeks, did the pain prevent you from carrying out your work/housework and other daily activities?

(Please tick one box)

No, not at all	1
I could continue with my work, but my work suffered	2
Yes, for one day	3
Yes, for 2-6 days	4
Yes, for more than 7 days	5

16. In the last two weeks, for how many days have you had to stay in bed because of the pain?

(Please tick one box)

None at all	1
Between 1 and 5 days	2
Between 6 and 10 days	3
For more than 10 days	4

17. In the last two weeks, has your sex life been affected by your pain?
(Please tick one box)

Not affected by the pain	☐ 1
Mildly affected by the pain	☐ 2
Moderately affected by the pain	☐ 3
Pain prevents any sex life at all	☐ 4
Does not apply	☐ 5

18. In the last two weeks, have your leisure activities been affected by your pain (including sports, hobbies and social life)?
(Please tick one box)

Not affected by the pain	☐ 1
Mildly affected by the pain	☐ 2
Moderately affected by the pain	☐ 3
Severely affected by the pain	☐ 4
Pain prevents any social life at all	☐ 5

19. In the last two weeks, has the pain interfered with your ability to look after yourself e.g. washing, dressing etc.?
(Please tick one box)

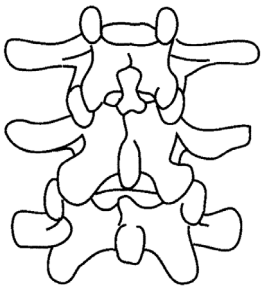
Not at all	☐ 1
Because of pain, I needed some help looking after myself	☐ 2
Because of pain, I needed a lot of help looking after myself	☐ 3
Because of pain, I could not look after myself at all	☐ 4

Thank you for your cooperation in completing this questionnaire.
This information is completely confidential and will only be seen by the research team

Please return the questionnaire in the enclosed pre-paid envelope

The Scottish Back Trial is being conducted by the Departments of Radiology, Orthopaedics, Neurosurgery and the Health Services Research Unit in the University of Aberdeen.

If you require further information please contact the trial co-ordinator, Maureen Gillan on 01224 551170



THE SCOTTISH BACK TRIAL

Study No. | | | | | |

FINAL FOLLOW-UP PATIENT QUESTIONNAIRE

Dear Participant

Thank you again for participating in The Scottish Back Trial. We would be very grateful if you would fill in this final questionnaire so that we know how you are now.

The Scottish Back Trial is a multi centre study funded by the NHS Research & Development Programme

First, we would like to ask you some questions about hospital visits and other treatments for your back problem. We are asking about the **last 16 months i.e. the time interval since the previous health questionnaire.** Please tick a 'YES' or 'NO' box and give extra details if you tick 'YES'.

During the past 16 months have you ***because of your back troubles:***

Had further outpatient consultations?	☐ NO	☐ YES	How many?	_____
Had imaging (e.g. MRI, X-ray)?	☐ NO	☐ YES	Where?	_____
Had physiotherapy?	☐ NO	☐ YES	Where?	_____
			How often?	_____
Seen a private physiotherapist/osteopath/ chiropractor?	☐ NO	☐ YES	How often?	_____
Had a back support/corset/brace?	☐ NO	☐ YES	Details?	_____
Been admitted to hospital?	☐ NO	☐ YES	How often?	_____
			Which hospital?	_____
Had surgery?	☐ NO	☐ YES	Which hospital?	_____
Had injections for your back?	☐ NO	☐ YES	How many?	_____
			Which hospital?	_____
Had any other special tests or procedures for your back?	☐ NO	☐ YES	Details?	_____
Seen your GP about your back?	☐ NO	☐ YES	How often?	_____
Had prescription medicines for your back?	☐ NO	☐ YES	How many?	_____
Bought any medicines for your back?	☐ NO	☐ YES	Details:	_____
Are you currently in paid employment?	☐ NO	☐ YES		
If YES, had days off work due to back problems?	☐ NO	☐ YES	How many?	_____
If not working, had days off normal activities due to back problems?	☐ NO	☐ YES	How many?	_____

Now please turn to the next page and complete the questionnaire.

The questionnaire is similar to the one you completed earlier and is designed to give us information about how your back trouble has affected your ability to manage everyday life. Please answer all the questions (even those that seem very alike).

Section 1

The following questions ask for your views about how well you are able to do your usual activities. If you are unsure about how to answer any question, please give the best answer you can and make any of your own comments if you like.

1. In general, would you say your health is:

(please tick one box only)

Excellent	☐ 1
Very Good	☐ 2
Good	☐ 3
Fair	☐ 4
Poor	☐ 5

2. Compared to one year ago, how would you rate your health in general now?
(please tick one box only)

Much better than one year ago	☐ 1
Somewhat better than one year ago	☐ 2
About the same	☐ 3
Somewhat worse than one year ago	☐ 4
Much worse than one year ago	☐ 5

The following questions are about activities you might do during a typical day.
Please tick ☑ **one** box on **each** line.

3. Does your health limit you in these activities? If so, how much?
(please tick one box only)

	Yes, limited a lot 1	Yes, limited a little 2	No, not limited at all 3
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐	☐	☐
Lifting or carrying groceries	☐	☐	☐
Climbing **several** flights of stairs	☐	☐	☐
Climbing **one** flight of stairs	☐	☐	☐
Bending, kneeling or stooping	☐	☐	☐
Walking **more than a mile** (1.6 km)	☐	☐	☐
Walking **half a mile** (500 metres)	☐	☐	☐
Walking **100 yards** (100 metres)	☐	☐	☐
Bathing and dressing yourself	☐	☐	☐

4. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?
(please tick either **Yes** or **No** to each question)

	Yes 1	No 2
Cut down on the **amount of time** you spent on work or other activities	☐	☐
Accomplished less than you would like	☐	☐
Were limited in the **kind** of work or other activities	☐	☐
Had **difficulty** performing the work or other activities	☐	☐

5. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

(please tick either **Yes** or **No** to each question)

	Yes 1	No 2
Cut down on the **amount of time** you spent on work or other activities	☐	☐
Accomplished less than you would like	☐	☐
Didn't do work or other activities as **carefully** as usual	☐	☐

6. During the *past 4 weeks*, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?
(please tick one box)

Not at all	☐ 1
Slightly	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

7. How much *bodily* pain have you had during the *past 4 weeks*?
(please tick one box only)

None	☐ 1
Very Mild	☐ 2
Mild	☐ 3
Moderate	☐ 4
Severe	☐ 5
Very Severe	☐ 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work including work both outside the home and housework?
(please tick one box only)

None at all	☐ 1
A little	☐ 2
Moderately	☐ 3
Quite a bit	☐ 4
Extremely	☐ 5

These questions are about how you feel and how things have been with you during the past month. (For each question, please indicate the one answer that comes closest to the way you have been feeling)

9. How much time during *the past month*: (please tick **one** box on **each** line)

	All of the time 1	**Most of the time** 2	**A good bit of the time** 3	**Some of the time** 4	**A little of the time** 5	**None of the time** 6
Did you feel full of life	☐	☐	☐	☐	☐	☐
Have you been a very nervous person	☐	☐	☐	☐	☐	☐
Have you felt so down in the dumps that nothing could cheer you up	☐	☐	☐	☐	☐	☐
Have you felt calm and peaceful	☐	☐	☐	☐	☐	☐
Did you have a lot of energy	☐	☐	☐	☐	☐	☐
Have you felt downhearted and low	☐	☐	☐	☐	☐	☐
Did you feel worn out	☐	☐	☐	☐	☐	☐
Have you been a happy person	☐	☐	☐	☐	☐	☐
Did you feel tired	☐	☐	☐	☐	☐	☐

10. During the *past 4 weeks,* how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
(please tick one box)

All of the time	☐ 1
Most of the time	☐ 2
Some of the time	☐ 3
A little of the time	☐ 4
None of the time	☐ 5

11. Please choose the answer that best describes how true or false each of the following statements is for you. (please tick one box on each line)

	Definitely true 1	Mostly True 2	Not sure 3	Mostly false 4	Definitely false 5
I seem to get ill more easily than other people	☐	☐	☐	☐	☐
I am as healthy as anybody I know	☐	☐	☐	☐	☐
I expect my health to get worse	☐	☐	☐	☐	☐
My health is excellent	☐	☐	☐	☐	☐

Section 2

Please indicate which statement describes your own health state **today**. Please answer all by placing a tick ☑ in **one** of the three options for each question.

1. Mobility

I have no problems in walking about	1
I have some problems walking about	2
I am confined to my bed	3

2. Self-care

I have no problems with self-care	1
I have some problems washing or dressing myself	2
I am unable to dress myself	3

3. Usual activities

I have no problems with performing my usual activities e.g. work, study, housework, family or leisure	1
I have some problems performing my usual activities	2
I am unable to perform my usual activities	3

4. Pain/discomfort

I have no pain or discomfort	1
I have moderate pain or discomfort	2
I have extreme pain or discomfort	3

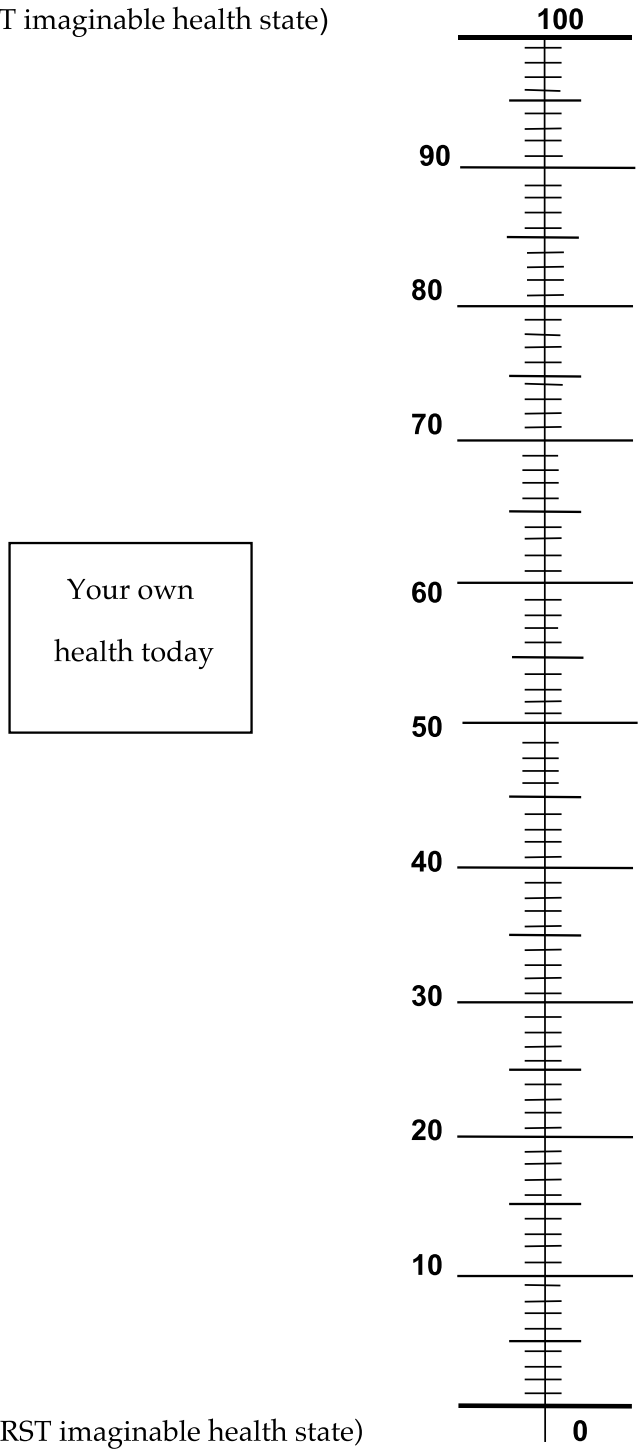
5. Anxiety/depression

I am not anxious or depressed	1
I am moderately anxious or depressed	2
I am extremely anxious or depressed	3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state is marked by 0.

We would like you to indicate on this scale how good or bad your own health is, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale best indicates how good or bad your health state is.

(BEST imaginable health state)



Your own health today

(WORST imaginable health state)

Section 3

YOUR BACK

1. In the last two weeks, for how many days did you suffer pain in the back or leg(s)?
(Please tick one box)

None at all	1
Between 1 and 5 days	2
Between 6 and 10 days	3
For more than 10 days	4

2. On the worst day during the last two weeks, how many painkilling tablets did you take?
(Please tick one box)

None at all	1
Less than 4 tablets	2
Between 4 and 8 tablets	3
Between 9 and 12 tablets	4
More than 12 tablets	5

3. Is the pain made worse by any of the following?
(Please tick all boxes that apply to you)

Coughing	1
Sneezing	2
Sitting	3
Standing	4
Bending	5
Walking	6

4. Does lying down ease the pain?

Yes	1
No	2

5. In your right leg, do you have any pain in the following areas?
(Please tick all boxes that apply to you)

Pain in the buttock	1
Pain in the thigh	2
Pain in the shin/calf	3
Pain in the foot/ankle	4

6. In your left leg, do you have any pain in the following areas?
(Please tick all boxes that apply to you)

Pain in the buttock	☐	1
Pain in the thigh	☐	2
Pain in the shin/calf	☐	3
Pain in the foot/ankle	☐	4

7. Do you have any loss of feeling in your legs?
(Please tick one box)

No	☐	1
Yes, just one leg	☐	2
Yes, both legs	☐	3

8. In your right leg, do you have any weakness or loss of power in the following areas?
(Please tick all boxes that apply to you)

The hip	☐	1
The knee	☐	2
The ankle	☐	3
The foot	☐	4

9. In your left leg, do you have any weakness or loss of power in the following areas?
(Please tick all boxes that apply to you)

The hip	☐	1
The knee	☐	2
The ankle	☐	3
The foot	☐	4

10. If you were to try and bend forwards without bending your knees, how far down do you think you could bend before the pain stopped you?
(Please tick one box)

I could touch the floor	☐	1
I could touch my ankles with the tips of my fingers	☐	2
I could touch my knees with the tips of my fingers	☐	3
I could touch my mid-thighs with the tips of my fingers	☐	4
I couldn't bend forwards at all	☐	5

11. On the worst night during the last two weeks, how badly was your sleep affected by the pain?
(Please tick one box)

Not affected at all	☐	1
I didn't lose any sleep but needed tablets	☐	2
It prevented me from sleeping but I slept for more than four hours	☐	3
I had only 2-4 hours sleep	☐	4
I had less than two hours sleep	☐	5

12. On the worst day during the last two weeks, did the pain interfere with your ability to sit down?

(Please tick one box)

I was able to sit in any chair as long as I liked	1
I could only sit in my favourite chair as long as I liked	2
Pain prevented me from sitting more than 1 hour	3
Pain prevented me from sitting more than 30 minutes	4
Pain prevented me from sitting more than 15 minutes	5
Pain prevented me from sitting at all	6

13. On the worst day during the last two weeks, did the pain interfere with your ability to stand?

(Please tick one box)

I could stand as long as I wanted without extra pain	1
I could stand as long as I wanted but it gave me extra pain	2
Pain prevented me from standing for more than 1 hour	3
Pain prevented me from standing for more than 30 minutes	4
Pain prevented me from standing for more than 15 minutes	5
Pain prevented me from standing at all	6

14. On the worst day during the last two weeks, did the pain interfere with your ability to walk?

(Please tick one box)

Pain did not prevent me walking any distance	1
Pain prevented me walking more than 1 mile	2
Pain prevented me walking more than 1/2 mile	3
Pain prevented me walking more than 1/4 mile	4
I can walk but less than 1/4 mile	5
I was unable to walk at all	6

15. In the last two weeks, did the pain prevent you from carrying out your work/housework and other daily activities?

(Please tick one box)

No, not at all	1
I could continue with my work, but my work suffered	2
Yes, for one day	3
Yes, for 2-6 days	4
Yes, for more than 7 days	5

16. In the last two weeks, for how many days have you had to stay in bed because of the pain?

(Please tick one box)

None at all	1
Between 1 and 5 days	2
Between 6 and 10 days	3
For more than 10 days	4

17. In the last two weeks, has your sex life been affected by your pain?
(Please tick one box)

Not affected by the pain	☐ 1
Mildly affected by the pain	☐ 2
Moderately affected by the pain	☐ 3
Pain prevents any sex life at all	☐ 4
Does not apply	☐ 5

18. In the last two weeks, have your leisure activities been affected by your pain (including sports, hobbies and social life)?
(Please tick one box)

Not affected by the pain	☐ 1
Mildly affected by the pain	☐ 2
Moderately affected by the pain	☐ 3
Severely affected by the pain	☐ 4
Pain prevents any social life at all	☐ 5

19. In the last two weeks, has the pain interfered with your ability to look after yourself e.g. washing, dressing etc.?
(Please tick one box)

Not at all	☐ 1
Because of pain, I needed some help looking after myself	☐ 2
Because of pain, I needed a lot of help looking after myself	☐ 3
Because of pain, I could not look after myself at all	☐ 4

Thank you for completing this questionnaire.
This information is completely confidential and will only be seen by the research team

Please return the questionnaire in the enclosed pre-paid envelope

THANK YOU FOR PARTICIPATING IN THE SCOTTISH BACK TRIAL.

The Scottish Back Trial is being conducted by the Departments of Radiology, Orthopaedics, Neurosurgery and the Health Services Research Unit in the University of Aberdeen.

If you require further information please contact the trial coordinator, Maureen Gillan on 01224 681818 ext 51170

Appendix 5

Data abstraction form 0–8 months and data abstraction form 9–24 months

THE SCOTTISH BACK TRIAL

8 MONTH DATA ABSTRACTION FORM

STUDY No | | | | | |

Trial entry date: _____ Data abstraction date: _____

Follow up date: _____

Has the patient had any of the following treatments/procedures?

❑ **OP APPOINTMENTS** **NO** **YES** Number: _____

❑ **IMAGING** **NO** **YES** If YES Date:

Tick all that apply	Number	DATE(s)	Day clinic(1)	X-ray (2)	Theatre (3)	Ward (4)	Other(5) *Please specify*
MRI (1)							
CT (2)							
STRESS DISCOGRAM(3)							
MYELOGRAM (4)							
BONE SCAN (5)							
X-RAY (6)							
OTHER (*please specify*) (7)							

❑ **PHYSIOTHERAPY** **NO** **YES** Where?: _____ Sessions: _____

❑ **INJECTIONS** **NO** **YES**

Tick all that apply	Number	DATE(s)	Day clinic(1)	X-ray(2)	Theatre(3)	Ward(4)	Other(5) *Please specify*
FACET(1)							
EPIDURAL(2)							
N ROOT INFILTRATION(3)							
TRIGGER POINT(4)							
SCLEROSANT(5)							
OTHER (*please specify*) (6)							

❑ **LUMBAR SUPPORT** **NO** **YES**

Tick all that apply		DATE
LUMBAR SUPPORT(1)		
CORSET(2)		
BRACE(3)		
INSOLES(4)		
OTHER (*please specify*) (5)		

❑ **OTHER DIAGNOSTIC TESTS/PROCEDURES** **NO** **YES**

Details	Number	DATE(s)	Day clinic(1)	X-ray(2)	Theatre(3)	Ward(4)	Other(5) *Please specify*

❑ **INPATIENT STAY** **NO** **YES**

Number of Days: _____ Date of Admission: _____

TRACTION	
OTHER (excluding bed rest or surgery) *please specify*	

❑ **SURGERY** **NO** **YES**

Tick all that apply		**DATE**			**DATE**
CHEMONUCLEOLYSIS(1)			LIGAMENT STABILISATION(4)		
DISC SURGERY(2)			PERCUTANEOUS DISCECTOMY(5)		
SPINAL FUSION(3)			OTHER *(please specify)*(6)		
Anterior					
Posterior					
Posterior + instrumentation					

❑ **MEDICATION** (excluding during surgical admission) **NO** **YES**

Please specify	DATE

Any other information which may be relevant:

THE SCOTTISH BACK TRIAL **24 MONTH DATA ABSTRACTION FORM**

Patient's Surname: _____ STUDY No | | | | | |

Trial entry date: _____ Data abstraction date: _____

Follow up date: _____

Has the patient had any of the following treatments/procedures?

❑ **OP APPOINTMENTS** **NO** **YES** Number: _____

❑ **IMAGING** **NO** **YES** If YES Date:

Tick all that apply	Number	DATE(s)	Day clinic(1)	X-ray (2)	Theatre (3)	Ward (4)	Other(5) *Please specify*
MRI(1)							
CT(2)							
STRESS DISCOGRAM(3)							
MYELOGRAM(4)							
BONE SCAN(5)							
X-RAY(6)							
OTHER (*please specfiy*)(7)							

❑ **PHYSIOTHERAPY** **NO** **YES** Where?: _____ Sessions: _____

❑ **INJECTIONS** **NO** **YES**

Tick all that apply	Number	DATE(s)	Day clinic (1)	X-ray (2)	Theatre (3)	Ward(4)	Other(5) *Please specify*
FACET(1)							
EPIDURAL(2)							
N ROOT INFILTRATION(3)							
TRIGGER POINT(4)							
SCLEROSANT(5)							
OTHER (*please specify*)(6)							

❑ **LUMBAR SUPPORT** **NO** **YES**

Tick all that apply		**DATE**
LUMBAR SUPPORT(1)		
CORSET(2)		
BRACE(3)		
INSOLES(4)		
OTHER (*please specify*) (5)		

❑ **OTHER DIAGNOSTIC TESTS/PROCEDURES** **NO** **YES**

Details	Number	DATE (s)	Day clinic (1)	X-ray (2)	Theatre (3)	Ward(4)	Other(5) *please specify*

❑ **INPATIENT STAY** **NO** **YES**

Number of Days: _____ Date of Admission: _____

TRACTION	

OTHER (excluding bed rest or surgery*) please specify*	

❑ **SURGERY** **NO** **YES**

Tick all that apply		DATE
CHEMONUCLEOLYSIS(1)		
DISC SURGERY(2)		
SPINAL FUSION(3)		
Anterior		
Posterior		
Posterior + instrumentation		

		DATE
LIGAMENT STABILISATION(4)		
PERCUTANEOUS DISCECTOMY(5)		
OTHER *(please specify)* (6)		

❑ **MEDICATION**
(excluding during surgical admission) **NO** **YES**

Please specify		DATE

Any other information which may be relevant:

Appendix 6

Diagnostic impact study: primary assessment form and secondary assessment form

THE SCOTTISH BACK TRIAL

DIAGNOSTIC IMPACT STUDY: PRIMARY ASSESSMENT

Please complete for ALL patients recruited into The Scottish Back Trial (even if not randomised to have a scan)

Name of person completing form :_____

Date:_____

1. WORKING DIAGNOSIS	**Please tick**
1. Symptomatic lumbar disc protrusion	
2. Root entrapment secondary to degenerative disease	
3. Neurogenic claudication	
4. Chronic LBP not covered by 1 to 3	
5. Other not covered by 1 to 4 (*Please specify*):	
CONFIDENCE	
On a scale of 0 to 100% how confident are you of this diagnosis?	%
OTHER RELEVANT DIAGNOSES:	

2. PROPOSED MANAGEMENT	**Please tick**
Discharge with reassurance	
Curative treatment	
Further investigations (*Please specify*):	
Symptomatic treatment (*Please specify*):	
Uncertain	

TREATMENT PROPOSED *Please tick*				**Please tick**
Physiotherapy/exercise		**Epidural injection**		
Manual therapy		**Facet injection**		
Medication		**Other injection**		
Traction		**Chemonucleolysis**		
Bed rest		**Surgery**		
Corset/support		**Other**	*Please specify:*	
CONFIDENCE				
On a scale of 0 to 100% how confident are you that this is the optimal management?				%

3. IF PATIENT IS RANDOMISED TO 'EARLY IMAGING'						**Please tick**
TYPE OF IMAGING REQUESTED						
MRI		**CT**		**Other**	*Please specify:*	
WHAT WOULD YOU EXPECT FROM THE SCAN?						*Please tick*
Establish diagnosis						
Confirm diagnosis						
Assess extent of/locate disease						
Exclude pathology						
Plan treatment						
Other *Please specify*:						
CONFIDENCE						
On a scale of 0 to 100% how confident are you that this examination will achieve your aims?						%

4. ANY ADDITIONAL COMMENTS:

Thank you for completing this form

STUDY NUMBER							

DIAGNOSTIC IMPACT STUDY: SECONDARY ASSESSMENT

Please complete when you first review this Scottish Back Trial Patient (even if they did not have a scan)

Name of person completing form:_____

Date:_____

1. WHAT IS THE DIAGNOSIS NOW?	**Please tick**
1. Symptomatic lumbar disc protrusion	
2. Root entrapment secondary to degenerative disease	
3. Neurogenic claudication	
4. Chronic LBP not covered by 1 to 3	
5. Other not covered by 1 to 4 (*Please specify*):	
CONFIDENCE	
On a scale of 0 to 100% how confident are you of this diagnosis?	%
OTHER RELEVANT DIAGNOSES:	

2. PROPOSED MANAGEMENT	**Please tick**
Discharge with reassurance	
Curative treatment	
Further investigations (*Please specify*):	
Symptomatic treatment (*Please specify*):	
Uncertain	

TREATMENT PROPOSED *Please tick*				**Please tick**
Physiotherapy/exercise		**Epidural injection**		
Manual therapy		**Facet injection**		
Medication		**Other injection**		
Traction		**Chemonucleolysis**		
Bed rest		**Surgery**		
Corset/support		**Other**	*Please specify:*	
CONFIDENCE				
On a scale of 0 to 100% how confident are you that this is the optimal management?				%

3. HAS THE PATIENT HAD A SCAN? *YES* ☐ *NO* ☐ *If YES:DATE of Scan*					
TYPE OF IMAGING					
MRI		**CT**		**Other**	*Please specify:*
PLEASE INDICATE SCALE OF CONTRIBUTION OF SCAN RESULTS:					
No contribution		**Considerable contribution**			
Minor contribution		**Extreme contribution**			
Moderate contribution					
HOW DID THE SCAN RESULTS CONTRIBUTE TO MANAGEMENT PLAN:					
	Please tick				*Please tick*
Establish diagnosis		**Exclude pathology**			
Confirm diagnosis		**Plan treatment**			
Assess extent of/ locate disease		**Other *Please specify*:**			

4. ANY ADDITIONAL COMMENTS:								
Thank you for completing this form	**STUDY NUMBER**							

Appendix 7

Concordance between alternative methods of collecting data on resource use: a comparison of patient questionnaires and hospital notes

Introduction

Health care resource use data are commonly estimated by abstraction from medical records or by patient self-report. Neither method is without its difficulties. Use of medical records can involve problems with access,[108] confidentiality and completeness,[109,110] while patient self-report can yield low response rates if via postal questionnaires or response bias if via interview.[111–116] Furthermore, respondents may be unwilling to disclose sensitive information.[117] The collection of data alongside RCTs raises a number of other issues, including the balance between comprehensive data collection and ensuring that data handling is manageable and does not overburden patients. Research itself is also costly and the resource implications of data collection also need to be considered.[118]

This study assesses the validity of alternative methods used to measure resource use in the Scottish Back Trial.[119] It examines the extent to which self-report data via postal questionnaires provided convergent data on NHS resource use with data from hospital notes.

Subjects and methods

The Scottish Back Trial

The Scottish Back Trial is a multicentre RCT comparing early use of sophisticated imaging (MRI and CT) for all patients referred with LBP with their selective and delayed use.

Subjects and collection of data

The first 116 patients recruited to the trial were included (mean age 46 years, range 19–84 years, male 50.9%, female 49.1%). All participants were recruited at one centre (Grampian University Hospitals NHS Trust).

Primary and secondary care resource use data were collected as part of the trial's economic evaluation. The areas of resource use investigated ranged from appointments and procedures in secondary care through GP visits, prescriptions and costs borne by the patient (e.g. private physiotherapy sessions). Three areas of resource use were investigated: outpatient visits, physiotherapy and injections. These were chosen as they occurred frequently and were relevant to participants in both arms of the trial.

Data were collected from three sources: participant-completed questionnaires, hospital notes and the best available third source. A third source was used as there is no 'gold standard' method for collecting resource use data, and it enabled the accuracy of questionnaires and hospital case notes to be assessed by triangulation. The third sources varied depending on the type of data sought. For outpatient visits and injections the hospital patient administration system was used; physiotherapy department records were used for physiotherapy.

The questionnaires were sent 8 months after recruitment with one reminder. Participants were asked to record use of health care from initial recruitment to the end of the 8-month follow-up period. Data from hospital case notes and the third source were collected retrospectively for the same time period.

Statistical methods

Pairwise comparisons between different methods of data collection were performed. For dichotomous variables the proportion of cases agreeing and a 95% CI around this proportion were calculated for each pair of comparisons. For continuous variables cross-tabulations were produced.

Non-returned questionnaires were coded as missing data. For hospital notes and patient administration system, data were coded as missing if the record could not be retrieved. For continuous variables, it was recorded that no events occurred if no information was noted in the retrieved records. When no record for

TABLE 22 *Data available for the 116 patients in the sample and percentage of data retrieved for each data source*

Area of resource use	Hospital notes: *N* (%)	Questionnaire: *N* (%)	Third source *N* (%)
Outpatient visit	116 (100)	88 (76)	116 (100)
Physiotherapy	116 (100)	92 (79)	105 (91)
Injection	116 (100)	91 (78)	116 (100)

TABLE 23 *Pairwise comparisons for each area of resource use between the alternative methods of data collection*

Area of resource use	Matched data available	Pairwise comparison[a] (%)				Percentage agreeing	95% CI
		Yes/yes	Yes/no	No/yes	No/no		
Questionnaire vs hospital notes							
Outpatient visits	88 (76%)	48	6	18	16	73	62 to 82
Physiotherapy	92 (79%)	49	6	15	22	77	69 to 86
Injection	91 (78%)	25	3	1	62	96	91 to 100
Questionnaire vs third source							
Outpatient visits	88 (76%)	51	3	18	16	76	67 to 85
Physiotherapy	83 (72%)	36	15	7	25	73	64 to 83
Injection	91 (78%)	13	15	1	62	82	75 to 90
Hospital notes vs third source							
Outpatient visits	116 (100%)	85	0	5	26	95	92 to 99
Physiotherapy	105 (91%)	51	23	2	29	76	68 to 84
Injection	116 (100%)	14	16	1	85	85	79 to 92

[a] If the event was recorded in the questionnaire and the hospital notes it was given a yes/yes response. Similarly, if the event was recorded in the questionnaire and not in the hospital notes, it was given a yes/no response.

physiotherapy was found, it was recorded that no episodes of care were provided.

Results

Table 22 shows the data available for each method of data collection for each area of resource use. The response rate for questionnaires was 79% (92/116), which, although acceptable,[110–112,120–123] is relatively poor compared with the other data sources, and they were not always complete (*Table 22*). Within each area, pairwise comparisons were performed only when data were available from all data collection methods.

Agreement between methods was generally good for dichotomous (yes/no) comparisons (*Table 23*). No method performed consistently. For example, questionnaires and hospital notes had the highest agreement for injections but the lowest for outpatient visits. Questionnaires and hospital notes had the highest agreement for physiotherapy and injections whereas questionnaires and the third source were lowest. However, for outpatient visits the highest agreement was between hospital notes and the third source.

Concordance in number of outpatient consultations and physiotherapy sessions was also examined (*Tables 24* and *25*). The number of outpatient visits by questionnaires and hospital notes agreed exactly in 38 cases, although questionnaires reported more episodes in 23 cases and fewer episodes in 27 cases. Data were missing from 28 questionnaires (*Table 24*).

Fewer physiotherapy episodes were reported by questionnaire than by hospital notes in 17 cases, more episodes in 13 cases and there was exact agreement in 24 cases. In addition, there were 62 cases where data were not available from one or both sources (summarised in *Table 25*).

Agreement between questionnaires and the third source for outpatient visits and physiotherapy sessions was shown in 43 and 27 cases respectively. Discrepancies followed a similar pattern to those shown in *Tables 24* and *25* (data not shown). There

TABLE 24 *Comparison of the number of outpatient visits recorded by both hospital notes and patient questionnaires*[a]

Questionnaire	Hospital notes					Total
	0	1	2	3	4	
0	17	16	4	3	1	41
1	1	8	1	1		11
2	3	8	7		1	19
3		2	1	4		7
4			3	1	2	6
5				1	1	2
6			1			1
7	1					1
Not returned	8	14	1	1		24
Not reported	1	2	1			4
Total	31	50	19	11	5	116

[a] Includes 7 people who reported that they had outpatient visits but recorded the number of visits as 0.

TABLE 25 *Comparison of the number of physiotherapy sessions recorded by both hospital notes and patient questionnaires*

Questionnaire	Hospital notes						Total
	0	1–5	6–10	11–15	≥ 16	Not reported	
0	22	6	0	0	0	9	37
1–5	0	5	1	1	0	6	13
6–10	2	2	5	1	0	3	13
11–15	0	0	1	1	1	2	5
≥ 16	0	0	2	2	2	1	7
Not returned	8	6	3	2	1	4	24
Not reported	4	4	2	0	2	5	17
Total	36	23	14	7	6	30	116

was agreement between hospital notes and the third source for outpatient visits and physiotherapy sessions in 93 and 44 cases, respectively (data not shown).

Discussion

It is unclear from the literature whether participant-completed questionnaires provide estimates of resource use that are as accurate as case notes.[124] The aim of this study was to assess the concordance between alternative methods of estimating resource use. Owing to the absence of a 'gold standard' method of data collection, accuracy was investigated by triangulating data from the two sources used in the study with the best available independent third source.

The focus of this study has been on resource use rather than cost as it is resource use rather than unit costs that varies by patient. Estimates of total cost by data collection method have not been made, as it was believed important to determine if the methods of data collection performed consistently across different areas of resource use.

Questionnaires were less likely to provide data, and concordance between questionnaires and the other data sources was lower than between hospital notes and the third source. Despite this, estimates of resource use provided by the different sources were broadly similar.

Although fewer data were available from questionnaires, the response rate was normal for this type of study.[110–112,120–123] A low response rate may not be a problem if values for non-responders are imputed, but this will introduce bias if responders differ from non-responders. In this study, no statistically significant differences were found between responders and non-responders in terms of age or sex. Comparison of responders and non-responders using hospital notes or third

sources showed no statistically significant differences with the one exception that non-responders had fewer outpatient visits (independent *t*-test, questionnaire versus hospital notes, $p = 0.006$, 95% CI = –0.91 to –0.16 visits; questionnaire versus third source, $p = 0.026$, 95% CI = –0.94 to –0.01 visits).

A potential cause of the lack of concordance between data sources may be systematic differences in the data that each can provide. For example, in at least 12 cases where participants reported no outpatient visits, the hospital notes recorded a visit within 3 weeks of trial recruitment. Discrepancies of this nature have also been reported elsewhere.[111]

Further systematic differences may be the result of recall bias by the patient. For example, it was expected that returned questionnaires would provide more reliable data than hospital notes in terms of physiotherapy sessions, as it was anticipated that questionnaires reported the number of physiotherapy sessions attended, rather than prescribed. The third source was explicitly designed to collect data on the number of sessions a patient received. As expected, differences were detected in the number of sessions recorded in hospital notes compared with questionnaires, but it was unclear if recall bias or poor patient compliance was responsible, but the comparatively smaller differences between the third source and hospital notes suggests the former.

Data abstraction from case notes is labour intensive and the issue faced by researchers is whether another, less costly, mode of data collection should be used. A crude estimate showed that it would cost an additional £20 to retrieve one more set of data using case note review. This cost would increase for a multicentre study where both time and travel costs of the researcher would need to be taken into account. Similarly, efforts to improve response rates, such as telephone prompts to confirm addresses and warn the patient of the arrival of the questionnaire, would also result in significant additional cost.

It is unlikely that data abstracted from hospital notes could supplant questionnaires as the only method of collecting data on resource use. Realistically, some aspects of resource use can only be obtained from patients, e.g. time off work and travel costs. In addition, while the use of other data collection methods may improve the quantity of data available, the overall quality may be no better (and possibly worse) than that obtained from questionnaires.

Conclusion

Although having lower response rates, questionnaires provide broadly similar data to hospital notes. More data may be obtained from hospital notes but it may not be of better quality and its collection will result in additional cost. Prescriptive statements about which form of data collection should be used cannot be made. The choice of data collection method should be based on the consideration of the type of data required and the costs of collecting it. Even if it were feasible, it may not be appropriate to attempt the same method of data collection across all areas of resource use. Rather, careful thought is required when designing the study regarding which data collection method should be used for each area of resource use. In this way, the best data can be made available from the resources available for research.

Appendix 8

Patient 'time and travel' questionnaire

Study Number | | | | | |

CONFIDENTIAL

TIME AND TRAVEL QUESTIONNAIRE(2)

The Scottish Back Trial is a joint project conducted by the Departments of Radiology, Orthopaedic Surgery, Neurosurgery and the Health Services Research Unit, University of Aberdeen.

Tel 01224 551170 Fax 01224 403032 email m.g.gillan@abdn.ac.uk

The Scottish Back Trial is funded by the NHS Research & Development Programme

HOW TO FILL IN THIS QUESTIONNAIRE

Please think about.your last GP and hospital appointments for your back problem

If you cannot remember the exact appointments please try to imagine how you would travel to your GP or the hospital and how much time it would take.

Please try to complete the whole questionnaire although it may seem that many of your answers are similar.

Most questions can be answered by putting a tick (✓) in the appropriate box. In a few questions you can tick more than one box.

When you have completed this questionnaire please return it in the reply paid envelope provided.

***Thank you* very much for your help.**

PHYSIOTHERAPY

1. Have you had physiotherapy for your back problems in the last 16 months?

Yes ☐ 1
No ☐ 2

2. If yes, where?

GP/local health centre ☐ 1
Hospital outpatient clinic ☐ 2
Hospital ☐ 3
Other ☐ 4

3. If other, where? _____

GP APPOINTMENTS

In this section please think about your last appointment with your GP (for your back) and complete the following questions in relation to that appointment.

4. How did you travel to your last GP appointment?
(Please tick all that apply)

Foot ☐ 1
Bus ☐ 2
Ambulance taxi ☐ 3
Car ☐ 4
Ambulance ☐ 5
Taxi ☐ 6
Home visit ☐ 7
Other ☐ 8

If other, what was it?

_____

5. Only answer if you travelled by 'bus, taxi or train to your last appointment.

What was the total fare (one way)? £ _____

6. Only answer if you travelled by 'private' car.

How far did you travel to the appointment (one way)? ☐ miles

7. How long did it take to travel to this appointment?

☐ hours ☐ minutes

8. Did anyone accompany you to your last GP appointment?
(Please tick one box only)

Yes ☐ 1
No ☐ 2

9. **If yes, who accompanied you?**
(Please tick all that apply)

Partner	☐ 1
Children	☐ 2
Other	☐ 3

If other, please specify

_____

10. **If you were accompanied to your last GP appointment, what would your main companion have been doing if they hadn't come with you?**

(Please tick one box only)

Paid work	☐ 1
Voluntary work	☐ 2
Housework	☐ 3
Child care/caring for a relative/friend	☐ 4
Leisure activities	☐ 5
Other	☐ 6

If other, please specify

_____

11. **What would you otherwise have been doing if you had not gone to the GP appointment?** *(Please tick one box only)*

Paid work	☐ 1
Voluntary work	☐ 2
Housework	☐ 3
Child care/caring for a relative/friend	☐ 4
Leisure activities	☐ 5
Other	☐ 6

If other, please specify

_____

12. **If you took time off paid work, did you lose any wages to attend the appointment?** *(Please tick one box only)*

Yes	☐ 1
No	☐ 2

13. **Did you have to get someone to look after any dependants or children you have while you were at your GP appointment?** *(Please tick one box only)*

Yes	☐ 1
No	☐ 2
Not applicable	☐ 3

14. **Have you had any other costs because of visiting your GP?**
(Please tick one box only)

Yes	☐ 1
No	☐ 2

If yes, for how much? £ _____

For what? _____

OUTPATIENT APPOINTMENT AT THE CLINIC

In this next section, please think about the last appointment you had at the outpatient clinic for your back problem.

15. How did you travel to the hospital appointment?
(Please tick all that apply)

- Foot ☐ 1
- Bus ☐ 2
- Ambulance taxi ☐ 3
- Car ☐ 4
- Ambulance ☐ 5
- Taxi ☐ 6
- Other ☐ 7

If other, what was it? _____

16. Only answer this question if you travelled by bus, taxi or train.
What was the total fare (one way)? £ _____

17. Only answer if you travelled by 'private' car.
How far did you travel to hospital appointment (one way)? ☐ miles

18. How long did it take to travel to the appointment? ☐ hours ☐ minutes

19. Did anyone accompany you to the appointment?
(Please tick one box only)

- Yes ☐ 1
- No ☐ 2

20. If yes, who accompanied you?
(Please tick all that apply)

- Partner ☐ 1
- Children ☐ 2
- Other ☐ 3

If other, please specify _____

21. If you were accompanied to your hospital appointment, what would your main companion have been doing if they hadn't come with you?
(Please tick one box only)

Paid work	☐ 1
Voluntary work	☐ 2
Housework	☐ 3
Child care/caring for a relative/friend	☐ 4
Leisure activities	☐ 5
Other	☐ 6

If other, please specify

_____

22. What would you otherwise have been doing if you had not gone to the hospital appointment? *(Please tick one box only)*

Paid work	☐ 1
Voluntary work	☐ 2
Housework	☐ 3
Child care/caring for a relative/friend	☐ 4
Leisure activities	☐ 5
Other	☐ 6

If other, please specify

_____

23. If you took time off paid work, did you lose any wages to attend the appointment? *(Please tick one box only)*

Yes	☐ 1
No	☐ 2

24. Did you have to get someone to look after any dependants or children you have while you were at the appointment?
(Please tick one box only)

Yes	☐ 1
No	☐ 2
Not applicable	☐ 3

25 Have you had any other costs because of the hospital appointment? *(Please tick one box only)*

Yes	☐ 1
No	☐ 2

If yes, for how much? £ _____

HOSPITAL STAY

Only answer if you have been admitted to hospital for your back problem in the last 16 months.

26. How many days did you stay in hospital? ☐ Days

27. How did you travel to the hospital for this stay?
(Please tick all that apply)

- Foot ☐ 1
- Bus ☐ 2
- Ambulance taxi ☐ 3
- Car ☐ 4
- Ambulance ☐ 5
- Taxi ☐ 6
- Other ☐ 7

If other, what was it?

_____

28. If you travelled by bus, taxi or train to the hospital, what was the fare (one way)? £ _____

29. If you travelled by car, how far did you travel to the hospital (one way)? ☐ miles

30. How long did the journey take to the hospital? ☐ hours ☐ minutes

31. Did anyone accompany you to the hospital ?
(Please tick one box only)

- Yes ☐ 1
- No ☐ 2

32. If yes, who accompanied you?
(Please tick all that apply)

- Partner ☐ 1
- Children ☐ 2
- Other ☐ 3

If other, please specify

_____

33. If you were accompanied to your hospital appointment, what would your main companions have been doing if they hadn't come with you?
(Please tick one box only)

Paid work	☐ 1
Voluntary work	☐ 2
Housework	☐ 3
Child care/caring for a relative/friend	☐ 4
Leisure activities	☐ 5
Other	☐ 6

If other, please specify

_____

34. Did you have to get someone to look after any dependants or children you have while you were in hospital?
(Please tick one box only)

Yes	☐ 1
No	☐ 2
Not applicable	☐ 3

35. What would you otherwise have been doing if you had not gone to the hospital? *(Please tick one box only)*

Paid work	☐ 1
Voluntary work	☐ 2
Housework	☐ 3
Child care/caring for a relative/friend	☐ 4
Leisure activities	☐ 5
Other	☐ 6

If other, please specify

_____

36. If you took time off paid work, did you lose any wages to attend the hospital? *(Please tick one box only)*

Yes	☐ 1
No	☐ 2

37 Have you had any other costs because of staying in hospital? *(Please tick one box only)*

Yes	☐ 1
No	☐ 2

If yes, for how much? £ _____

What for? _____

Health Technology Assessment Programme

Prioritisation Strategy Group

Members

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We look forward to hearing from you.

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