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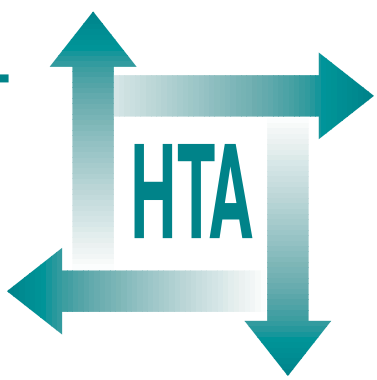

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This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Diagnostics and Imaging Panel and funded as project number 93/17/11.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

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Contents

List of abbreviations

BNF	British National Formulary
CSAG	Clinical Standards Advisory Group
CT	computed tomography
CI	confidence interval*
DDD	defined daily dose
df	degrees of freedom
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
ICER	incremental cost-effectiveness ratio
MRI	magnetic resonance imaging
NSAIDs	non-steroidal anti-inflammatory drugs
RCT	randomised controlled trial
sd	standard deviation
se	standard error
SF-36	Short Form with 36 items

* Used only in tables

Executive summary

Aim

A study in general practice to compare short- and long-term outcomes for patients with low back pain who are referred or not referred for lumbar spine X-ray after first presentation.

Design

Randomised controlled trial (RCT) in UK general practices, with an observational arm to enable comparisons to be made with patients not recruited to the trial.

Setting

A total of 94 practices in four health authorities in the South Thames Region, recruiting patients over 26 months.

Subjects

Patients who consulted their general practitioner (GP) with low back pain and who had not consulted in the previous 4 weeks.

Intervention

Random allocation to immediate referral for X-ray or not.

Main outcome measures

Roland and Morris disability, Hospital Anxiety and Depression, EuroQol, Short Form with 36 items (SF-36), consultations and referrals at 6 weeks and 1 year.

Results

A total of 153 patients were recruited to the RCT, and 506 patients were recruited to the observational study.

In the RCT, referral for X-ray led to a small improvement in patient psychological well-being over the next 12 months, but there were no differences in physical outcomes, further consultations or referrals to other health professionals. Patients referred for X-ray have higher costs in the short term than patients who are not, a difference that is almost entirely due to the cost of the X-ray itself. There were no significant differences in costs over a 1-year period.

In the observational arm, referral for X-ray was associated with length of episode at presentation, which is an indicator of poor prognosis. Patients referred for X-ray had poorer physical outcomes at 6 weeks and 1 year; however, after adjustments were made for length of episode at presentation, effect sizes were similar to those in the RCT. In the observational arm, patients referred for X-ray had higher costs, both in the short term and in the long term. The poorer prognosis of patients referred for X-ray probably explains these differences.

While the study may have less internal validity than a fully randomised study of the same size, the consistency of the findings from the RCT and the observational arm support the generalisability of the results to a wider population.

Conclusions

There are few significant differences at 6 weeks or 1 year between patients who are referred for lumbar spine X-ray and those who are not. Patients who are referred appear to be in better mental health as measured within the SF-36 quality of life measure.

Implications for healthcare

- Existing guidelines are sound. Early X-ray is not indicated, although it might still be considered when patient anxiety is a major feature.
- This reinforces the message that the benefit from early X-ray is negligible and that the X-ray dose is high.
- NHS costs at 6 weeks are higher among those referred for X-ray.
- This study suggests that there is little evidence that early X-ray referral leads to less morbidity reflected in time off work.

Research questions

- Should there be a more active approach by GPs to encourage patients to reconsult if symptoms do not improve within 6–8 weeks?
- Are there other investigations for back pain of duration greater than 8 weeks that are cost-effective?
- We also suggest a qualitative investigation into X-ray referral decisions.

Chapter 1

Introduction

In 1979, the Department of Health and Social Security reported "a profound and widespread dissatisfaction with what is available to help people who suffer from back pain" and that "medical practice ... pursues policies for management and certification that needlessly prolong the period of incapacity".[1] In 1994, the Clinical Standards Advisory Group (CSAG) suggested that, although there was increased awareness of back pain, dissatisfaction had also increased and NHS services were unsatisfactory and not solving the problem.[2]

Back pain is a common problem, with a reported lifetime prevalence varying from 58%[3] to 80%.[4] In the Morbidity Statistics from General Practice: Third National Study 1981–1982,[5] which took into account lumbar, thoracic and sacroiliac back pain, lumbar disc prolapse and other unspecified back pain, the estimated incidence was 35 per 1000 persons at risk. The 1991–1992 study indicated that the incidence was similar to this – at least 31 per 1000, with 7% of the adult population consulting their general practitioner (GP) each year for back pain.[6] The true prevalence in the community is probably higher. In 1996, 40% of adults reported having had lower back pain in the previous year, with 15% reporting pain on the day of interview; however, fewer than half reported having visited a medical practitioner or specialist in the previous year.[7] A 1998 UK postal survey by Waxman, Tennant and Helliwell estimated lifetime prevalence to be 62%,[8] again with only half of those suffering back pain in the previous year having consulted their GP.

However the situation is viewed, a significant number of people are affected, with concomitant consequences for the healthcare system and society in general; the annual cost to the NHS of caring for and treating those with back pain is estimated to be in excess of £500 million.[2] Given that in one study 60% of employed people had time off work through back pain,[9] it is clear that the high number of working days lost[7] and the cost to patient, society and the health service mean that appropriate management of back pain is important, particularly amongst the working population.

However, until recently there have been few studies with evidence from primary care on the most appropriate management of back pain, and the impact of a GP referring a patient for X-ray is not known. This study assesses whether the outcome for patients with low back pain is affected by such a referral.

Patient symptoms, history and prognosis

A number of studies have highlighted the presenting symptoms that are likely to indicate a poor prognosis. Their evidence has contributed to the evidence base on which GPs can make management decisions. Most patients have uncomplicated low back pain – only very rarely is there underlying malignancy or neurological deficit – and most patients, although not all, who consult with back pain improve within a few weeks.[10] A history of pain for longer than 1 week and a limited ability to leg-raise at initial consultation have been shown to be consistent with a poor outcome.[11] Other factors that indicate a poor prognosis are pain that is worse on standing or lying, a past history of back pain, and a high level of disability.[9] Longer duration of symptoms, pain that radiates to the leg, widespread pain and restricted spinal movement were associated with persistence of symptoms in the study by Thomas and co-workers.[12]

In one well-conducted study carried out in France, 90% of patients who presented with a less than 3-day history of non-radiating acute low back pain recovered within 2 weeks.[9] The inherent differences between French and UK primary healthcare systems may lead to differences in GP and patient behaviour, and it may not be possible to extrapolate these figures to a UK population. Croft and co-workers[13] found that only 10% of patients who consulted their GP had been in pain for less than 2 weeks. They also found that, although only 25% of these patients had fully recovered 12 months later, 90% had ceased to consult.

Although it is not clear which patients will be affected, it is known that a small minority will go

on to develop chronic back pain with continued disability and psychiatric morbidity, and that such patients may become unable to fulfil normal social and work roles and continue to present with complex psychosocial and occupational problems. It has been suggested that there are various psychological factors that act as barriers to a successful outcome for patients with low back pain.[14] In one study, 38% of patients who reported back pain in primary care were classified as having a psychological disorder,[15] and in another study symptoms of psychological distress in people without back pain predicted the likely onset of subsequent back pain.[16] In a recent UK general practice-based study, pain was likely to persist among patients who, in addition to having more severe clinical symptoms, were smokers, were less satisfied with their employment and had higher levels of psychological distress and lower self-rated levels of general health and physical activity.[12] It has been shown that workers who take in excess of 1 week's absence as a result of low back trouble have significantly more negative attitudes and beliefs than workers who take shorter lengths of time off work,[17] although it is not clear which is the cause and which is the effect.

The level of disability, and thus the readiness to consult, are influenced not only by the level of pain and the response to the pain, but also by the patients' attitudes and beliefs, their level of psychological distress, their social environment and their illness behaviour in general. At the acute stage of an episode, consulting behaviour is, not surprisingly, influenced by the severity of pain; however, later those who consult their GP are more likely to have increased disability and depression.[18] One study showed that those who report low back pain but who do not consult their doctor are more likely to be dissatisfied with their work.[19] Those who do not consult are less likely to be in severe pain and are more likely to be employed and to have previous experience of spontaneous resolution of back pain.[8]

The management of back pain by GPs is not straightforward. It is considered that recovery is assisted by returning to or continuing normal daily activities rather than through bed rest.[20] According to Dutch guidelines, symptomatic pain relief is to be used to facilitate reactivation of the patient. A report on the management of over 500 Dutch patients who had at least a 3-month history of back pain indicated that 64% of those who had visited their GP in the previous year received medication, primarily non-steroidal anti-inflammatory drugs (NSAIDs), 14% were advised to submit to bed rest and 14% were referred for X-ray.[21] In the study by Dodd,[7] nearly two-thirds (62%) of the 38% who had visited their GP were given a prescription, 27% received advice and 21% were referred for X-ray. Significantly more men than women were referred. Waddle compared care for back pain in the UK with that in the USA and found that medical care for low back pain in the USA is specialist-oriented, uses high-level technology and is of high cost, but 40% of US patients seek chiropractic care for low back pain instead. In the UK, NHS care for low back pain has been reported as being under-funded and often as being "too little, too late"; 55% of UK patients pay for private therapy in addition to or instead of NHS care. However, the outcome for patients, whether in the UK or the USA, is similar.[22]

Use of lumbar spine X-rays and guidelines for their use

Lumbar spine radiography is the most common investigation undertaken for low back pain in primary care.[23] In a 1981 study, lumbar spine radiography accounted for 5% of all radiographic investigations in NHS X-ray departments (including routine preoperative chest X-rays).[24] At St George's Healthcare Trust, departmental records for 1994 indicate that lumbar spine examinations accounted for 12% of all requests for diagnostic radiology from GPs. Overall, spine examinations accounted for 21% of X-ray requests, which is similar to the percentage of referrals from 22 practices in mainly rural England.[25] However, acute back pain is usually due to conditions that cannot be diagnosed from plain radiography,[23] which can identify features associated with ageing but is not particularly sensitive to lesions. In addition, not only is plain radiography resource-intensive, its unjustifiable use may lead to unnecessary exposure to potentially harmful radiation. Lumbar spine radiography uses a particularly high level of radiation compared with other plain X-rays, and guidelines produced by the Royal College of Radiologists[23] suggest that lumbar spine radiography should be used only when there is concern about significant underlying pathology.

The Royal College of Radiologists introduced consensus guidelines for doctors on making the best use of departments of clinical radiology in 1991; these guidelines are regularly updated and the third edition[23] was in use between 1995 and 1998, the duration of this study. These guidelines recommend that unless pain is persistent or progressive or there are neurological signs accompanying the pain there should be a delay of 6–8 weeks before X-ray. In 1994 the CSAG[2] provided guidelines, the aim of which was to provide evidence-based recommendations to first-contact clinicians on the management of low back pain and to ensure a multi-disciplinary approach to back pain management through the development and review process and through local implementation. Their report was focused on NHS services and was not fully evidence-based. In the light of the CSAG report, the Royal College of General Practitioners went on to produce evidence-based national clinical guidelines for the management of acute back pain.[26] The specific recommendation concerning X-rays (that X-rays are not routinely indicated in simple backache) was based on limited research evidence from the US Agency for Health Care Policy and Research guidelines[27] and the Royal College of Radiology guidelines.[23] Certain signs and symptoms are "red flagged" as requiring immediate attention and referral, though not necessarily X-ray. According to the Royal College of General Practitioners' guidelines, "red flags" include:

- significant trauma, or mild trauma in those aged over 50 years
- a history of prolonged corticosteroid use
- osteoporosis
- recent infection
- fever with a temperature over 100°F
- low back pain that is worse with rest
- previous carcinoma
- intravenous drug abuse
- unexplained weight loss
- acute back pain in patients aged over 70 years.

In 1994, Oakeshott, Kerry and Williams reported on an evaluation of the Royal College of Radiologists guidelines.[28] This report found that there was a significant reduction in referral for X-ray but also that half of the referrals did not conform to the guidelines.[29] Others have also shown that inappropriate use of X-rays can be reduced by the introduction of guidelines[30] but that there continues to be considerable variation in GP attitude[31] and behaviour.[32]

In a controlled intervention study in the USA,[33] neither clinical practice guidelines nor practice pattern feedback guidelines were associated with a significant decrease in the use of lumbar spine imaging; other factors were considered important, including practice setting, patient expectations and patient behaviour.

Costs

In 1994 it was estimated that for a GP practice list size of 10,000 patients the annual cost to the NHS for treating and managing back pain approached £88,000 (*Table 1*).[2]

In 1994 the CSAG recommended[2] that apart from more resources and services, there needed to be a change in attitude towards back pain and its management, by both GPs and patients. It has been suggested that there is a need for a revolution in the early management of back pain.[34] One of the philosophies of the Health Technology Assessment (HTA) assessment programme that funded this study is that time and money should not be wasted on ineffective interventions and that effective interventions should be fully exploited.

TABLE 1 *Estimate of NHS costs for treating and managing back pain per 10,000 patients*

2180 GP consultations	£23,700
Prescribed drugs	£8000
440 outpatients visits	£13,000
150 inpatients days	£ 20,000
1270 physiotherapy sessions	£11,000
90 visits to Accident and Emergency departments	£3000
270 X-rays	£8000

Context of this study

It is not known which patients consulting with low back pain are X-rayed and which are not. GPs, whose referral and prescribing behaviour has been shown to be associated with patients' expectations,[35] continue to refer anxious patients for reassurance even though the result is likely to be negative.[32,36] GPs perceive a pressure to refer orthopaedic and rheumatology patients, particularly for patient reassurance or when there is the opportunity for a private referral.[37] Radiologists and GPs have been found to be generally in agreement with the clinical indications for requesting radiographs, but in a survey of GPs nearly 80% sometimes requested investigations for their own or their patients' reassurance. It was noted by Neal that sometimes X-rays are requested for therapeutic purposes,[36] but it is not known whether the very fact that a GP requests an X-ray, regardless of the result, has any impact on the patient or on his or her management.

It may be that GPs continue to refer for X-ray in the absence of alternatives. In 1994, the CSAG recommended support services for the management of simple backache in primary care, but the availability of these services remained limited, even by 1999.[38] Apart from radiology, the recommended services were:

- improved standards and access to physiotherapy to include symptomatic treatment, manipulation, rehabilitation and education
- acute pain relief services
- GP prescription of lumbrosacral supports for short-term symptomatic relief (currently available on prescription from a hospital specialist only)
- a second opinion from specialist physiotherapist or GP with special interest and expertise
- a rehabilitation service.

It is not clear whether the result of X-rays requested by GPs has any impact on the patient or on patient management. One of us (DD) found that, although two-thirds of patients studied had some abnormality on the X-ray, GPs reported that their clinical management was altered in only 2% of cases.[29] In another study,[39] a similar proportion – 70% of patients – was found to have degenerative changes; those with X-ray evidence of degenerative disease were more likely to receive NSAIDs. Patients who were told that they had degenerative joint disease expressed greater satisfaction with their care and were less likely to seek alternative care than patients with similar X-ray results who were not given a diagnosis.

A full assessment of the effect of early referral of patients with back pain for X-ray requires the consideration both of patients referred for X-ray and of those not referred for X-ray. The one randomised trial of referral to X-ray[40] was a small study carried out over 10 years ago in the USA. It compared patients referred for X-ray with those given a brief educational input on the limitations of lumbar spine X-rays. This study showed no difference at 3 months in physical or psychological functional status, but the X-ray group were more likely to believe that all patients should be offered an X-ray for back pain.

Thus there may be a variety of reasons why GPs refer or do not refer patients with back pain for X-ray; both patient and practice factors need to be considered.

Chapter 2

Aims of this study

The aims of the study are:

- to compare outcomes in patients who are referred for X-ray at first presentation to their GP with those who are not so referred
- to describe the use of early plain radiography in patients presenting to their GP with low back pain
- to compare costs for patients who are referred for X-ray at first presentation to their GP with those who are not so referred.

Chapter 3
Method

Study sites

Three hundred and three general practices were approached consecutively. The practices that were initially approached were those in the London Boroughs of Merton and Wandsworth that routinely refer patients to St George's Healthcare Trust; subsequently practices in other health authorities that refer to other hospitals were approached. Payment of £10 per patient recruited was offered to general practices in recognition of the additional administrative work required by the study.

Subjects

GPs were asked to recruit all patients aged 16–64 years who consulted with low back pain. Pregnant women were excluded, as were patients who had consulted with back pain within the previous 4 weeks and patients with flu-like symptoms. A flyer with information about the study was produced for the patients' waiting rooms (appendix 1). Patients recruited to the study were given an information sheet and asked to sign a consent from (appendices 2 and 3). The consent form was returned to the researchers, who sent an information leaflet (appendix 4) to the patient. This acted as a reminder to return the questionnaire if the patient had not already done so.

Study design

The study design was a mixed observational and randomised controlled trial (RCT) and patients could be recruited either to the observational study or to the randomised trial at the GP's discretion. The choice provided by this study design allowed flexibility to GPs who were concerned about entering a patient into the RCT for X-ray at first presentation. Once a patient had consented to take part in the RCT, the GP randomly allocated the patient to immediate referral for X-ray or not, using sealed opaque envelopes supplied by the research team. Patients who refused to be take part in the randomised trial or patients whom the GP did not wish to randomise were invited to take part in the observational study. All patients were asked to complete a questionnaire on recruitment, at 6 weeks and again at 1 year after consultation. A further patient information leaflet (appendix 5) accompanied the 6-week questionnaire. Non-responders were followed up. All patients were followed up at 1 year through a search of their GP-held notes for information on consulting behaviour, referrals, prescriptions, certified time off work, previous history and radiology reports.

We considered that recruitment during a normal consultation was the most appropriate method, since taking randomisation out of the consultation would create an artificial situation. The large number of GPs involved in recruiting patients gave us the opportunity to study doctor and practice characteristics that might influence whether patient are referred or not.

Consent and ethical approval

Ethical approval was sought and granted from each of the four health authorities in which the study took place. Recruiting GPs explained the study and gave each patient an information sheet before asking the patient to sign a consent form.

Questionnaires

All patients were given the first questionnaire (appendices 2 and 3) by the GP immediately after consent. This was to be returned by Freepost to the research team. Further questionnaires (appendix 6) were sent by the research team 6 weeks and 1 year after the initial consultation. Up to two reminder letters were sent and one phone call was made to non-responders after 2 weeks in the case of the 6-week questionnaire and after 1 month in the case of the 1-year questionnaire.

The questionnaires included:

- the Roland and Morris disability scale
- the Hospital Anxiety and Depression Scale (HADS)

- the SF-36
- EuroQol.

The Roland and Morris disability scale[41] is a self-administered measure derived from the Sickness Impact Profile, in which a higher number on a 24-point scale reflects a greater level of disability. Since its development it has been found to be able to detect change among patients with initial scores in the central portion of the scale (between 4 and 20 points). It is less reliable for detecting improvement among patients with scores of less than 4 or for detecting deterioration among patients who have scores of more than 20.[42] It has been used and evaluated more frequently than other similar scales and thus there is more certainty about its validity.[43]

The HADS [44] is designed to detect the presence and severity of mild forms anxiety and depression in non-psychiatric patients. It has been used in a wide variety of situations and has been well validated. Half of the 14-item scale relates to anxiety and half to depression; the questions ask for responses related to feelings during the preceding week. It is self-administered and takes about 2 minutes to complete.

The SF-36[45] is a 36-item generic health status questionnaire designed for use in clinical practice and research, health policy evaluations and general population surveys. It was constructed for self-administration by people 14 years of age and older, it is easy to use, acceptable to patients, and fulfils stringent criteria of reliability and validity. The SF-36 has been used by the Health Survey for England[46] making comparisons with the general population possible. It includes scales that assess eight health concepts:

- limitations in physical activities because of health problems
- limitations in usual role activities because of physical health problems
- bodily pain
- general health perceptions
- vitality (energy and fatigue)
- limitations in social activities because of physical or emotional problems
- limitations in usual role activities because of emotional problems
- general mental health (psychological distress and well-being).

EuroQol is a measure of self-reported health status as defined by five dimensions: mobility, self-care, usual activity, pain and discomfort, and anxiety and depression. A person's health status as indicated by responses to this questionnaire can be converted into a numerical value by use of a scoring system based on time trade-off valuations in a UK population sample.[47] It also uses a thermometer-type visual scale that ranges from best imaginable state of health to worst imaginable state of health to obtain health-related quality of life valuations directly from patients. This questionnaire was newly developed at the outset of this study; there was little available evidence of its validity and reliability in different populations, although it was used in the 1996 Health Survey for England.[46]

In addition to these four measures, further questions for each of the questionnaires were devised.

- At recruitment, the questionnaire also collected information about employment status, patient expectations and satisfaction with care and about whether the patient had been referred by his or her GP for X-ray and, if so, where the patient had been referred to.
- The 6-week questionnaire collected information about appointments with private and NHS specialists (including physiotherapists and other therapists), referral for X-ray, time off work both for sickness and for hospital appointments, and satisfaction with care.
- The 1-year questionnaire collected information about referrals (including referrals for X-ray) and about time off work both for sickness and for hospital appointments.

At 12 months the GP-held notes of all patients were searched, whether or not they had responded to the interim questionnaires since their first consultation. We attempted to trace the notes of patients who had changed to a new GP through the Health Authority or by contacting the patient. Patients were lost to follow up if they moved outside the area, the GP could not be traced or the new GP refused access to the notes.

Information collected from the notes (appendix 7) included details about:

- sickness certification in the year before and since recruitment
- prescriptions, including dose and duration of course of medication
- referrals for back pain
- relevant past medical history
- X-ray history and results
- GP consultations.

The study population

Sample size calculations

Using data from Roland, Morrell and Morris,[11] we expected that 42 per 1000 patients aged between 16 and 64 years would consult their GP in 1 year with a new episode of back pain. Expecting each GP to have 1200 registered patients in this age range, we anticipated that each GP would see 25 suitable patients in a 6-month period. An audit of referrals at St George's Hospital Radiology Department indicated a mean of 16 referrals for lumbar spine radiology per GP per year, although we estimated that only five of these would be eligible for the study, of whom three might be eligible for randomisation. Thus we estimated that from 100 GPs we would be able to randomise 300 patients. Our original intention was to follow 500 patients who were not referred for X-ray. Roland and Dixon[48] found that 40% of patients were still consulting for back pain after 2 weeks. Assuming that 40% of those not referred for X-ray still consulted after 2 weeks, we estimated that 150 patients in each group would enable us to detect a fall to 25% in the referred patients, with a power of 80% at the 5% significance level. Allowing for loss to the study, we aimed to recruit 100 GPs each to recruit ten patients over a 6-month period.

Representativeness of the sample

In order to determine the percentage of eligible patients recruited to the study and to assess the representativeness of the main study sample, we used computer records at three sample practices to compare the consulting rates of all patients who had low back pain with the consulting rates of patients recruited to the study. These sample practices were chosen because they had suitable computer systems to which they were willing to give us access. Details of age, sex and number of consultations in the year before and after the index consultation were recorded.

Search strategies were devised after discussion with practice staff over the most likely diagnostic or symptom codes. In two practices, all the patients were identified by searching for "low back pain"; at the other practice, the terms "musculoskeletal", "spine", "injury", "backache" or "sciatica" were used. Patients were excluded if they were aged under 16 or over 64 years or if they had consulted in the previous 4 weeks. A note search was carried out using the patient's notes, computerised records (or both). The notes were searched for the same period that the practice had been recruiting patients.

Project milestones

Appendix 8 gives details of the milestones set at the outset of the project with revisions made during its course. The course of patients through the study is shown in *Figure 3*.

GP and patient recruitment

In a pilot phase, the first 11 GPs from eight practices who were recruited were used to assess the feasibility of the study process. In 3 months these 11 GPs had recruited seven patients to the RCT and ten patients to the observational study compared with the anticipated 15 patients to the RCT and 55 patients to the observational study. Six GPs recruited no patients at all and only two GPs randomised patients. This monitoring process showed that the randomisation was feasible but that only a few GPs were likely to recruit randomised patients. Only one GP from each of these 11 practices recruited patients.

Recruitment started with approaches to practices near hospital X-ray departments in St. George's Healthcare Trust. As a result of poor patient recruitment from these practices the protocol was subsequently extended to include all practices in the Merton, Sutton & Wandsworth, Croydon, Kingston & Richmond, and East Surrey Health Authorities. All 303 practices in the four Health Authorities were approached by letter to the senior partner, which was followed up by a phone call. The research assistant visited practices that showed an interest in the study and explained the study at a practice meeting.

The initially low practice and patient recruitment led to discussion with HTA, and the original protocol was amended when funding for a longer recruitment period was made available. The recruitment period was extended for recruiting practices; for some practices the patient recruitment period was extended up to 1 year.

Phone calls were made to the GPs by an experienced researcher to explore reasons for non-recruitment and to offer help where possible. GPs reported the following barriers to patient recruitment during the consultation:

- pressure of time
- patient language and literacy problems
- GPs' forgetting about the study, particularly when there had been few patients consulting with back pain.

Initially there was some confusion over the study design but this was clarified by redesigning the GP information sheet (appendix 9). The revised information sheet (appendix 10) was circulated to all GPs in the study. This information sheet was laminated and could be put in a prominent place on the GP's desk to act as a reminder. When the first patient from a particular GP was recruited to the RCT the GP was contacted to verify that the correct procedure had been followed. Letters of thanks were sent when a patient was recruited. Regular reminder phone calls were made at intervals negotiated with the GP (weekly, fortnightly or monthly), and newsletters were produced to remind GPs of the study and to give information about progress (appendices 11 and 12).

X-ray assessment

Radiological abnormality on lumbar spine X-rays was assessed from reports rather than by reviewing films, partly because GPs use reports not the films themselves in their day-to-day management of back pain. Moreover, obtaining films from all the hospitals at which patients had had X-rays would have been a severe logistical problem. When difficulty was experienced obtaining reports from other hospitals, direct contact between the radiology department at St George's and the radiology department at the other hospital usually resulted in the information being obtained.

Using reports rather than the films resulted in a restriction in the number of categories to which the X-ray findings were allocated. It was not possible to differentiate between minor disc change and minor degenerative change or between major disc change and major degenerative change on the basis of the reports. The following categories were used:

- normal
- minor disc or degenerative change
- major disc or degenerative change
- other.

Analysis

The long-term benefit of early referral for X-ray was determined by comparing patients in each group of the randomised trial. Disability scores, SF-36 scores, anxiety and depression scores and EuroQol scores were compared using t-tests. Regression analysis was used to adjust for age, sex and length of episode of back pain at recruitment. Because SF-36, HADS and EuroQol scores are not distributed normally, "boot-strapping" was used in the final analysis of outcomes at 6 weeks and at 1 year.[49] Length of episode, number of previous episodes, pain score and satisfaction with GP were compared in the two intervention groups using chi-squared test for trend. Other variables were analysed using odds ratios. Logistic regression was used to adjust for baseline characteristics of age, sex and length of episode.

A secondary analysis compared all patients referred with those not referred, adjusting for baseline characteristics that allows patients who were thought to be unsuitable for randomisation to be included in the analysis. The observational patients allow analysis of the representativeness of the randomised sample as well as the opportunity to investigate factors that influence referral for back pain.

All the patients in both the trial and observational arm were entered into a final model with randomisation status (randomised or not randomised), age, sex and length of episode as covariates and the interactions between randomisation status and the other covariates. This model, which was proposed to analyse comprehensive cohort studies, assumes that the treatment effect is the same in both randomised and non-randomised patients but allows prognosis to vary with randomisation status.[50] It combines all the data from the study and hence gives an overall estimate of the treatment effect. However, this model should be treated with caution because a formal test of the assumption of uniform treatment effect would require that the interaction term should be fitted between the treatment effect and the randomisation status, and the number of patients randomised was too small to give adequate power for this analysis. Only a descriptive comparison of the results from observational and randomised patients could be carried out.[51]

Characteristics of patients referred and not referred for X-ray in the observational study were compared using χ^2 test and odds ratios to identify factors relating to referral for X-ray. Factors investigated were demographic details, expectations of treatment, length of present episode, disability, severity of pain, past history and GP characteristics. Logistic regression

was used to adjust for age, sex and length of episode.

Patient or practice factors found to be significantly associated with referral were entered into a multiple logistic regression model. The model was adjusted for the clustering effect of several patients being recruited from the same practice using the statistical package STATA and weighted by the inverse of the number of patients from the practice, thus giving each practice equal weight. Analysis was carried out using STATA.[52]

Economic evaluation

The aim of the economic evaluation was to assess the cost-effectiveness of X-ray for low back pain in general practice. As far as possible, we sought to follow the "reference case analysis" methods recommended by the US panel of cost-effectiveness.[53] The outcome measure intended for use as the denominator of the cost-effectiveness ratio was the EuroQol. This is one of the recommended instruments for economic evaluations, since it is calibrated by health state valuations obtained using the time trade-off method in a UK population.[54]

For the purpose of the economic evaluation, where it is appropriate to conclude that there is no evidence of health effect a simple comparison of costs is sufficient. Cost-minimisation analysis[55] and (for completeness) a cost-effectiveness analysis were carried out.

Cost-minimisation analysis

Back pain related costs were estimated for the two groups of patients in the randomised trial, and for the two groups of patients in the observational study. Costs were estimated over two time periods: from recruitment to 6 weeks, and from recruitment to 1 year. The direct costs of healthcare utilisation and the indirect cost of time off work were both evaluated, but they are reported separately. Costs were estimated from the perspective of society, and the costs of private consultations are therefore included along with NHS costs. However, no attempt was made to evaluate the cost of over-the-counter medications or patient transport.

Data on healthcare utilisation related to low back pain was obtained from the case notes and from questionnaire data. Patients were excluded from the 0–6 week economic evaluation if their case notes had not been reviewed or if they had not completed the 6-week questionnaire. The number of patients is shown in *Figure 3*.

The notes were used to identify the number of X-rays, the number of GP consultations and the quantities of prescribed medications for each patient. Other radiological investigations, such as computed tomography (CT) or magnetic resonance imaging (MRI) scans were noted; however, they were excluded from the economic analysis because they are most likely to have resulted from secondary care referrals and so would not be reliably recorded in primary care notes. The reference consultation with the GP (the consultation at which the patients were recruited) was not included in the economic analysis; neither were episodes of inpatient care.

When the precise quantities of medications prescribed were not stated in the notes, these were estimated by the following procedure.

- If the size of tablet was not specified, the smallest available size was assumed.
- If no brand was specified, the cheapest proprietary brand or non-proprietary alternative was assumed.
- If the duration of medication but not the daily dose was recorded, then an average dose based on the World Health Organisation defined daily dose (DDD)[56] was assumed.
- If the daily dose but not the number of days was recorded, then duration based on the average for the type of medication for the study population was assumed.
- If neither the daily dose nor the number of days was recorded, then both of the above assumptions were employed.

The DDDs and mean duration used to estimate the quantities of prescribed medications are shown in appendix 13.

The numbers of visits to other healthcare professionals and complementary therapists were taken from the patient questionnaires. Patient questionnaire data were also used to estimate the number of days taken off work because of back pain. Questions of recall bias and inconsistency between the questionnaire at 6 weeks and the questionnaire at 12 months also apply to these data, but it was judged to be the best available source of information. No attempt was made to reconcile these two sets of questionnaire data. Data were collected from the notes on certified sick leave, but such data are likely to give a gross underestimate of the total amount of time off

work because of self-certification. Only patients in paid employment were asked to estimate sick leave due to back pain. The estimated value of indirect costs is thus likely to be conservative, since leisure time and time spent in unpaid and voluntary activities has a value to individuals and to society. Time taken off work for healthcare consultations and X-rays was also estimated from questionnaire data. This included the patients' own time and the time of any accompanying persons. No estimate was made of time taken off work for GP consultations.

Costs were estimated at a patient level by multiplying the quantities of various resources used by unit costs (appendix 13 and *Table 2*). Unit costs for resource items were taken from published national sources whenever possible in order to improve the generalisability of the results. National data for unit costs of diagnostic costs are not available. The unit cost of a lumbar X-ray was taken from the radiology department at St George's Hospital Trust. List prices at three other local hospitals showed unit costs of around £30 for X-rays in Band B, which includes lumbar spine X-ray. St George's apparently higher costs may include more on-costs, but this information is not available. However, the effect of changing the unit cost of X-rays was tested in a sensitivity analysis. Prescribed medications were costed using British National Formulary (BNF)[57] NHS net prices, which do not include dispensing costs. These were estimated at 10% of net prices. Prescription charges were not estimated, since the intended perspective for the analysis was societal: prescription charges represent a transfer within society, and so cancel out of calculations. However, it should be noted that prescription charges represent a real cost to patients. The costs of consultations with GPs and members of the professions allied to medicine were taken from estimates by the Personal Social Services Study Unit at the University of Kent.[58] The cost of a hospital outpatient appointment was obtained from the Chartered Institute of Public Finance Accountants – Healthcare Financial Management Association database,[59] which contains average cost by speciality. The costs of consultations with complementary therapists were estimated by a telephone survey of local practitioners. The value of time lost from paid employment was estimated at £8 per hour, based on the median wage for adults in full time employment.[60] All costs were estimated at current prices (1999–2000), where necessary adjusting for inflation. Since costs were not estimated over more than 12 months, discounting was not necessary.

All costs were up-rated to 1999–2000 values using estimated average annual inflation rate of 2%.

Standard t-tests were used to investigate differences in mean costs:

- between the RCT X-ray group and the control group
- between the patients in the observational study who were referred for X-ray at the reference consultation and those who were not.

Standard methods of statistical inference for the analysis of cost data[61] are in question because distributions of healthcare costs do not usually conform to the assumptions required for traditional parametric methods. In particular, they are rarely distributed normally. For policy purposes we wished to estimate the mean difference in

TABLE 2 *Unit costs of main resource items*

Resource item	£ (1999–2000 values)	Source
Lumbar spine X-ray	42	Local data
GP consultation	11	Netten and Dennett 1997[58]
Hypnotics and anxiolytics (mean per DDD)	0.24	BNF March 1999[57]
Analgesics (mean per DDD)	0.52	BNF March 1999[57]
NSAIDs (mean per DDD)	0.32	BNF March 1999[57]
Hospital consultant visit (orthopaedics)	55	CIPFA–HFMA Health Database 1995–1996[59]
Physiotherapist appointment	11	Netten and Dennett 1997[58]
Osteopath, chiropractor or acupuncture appointment	30	Telephone survey of local therapists
Reflexologist, massage or aromatherapy	25	Telephone survey of local therapists
Time lost from paid employment (per hour)	8	New Earnings Survey 1997, median wage for adult on full-time rate[60]

costs between the treatment groups. Therefore, provided that the samples are sufficiently large, the central limit theorem will apply, and traditional parametric methods will be appropriate. Each of the study groups was large enough (with at least 50 patients) and t-tests are robust to departures from normality in large samples.[62]

In order to test the robustness of the results to changes in unit cost estimates, a simple one-way sensitivity analysis was conducted.[63] The unit costs for the main resource items (X-rays, GP consultations, physiotherapy, hospital outpatient appointments, and consultations with complementary therapists) were varied by +100% and –50%, and the impact on the groups' mean costs and the t-values was observed.

Cost-effectiveness analysis

The results of economic evaluations are presented as an incremental cost-effectiveness ratio (ICER). This is the difference in mean costs (incremental cost) divided by the difference in mean effects (incremental effect). It shows the expected additional expenditure that would be required to obtain one additional unit of effect.

Non-parametric bootstrapping has been recommended for the estimation of ICER confidence intervals.[64] Traditional parametric methods may not be appropriate because the ICER is a ratio statistic (and so may have undefined moments). We used non-parametric bootstrap regression (with re-sampling of residuals)[65] to replicate 2000 pairs of incremental costs and incremental effects.

When these replicates are widely spread it is not appropriate to use confidence intervals for the ICER, because they may have very different implications in terms of cost-effectiveness.[66] The acceptability curve[67] is used as an alternative means of representing the results of a cost-effectiveness analysis by showing the "probability that the intervention is cost-effective" as a function of the maximum amount that the decision maker would be willing to pay for a unit of effectiveness.

Chapter 4

Results

Recruitment

A total of 229 GPs from 126 practices agreed to take part in the study. We did not insist that all GPs in the practice took part. Thirty-two practices did not recruit any patients, 15 GPs recruited to the randomised trial only, 65 GPs recruited to the observation study only and 58 GPs recruited patients to both parts of the study. Each GP recruited up to seven patients to the RCT (*Figure 1*) and up to 20 patients to the observation study (*Figure 2*).

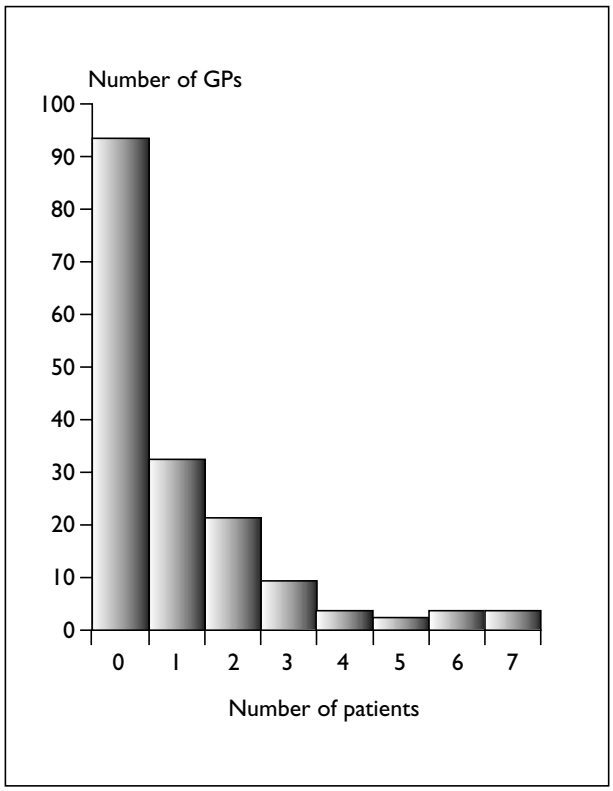

FIGURE 1 *Number of patients recruited by each GP to RCT*

Study flow chart

The progress of these patients through the study is demonstrated in *Figure 3*.

Characteristics of participants in the study

Practice characteristics

The percentage of practices recruiting patients to the study varied from 26% in Kingston &

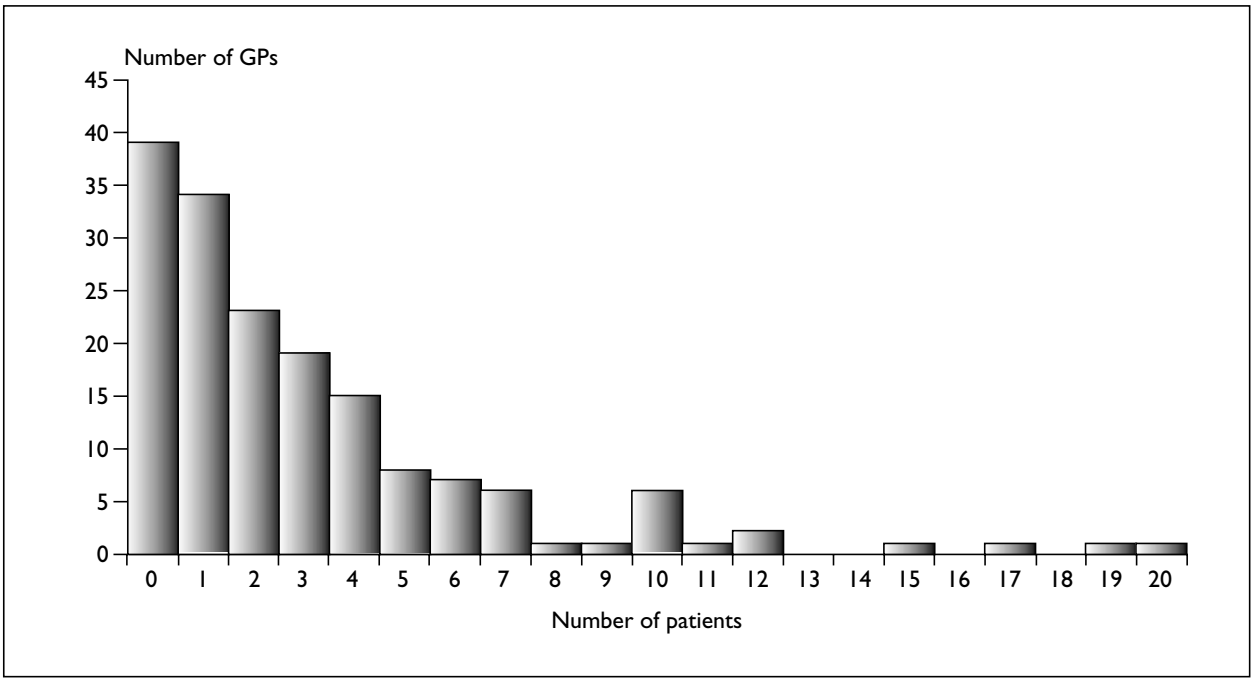

FIGURE 2 *Number of patients recruited by each GP to observational study*

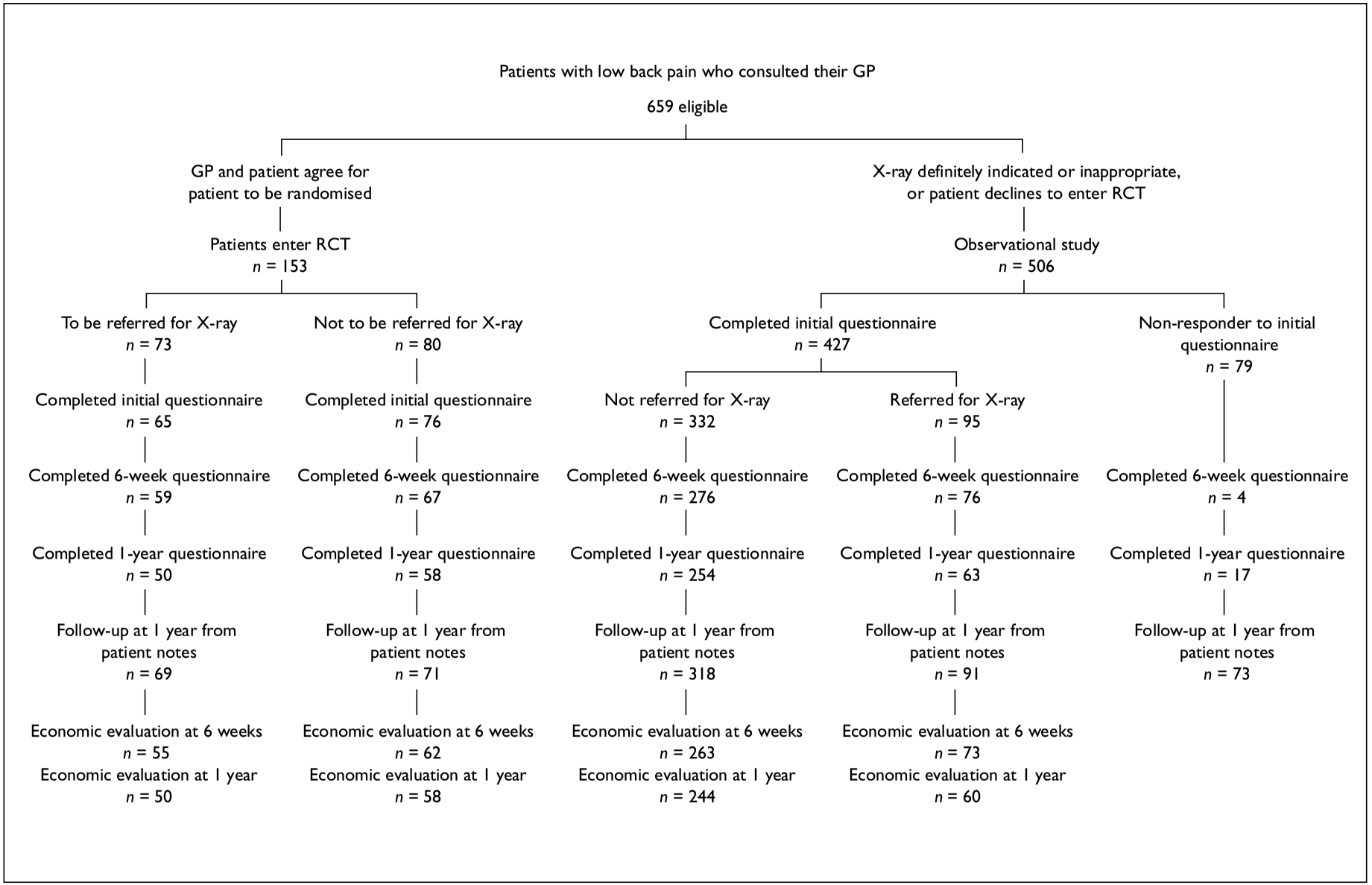

FIGURE 3 *Number of patients recruited by each GP to RCT*

TABLE 3 *Practice characteristics by Health Authority for all patients in the study*

	Merton, Sutton & Wandsworth *n* (%)	Croydon *n* (%)	East Surrey *n* (%)	Kingston & Richmond *n* (%)	All *n* (%)
Fund holding at time (*n* = 92)	17 (43)	4 (17)	7 (41)	9 (82)	37 (40)
More than two partners (*n* = 94)	7 (17)	6 (25)	13 (72)	8 (73)	34 (36)
Has deprivation payments (*n* = 82)	16 (50)	10 (48)	2 (11)	1 (9)	29 (35)
On site physiotherapist (*n* = 88)	4 (11)	2 (10)	4 (22)	3 (27)	13 (15)
Any on site therapist* (*n* = 88)	10 (26)	5 (24)	4 (22)	4 (36)	23 (26)
More than 30 minutes by car to X-ray department (*n* = 91)	4 (10)	1 (5)	2 (11)	1 (9)	8 (9)

* *Chiropracter* (n = *2), osteopath* (n = *1), aromatherapist* (n = *1), counsellor* (n = *1), acupuncturist* (n = *1), homoeopath* (n = *1), physiotherapist* (n = *13), no details* (n = *5)*

Richmond to 35% in Croydon; overall 31% of practices recruited at least one patient to the study. *Table 3* shows the practice characteristics by health authority. Nearly half the practices in Merton, Sutton & Wandsworth and Croydon were in receipt of deprivation payments whereas practices in the other two health authorities were mainly in more affluent areas. Fundholding varied from 17% in Croydon to 82% in Kingston & Richmond. There was less variability in the accessibility of X-ray departments and the presence of on-site therapists.

Patient characteristics

The average age of the patients was 41.8 years and 52% were women. Pain had been present for less than 1 week in 28% of the patients and for more than 6 months in 22% (*Table 4*). The mean number of consultations in the year before recruitment was 4.0; this compares with the national average of 3.8.[6]

TABLE 4 *Length of present episode of back pain*

	Number of patients (*n* = 548)	% of patients
Less than 1 week	156	28
1–4 weeks	156	28
4 weeks to less than 8 weeks	55	10
8 weeks to 6 months	59	11
More than 6 months	122	22

The level of pain experienced by the patients at the time of completion of the recruitment questionnaire is shown in *Table 5*.

Patients were classified as "in work" if they stated on the initial questionnaire that they were employed or self-employed. Patients were classified as "off sick" if they reported being off sick from work. Thus the "off-sick" category includes those on certificated or uncertificated sick leave or disability allowance; it may also include patients who were unemployed.

Responders and non-responders to patient questionnaire

Patients who did not respond to the recruitment questionnaire were more likely to be younger and male. A total of 301 (53%) of 568 responders were female compared with 42 (50%) of the 84 non-responders. Non-responders were also likely to be on average 5 years younger than those who

TABLE 5 *Level of pain experienced at the time of completion of the recruitment questionnaire*

	Number of patients (*n* = 555)	% of patients
No pain at all	6	1
Little pain	67	12
Moderate pain	205	37
Quite bad pain	155	28
Very bad pain	101	18
Almost unbearable pain	21	4

TABLE 6 *Comparison of responders and non-responders to initial questionnaire*

Information from patients' notes	Number of patients	Non-responders (*n* = 84)	Responders (*n* = 536)
		Mean (SD) *n* (%)	Mean (SD) *n* (%)
Consultations in past year, mean (SD)	618	4.0 (4.0)	3.5 (3.3)
Consulted with back pain in past year	618	138 (26)	18 (21)
Consulted in past 4 weeks	618	78 (15)	10 (12)
Lumbar spine X-ray in past 5 years	619	48 (9)	9 (11)
Lumbar spine X-ray at recruitment	620	141 (26)	8 (10)*

*p < 0.01

returned questionnaires (42.4 years, standard deviation (SD) 11.7 compared with 37.5 years, SD 11.7; $p < 0.001$).

Using information from the note searches, there was no difference in consulting history between the two groups (*Table 6*), and about 10% of each group had had an X-ray of the lumbar spine in the previous 5 years. Non-responding patients were less likely to have been referred for X-ray at recruitment. Seven patients completed consent forms only and then changed GP; their notes could not be accessed. The notes of 32 of the responding patients could not be traced. The notes of 620 patients were searched; there are some missing data from two of these notes.

Patients referred for X-ray

The questionnaire asked patients if their GP had referred them for an X-ray at the recruitment visit. A total of 179 patients reported being referred for X-ray (*Figure 4*). Of these 179 patients, 19 had entries in their GP notes indicating that they had been referred but not for a lumbar X-ray, that the referral was not made at the time of the recruitment visit or that they had had an X-ray before recruitment. Since there was no mention of lumbar X-ray at recruitment for these patients, they were all considered as not having been referred for X-ray for the purposes of the analyses. Two patients who had a report of an X-ray at recruitment in their notes nevertheless reported not having been referred for X-ray; they were included in the analysis as having been referred. Otherwise, for the purposes of analysis of referral for X-ray, the patient's account was taken. Thirteen patients had no mention of a referral in their GP notes but a report was obtained from the X-ray department indicated by the patient on the questionnaire. A further 12 patients reported that they had been referred, but there was no record of this in the GP notes or at the hospital. It is possible that these patients were referred but either did not attend or that the X-ray report was not traced. Thus, our definition of referral possibly leads to an over estimate of the number of X-rays. On the other hand, of the 139 referrals notified from other records, 13 (9%) were not in the GP-held patient notes, leading to an underestimation of the referral rate from this source.

Therefore, 162 patients were analysed as having been referred for an X-ray. Reports were available for 135 of these patients. X-ray records were found in GP notes for a further five patients who had consented to participate in the trial but who had not completed any questionnaire.

A total of 40% of the patients had normal X-rays (*Table 7*). X-ray classification of patients in the RCT group was very similar to those in the observational group. The seven patients whose X-rays are classified as "other" in *Table 7* include two patients with spondylolysis and grade II spondylolisthesis. This pathology was almost certainly long standing, and it is a cause of back pain that can affect the ability to work. A third patient was suspected of having spondylolysis but this was not confirmed by a subsequent report of oblique views. One patient was reported as having a developmental abnormality with spina bifida occulta throughout the lumbar spine. One patient had suspected vertebral body haemangiomas; again these were longstanding. One patient had a sigmoid scoliosis with an old partial collapse of the first lumbar vertebra. One patient was reported as having diffusely abnormal bone texture, suggesting demineralisation; the exact cause was difficult to evaluate from the report. There were no acute problems in any of these patients.

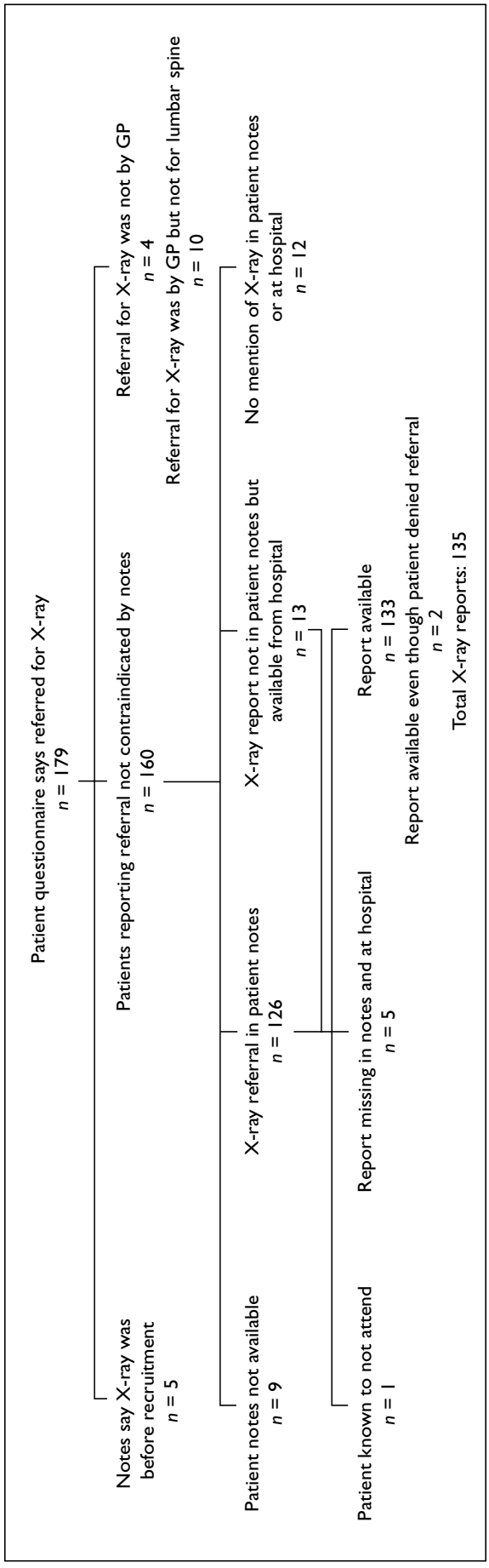

FIGURE 4 *GP accounts of referral for X-ray*

TABLE 7 *Results of patient X-rays at recruitment*

X-ray findings	RCT patients		Observational patients	
	n	%	*n*	%
Normal	22	39	35	42
Mild	24	42	28	34
Moderate or severe changes	9	16	15	18
Other	2	4	5	6
Total	**57**		**83**	

The randomised controlled trial

Characteristics of patients at recruitment to RCT

Table 8 shows that there is little difference in the patients in the RCT whether or not they were referred for X-ray. Patients who were referred for X-ray reported having been in pain for longer than those who were not referred, and they had a history of fewer GP consultations in the year before recruitment and had better physical functioning on the SF-36.

Randomised patients at 6 weeks and 1 year

Physical health as measured by the SF-36, EuroQol, and Roland and Morris scores were similar in both groups at both times (*Table 9*). There was a tendency towards poorer outcomes among those patients who were not referred. The mental health subscales of the SF-36 showed significantly poorer outcomes in the not-referred group at 6 weeks and 1 year; these patients also had significantly poorer scores on the vitality subscale at 6 weeks. Patients referred for X-ray tended to have been in pain for longer. After adjusting for length of episode, age and sex, differences on the SF-36 between patients referred for X-ray and those not referred were similar to the unadjusted differences, although no longer significant on the vitality sub-scale (*Table 10*).

Satisfaction was reported to be similar in both groups at 6 weeks. Similar numbers of patients consulted within 6 week of recruitment (*Table 11*) and similar numbers of patients were referred to other health professionals. Further analysis of consultations and referral is included in the economics section.

TABLE 8 *Baseline characteristics of RCT patients referred and not referred for X-ray*

Part 1: Social details

Patient characteristics	Number of patients	Referred for X-ray (*n* = 73) *n*	%	Not referred for X-ray* (*n* = 79) *n*	%
Age, mean (SD)	152	43.3	12.4	43.9	12.0
Female	152	31	42	45	57
In work	143	52	78	49	64
Social class I and II	124	21	35	16	25

*One patient was lost entirely to follow up

Part 2: Pain and history details from recruitment questionnaire

	Referred for X-ray (*n* = 65) *n*	%	Not referred for X-ray (*n* = 76) *n*	%
Pain score on day of questionnaire (*n* = 140)				
Little or no pain	8	12	9	12
Moderate to bad pain	43	66	51	68
Very bad or unbearable pain	14	22	15	20
Past history of back pain (*n* = 127)				
No past history	16	27	16	24
One or two previous episodes	11	19	13	19
Three or more episodes	32	54	39	57
Off sick (*n* = 141)	17	26	17	22
Length of episode (*n* = 138)		*		
< 1 week	14	22	22	30
1 to < 8 weeks	27	42	36	49
8 weeks to < 6 months	3	5	4	5
6 months and longer	20	31	12	16

*p < *0.05*

Part 3: Consulting and referral history

	Referred for X-ray (*n* = 69) *n*	%	Not referred for X-ray (*n* = 71) *n*	%
Consultations in past year, mean (SD)	3.5	3.2	4.8	4.4*
Consulted for back pain in past year	19	28	17	24
Consulted for pain in past 4 weeks	13	19	10	14
Lumbar spine X-ray in past 5 years	5	7	10	14
Referral to other health professional at recruitment	15	22	14	20

*p < *0.05*

continued

TABLE 8 contd *Baseline characteristics of RCT patients referred and not referred for X-ray*

Part 4: Physical and mental function scales

	Referred (*n* = 65)	Not referred (*n* = 76)	Difference (95% CI)
	Mean (SD)	**Mean (SD)**	
SF-36			
Physical functioning (*n* = 133)	66 (24)	57 (28)	–9 (–17 to 0)*
Physical role (*n* = 132)	40 (43)	34 (40)	–6 (–20 to 9)
Bodily pain (*n* = 140)	38 (21)	36 (20)	–2 (–9 to 4)
General Health (*n* = 134)	68 (21)	65 (23)	–3 (–11 to 5)
Vitality (*n* = 139)	48 (21)	45 (23)	–3 (–10 to 4)
Social functioning (*n* = 140)	66 (26)	63 (25)	–3 (–11 to 5)
Emotional role (*n* = 132)	66 (43)	64 (42)	–2 (–16 to 13)
Mental Health (*n* = 138)	68 (18)	66 (17)	–2 (–8 to 4)
EuroQol subjective scale (*n* = 138)	67 (18)	62 (20)	–5 (–11 to 2)
HADS			
Depression score	5.0 (3.3)	5.4 (3.9)	0.3 (–0.9 to 1.6)
Anxiety score	7.4 (4.6)	8.2 (4.6)	0.8 (–0.8 to 2.4)
Roland and Morris score (*n* = 141)	10.2 (5.5)	10.9 (5.3)	0.7 (–1.1 to 2.5)

*p < *0.05*

Part 5: Patient expectation

	Referred (*n* = 65)		Not referred (*n* = 76)	
What did you expect from the GP? (*n* = 141)	***n***	**%**	***n***	**%**
Advice	34	52	45	59
Prescription	29	45	43	57
Sickness certificate	5	8	9	12
X-ray	17	26	14	18
Referral to specialist	28	43	22	29

Part 6: Patient satisfaction

	Referred (*n* = 65)		Not referred (*n* = 76)	
How satisfied were you?	***n***	**%**	***n***	**%**
Very satisfied	38	59	37	49
Satisfied	21	33	27	36
Indifferent	4	6	6	8
Dissatisfied	1	2	4	5
Very dissatisfied	0	0	1	1

TABLE 9 *RCT patients at 6 weeks and 1 year after recruitment*

	6 weeks					1 year				
	Referred for X-ray		Not referred for X-ray		Difference (95% CI)	Referred for X-ray		Not referred for X-ray		Difference (95% CI)
	n	mean (se)	*n*	mean (se)		*n*	mean (se)	*n*	mean (se)	
SF-36										
Physical functioning	56	67 (3)	65	65 (3)	–2 (–12 to 7)	46	75 (3)	52	73 (3)	–2 (–10 to 7)
Physical role	55	41 (6)	64	45 (5)	4 (–12 to 20)	44	66 (6)	53	67 (5)	0 (–16 to 16)
Pain	57	49 (3)	67	49 (3)	–1 (–10 to 8)	46	63 (4)	54	63 (3)	–1 (–11 to 9)
General Health	55	69 (3)	65	67 (3)	–2 (–10 to 6)	45	68 (3)	53	67 (3)	–1 (–10 to 7)
Vitality	57	54 (2)	66	46 (3)	–8 (–15 to -0)*	46	57 (3)	52	52 (3)	–4 (–13 to 4)
Social functioning	57	72 (3)	67	67 (4)	–5 (–15 to 4)	46	81 (4)	56	79 (4)	–2 (–12 to 8)
Emotional role	54	75 (5)	64	65 (5)	–10 (–24 to 5)	44	82 (5)	53	78 (5)	–4 (–18 to 10)
Mental Health	57	74 (2	66	65 (2)	–9 (–15 to –3)**	46	77 (2)	52	70 (2)	–7 (–14 to 0)*
EuroQol subjective scale	57	74 (3)	64	67 (3)	–7 (–15 to 1)	46	74 (3)	54	76 (2)	2 (–5 to 9)
HADS										
Depression	57	4.7 (0.4)	65	5.1 (0.5)	0.5 (–0.9 to 1.8)	46	3.8 (0.5)	56	4.1 (0.5)	0.3 (–1.1to 1.7)
Anxiety	57	6.8 (0.5)	65	7.7 (0.6)	0.9 (–0.7 to 2.5)	46	6.3 (0.6)	53	6.7 (0.6)	0.4 (–1.4 to 2.1)
Roland and Morris	59	5.9 (0.7)	67	6.9 (0.8)	1.0 (–1.1 to 3.0)	46	4.5 (0.8)	57	4.3 (0.7)	-0.2 (–2.2 to 1.8)

* $p < 0.05$, ** $p < 0.01$

TABLE 10 *Adjusted differences in SF36, EuroQol, HADS and disability scores between patients not referred for X-ray and patients referred for X-ray in the RCT at 6 weeks and 1 year*

	Adjusted difference (not referred – referred) Scores (95% CI)	
	6 weeks	**1 year**
SF-36		
Physical functioning	–2 (–11 to 7)	–4 (–13 to 4)
Physical role	7 (–11 to 22)	–5 (–21 to 11)
Pain	–1 (–10 to 7)	–4 (–14 to 6)
General health	–3 (–11 to 5)	–4 (–12 to 4)
Vitality	–7 (–14 to 0)	–6 (–14 to 2)
Social functioning	–4 (–14 to 5)	–5 (–15 to 5)
Emotional role	–8 (–22 to 6)	–7 (–20 to 6)
Mental health	–8 (–14 to –1)*	–8 (–15 to –2)*
EuroQol subjective scale	–6 (–13 to 1)	1 (–7 to 8)
HADS		
Anxiety	0.6 (–1.0 to 2.2)	0.6 (–1.1 to 2.4)
Depression	0.5 (–0.8 to 1.8)	0.7 (–0.6 to 2.1)
Roland and Morris	0.7 (–1.4 to 2.7)	0.3 (–1.6 to 2.2)

*$p < 0.05$ *using bootstrap method*

TABLE 11 *GP consultations and referrals for back pain at 6 weeks and 1 year and satisfaction at 6 weeks subsequent to recruitment to RCT*

	Referred for X-ray (*n* = 69) *n* (%)	Not referred for X-ray (*n* = 71) *n* (%)	Odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Consulted for back pain				
Within 6 weeks (*n* = 140)				
6 weeks to 1 year (*n* = 140)	23 (33)	26 (37)	0.9 (0.4 to 1.7)	0.8 (0.4 to 1.8)
Referred to other health professional	22 (32)	28 (39)	0.7 (0.4 to 1.4)	0.7 (0.3 to 1.4)
Within 6 weeks (*n* = 140)	22 (32)	20 (28)	1.2 (0.6 to 2.5)	1.5 (0.7 to 3.5)
6 weeks to 1 year (*n* = 140)	31 (45)	33 (46)	0.9 (0.5 to 1.8)	1.1 (0.5 to 2.3)
Satisfaction at 6 weeks (n = 139)				
Very satisfied	19 (33)	19 (28)	1.2 (0.6 to 2.6)*	1.3 (0.6 to 3.0)*
Satisfied	26 (45)	28 (42)		
Indifferent	8 (14)	14 (21)		
Dissatisfied	5 (9)	5 (7)		
Very dissatisfied	0 (0)	1 (1)		

**odds ratio for "very satisfied" versus the rest*

Compliance with randomisation

Of the 80 patients allocated to no X-ray in the RCT, one patient was lost to follow up and one patient reported being referred for X-ray by the GP and this was confirmed in the patients notes. A further three patients said that they had been referred but this was not confirmed in the notes.

Of the 73 patients allocated to X-ray, three said that they had been not referred, which was confirmed by their notes. A further patient

who claimed to have been referred had no such record in the patient notes.

All analysis of the trial has been performed according to the group to which the patient was randomised.

The observational study

Characteristics of patients at recruitment to observational study

The comparison of baseline characteristics of patients referred and not referred is shown in *Table 12*. Patients who were referred for X-ray were on average 3 years older than those who were not referred. Referral for X-ray was more likely among patients who had been in pain for more than 8 weeks and was less likely among patients who were off sick. Patients who were off sick consulted earlier in the episode (88% patients who were off sick consulted with episodes of less than 8 weeks of pain, compared with 58% of patients who were not off sick). However, adjusting for length of the present episode did not change the odds ratios.

TABLE 12 *Baseline characteristics of observational patients who were referred for X-ray and not patients who were not referred for X-ray*

Part 1: Social details

	Referred for X-ray (*n* = 95)	Not referred for X-ray (*n* = 332)	Odds ratio (95% CI)	Adjusted odds ratio[a] (95% CI)
	n (%)	*n* (%)		
Mean age (SD) (*n* = 427)	44.6 (10.0)	41.1 (11.8)	1.03 (1.00 to 1.05)*	
Female (*n* = 427)	54 (57)	177 (53)	0.87 (0.55 to 1.4)	
In work (*n* = 427)	64 (67)	255 (77)	0.62 (0.38 to 1.03)	0.76 (0.44 to 1.3)
Social class I and II (*n* = 347)	21 (28)	93 (34)	0.73 (0.42 to 1.28)	0.76 (0.42 to 1.4)

[a] *Adjusted for age, sex and history of pain > 8 weeks;* * $p < 0.05$

Part 2: Social details

	Referred for X-ray (*n* = 95)	Not referred for X-ray (*n* = 332)	Odds ratio (95% CI)	Adjusted odds ratio[a] (95% CI)
	n (%)	*n* (%)		
Pain score on day of questionnaire (*n* = 415)				
Little or no pain	11 (12)	45 (14)	1.00	
Moderate to bad pain	61 (66)	205 (63)	1.2 (0.59 to 2.5)	1.3 (0.61 to 2.8)
Very bad or unbearable	20 (22)	73 (23)	1.1 (0.49 to 2.6)	1.5 (0.62 to 3.5)
Past history of back pain (*n* = 401)				
No past history	27 (31)	94 (30)	1.00	1.00
1 or 2 previous episodes	12 (14)	68 (22)	0.61 (0.29 to 1.3)	0.70 (0.32 to 1.5)
3 or more episodes	47 (55)	153 (49)	1.1 (0.62 to 1.8)	1.1 (0.61 to 1.9)
Off sick (*n* = 427)	15 (16)	116 (35)	0.35 (0.19 to 0.63)***	0.35 (0.18 to 0.70)**
Length of episode (*n* = 410)				
less than 1 week	15 (17)	105 (33)	1.00***	1.00**
1 to < 8 weeks	29 (32)	119 (37)	1.7 (0.87 to 4.2)	1.7 (0.85 to 3.3)
8 weeks to < 6 months	18 (20)	34 (11)	3.7 (1.7 to 8.1)	3.7 (1.7 to 8.2)
6 months and over	28 (31)	62 (19)	3.2 (1.6 to 6.4)	3.2 (1.6 to 6.4)

[a] *Adjusted for age, sex and history of pain > 8 weeks*

** $p < 0.01$, *** $p < 0.001$

continued

TABLE 12 contd *Baseline characteristics of observational patients who were referred for X-ray and not patients who were not referred for X-ray*

Part 3: Consulting and referral history

	Referred for X-ray (*n* = 91)	Not referred for X-ray (*n* = 316)	Odds ratio (95% CI)	Adjusted odds ratio[a] (95% CI)
	n (%)	*n* (%)		
Mean number of consultations in past year, mean (SD) (*n* = 405)	3.9 (4.1)	4.0 (3.9)		
Consulted for back pain in last year (*n* = 405)	32 (35)	73 (23)	1.8 (1.1 to 3.0)*	1.6 (0.94 to 2.7)
Consulted in last 4 weeks (*n* = 405)	10 (11)	46 (15)	0.72 (0.35 to 1.5)	0.59 (0.26 to 1.3)
Lumbar spine X-ray in last 5 years (*n* = 406)	4 (4)	29 (9)	2.2 (0.75 to 6.4)	2.6 (0.85 to 8.0)
Referral to health professional at recruitment (*n* = 406)	24 (26)	49 (16)	1.9 (1.1 to 3.4)*	1.8 (1.0 to 3.2)

[a] *Adjusted for age, sex and history of pain > 8 weeks*

* $p < 0.05$

Part 4: Physical and mental function scales

	Referred for X-ray (*n* = 95)	Not referred for X-ray (*n* = 332)	Difference (not referred – referred) (95% CI)	Adjusted difference[a] (95% CI)
	mean (SD)	mean (SD)		
SF-36				
Physical functioning (*n* = 414)	60 (24)	63 (27)	3 (–3 to 9)	0 (–7 to 6)
Physical role (*n* = 400)	31 (36)	46 (43)	15 (6 to 25)**	10 (0 to 20)
Bodily pain (*n* = 423)	41 (22)	45 (26)	4 (–2 to 10)	2 (–4 to 8)
General health (*n* = 407)	71 (17)	70 (20)	–1 (–6 to 4)	–4 (–9 to 1)
Vitality (*n* = 420)	47 (19)	51 (22)	4 (–1 to 9)	0 (–4 to 5)
Social functioning (*n* = 423)	63 (25)	67 (27)	4 (–3 to 10)	0 (–6 to 6)
Emotional role (*n* = 395)	64 (45)	71 (41)	7 (–3 to 16)	–2 (–12 to 8)
Mental health (*n* = 417)	70 (17)	69 (19)	–1 (–5 to 4)	–3 (–8 to 1)
HADS				
Depression score (*n* = 413)	4.8 (3.2)	5.0 (3.9)	0.3 (–0.6 to 1.1)	0.7 (–0.2 to 1.6)
Anxiety score (*n* = 416)	7.5 (4.0)	7.1 (4.3)	–0.4 (–1.4 to 0.6)	–0.1 (–1.1 to 0.9)
EuroQol subjective scale (*n* = 418)	66 (18)	63 (21)	–3 (–8 to 2)	–4 (–8 to 1)
Roland and Morris score (*n* = 427)	10.9 (5.5)	10.8 (5.4)	–0.1 (–1.4 to 1.2)	–0.3 (–1.6 to 1.0)

[a] *Adjusted for age, sex and history of pain > 8 weeks*

** $p < 0.01$

continued

TABLE 12 contd *Baseline characteristics of observational patients who were referred for X-ray and not patients who were not referred for X-ray*

Part 5: Patient expectation				
	Referred for X-ray (*n* = 95)	**Not referred for X-ray (*n* = 332)**	**Odds ratio (95% CI)**	**Adjusted odds ratio[a] (95% CI)**
	***n* (%)**	***n* (%)**		
What did you expect from the GP? (*n* = 427)				
Advice	50 (53)	209 (63)	0.65 (0.41 to 1.0)	0.70 (0.43 to 1.2)
Prescription	37 (39)	164 (49)	0.65 (0.41 to 1.0)	0.83 (0.51 to 1.4)
Sickness certificate	9 (9)	50 (15)	0.59 (0.28 to 1.2)	0.60 (0.26 to 1.3)
X-ray	61 (64)	35 (11)	15.2 (8.8 to 26.3)***	13.0 (7.4 to 23.0)***
Referral to specialist	40 (42)	105 (32)	1.6 (0.98 to 2.5)	1.5 (0.93 to 2.5)
[a]*Adjusted for age, sex and history of pain > 8 weeks*				
*** p < *0.001*				

Part 6: Patient satisfaction		
	Referred for X-ray (*n* = 94)	**Not referred for X-ray (*n* = 325)**
	***n* (%)**	***n* (%)**
How satisfied were you? (*n* = 419)***		
Very satisfied	59 (63)	150 (46)
Satisfied	33 (35)	130 (40)
Indifferent	0 (0)	33 (10)
Dissatisfied	1 (1)	8 (2)
Very dissatisfied	1 (1)	4 (1)
*** p < *0.001*		

Pain and disability scores were similar in both groups. Most SF-36 subscales were similar, but the physical role was reduced for patients who were referred for X-ray. This difference was reduced when adjusted for age, sex and length of episode. Anxiety and depression scores were similar in both groups.

Patients who were referred for X-ray were more likely to report that they expected to be referred and were also more satisfied with their GP care. They were also more likely to have consulted in the past year for back pain and to be referred to another health professional at the initial consultation, usually a physio-therapist. Further analysis of which patients were referred for X-ray is given below.

Observational patients at 6 weeks and 1 year

Patients who were referred for X-ray had poorer outcomes on the Roland and Morris disability scale and on the SF-36 physical functioning and pain scales (*Table 13*). They were also more likely to be referred to another health professional at the initial consultation or in the first 6 weeks after consultation. Patients referred for X-ray were more likely to reconsult both in the first 6 weeks and during the period between 6 weeks and 1 year after the first consultation.

When adjustments were made for length of episode, age and sex, differences in the physical subscales were reduced. The adjusted outcomes on the emotional role and mental health subscales were better in the referred group, although only mental health at 6 weeks was significantly different. Vitality was also significantly better in the referred group at 6 weeks (*Table 14*).

When adjustments were made for initial length of episode, age and sex, patients who were referred had twice the odds of reconsulting

TABLE 13 *Comparison of the SF36, EuroQol, HADS and the Roland and Morris score for patients in the observational study at 6 weeks and 1 year after recruitment*

	6 weeks					1 year				
	Referred for X-ray		Not referred for X-ray		Difference (not referred – referred) (95% CI)	Referred for X-ray		Not referred for X-ray		Difference (not referred – referred) (95% CI)
	n	mean (se)	*n*	mean (se)		*n*	mean (se)	*n*	mean (se)	
SF-36										
Physical functioning	69	63 (3)	265	71 (2)	7 (1 to 14)*	60	70 (3)	240	74 (2)	4 (–2 to 11)
Physical role	70	46 (5)	259	54 (3)	8 (–3 to 20)	59	61 (5)	238	69 (3)	8 (–3 to 19)
Pain	73	49 (3)	274	56 (2)	7 (0 to 14)*	63	58 (3)	252	65 (2)	7 (0 to 14)*
General health	69	69 (2)	263	68 (1)	–1 (–6 to 4)	58	67 (3)	244	68 (1)	1 (–5 to 7)
Vitality	73	54 (2)	273	52 (1)	–2 (–7 to 4)	62	53 (3)	250	56 (1)	3 (–3 to 9)
Social functioning	74	69 (3)	274	74 (2)	5 (–2 to 12)	63	77 (3)	252	81 (1)	5 (–2 to 12)
Emotional role	70	70 (5)	262	67 (3)	–2 (–14 to 9)	58	79 (5)	233	78 (2)	–1 (–11 to 10)
Mental health	73	71 (2)	270	68 (1)	–4 (–9 to 1)	62	71 (2)	249	71 (1)	0 (–5 to 5)
EuroQol subjective scale	73	70 (2)	270	72 (1)	2 (–3 to 7)	62	72 (2)	250	75 (1)	3 (–3 to 8)
HADS										
Anxiety	71	7.2 (0.4)	269	7.3 (0.3)	0.2 (–1.0 to 1.3)	61	6.3 (0.5)	248	6.5 (0.3)	0.2 (–0.9 to 1.4)
Depression	72	4.2 (0.4)	269	4.5 (0.3)	0.2 (–0.8 to 1.3)	62	3.7 (0.4)	248	4.1 (0.2)	0.3 (–0.7 to 1.4)
Roland and Morris	76	6.7 (0.6)	276	5.4 (0.3)	–1.3 (–2.7 to 0.0)	63	5.6 (0.6)	254	4.2 (0.3)	–1.4 (–2.8 to 0.0)*

*$p < 0.05$

TABLE 14 *Adjusted difference in SF36, EuroQol, HADS and Disability scores adjusted for age sex and length of initial episode between patients referred for X-ray patients not referred for X-ray in the observation study at 6 weeks and 1 year*

	Adjusted difference in scores (not referred – referred) (95% CI)	
	6 weeks	**1 year**
SF-36		
Physical functioning	1 (–5 to 8)	–3 (–9 to 3)
Physical role	0 (–12 to 11)	2 (–9 to 14)
Pain	1 (–5 to 7)	2 (–5 to 8)
General health	–5 (–10 to 1)	–3 (–9 to 3)
Vitality	–6 (–11 to 0)*	–1 (–7 to 5)
Social functioning	1 (–6 to 8)	0 (–6 to 7)
Emotional role	–7 (–19 to 6)	–9 (–19 to 1)
Mental health	–6 (–11 to –1)*	–3 (–8 to 2)
EuroQol subjective scale	–0.7 (–6.0 to 4.2)	–0.5 (–5.6 to 4.9)
HADS		
Anxiety	0.8 (–0.3 to 2.0)	1.0 (–0.1 to 2.0)
Depression	1.0 (0.1 to 2.0)*	1.1 (0.1 to 2.0)*
Roland and Morris	–0.2 (–1.7 to 1.2)	–0.3 (–1.8 to 1.0)

$p < 0.05$ using bootstrap method

in the first 6 weeks. This odds ratio reduced to 1.6 for the remaining period. Patients referred for X-ray showed higher levels of satisfaction at 6 weeks (*Table 15*). Levels of anxiety and depression as measured on the HADS were also better in the referred group, but the difference was significant only for depression. These results were similar to those found in the randomised controlled part of this study, which suggests that baseline differences in prognosis as determined from the length of the episode could explain differences in outcome in the unadjusted results.

TABLE 15 *GP consultations and referrals for back pain at 6 weeks and 1 year and satisfaction at 6 weeks subsequent to recruitment as observation patients*

	Referred for X-ray (*n* = 91)	**Not referred for X-ray (*n* = 313)**	**Odds ratio (95% CI)**	**Adjusted odds ratio[a] (95% CI)**
Consulted for back pain				
Within 6 weeks	38 (42)	92 (29)	1.7 (1.1 to 2.8)*	2.1 (1.2 to 3.5)**
6 weeks to 1 year	40 (44)	89 (28)	2.0 (1.2 to 3.2)**	1.6 (0.95 to 2.7)
Referred to other health professional				
Within 6 weeks	40 (44)	73 (23)	2.6 (1.7 to 4.2)***	2.4 (1.4 to 3.9)***
6 weeks to 1 year	53 (57)	117 (37)	2.3 (1.4 to 3.6)***	1.9 (1.2 to 3.2)*
Satisfaction at 6 weeks				
Very satisfied				
Satisfied	28 (37)	64 (23)	2.0 (1.1 to 3.4)*	2.6 (1.4 to 4.8)**
Indifferent	32 (43)	139 (51)		
Dissatisfied	12 (16)	45 (16)		
Very dissatisfied	2 (3)	21 (8)		
	1 (1)	6 (2)		

[a]Odds ratio for "very satisfied" versus the rest

$p < 0.05$, $p < 0.01$, $p < 0.001$

Comparison of randomised and observational patients

Patients recruited to the RCT were similar to those recruited to the observational study. Although the severity of pain at the time of the questionnaire was similar, patients in the trial were more limited by their pain over the previous 4 weeks (on the SF-36 pain score) and had poorer general health perception on the SF-36 (*Table 16*). Consultation rates and referral rates to other health professionals were similar in the two groups of patients.

Combining randomised and observational patients

In both arms of the study, significant differences at both 6 weeks and 1 year were observed in the psychological subscales rather than physical subscales. Confidence intervals are fairly wide, particularly for the randomised patients. Since there were few differences between the observational and randomised patients, we combined the results from the two parts of the study, thereby increasing the power of the analysis. These results should be treated with caution because they assume the same treatment effect in both arms of the study, although the analysis allows the prognosis to vary between randomised and non-randomised patients by fitting a randomisation status factor in the model (see the analysis in chapter 3 for a full description of model). A formal test of the difference in treatment effect between randomised and non-randomised patients would not have had sufficient power and so was not carried out.

Table 17 gives the combined results from the observational study and the RCT. On the whole, differences between referred and not referred patients are more marked for mental health and emotional scales and indicate a poorer outcome for patients who are not referred for X-ray after adjusting for initial prognosis.

X-rays and diagnoses during the 1-year follow-up period

In the RCT, ten patients (14%) in the group who were randomised to no referral for X-ray did receive an X-ray in the 12 months after recruitment, and 45 patients out of 316 (14%) in the observation group were referred for X-ray in the 12 months after recruitment. Reports were available for 49 of these 55 patients (*Table 18*).

Results for patients who were referred at recruitment are reported above (see "Patients referred for X-ray").

The search of patients' notes revealed five patients who had been referred for X-ray with new diagnoses during the follow-up period:

- osteopenia (two cases)
- osteoporosis
- cervical spondylitis
- osteoarthritis.

Three of these patients were in the trial and two were in the observation group. In addition, one patient in the observation group was diagnosed with lymphoma with spinal involvement. This patient was not referred for X-ray by his GP; he presented to casualty 3 months after his initial visit to the GP.

Patients lost to study

Among those who responded to the initial questionnaire, 84% responded to the questionnaire at 6 weeks and 74% also responded to the questionnaire at 1 year. *Table 19* shows that response rates were similar from those patients who were referred and those who were not referred in the RCT but they were lower in the patients in the observational study who were not referred.

Table 20 compares values for all patients who responded to the initial questionnaire with those who responded at 6 weeks and 1 year. Apart from being older, there were no other significant differences among patients who completed a questionnaire at 6 weeks. Those who completed the questionnaire at 1 year had better mental health as measured by the Hospital Anxiety and Depression Scale (HADS) and the SF-36 scales for mental health, emotional role and social functioning. Non-responders had been in pain longer.

Patients with "red-flag" symptoms

Data from the search of patients' notes at 1 year indicates that three patients had a previous history of cancer. One of these was entered into the RCT and referred for X-ray, and the other two were in the not-referred observational group. Four patients had taken corticosteroids in the past year for an unknown period of time; all of these were in the observational group and none was referred for X-ray.

TABLE 16 *Comparison of RCT and observational patients*

Part 1: Social details		
	RCT (*n* = 141)	**Observational (*n* = 427)**
	***n* (%)**	***n* (%)**
Age (*n* = 568), mean (SD)	44.1 (12.0)	41.9 (11.5)
Female (*n* = 568)	70 (50)	231 (54)
In work (*n* = 568)	99 (70)	319 (75)
Social class I and II (*n* = 468)	35 (29)	114 (33)
Part 2: Pain history and details from recruitment questionnaire		
	RCT (*n* = 141)	**Observational (*n* = 427)**
	***n* (%)**	***n* (%)**
Pain score on day of questionnaire (*n* = 555)		
Little or no pain	17 (12)	56 (13)
Moderate to bad pain	94 (67)	266 (64)
Very bad or unbearable pain	29 (21)	93 (22)
Past history of back pain (*n* = 528)		
No past history	32 (25)	121 (30)
One or two previous episodes	24 (19)	80 (20)
Three or more episodes	71 (56)	200 (50)
Off sick (*n* = 568)	34 (24)	131 (31)
Length of episode (*n* = 548)		
Less than 1 week	36 (26)	120 (29)
1 to < 8 weeks	63 (46)	148 (36)
8 weeks to < 6 months	7 (5)	52 (13)
6 months and over	32 (23)	90 (22)
Part 3: Consulting and referral history		
	RCT (*n* = 129)	**Observational (*n* = 407)**
	***n* (%)**	***n* (%)**
Consultations in past year, mean (SD)	4.3 (4.0)	4.0 (4.0)
Consulted for back pain in past year	33 (26)	105 (26)
Consulted in past 4 weeks	22 (17)	56 (14)
Lumbar spine X-ray in past 5 years	15 (12)	33 (8)
Referral to other health professional at recruitment	25 (20)	73 (18)

continued

TABLE 16 contd *Comparison of RCT and observational patients*

Part 4: Physical and mental function scales		
	RCT (*n* = 141)	**Observational (*n* = 427)**
	Mean (SD)	**Mean (SD)**
SF-36		
Physical functioning (*n* = 547)	61 (26)	62 (27)
Physical role (*n* = 531)	37 (41)	43 (42)**
Bodily pain (*n* = 562)	37 (20)	44 (25)*
General health (*n* = 540)	66 (22)	70 (20)*
Vitality (*n* = 558)	46 (22)	50 (21)
Social functioning (*n* = 562)	64 (25)	66 (27)
Emotional role (*n* = 526)	65 (42)	69 (42)
Mental health (*n* = 554)	67 (18)	69 (19)
HADS		
Depression score (*n* = 548)	5.2 (3.6)	5.0 (3.8)
Anxiety score (*n* = 550)	7.9 (4.6)	7.2 (4.2)
Roland and Morris score (*n* = 568)	10.6 (5.4)	10.9 (5.5)
EuroQol subjective scale (*n* = 556)	64 (19)	63 (20)
*$p < 0.05$, **$p < 0.01$		

Part 5: Patient expectation		
	RCT (*n* = 141)	**Observational (*n* = 427)**
	***n* (%)**	***n* (%)**
What did you expect from the GP?		
Advice	79 (56)	259 (61)
Prescription	72 (51)	201 (47)
Sickness certificate	14 (10)	59 (14)
X-ray	31 (22)	96 (22)
Referral to specialist	50 (35)	145 (34)

Part 6: Patient satisfaction		
	RCT (*n* = 141)	**Observational (*n* = 427)**
	***n* (%)**	***n* (%)**
How satisfied were you?		
Very satisfied	75 (54)	209 (50)
Satisfied	48 (35)	163 (39)
Indifferent	10 (7)	33 (8)
Dissatisfied	5 (4)	9 (2)
Very dissatisfied	1 (1)	5 (1)

Patient and practice characteristics associated with patient referral for X-ray in observational study

Patient factors associated with referral for X-ray were age, length of episode, consulting in the previous year and not being off sick. Patients who were referred for X-ray were also more likely to be referred to another health professional. Details are given above (see "The observational study").

Practice factors associated with referral for X-ray were the health authority in which the practice was situated and the presence of an on-site therapist at the practice (*Table 21*). Referral was also significantly more likely in fundholding practices after adjustments had

TABLE 17 *Differences between all not referred and referred patients at 6 weeks and 1 year*

	Difference adjusted for age, sex and length of episode	
	6 weeks	**1 year**
SF36		
Physical functioning	0 (–5 to 5)	–4 (–8 to 1)
Physical role	3 (–7 to 12)	0 (–9 to 9)
Pain	0 (–5 to 5)	0 (–6 to 5)
General Health	–4 (–8 to 0)	–3 (–8 to 2)
Vitality	–6 (–2 to –11)*	–3 (–8 to 2)
Social functioning	–1 (–7 to 5)	–2 (–7 to 4)
Emotional role	–7 (–16 to 2)	–8 (–16 to –1)*
Mental Health	–7 (–10 to –3)***	–5 (–9 to –1)*
EuroQol subjective scale	–3 (–7 to 2)	–0 (–4 to 4)
HADS		
Anxiety	0.8 (–0.2 to 1.6)	0.8 (0.1 to 1.8)*
Depression	0.8 (0.0 to 1.6)*	1.0 (0.2 to 1.7)*
Roland and Morris	0.1 (–1.0 to 1.3)	–0.1 (–1.3 to 0.9)

*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

been made for age, sex and length of episode. Distance by car to the nearest X-ray department was also related to referral, but the difference was not significant.

When analysed with adjustments for practice clustering, the presence of an on-site therapist was still a strong predictor a referral; odds ratio 3.9 (confidence interval 1.6 to 9.4) (*Table 22*). When adjusted for the presence of an on-site therapist, referral for X-ray was more likely in practices that were receiving deprivation payments but the difference was no longer significant. Variation between health authority was partly explained by presence of on-site therapists: none of the odds ratios was significantly different from 1.0.

Representativeness of the patients recruited

A total of 84 patients were identified from the records of the three sample practices, of whom 15 (18%) had been recruited to the study. *Table 23* compares patients who were identified but who were not recruited with patients who were recruited from the sample practices and with all patients who were recruited to the study.

Patients who were not recruited to the study in the sample practices were similar in age,

TABLE 18 *Results for those X-rayed during follow-up period*

	RCT patients		**Observational patients**	
	n	**%**	***n***	**%**
Normal	4	50	17	43
Mild	2	25	10	25
Moderate/severe	1	13	10	24
Other	1	13	3	8
Total	**8**		**40**	

TABLE 19 *Response to patient questionnaires*

	RCT patients		**Observational patients**	
	***n* (%)**		***n* (%)**	
	Referred for X-ray	**Not referred for X-ray**	**Referred for X-ray**	**Not referred for X-ray**
Initial questionnaire	65	76	332	95
6-week questionnaire	59 (91)	67 (88)	276 (83)	76 (80)
1-year questionnaire	46 (71)	57 (75)	254 (77)	63 (66)

TABLE 20 *Characteristics of patients who responded to questionnaires at baseline, 6 weeks and 1 year*

	Patients with initial questionnaire (*n* = 568)	**Patients with 6-week questionnaire (*n* = 478)**	**Patients with 1-year questionnaire (*n* = 420)**
	***n* (%)**	***n* (%)**	***n* (%)**
Age, mean (SD)	42.4 (11.7)	43.0 (11.4)**	43.5 (11.7)**
Female	301 (53)	257 (54)	232 (55)
In work	418 (74)	350 (73)	313 (75)
Social class I and II	149 (32)	125 (32)	107 (31)
Pain score on day of questionnaire			
Little or no pain	73 (13)	63 (13)	56 (14)**[a]
Moderate to bad pain	360 (65)	307 (65)	280 (68)
Very bad or unbearable pain	122 (22)	99 (21)	77 (19)
Past history of back pain			
No past history	153 (29)	129 (29)	104 (27)
One or two previous episodes	104 (20)	86 (19)	79 (20)
Three or more episodes	271 (51)	228 (51)	208 (53)
Mean Roland and Morris score (SD)	10.8 (5.4)	10.7 (5.3)	10.7 (5.3)
Off sick	165 (29)	135 (28)	120 (29)
Length of episode			
Less than 1 week	156 (28)	135 (29)	125 (31)**[a]
1 to < 8 weeks	211 (39)	180 (39)	155 (38)
8 weeks to < 6 months	59 (11)	48 (10)	45 (11)
6 months and over	122 (22)	97 (21)	81 (20)
Number of consultations in past year, mean (SD)	4.0 (4.0)	4.2 (4.0)	4.1 (4.0)
Consulted in past year for back pain	138 (26)	119 (26)	101 (25)
Consulted in past 4 weeks	78 (15)	69 (15)	59 (15)
Lumbar spine x-ray in past 5 years	48 (9)	41 (9)	34 (8)
Referral to health professional at recruitment	98 (18)	83 (18)	80 (20)
SF-36			
Physical functioning	62 (26)	62 (26)	63 (26)
Physical role	42 (42)	42 (42)	42 (42)
Bodily pain	42 (24)	43 (25)	43 (24)
General health	69 (20)	70 (20)	70 (20)
Vitality	49 (22)	49 (22)	50 (21)
Social functioning	66 (26)	66 (26)	67 (26)*
Emotional role	68 (41)	69 (41)	72 (40)**
Mental health	69 (18)	69 (18)	69 (18)*
HADS			
Depression score	5.0 (3.7)	5.0 (3.7)	4.8 (3.6)*
Anxiety score	7.4 (4.3)	7.3 (4.3)	7.1 (4.1)*

[a] χ^2 *test for trend*

p-*values are for non-responders versus responders,* * $p < 0.05$, ** $p < 0.01$

TABLE 21 *Practice characteristics for patients referred for X-ray on observational study*

	Referred for X-ray (*n* = 95)	Not referred for X-ray (*n* = 332)	Odds ratio	Adjusted odds ratio[a]
	n (%)	*n* (%)		
Fund holding at time (*n* = 425)	47 (51)	131 (40)	1.6 (0.99 to 2.5)	1.7 (1.0 to 2.7)*
More than two partners (*n* = 427)	48 (51)	183 (55)	0.83 (0.53 to 1.3)	0.96 (0.58 to 1.6)
Has deprivation payments (*n* = 409)	27 (31)	72 (22)	1.6 (0.94 to 2.7)	1.4 (0.82 to 2.5)
Any on-site therapist (*n* = 423)	36 (39)	60 (18)	2.8 (1.7 to 4.7)***	3.1 (1.8 to 5.3)***
> 30 minutes by car to X-ray department (*n* = 424)	6 (6)	36 (11)	0.55 (0.22 to 1.3)	0.53 (0.21 to 1.3)
Health authority				
Merton, Sutton & Wandsworth	36 (38)	75 (23)	1.0**[b]	1.0*[b]
Croydon	24 (25)	109 (33)	0.46 (0.25 to 0.83)	0.46 (0.25 to 0.88)
East Surrey	17 (18)	100 (30)	0.35 (0.18 to 0.68)	0.40 (0.20 to 0.80)
Richmond	18 (19)	48 (14)	0.78 (0.40 to 1.5)	0.89 (0.44 to 1.8)

[a] *Adjusted for age, sex and length of episode*
[b] χ^2 *test, 3 df*
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

TABLE 22 *Practice characteristics adjusted for patient factors and practice clustering*

	Odds ratio adjusted for age, sex, length of episode > 8 weeks and practice clustering (95% CI)	Odds ratio additionally adjusted for presence of on-site therapist (95% CI)
Fundholding at time	1.4 (0.63 to 3.2)	0.89 (0.36 to 2.2)
More than two partners	1.0 (0.48 to 2.2)	1.0 (0.46 to 2.2)
Receives deprivation payments	2.2 (0.92 to 5.4)	1.9 (0.78 to 4.4)
Any therapist on site	4.0 (1.6 to 9.5)**	–
> 30 minutes by car to radiology department	0.6 (0.12 to 3.1)	0.32 (0.06 to 1.6)
Health authority		
Merton, Sutton & Wandsworth	1.0	1.0
Croydon	0.35 (0.13 to 1.0)*	0.45 (0.16 to 1.2)
East Surrey	0.59 (0.21 to 1.6)	0.78 (0.27 to 2.3)
Richmond	0.97 (0.29 to 3.3)	1.0 (0.26 to 4.2)

* $p < 0.05$, ** $p < 0.01$

sex and consultation and X-ray history to those recruited to the study. They had fewer referrals for X-ray at their initial consultation and fewer referrals to other health professionals. However, recruited patients from these practices also had fewer referrals and X-rays than the bulk of patients recruited to the study.

Economic evaluation

Cost minimisation analysis

Healthcare resource use

The majority of back pain-related resource use occurred in the first 6 weeks after recruitment (*Table 24*), although the number of patients

TABLE 23 *Comparison of patients identified from computer searches in three sample practices with patients recruited to the study*

		Patients identified from computer search in sample practices	
	All recruited patients (*n* = 620)	**Recruited (*n* = 14)**	**Not recruited (*n* = 69)**
	***n* (%)**	***n* (%)**	***n* (%)**
Mean age (SD)	42.0 (11.7)	41.5 (7.8)	40.1 (13.2)
Female	322 (52)	10 (67)	36 (52)
At time of initial consultation			
Consultations in the past year, mean (SD)	4.0 (3.9)	4.5 (4.1)	3.6 (4.4)
Consulted for back pain in the past year	156 (25)	1 (7)	19 (28)
Consulted in the past 4 weeks	88 (14)	1 (7)	6 (9)
Lumbar spine X-ray in past 5 years	57 (9)	1 (7)	8 (12)
Lumbar spine X-ray referral	149 (24)	2 (14)	8 (12)*
At 6 weeks and at 1 year			
Consulted			
Up to 6 weeks	210 (34)	5 (36)	16 (24)
6 weeks to 1 year	208 (34)	1 (7)	16 (24)
Referred to other health professional			
Up to 6 weeks	174 (28)	2 (13)	8 (12)**
6 weeks to 1 year	263 (42)	4 (27)	13 (19)**

p *values are for patients recruited compared with those not recruited;* *p < *0.05,* **p < *0.01*

TABLE 24 *Healthcare resource use for low back pain: 0–6 weeks*

	Number of patients (*n* = 453)	**% of patients**	**Mean quantity[a]**	**SD**
Hypnotics and anxiolytics	33	7	7.2	4.5
Analgesics	88	19	14.9	8.2
NSAIDs	195	43	27.7	16.0
Other drugs	7	2	26.9	45.7
GP consultation	149	33	1.6	1.0
Hospital consultant	35	8	1.6	0.8
Physiotherapist	131	29	4.1	3.2
Osteopath	43	9	3.2	2.3
Chiropractor	20	4	5.0	3.3
Other consultations	12	3	2.8	1.6
Lumbar spine X-ray	132	29	1	0

[a]*Mean quantity of resource used (number of consultations or DDDs for medications) per patient who made use of the resource*

making use of services, and the average quantities used per patient, did increase over the remainder of the year (*Table 25*). Of the 453 patients included in the 6-week economic evaluation, 132 (29%) had a lumbar X-ray. At 1 year, 141 out of 412 patients (34%) had had an X-ray.

A total of 149 patients (33%) consulted their GP during the 0–6 week period, whereas by 1 year 225 (55%) had consulted. The most commonly prescribed medications were NSAIDs (43% of patients were prescribed NSAIDs within 6 weeks and 51% within 1 year) and

TABLE 25 *Healthcare resource use for low back pain: 0–12 months*

	Number of patients (*n* = 412)	% of patients	Mean quantity[a]	SD
Hypnotics and anxiolytics	37	9	8.5	5.9
Analgesics	95	23	17.7	10.8
NSAIDs	210	51	32.7	26.0
Other drugs	7	2	35	45.2
GP consultation	225	55	2.4	2.1
Hospital consultant	64	16	2.2	1.9
Physiotherapist	124	30	7.1	7.5
Osteopath	43	10	4.1	2.3
Chiropractor	18	4	7.4	6.3
Other consultations	19	5	3.9	6.2
Lumbar spine X-ray	141	34	1	0

[a]*Mean quantity of resource used (number of consultations or DDDs for medications) per patient who made use of the resource*

analgesics (19% within 6 weeks and 23% within 1 year). A small proportion of patients were prescribed hypnotics or anxiolytics (7% within 6 weeks and 9% within 1 year). Around 29% of patients reported consulting a physiotherapist in the first 6 weeks, about the same proportion who reported such a consultation at 1 year. Similarly, around 10% of patients reported consulting an osteopath in each period. A hospital consultant was seen by 8% of patients in the first 6 weeks and by 16% of patients at 1 year.

In order to compare healthcare utilisation for the four study groups, resources were grouped into three broad categories: prescribed medications (in DDD units), GP consultations and "other" consultations. The mean quantities of these resource groups used per patient are shown for the RCT groups in *Table 26* and *Table 27*. The mean quantities were greater for those not referred for than for those referred with the exception of non-GP consultations during the first 0–6 weeks. However, none of the differences was significant at the 0.05 level.

TABLE 26 *Mean resource use for low back pain per patient in RCT: 0–6 weeks*

	Referred for X-ray (*n* = 55)		Not referred for X-ray (*n* = 62)		*p* value (t test)
	Mean	SD	Mean	SD	
Medications (DDDs)	13.6	19.0	19.2	26.3	0.19
GP consultations	0.5	0.7	0.6	1.1	0.35
Other consultations	2.2	3.2	1.8	3.4	0.50

TABLE 27 *Resource use for low back pain per patient in RCT: 0–12 months*

	Referred for X-ray (*n* = 50)		Not referred for X-ray (*n* = 58)		*p* value (t test)
	Mean	SD	Mean	SD	
Medications (DDDs)	20.8	33.0	24.2	28.5	0.57
GP consultations	1.0	1.6	1.6	2.1	0.11
Other consultations	2.4	3.4	3.1	6.4	0.49

TABLE 28 *Resource use for low back pain per patient in observational study: 0–6 weeks*

	Referred for X-ray (*n* = 73)		Not referred for X-ray (*n* = 263)		*p* value (t test)
	Mean	SD	Mean	SD	
Medications (DDDs)	12.1	17.2	16.0	18.6	0.1
GP consultations	0.7	1.0	0.5	0.9	0.14
Other consultations	2.8	3.3	1.6	2.8	0.003

TABLE 29 *Resource use for low back pain per patient in observational study: 0–12 months*

	Referred for X-ray (*n* = 60)		Not referred for X-ray (*n* = 244)		*p* value (t test)
	Mean	SD	Mean	SD	
Medications (DDDs)	15.4	20.5	21.7	27.7	0.10
GP consultations	1.6	2.2	1.1	1.8	0.06
Other consultations	5.9	11.2	2.9	5.8	0.003

Resource utilisation for patients in the observational study is shown in *Table 28* and *Table 29*. The mean use of prescribed medications was less for the patients who were referred for an X-ray than for those who were not, but this difference was not statistically significant over either time period. The mean number of GP consultations was greater for the patients referred for X-ray than for those who were not referred, though again these differences did not reach statistical significance for either time period. However, there were significant differences in the mean number of other consultations over 0–6 weeks and 0–12 months: the number of non-GP consultations was greater for patients who received an X-ray than for those who did not.

Direct social costs of healthcare

The frequency distributions of direct social costs for the four study groups are shown in *Figure 5* and *Figure 6*. The cost distributions are positively skewed with a wide dispersion, as is commonly found with cost data. The majority of the patients from both the randomised and observational studies who were not referred for X-ray had zero costs or very low costs. As might be expected, the mode for the intervention groups was shifted to about £40 by the cost of the X-ray.

The mean direct costs for the RCT patients are shown in *Table 30* and *Table 31*. The mean direct cost is significantly greater for the intervention group at 6 weeks, with a mean difference of £41.90. This difference is largely due to the cost of the X-ray itself: there is no significant difference in the cost of prescriptions, GP consultations or other consultations. By 12 months the significance of the cost difference has been lost, because of rises in the cost of GP and other consultations for the control group, which off-set the extra cost of X-rays for the intervention group.

The social direct costs for the patients in the observational study are shown in *Table 32* and *Table 33*. The patients who were referred for an X-ray at first consultation had significantly higher costs than those who were not referred. The mean difference was £63 per patient at 6 weeks and £117 per patient at 12 months. Over both time periods, there were significant differences in the cost of NHS consultations, in addition to significant differences in the cost of X-rays.

Time off work and indirect costs

The mean number of reported days off work by study group are shown in *Table 34* and *Table 35*. There was a large degree of variation in these data. No significant differences were found between those referred and those not referred, either within the randomised study or within the observational study.

The mean estimated indirect costs of time off work (both for sick leave and time off for healthcare) are shown in *Table 36* and *Table 37*.

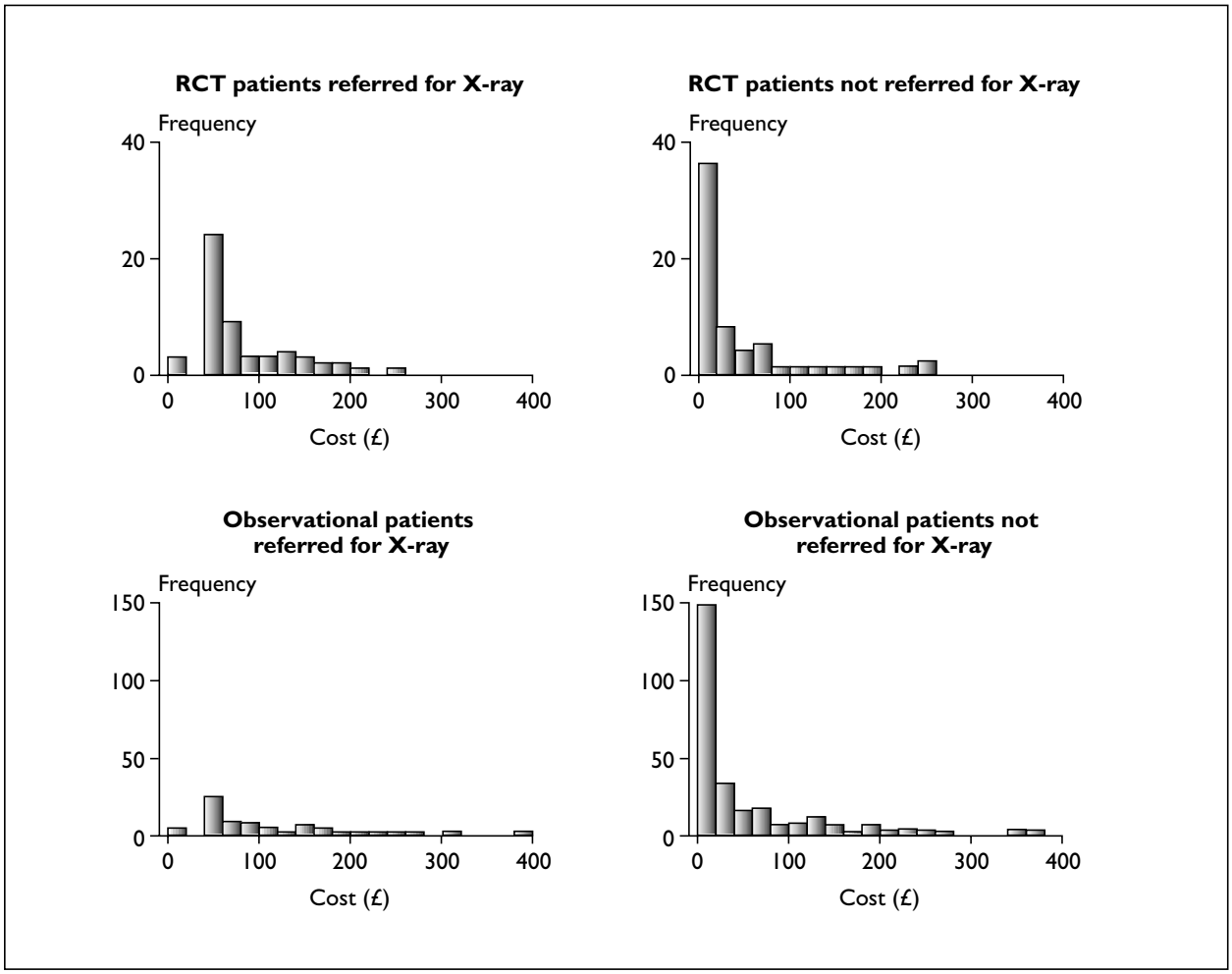

FIGURE 5 *Frequency distributions of direct social costs (£) by study group: 0–6 weeks*

As might be expected, no significant differences between the study groups were found.

Sensitivity analysis

The results of the sensitivity analysis of direct costs for the RCT groups are shown in *Table 38* and *Table 39*. The unit costs for the main resource items (X-rays, GP consultations, physiotherapy, hospital outpatient appointments and consultations with complementary therapists) varied by +100% and –50%, and the impact on the groups' mean costs and the t-values was observed.

The significance of the difference between the RCT study groups at 6 weeks was sensitive to the cost of an X-ray. At a cost per X-ray of £18 or less, there was no significant difference between the groups, whereas above this cost patients who were referred were significantly more expensive than those who were not. In the baseline analysis there was no significant difference between the RCT groups over the whole 12 months. In order for those who were referred to become significantly more expensive than those who were not over this period, the cost of an X-ray needs to rise to £88 or more. The RCT results were not sensitive to any other changes tested in the sensitivity analysis over either time period.

The direct cost sensitivity analysis results for the observational study groups are shown in *Table 40* and *Table 41*. Under the initial analysis the patients who were referred for an X-ray at first consultation were significantly more expensive than those who were not over 0–6 weeks and over 0–12 months. The significance of this difference was robust to all of the changes tested in the sensitivity analysis.

Changes in the estimated value of patient time from £4 per hour to £16 per hour made no difference to the indirect cost results: the difference remained non-significant for both time periods for both the RCT and observational study groups.

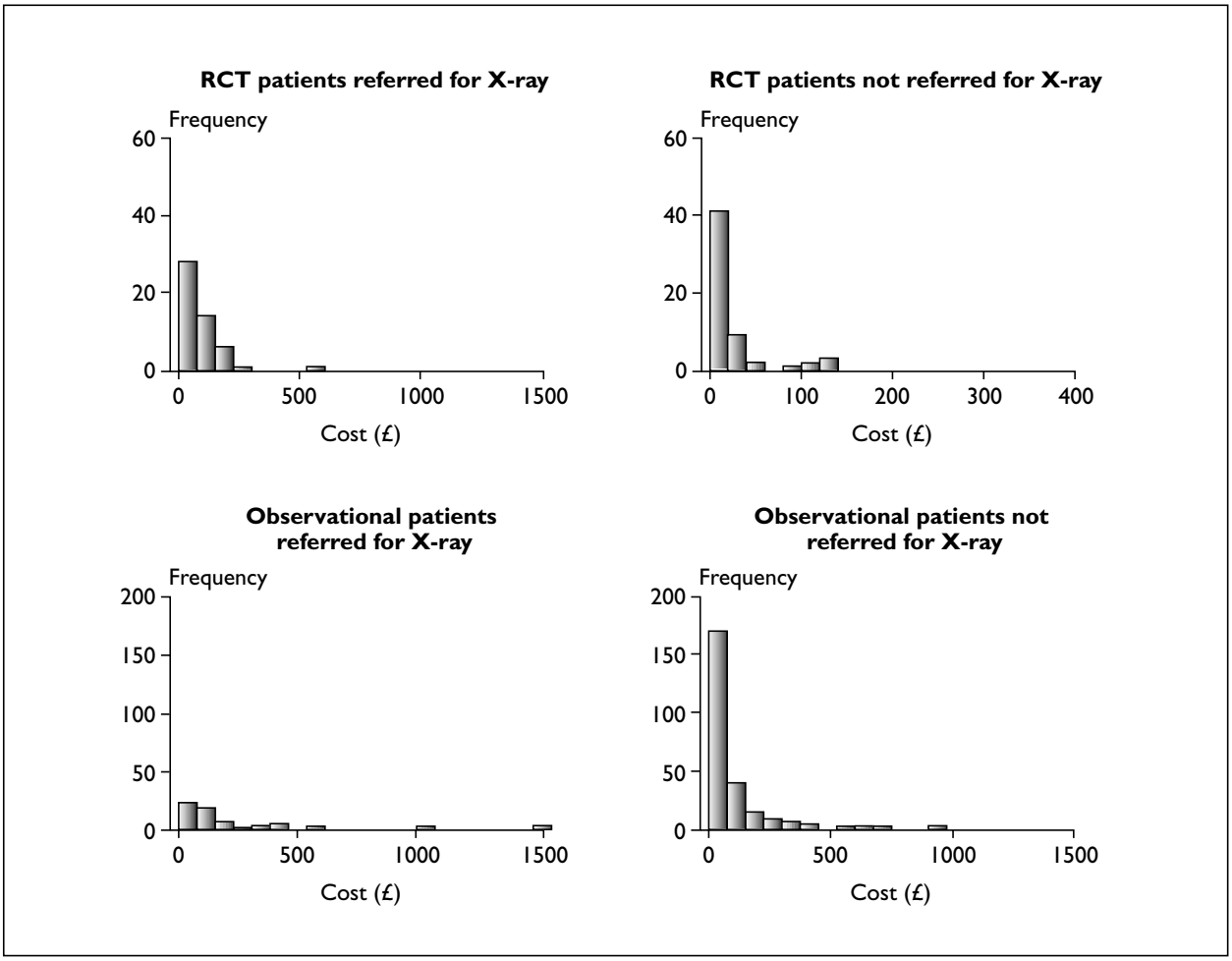

FIGURE 6 *Frequency distribution of direct social costs (£) by study group: 0–12 months*

TABLE 30 *Direct social costs (£) per patient in RCT: 0–6 weeks*

	Referred for X-ray (*n* = 55)		Not referred for X-ray (*n* = 62)		*p* value (t test)
	Mean	**SD**	**Mean**	**SD**	
X-rays (NHS)	38.9	11.0	3.4	11.5	< 0.001
Prescribed medications (NHS)	2.6	4.6	4.7	9.4	0.14
GP consultations (NHS)	4.8	7.6	6.5	11.1	0.35
Other consultations (NHS)	18.3	31.8	10.8	28.3	0.18
Other consultations (private)	17.4	42.5	14.7	44.4	0.75
Total	**82.0**	**55.2**	**40.1**	**62.9**	**< 0.001**

Cost-effectiveness analysis

In the RCT, a difference of 8 percentage points was found in the mean SF-36 mental health scores for the patients who were referred for X-ray and those who were not, after adjustment for age, sex and length of episode (see *Table 10*). Although not large, this difference was statistically significant, and it led us to consider a cost-effectiveness analysis using the SF-36 mental health dimension as the measure of health outcome.

The RCT comparison provides an estimate of £42 per patient for the incremental direct

TABLE 31 *Direct social costs (£) per patient in RCT: 0–12 months*

	Referred for X-ray (*n* = 50)		Not referred for X-ray (*n* = 58)		*p* value (t test)
	Mean	**SD**	**Mean**	**SD**	
X-rays (NHS)	38.6	11.5	6.5	15.3	< 0.001
Prescribed medications (NHS)	4.6	9.8	6.4	10.4	0.36
GP consultations (NHS)	10.8	16.9	17.0	21.9	0.11
Other consultations (NHS)	14.3	31.7	29.8	60.9	0.11
Other consultations (private)	28.9	75.9	29.0	85.1	0.99
Total	**97.3**	**84.6**	**88.6**	**129.2**	**0.68**

TABLE 32 *Direct social costs (£) per patient in observational study: 0–6 weeks*

	Referred for X-ray (*n* = 73)		Not referred for X-ray (*n* = 263)		*p* value (t test)
	Mean	**SD**	**Mean**	**SD**	
X-rays (NHS)	38.5	11.6	1.4	7.6	< 0.001
Prescribed medications (NHS)	3.0	6.4	3.5	5.2	0.51
GP consultations (NHS)	7.0	11.1	5.0	9.8	0.14
Other consultations (NHS)	28.2	59.9	12.5	31.2	0.003
Other consultations (private)	30.1	63.2	21.4	56.4	0.26
Total	**106.7**	**82.4**	**43.8**	**67.2**	**< 0.001**

TABLE 33 *Direct social costs (£) per patient in observational study: 0–12 months*

	Referred for X-ray (*n* = 60)		Not referred for X-ray (*n* = 244)		*p* value (t test)
	Mean	**SD**	**Mean**	**SD**	
X-rays (NHS)	40.6	7.6	3.8	12.1	< 0.001
Prescribed medications (NHS)	4.3	8.9	4.9	8.5	0.66
GP consultations (NHS)	17.0	23.0	11.4	19.2	0.06
Other consultations (NHS)	71.6	117.5	22.5	71.3	< 0.001
Other consultations (private)	57.8	221.1	31.9	94.0	0.16
Total	**191.2**	**252.2**	**79.5**	**124.8**	**< 0.001**

TABLE 34 *Days off work for those in paid employment by study group: 0–6 weeks*

	RCT		Observational trial	
	Referred for X-ray (*n* = 39)	**Not referred for X-ray (*n* = 39)**	**Referred for X-ray (*n* = 50)**	**Not referred for X-ray (*n* = 191)**
Mean	2.13	5.26	4.56	3.75
SD	6.34	10.42	9.19	8.02
p value	0.11		0.54	

TABLE 35 *Days off work for those in paid employment by study group: 0–12 months*

	RCT		Observational trial	
	Referred for X-ray (*n* = 39)	**Not referred for X-ray (*n* = 38)**	**Referred for X-ray (*n* = 39)**	**Not referred for X-ray (*n* = 179)**
Mean	8.46	6.16	3.21	4.99
SD	31.36	18.6	7.7	16.81
p value	0.72		0.52	

TABLE 36 *Indirect costs (£) by study group: 0–6 weeks*

	RCT		Observational trial	
	Referred for X-ray (*n* = 55)	**Not referred for X-ray (*n* = 62)**	**Referred for X-ray (*n* = 74)**	**Not referred for X-ray (*n* = 262)**
Mean	102.4	211.6	197.2	198.4
SD	347.0	551.2	501.1	486.9
p value	0.21		0.99	

TABLE 37 *Indirect costs (£) by study group: 0–12 months*

	RCT		Observational trial	
	Referred for X-ray (*n* = 50)	**Not referred for X-ray (*n* = 58)**	**Referred for X-ray (*n* = 60)**	**Not referred for X-ray (*n* = 244)**
Mean	422.4	258.2	325.3	335.2
SD	1781.6	977.5	1525	1382.9
p value	0.55		0.96	

TABLE 38 *Sensitivity analysis of direct social costs (£) per patient in RCT: 0–6 weeks*

	Referred for X-ray (*n* = 55)		**Not referred for X-ray (*n* = 62)**		***p* value (t test)**
	Mean	**SD**	**Mean**	**SD**	
Mean cost[a]	82	55	40	63	< 0.001
If X-ray cost is £20	62	54	38	60	0.03
If X-ray cost is £80	117	59	43	69	< 0.001
If GP cost is £5	79	54	37	59	< 0.001
If GP cost is £20	86	57	46	70	< 0.001
If consultant cost is £25	79	52	39	59	< 0.001
If consultant cost is £100	86	64	42	69	< 0.001
If physiotherapist cost is £5	72	47	31	49	< 0.001
If physiotherapist cost is £20	99	75	55	90	0.005
If complementary treatment cost is £15/£12	75	46	37	59	< 0.001
If complementary treatment cost is £60/£50	91	77	46	78	0.003

[a] *For unit costs, see* Table 3; *mean cost is based on data in* Table 30

TABLE 39 *Sensitivity analysis of direct social costs (£) per patient in RCT: 0–12 months*

	Referred for X-ray (*n* = 50)		Not referred for X-ray (*n* = 58)		*p* value (t test)
	Mean	SD	Mean	SD	
Mean cost[a]	97	85	89	129	0.68
If X-ray cost is £20	77	84	85	126	0.70
If X-ray cost is £80	132	86	94	136	0.09
If GP cost is £5	92	83	80	124	0.56
If GP cost is £20	107	89	104	140	0.89
If consultant cost is £25	93	69	78	116	0.45
If consultant cost is £100	105	113	104	155	0.99
If physiotherapist cost is £5	88	80	77	108	0.54
If physiotherapist cost is £20	113	98	109	169	0.87
If complementary treatment cost is £15/£12	88	72	80	112	0.65
If complementary treatment cost is £60/£50	113	116	106	174	0.82

[a] *For unit costs, see* Table 3; *mean cost is based on data in* Table 31

TABLE 40 *Sensitivity analysis of direct social costs (£) per patient in observational study: 0–6 weeks*

	Referred for X-ray (*n* = 73)		Not referred for X-ray (*n* = 263)		*p* value (t test)
	Mean	SD	Mean	SD	
Mean cost[a]	107	82	44	67	< 0.001
If X-ray cost is £20	87	82	43	66	< 0.001
If X-ray cost is £80	142	85	45	70	< 0.001
If GP cost is £5	103	81	41	66	< 0.001
If GP cost is £20	113	86	48	71	< 0.001
If consultant cost is £25	101	77	40	62	< 0.001
If consultant cost is £100	115	97	50	79	< 0.001
If physiotherapist cost is £5	99	80	39	64	< 0.001
If physiotherapist cost is £20	121	93	52	77	< 0.001
If complementary treatment cost is £15/£12	91	60	35	49	< 0.001
If complementary treatment cost is £60/£50	138	144	61	111	< 0.001

[a] *For unit costs, see* Table 3; *mean cost is based on data in* Table 32

cost at 6 weeks. The incremental effect was estimated at 8 percentage points. We might thus estimate the cost-effectiveness of early GP referral for X-ray for low back pain at £5.25 per percentage point gain in the SF-36 mental health dimension.

The distributions of the replicated incremental costs and incremental effects at 6 weeks and 12 months are shown in *Figure 7*.

The replicates are plotted on the cost-effectiveness plane in *Figure 8*. The 6-week

TABLE 41 *Sensitivity analysis of direct social costs (£) per patient in observational study: 0–12 months*

	Referred for X-ray (*n* = 60)		Not referred for X-ray (*n* = 244)		*p* value (t test)
	Mean	SD	Mean	SD	
Mean cost[a]	191	252	74	125	< 0.001
If X-ray cost is £20	170	252	72	123	< 0.001
If X-ray cost is £80	228	252	78	129	< 0.001
If GP cost is £5	182	250	68	121	< 0.001
If GP cost is £20	206	258	85	133	< 0.001
If consultant cost is £25	169	243	68	110	< 0.001
If consultant cost is £100	225	277	84	157	< 0.001
If physiotherapist cost is £5	173	237	65	114	< 0.001
If physiotherapist cost is £20	222	291	90	151	< 0.001
If complementary treatment cost is £15/£12	162	160	62	102	< 0.001
If complementary treatment cost is £60/£50	235	419	98	186	< 0.001

[a] *For unit costs, see* Table 3*; mean cost is based on data in* Table 33

points mostly lie within the upper right quadrant, where the early referral for X-ray is both more costly and more effective than delayed referral or no referral. However, many points lie in the upper left quadrant, where the intervention is more costly and less effective (the ICER is negative). At 12 months the points are spread across all four quadrants.

The acceptability curves for the 6-week and 12-month RCT comparison are shown in *Figure 9*. Given the traditional 95% confidence level, immediate referral for X-ray is cost-effective provided that we are willing to pay £93 or more per percentage point improvement in SF-36 mental health scale at 6 weeks or to pay £10 or more per percentage point improvement at 12 months.

Summary of results

Randomised controlled trial

Comparison between the groups who were referred for X-ray and who were not referred for X-ray showed:

- no statistically significant differences on the physical subscales of the SF-36, EuroQol, the Hospital Anxiety and Depression Scale or the Roland and Morris disability scale after 6 weeks and 1 year
- statistically significant better mental health and vitality scores on the SF-36 among the referred group at 6 weeks and in mental health scores at 1 year.

Economic evaluation showed that patients who were randomised to referral:

- had higher costs in the first 6 weeks than patients who were not immediately referred, a difference that was almost entirely due to the cost of the X-ray itself
- did not have significantly different numbers of prescriptions or of GP and other consultations.

Observational study

In the observational study referral was associated with the following patient factors:

- older age
- longer length of episode
- patient not reporting being "off sick"
- decreased physical role on the SF-36.

In the observational study after adjusting for age, sex and length of episode, referral was associated with the following practice factors:

- health authority in which the practice was situated

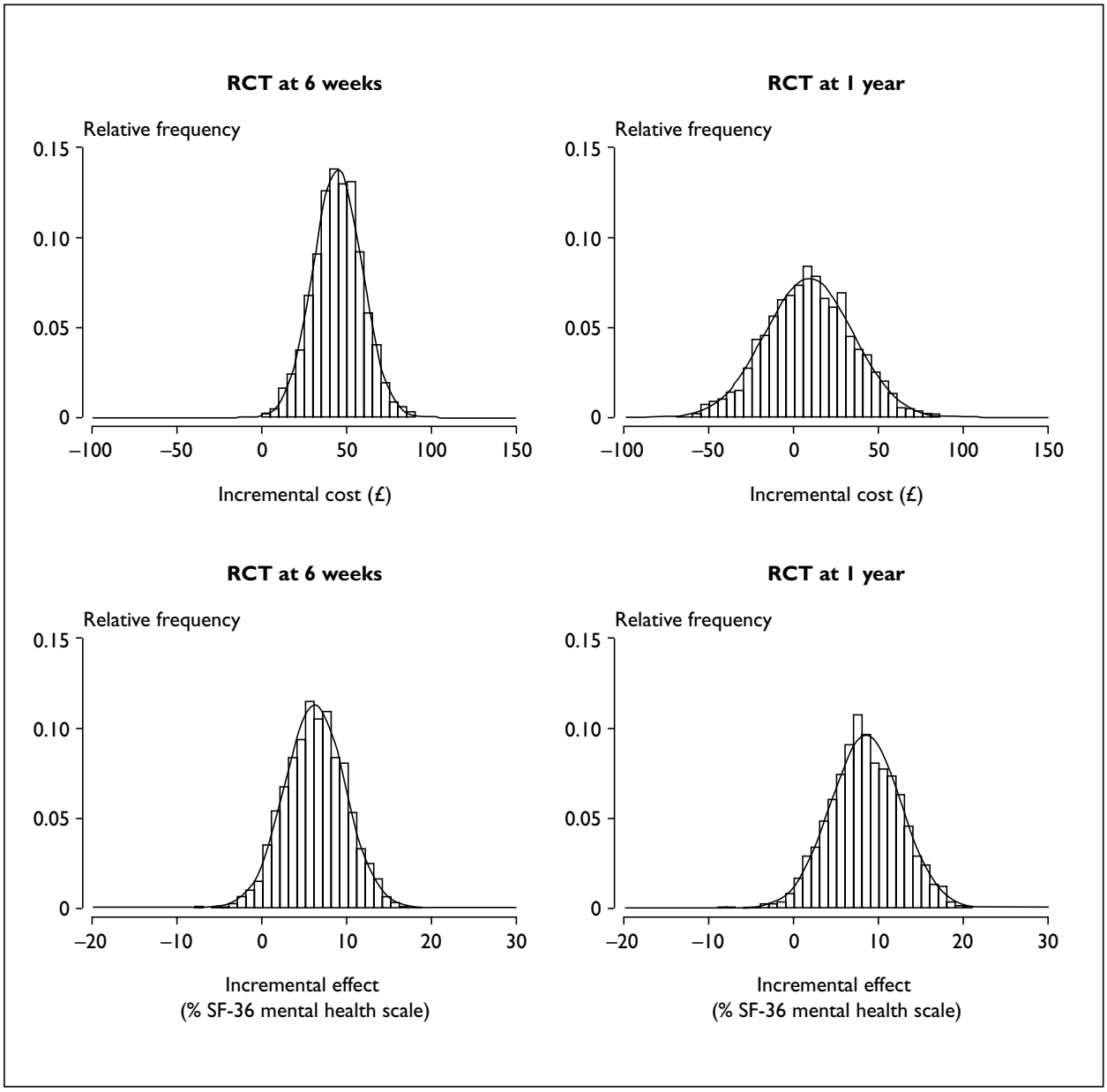

FIGURE 7 *Distributions of 2000 bootstrap replicates of incremental direct costs and effects for RCT*

- the presence of an on-site therapist
- whether or not the practice was a fundholding practice.

In the observational study patients who were referred for X-ray showed the following statistically different differences:

- they had poorer physical functioning and limitations due to pain at 6 weeks, and these differences could be accounted for by age, sex and length of episode at initial consultation
- they were more likely to consult again within 6 weeks and to continue to consult after 6 weeks
- they were more likely to be referred for further assessment or treatment (to a hospital consultant, a physiotherapist, a chiropractor or an osteopath)
- they had lower vitality and mental health scores at 6 weeks after adjustments age, sex and length of episode, although this difference was not maintained at 1 year
- they had less anxiety and depression after adjustments for age, sex and length of episode, and this difference was significant for depression at 6 weeks and 1 year
- they reported greater satisfaction with their GP initially and at 6 weeks.

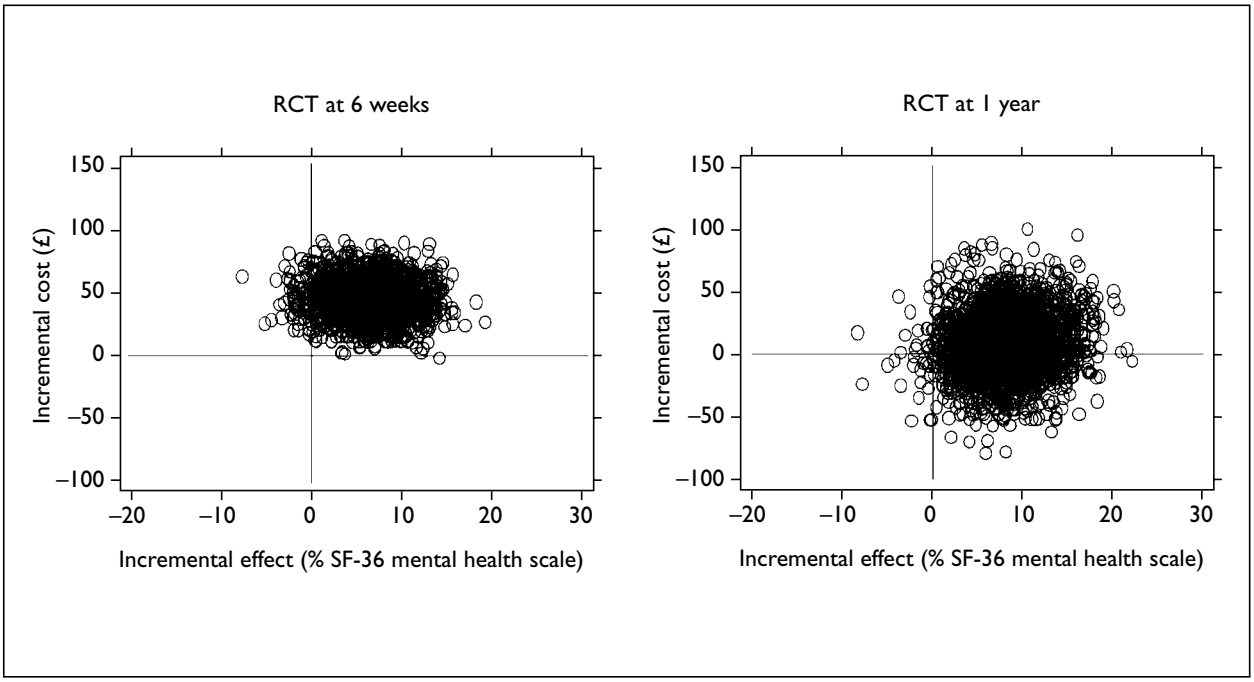

FIGURE 8 *Distribution of 2000 bootstrap replicates on the cost-effectiveness plane*

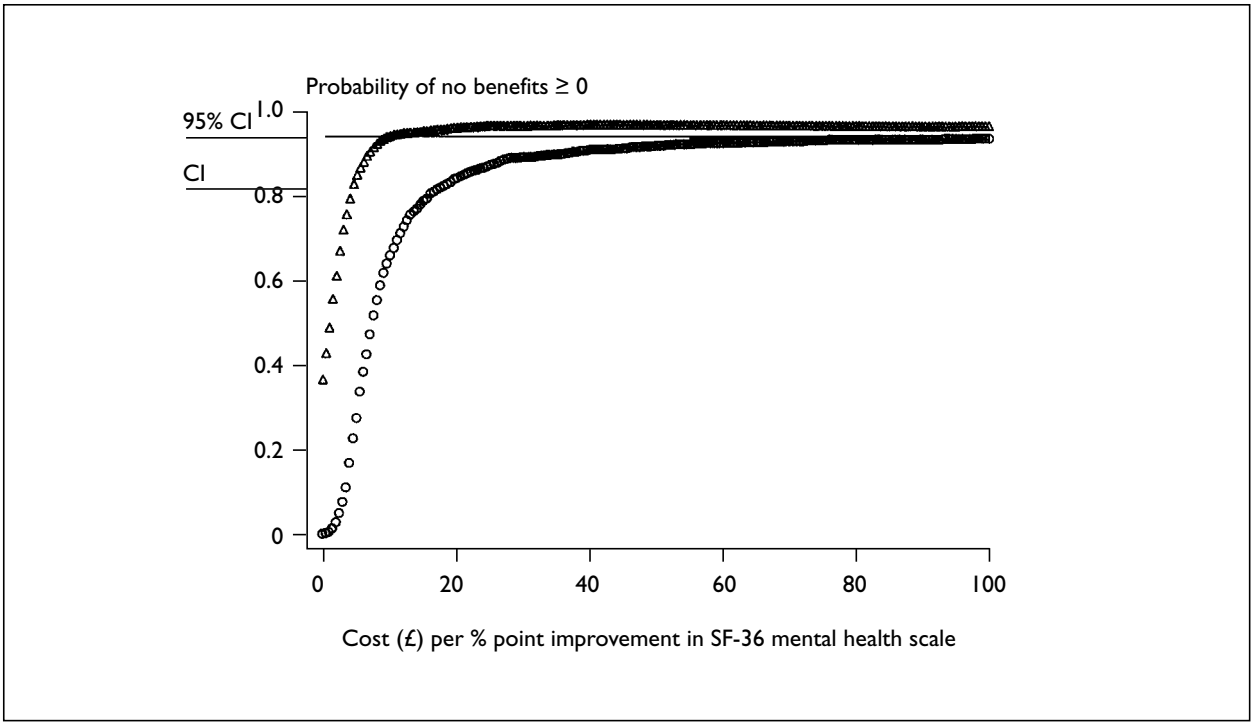

FIGURE 9 *Cost-effectiveness acceptability curve derived from 2000 bootstrap replicates (○, 6-week results; △, 1-year results)*

Chapter 5
Discussion

Summary

This study is the first randomised controlled clinical trial based in UK general practice to look at whether a referral for an X-ray by the GP affects short- and long-term outcomes for patients who consult with low back pain. The inclusion of an observational arm enabled comparisons to be made with those patients who were not randomised, thereby offsetting the "unnatural" situation of recruiting into a trial by GPs.

Our results suggest that referral for X-ray by the GP may lead to a small improvement in patient psychological well-being over the next 12 months, but there were no differences in physical outcomes between those referred and those not referred for X-ray. In the observational study, patients referred for X-ray had poorer physical outcomes at 6 weeks and 1 year, but they also had features that indicate a poorer prognosis at the time of referral for X-ray.

When the results of the randomised and observational patients were compared, the effect sizes were similar after adjustment for baseline predictors of prognosis had been made. This suggests that the results are generalisable to wider groups of back pain patients than the groups that were willing to enter the trial.

In the randomised trial, patients who were referred for X-ray at their first consultation with low back pain had higher costs in the short term (6 weeks) than patients who were not immediately referred, a difference that is almost entirely due to the cost of the X-ray itself. There is no statistically significant difference in costs over 1 year. In the observational study, the economic evaluation shows that patients who were referred for X-ray had higher costs than those who were not referred, both in the short term and in the long term. Again, features indicating poorer prognosis of observational patients referred for X-ray may explain these differences.

The study design

RCTs have become established as the gold standard for comparing new drug treatments with existing therapies. More recently this has extended to behavioural interventions and investigations. The NHS Research and Development HTA programme, of which the current study forms part, has a strong emphasis on randomised trials. However, it may be difficult to obtain the cooperation both of doctors and of patients if the intervention under study has become part of routine practice, when patients and doctors may hold strong preconceived views about its value.

The use of lumbar spine X-rays is just such a well-established intervention. However, the limitations, including the delivery of high doses of radiation have been widely publicised through the dissemination of guidelines.[28,68,69] When planning this study, we felt that GPs would only be prepared to randomise a small proportion of their patients and that it would be difficult to be prescriptive about which patients should be randomised. Consequently, a study design was adopted so that, if the GP did not wish to randomise a particular patient, that patient could be part of an observational study running alongside the randomised trial. This design has been called a "comprehensive cohort study" by Olschewski and Scheurlen.[70] They argue that this approach should be reserved for trials in which a relatively large proportion of eligible patients refuse randomisation because they or their doctors have a definite preference and when the *a priori* probability of there being no difference is high. It is not intended as a substitute for a randomised comparison, and sample sizes must be calculated on the randomised cohort alone. The strength of this study lies in this design; by having an observational arm we believe that we have overcome some of the problems of bias that are sometimes brought about by relying on GPs to recruit patients to trials.[71] These non-randomised patients can then be used to investigate the external validity of the results from the randomised trial.

In this study only 23% of the patients recruited were entered into the randomised trial, primarily because of their GPs' attitude to X-rays for low back pain. Some GPs who did not recruit any patients to the randomised trial recruited many patients to the observational study; only 42% of the GPs recruited patients to both studies. In terms of patient characteristics, patients in the trial were similar to those in the observational study, although they were slightly older and more limited by pain. In particular they were similar in terms of the length of time that they had been in pain before consulting, one of the consistent indicators of prognosis.[11,12,72]

Data collection instruments

An international panel of experts has put together a recommended series of instruments to use to encourage standardisation of outcome measurement in trials relating to back pain.[73] The instruments need to be reliable, valid, responsive and practical, and they need to include a measure of general health status, a measure of severity and frequency of symptoms, a measure of satisfaction with symptoms and a measure of satisfaction with medical care. Their recommended instruments included three that were used in this study: the Roland and Morris disability measure, SF-36 and EuroQol. Other experts have suggested caution when results are interpreted on the basis of disease-specific questionnaires and they recommend inclusion of generic instruments,[74] although there is argument about their ability to discriminate and their sensitivity to change.[75] In this study we also included a question on patients' satisfaction with their GP care in line with the panel's recommendations.

However, since the inception of this study there has been concern expressed about the use of the EuroQol in some patient groups. In a study of rheumatology patients[76] the distribution of EuroQol scores had many gaps and was not continuous. The distribution of the EuroQol scores in this study was bimodal, the two parts corresponding to patients who had moderate discomfort and extreme discomfort as measured on the pain subscale. Initially nearly all the patients were in pain. At 6 weeks and 1 year the peak associated with extreme pain diminished and another peak appeared on the scale, corresponding to no pain. The EuroQol appears to be dominated by the pain scores when applied to a group of patients for whom pain is the dominant symptom. Further validation may be required before it can be considered to be the appropriate measure of quality of life in patients such as we have studied here.

Recruitment

The difficulties of recruiting patients into RCTs are not new,[71,77] and some trials have been abandoned on account of low recruitment.[78,79] The importance of random allocation to control and intervention groups is also well recognised. However, the balance between the logistics of carrying out research in the day-to-day clinical setting and the scientific requirements of a trial need to be taken into account. Those that succeed are more likely to have minimised GP involvement and disruption to practice procedures while compensating for any additional time commitment. However the question of what constitutes adequate compensation remains unanswered. The relevance of the research question to the individual GP has some bearing on this. Ethical issues surrounding the doctor–patient relationship perhaps need to be considered,[80,81] and an awareness of the ineffectiveness of results of some studies may have made GPs reluctant either to take part themselves or to recruit some patients to the trial.[82,83] It may also be difficult to find time within the consultation to explain the randomisation process and obtain informed consent.

In this study the GPs' role was kept to a minimum, the inclusion criteria were simple and the GPs were not required to undertake any extra examinations of the patients for the purposes of the study. In spite of our attempts to maintain motivation and impetus among GPs through regular contact, we were not able to recruit the prerequisite number of patients. Post-hoc sample size calculations showed that the numbers recruited would allow us to detect a fall in re-consultation rates from 40% to 19% with 80% power and 5% significance. In other words, we were able to detect a halving of the re-consultation rate among those patients who were referred for X-ray. Since the observed re-consultation rate is higher in the referred group among both the randomised and observational patients, it is unlikely that there is a substantial increase in consultation rates among patients who are not referred for X-ray.

Comparison of randomised and observational patients

There were differences between the patients in the randomised arm of the trial who were referred for X-ray and those in the observational arm of the trial who were referred. In the observational study, there was a strong relationship between referral for X-ray and length of episode. Length of episode on presentation has been found to predict outcome.[11,12,72] Therefore, referred patients might be expected to have poorer outcomes than those who were not referred. To improve the comparability of groups, all outcomes on the SF-36, HADS, EuroQol and Roland and Morris disability scores were adjusted for age, sex and length of episode.

Even though random allocation was used to minimise bias in recruitment, patients in the referred group of the randomised trial were also more likely to have been in pain longer, although the relationship was not as marked as in the observational group. The outcomes were adjusted in the same way as they were in the observational study. Although the effect sizes are slightly greater in the adjusted analysis, they are still evident in the unadjusted results.

When the results were compared, the effect size were similar after adjustment in both the randomised and non-randomised groups. It is likely then that the results can be generalised to a wider group of patients with back pain than those willing to enter the trial. However, the number of patients recruited to the trial did not permit a formal analysis of the interaction between randomisation and treatment effect, and this comparison needs to be interpreted with caution.

One exception to the similarity between the groups was patient satisfaction. However, it is possible that the selection process of the trial may affect patient satisfaction. Any trial imposes an artificial situation. The process of randomisation introduces uncertainty into the consultation, and this affects the doctor–patient relationship. In this study, if both patient and GP were ambivalent about patient referral for X-ray, the normal complex decision making and negotiation process is reduced to the process of randomisation. A patient's ambivalence about being referred for X-ray may reduce the impact on satisfaction with care compared with the situation in which the patient has strong views that may conflict with those of the doctor. This may explain why referral for X-ray had no effect on patient satisfaction in the randomised trial, whereas in the observational study referred patients were more than twice as likely to report being very satisfied with the care provided by their GP.

Patient population

A recent study by Croft and co-workers[13] found that only one-tenth of patients consulted within 1 week of pain onset. We found that 27% of our patients had been in pain for less than 1 week. On the other hand. Roland and Morris[10] reported that 62% of their patients had been in pain for less than 1 week. Their study used the same inclusion criteria as our study but it was carried out in the early 1980s. It may be that consulting behaviour has changed in the intervening years, perhaps partly due to changes in requirements for sickness certification or the introduction of appointment systems. Different consultation patterns may also explain why the GPs in this study found it difficult to recruit patients according to the Roland and Morris criteria.

Although only 17% of eligible patients who consulted with back pain were recruited to the study in the three sample practices where searches were carried out, there was no evidence to suggest that the patients who were recruited were unrepresentative in terms of consulting history, age or sex. Conversations with GPs suggested that other factors such as time pressures were the main factors that hindered recruitment, rather than the patients themselves.

We had aimed to identify patients who consulted with new episodes of back pain by recruiting patients who had not consulted within the past 4 weeks. Some patients reported long histories of pain; however, at least 85% of the patients were consulting for the first time in that episode or had not consulted for at least 1 year. Thus the majority of patients in the trial were recruited at their first consultation for a new episode of back pain.

Covariate analysis

We used length of episode of back pain as a measure of prognosis. This was chosen for pragmatic reasons because, unlike other prognostic measures such as limited straight leg raising, it could be obtained from questionnaire data. Length of episode before consultation has been shown to be important in determining the

probability of early resolution of symptoms.[11,12,72] We used a cut-off point for length of episode at 8 weeks, which corresponds to the Royal College of Radiologists' recommendations that X-rays should not be performed routinely unless symptoms persist for more than 6–8 weeks.

Because the questionnaire was completed after the decision to X-ray was made known, the results were not adjusted for baseline values of the SF-36, HADS or EuroQol. These values may have been affected by the decision to refer for X-ray. Patients' report of the length of episode may be biased but since there were few patients whose length of episode was close to the cut-off point of 8 weeks, any such bias is unlikely to have an appreciable effect on the results.

Appropriateness of referral for X-ray

Guidelines for X-ray referral differ, but they generally discourage the routine use of lumbar spine X-rays for patients who present with back pain; the Royal College of General Practitioners' guidelines[26] have been shown to be effective[13,84] in reducing referrals for lumbar spine X-ray. Patients with shorter episodes of pain have better prognosis[10] and the Royal College of Radiologists' guidelines that were current during the study[23] recommended waiting 6–8 weeks before referral for X-ray and that referral should then occur only if symptoms are not resolving. However, up to 50% of referrals do not conform to guidelines,[28,29] which suggests that a significant number of inappropriate referrals are being made by GPs.

In this study we found that those patients who were referred for X-ray were more likely to have been in pain for longer. Patients who presented more than 8 weeks after the onset of pain were twice as likely to be referred; this suggests that GPs were following guidelines. However, 13% of the referred group had been in pain for less than 1 week. In this study, 54% of patients reported having consulted within 4 weeks of onset whereas only 17% waited to consult until between 4 weeks and 4 months, by which time referral might have been more appropriate.

Disability from back pain is a complex biopsychosocial problem, and it is not solved by traditional medical treatment. On the one hand, patients and GPs need to aim to "de-medicalise" management and to feel comfortable without a referral for an X-ray. X-rays of lumbar spine involve 120 times the radiation of a chest X-ray, the yield of positive findings is low, acute pain correlates poorly with degenerative changes seen on X-rays, and serious pathology can exist in the presence of normal X-ray.

On the other hand, although less than 1% of patients with low back pain are suffering from serious spinal disease, it is important to identify these patients, and this process includes early and appropriate referral. The guidelines for X-ray referral for back pain describe serious features – "red flags" – which are intended to help identify such patients.[2,23,26] In addition X-rays may be considered for patients whose symptoms have not resolved in 6–8 weeks. However, since plain X-rays may be falsely reassuring, full blood count and erythrocyte sedimentation rate may also be used for ruling out malignancy or infection. In our study, one patient was diagnosed with a spinal tumour after presenting to casualty 3 months after his recruitment at initial GP consultation. This patient had been in pain for 4 weeks at recruitment and did not present to his GP again for more than 6 weeks, at which time he was referred to a physiotherapist. It is known that patients often do not continue to consult, despite continuing pain.[13] In this study 67% of patients did not reconsult; this was not related to improvement in symptoms.

Therefore it cannot be assumed that patients who are not initially referred for X-ray will reconsult in the following 6 weeks, even if the symptoms do not resolve. The presence of symptoms does not of itself lead to consultation; multiple socioeconomic, demographic and psychological factors impinge.[85,86] Just as issuing delayed or post-dated prescriptions has provided a useful alternative in the management of upper respiratory tract infection,[87] an opportunity for reassessment may be a useful alternative to immediate referral for X-ray. Further investigation would be required to determine the effect of such an approach.

Patient expectations

Patients' expectations of their management by the GP have been shown to influence the GPs' referral behaviour,[35] and pressure from patients

to refer is related to both GP characteristics and the nature of the referral.[88] In a US study[89] that assessed variability amongst physicians in their use of lumbar spine imaging, non-clinical factors such as patient age, work status, time constraints and access were important in the decision-making process. Physicians report that referral serves a symbolic function in gaining trust with the patient.

In this study we have shown that more patients who had an X-ray reported that they had expected one. As well as patient expectations that influenced GP referral behaviour, the very referral itself may influence the patients' view that X-rays are useful in determining the cause of back pain, as in the US trial.[40] This may have led to an over-reporting of expectation by the referred patients. Whichever is the case, it may well be that considerable educational input is required for both healthcare staff and patients to offset the perceptions of the necessity of X-rays.

Referral to other health professionals

The presence of an on-site therapist in this study was significantly associated with an increased likelihood of being referred for X-ray in the observational study. At least 20 patients in our study were referred to a chiropractor and 130 to a physiotherapist. There is wide variation in the availability of on-site physiotherapists and other therapists[90] and in the total number of therapists working in each district.[2] The increased availability of such services was recommended by the CSAG,[2] although it is not clear whether such referrals are beneficial or cost-effective.[88]

Economic evaluation

The economic evaluation of the randomised trial shows that patients referred for X-ray at their first consultation with low back pain have higher costs in the short term than patients who are not immediately referred. Based on the local cost of £42 for a lumbar spine X-ray, over a 6-week period the expected cost is £42 higher for the X-ray group, a difference that is thus almost entirely due to the cost of the X-ray itself. The expected cost remains higher for the X-ray group over 12 months, but the difference is no longer statistically significant. These results are sensitive to the price of X-rays – below £18, the significance of the 6-week difference is lost; above £88, the difference over 12 months becomes significant. The results are not sensitive to any other price changes. There is no evidence that the X-ray group took any more days off work due to back pain over the follow-up period, or that their indirect costs were any greater than for the non X-ray group. However, variation in the number of reported days off work was high, and the sample size may have been insufficient to detect a difference when one existed.

With respect to the observational study, the economic evaluation shows that patients who are referred immediately for X-ray had higher costs than those who were not referred immediately, both in the short term and in the long term. The expected cost was £63 higher for those referred for X-ray over 6 weeks, and £117 higher over 12 months. These differences resulted largely from differences in the number of NHS referrals and from the cost of X-rays. The scale of the differences in the quantities of resources used was such that the direct costs remained significantly higher for the X-ray group under a wide range of unit cost assumptions. It is not possible to determine whether the observed cost differences arose from the GP's decision to refer for X-ray, or whether the decision to use X-rays and other resources resulted from some other characteristic of the patient or the GP. As with the randomised study, no significant differences were found in days off work or indirect costs.

There was no significant difference between the RCT groups for most of the outcome measures tested. We might thus conclude that the additional expenditure on an immediate X-ray is not justified. However, a small improvement was observed in the mental health dimension of the SF-36 for the patients who were randomised to immediate X-ray compared with those who were randomised to the control group. Whether this gain is "worth" the additional expenditure requires a judgement about the societal value of such small improvements. The cost-effectiveness analyses suggest that if an improvement of 1 percentage point in the SF-36 mental health scale at 6 weeks is judged to be worth £93 or more, then the intervention is "cost-effective" (at a 95% level of confidence). If 1 percentage point improvement at 12 months is valued at £10 or more, then the intervention may be deemed cost-effective.

Limitations of the study

In a quantitative study such as this, qualitative factors pertinent to the consultation (such as the rapport between the doctor and patient, or faith in the doctor's judgement or ability) cannot be measured. This is a limitation when values that may be affected by the consultation, such as patients' expectations, are considered. In addition, expectations before the consultation cannot be assessed – only the recollection of these expectations after the consultation.

Our objective data is limited, since we did not want to burden the GPs with carrying out any extra physical measurements in order to minimise recruitment problems.

We have no method of checking the completeness of recording of patient referrals, particularly self-referrals, in the case notes, and this may lead to limitations in the collection of cost data. Even for NHS referrals, the number of visits is often not recorded in the GP notes. However, although patient recall is prone to error, there is no reason to suppose that the accuracy of questionnaire data will be any different for the intervention and control group patients.

It is possible that some of the effect of the referral for X-ray on the mental health scores is due to bias of the patients who responded to the 6-week and 1-year questionnaires. There were few differences between responders and non-responders at 6 weeks but patients who responded at 1 year were in better mental health at baseline and less likely to have been referred for X-ray. It is therefore unlikely that differences in mental health at 6 weeks were affected by response bias but it is possible that the 1-year differences may be over-estimated.

Owing to the complexity of measuring quality of life and psychological health, 12 different salient comparisons were made at each time point both for the observational and the randomised patients. In assessing the results, we have sought to look at effect sizes and the consistency of the results. Although there is an increased possibility of a type 1 error, the consistency of the results in the randomised trial and the observational study and on the different scales of measurement means that it is unlikely that the differences observed are due to chance alone. For simplicity, we have analysed only one outcome to determine cost-effectiveness; differences on the SF-36 mental health score were the main effect in the randomised trial.

Chapter 6
Conclusions

This study is the first RCT trial based in UK general practice to have looked at whether a GP referral for X-ray affects short- and long-term outcomes for patients who consult with low back pain. Like others, we encountered recruitment problems in assessing a well-established health technology.[91] Nevertheless, the main findings of the RCT support the null hypothesis of the research question addressed: that there is no difference in outcomes of those referred for X-ray after first presentation to their GP with those who are not so referred.

In the RCT, no statistically significant differences were found between the patients who were referred for X-ray and those who were not in terms of quality of life or mental, physical and disability scores after 6 weeks or 1 year. However, once age, sex and length of initial episode of back pain were taken into account, those referred had slightly better mental health and emotional and vitality scores.

In the observational study, patients who were referred for X-ray were more likely to reconsult within 6 weeks and to continue to consult after 6 weeks. They were also more likely to be referred to another health professional, and they had slightly lower vitality and mental health scores at 6 weeks (but not at 1 year) after adjustment for age, sex and for length of episode. They were less anxious and depressed after adjustment for age, sex and length of episode. Those referred for X-ray reported greater satisfaction with their GP both initially and at 6 weeks.

Economic evaluation showed that patients in the RCT who were referred for X-ray at their first consultation for low back pain have higher costs in the short term than patients who are not immediately referred. This difference is almost entirely due to the cost of the X-ray itself. There were significantly higher costs from increased consultations with GP and other health professionals, in addition to the significantly higher costs from the X-rays for those referred in the observational group. The 1 percentage point improvement in mental health scores at 6 weeks, at a cost of £93, must still be offset by the potential "cost" of radiation and the potential "benefit" of a reduction in the probability of failing to detect serious disease. On the other hand, at a societal level, there is no evidence that days lost from work are influenced by X-ray.

We suggest that education in management of back pain for both patients and health professionals should reiterate current guidelines and emphasise that referral for X-ray is not necessarily the appropriate immediate course of action. This has cost benefits and protects patients from unnecessary radiation. This study shows that patients do not necessarily reconsult even if pain continues beyond 6 weeks; GPs may therefore like to consider encouraging such patients to reconsult.

When considering what resources to provide, primary care groups and trusts should reflect on the cost implications of the provision of in-house therapists. Patient who were referred for X-ray in the observational study were also more likely to be referred to another health professional; the presence of an on-site therapist was a strong indicator for referral.

Given the differences in patient satisfaction, further research is necessary to consider the doctor–patient interaction in addressing issues of trust, confidence and reassurance.

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Appendix 1

Waiting room flyer

Are you seeing the doctor about your back?

If you are aged between 16 & 64 then we would like your help in an important study looking at the effects of back pain on peoples' lives.

We are a team of researchers from St. George's Hospital Medical School who are carrying out this study for the Dept. of Health.

If you have visited the GP because of your back in the last 4 weeks or if you are pregnant then you are not eligible for this study.

Please ask your GP for a questionnaire

We need *your* help to help others who have back pain like you.

Your care from your GP will not be affected whether or not you agree to take part in this study

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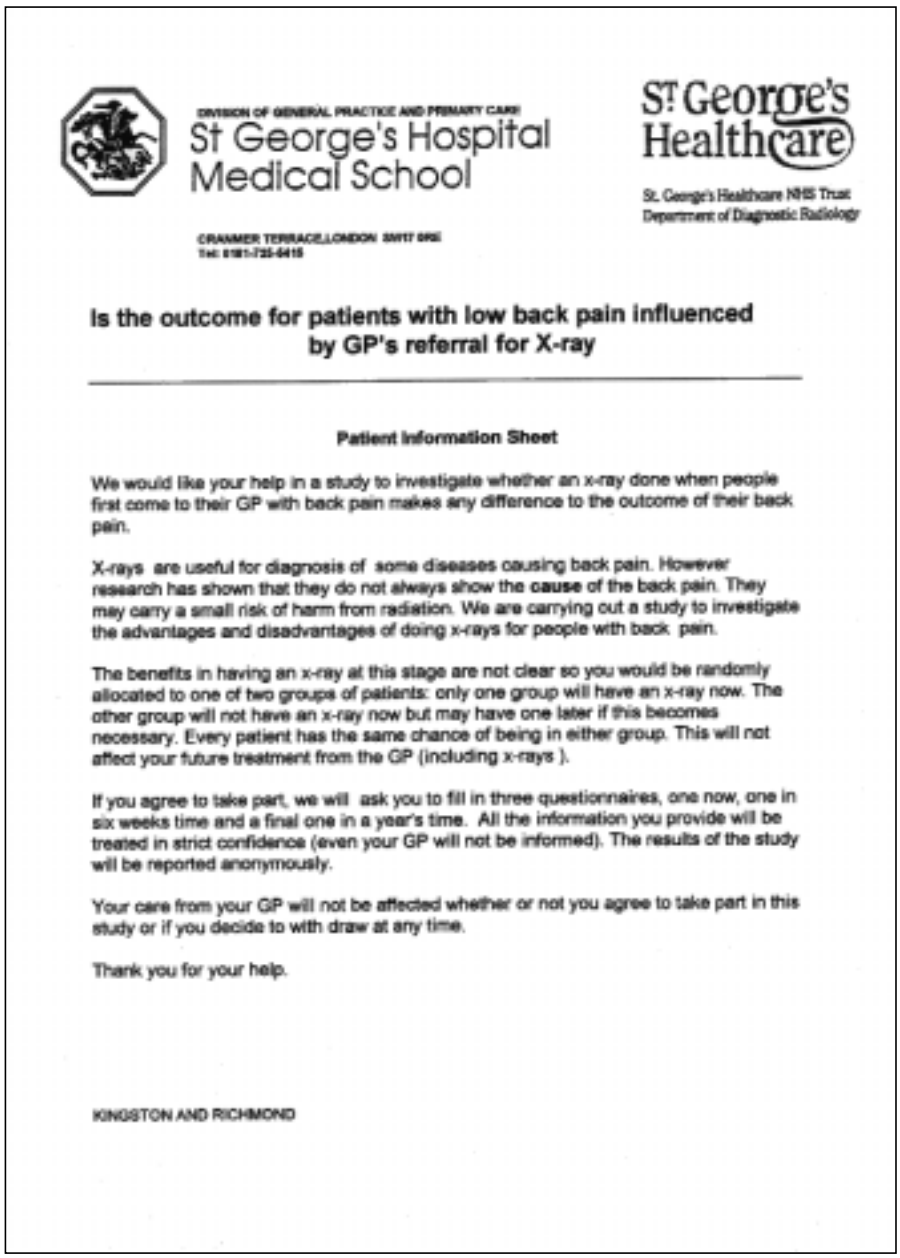
Appendix 2

Patient invitation letter, consent form and initial questionnaire for RCT



DIVISION OF GENERAL PRACTICE AND PRIMARY CARE
St George's Hospital Medical School

CRANMER TERRACE, LONDON SW17 0RE
Tel: 0181-725-6418

St George's Healthcare
St. George's Healthcare NHS Trust
Department of Diagnostic Radiology

Is the outcome for patients with low back pain influenced by GP's referral for X-ray

Patient Information Sheet

We would like your help in a study to investigate whether an x-ray done when people first come to their GP with back pain makes any difference to the outcome of their back pain.

X-rays are useful for diagnosis of some diseases causing back pain. However research has shown that they do not always show the **cause** of the back pain. They may carry a small risk of harm from radiation. We are carrying out a study to investigate the advantages and disadvantages of doing x-rays for people with back pain.

The benefits in having an x-ray at this stage are not clear so you would be randomly allocated to one of two groups of patients: only one group will have an x-ray now. The other group will not have an x-ray now but may have one later if this becomes necessary. Every patient has the same chance of being in either group. This will not affect your future treatment from the GP (including x-rays).

If you agree to take part, we will ask you to fill in three questionnaires, one now, one in six weeks time and a final one in a year's time. All the information you provide will be treated in strict confidence (even your GP will not be informed). The results of the study will be reported anonymously.

Your care from your GP will not be affected whether or not you agree to take part in this study or if you decide to with draw at any time.

Thank you for your help.

KINGSTON AND RICHMOND

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DIVISION OF GENERAL PRACTICE AND PRIMARY CARE
St George's Hospital Medical School

GRANMER TERRACE,LONDON SW17 0RE
Tel: 0181-725-5415

St George's Healthcare
St. George's Healthcare NHS Trust
Department of Diagnostic Radiology

Is the outcome for patients with low back pain influenced by GP's referral for X-ray

Consent Form

I have read the patient information sheet and agree to take part in the St. George's Back Pain study. I will be sent two more questionnaires through the post.

I understand that I have the right not to take part in the study or to withdraw from it at any time, without having to state my reasons and that this will in no way affect my present or future treatment.

Name:..... Signed :.....

Address: .....

.....

Tel . No. .....

Date .....

General Practitioner.....

Witness.....

KINGSTON AND RICHMOND

St George's Hospital Medical School
Department of General Practice and Primary Care

St George's Healthcare
Department of Diagnostic Radiology

LOW BACK PAIN STUDY
Randomised Trial

Initial Questionnaire

Some of the questions are very similar. Please be patient and answer all the questions by ticking the most appropriate box. ***First, we would like to ask you some questions about yourself.***

1. Name:.....Patient No:.....

   Address:.....

   .....Tel No:.....

2. Age:..... Date:.....

3. Sex:.....

Is the pain in your back at or below your waist? a. Yes [ ] b. No [ ]

Are you pregnant? a. Yes [ ] b. No [ ]

Are you suffering from 'flu or other feverish illness at the moment? a. Yes [ ] b. No [ ]

Have you visited your GP about your back in the last 4 weeks? a. Yes [ ] b. No [ ]

4. *Are you? (Please tick one)*

a. Employed	[ ]
b. Self Employed	[ ]
c. Unemployed	[ ]
d. Retired	[ ]
e. Student	[ ]
f. Looking after the house	[ ]

If you have any questions about this study please contact:
Kofi Anie
Tel 0181-725-2773
Fax 0181-767-7697

Department of General Practice and Primary Care
St. George's Hospital Medical School
Cranmer Terrace, London SW17 0RE

5. If you are employed, are you working? a. Full-Time [ ] b. Part-Time [ ]

6. What is your Occupation?.....
(Please give last occupation if not working at the moment)

7. If you are in paid employment, are you off at the moment because of your back? a. Yes [ ] b. No [ ]

8. How many days have you been off work in the last month, because of your back?.....

We would also like to ask you about the problem with your back.

9. How long have you had the present back pain episode?.....

10. Have you had similar back pain in the past? a. Yes [ ] b. No [ ]

11. If yes, how many times?.....

12. How long did the worst back pain episode last?.....

13. Did your GP refer you to hospital for an X-ray today? a. Yes [ ] b. No [ ]

14. If yes, which hospital?.....

15. Have you ever had an X-ray of your back before today? a. Yes [ ] b. No [ ]

When your back hurts, you may find it difficult to do some of the things you normally do.

*This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **today**. As you read the list, think of yourself **today**.*

When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one.

*Remember, only tick the sentence if you are sure that it describes you **today**.*

16. I stay at home most of the time because of my back. [ ]

17. I change position frequently to try and get my back comfortable. [ ]

18. I walk more slowly than usual because of my back. [ ]

19. Because of my back I am not doing any of the jobs that I usually do around the house. [ ]

20. Because of my back, I use a handrail to get upstairs. [ ]

21. Because of my back, I lie down to rest more often. [ ]

22. Because of my back, I hold on to something to get out of an easy chair. [ ]

23. Because of my back, I try to get other people to do things for me. [ ]

24. I get dressed more slowly than usual because of my back. [ ]

25. I only stand up for short periods of time because of my back. [ ]

26. Because of my back, I try not to bend or kneel down. [ ]

27. I find it difficult to get out of a chair because of my back. [ ]

28. My back is painful almost all the time. [ ]

29. I find it difficult to turn over in bed because of my back. [ ]

30. My appetite is not very good because of my back pain. [ ]

31. I have trouble putting on my socks (or stockings) because of the pain in my back. [ ]

32. I only walk short distances because of my back pain. [ ]

33. I sleep less well because of my back. [ ]

34. Because of my back pain, I get dressed with help from someone else. [ ]

35. I sit down for most of the day because of my back. [ ]

36. I avoid heavy jobs around the house because of my back. [ ]

37. Because of my back pain, I am more irritable and bad tempered with people than usual. [ ]

38. Because of my back, I go upstairs more slowly than usual. [ ]

39. I stay in bed most of the time because of my back. [ ]

Now we want you to give us an idea of just how bad your back pain is at the moment.

40. Here is a thermometer with various grades of pain from "no pain at all" at the bottom to "the pain is almost unbearable" at the top. We want you to put a cross by the words that describe your pain best. Remember, we want to know how bad your pain is ***at the moment***

We would like to know the reason for visiting the GP today.

41. When you attended the surgery today, which of the following did you expect from your GP? *(Please tick any that apply).*

a. Prescription	[ ]
b. Advice	[ ]
c. Referral for X-ray	[ ]
d. Certificate off work	[ ]
e. Referral to Specialist (eg. Consultant, Physiotherapist)	[ ]

42. How satisfied were you with your GP's approach? *(Please tick one).*

a. Very Satisfied	[ ]
b. Satisfied	[ ]
c. Indifferent	[ ]
d. Dissatisfied	[ ]
e. Very Dissatisfied	[ ]

We would like to ask you about your health in general and 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.

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

Excellent	[ ]
Very good	[ ]
Good	[ ]
Fair	[ ]
Poor	[ ]

44. Compared to one year ago, how would you rate your health in general now?:

Much better now than one year ago	[ ]
Somewhat better now than one year ago	[ ]
About the same	[ ]
Somewhat worse now than one year ago	[ ]
Much worse now than one year ago	[ ]

45. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much? *(Please tick one box on each line).*

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	[ ]	[ ]	[ ]
Moderate activities, such as moving a table, pushing 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	[ ]	[ ]	[ ]
Walking half a mile	[ ]	[ ]	[ ]
Walking 100 yards	[ ]	[ ]	[ ]
Bathing and dressing yourself	[ ]	[ ]	[ ]

46. 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.

	Yes	No
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 (eg. it took extra effort)	[ ]	[ ]

47. 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)?

	Yes	No
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	[ ]	[ ]

48. 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?

Not at all	[ ]
Slightly	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

49. How much bodily pain have you had during the past 4 weeks?

None	[ ]
Very mild	[ ]
Mild	[ ]
Moderate	[ ]
Severe	[ ]
Very Severe	[ ]

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

Not at all	[ ]
A little bit	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

These questions are about how you feel and how things have been with you during the past 4 weeks. (For each question please indicate the one answer that comes the closest to the way you have been feeling).

51. How much time during the past 4 weeks: *(Please tick one box on each line)*

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
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?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

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

All of the time	[ ]
Most of the time	[ ]
Some of the time	[ ]
A little of the time	[ ]
None of the time	[ ]

53. How true or false is each of the following statements for you? *(Please tick one box on each line)*

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
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	[ ]	[ ]	[ ]	[ ]	[ ]

By placing a tick in one box in each group below, please indicate which statements best describe your own health state <u>today</u>.

54. Mobility

I have no problems in walking about	[ ]
I have some problems in walking about	[ ]
I am confined to bed	[ ]

55. Self-Care

I have no problems with self-care	[ ]
I have some problems washing or dressing myself	[ ]
I am unable to wash or dress myself	[ ]

56. Usual Activities

I have no problems with performing my usual activities (eg. work, study, housework, family or leisure activities)	[ ]
I have some problems with performing my usual activities	[ ]
I am unable to perform my usual activities	[ ]

57. Pain / Discomfort

I have no pain or discomfort	[ ]
I have moderate pain or discomfort	[ ]
I have extreme pain or discomfort	[ ]

58. Anxiety / Depression

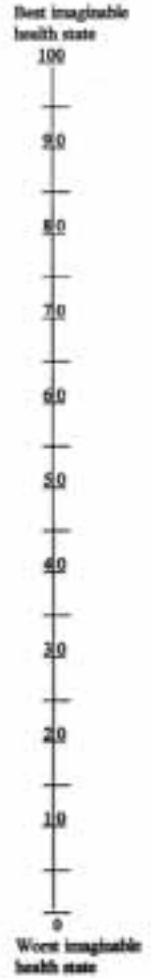
I am not anxious or depressed	[ ]
I am moderately anxious or depressed	[ ]
I am extremely anxious or depressed	[ ]

59.

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 you can imagine is marked by 0.

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

Your own health state today



might be helpful please let us know.

E-mail

If you are a regular e-mail user, you might prefer us to send messages in this way. Simply send us your e-mail address as soon as possible to:

skerry@sghms.ac.uk

Any Questions.....?

In view of the likely questions that patients may ask you with regard to the questionnaire, we have devised a short coloured leaflet which we send to all patients when we have received their consent form. This answers some of their "most asked questions" and reminds them to send their questionnaires back. In particular, it also explains that if they have difficulty filling out all of the questionnaire they should simply fill in as much as they are able to. We enclose a copy for your interest.

Who's who in the Team.

Sally Kerry: Project Manager and Principal investigator.

Tel: 0181 725 2785 (Tue, Wed, Fri)

Kofi Anie: Researcher Practice recruitment and patient follow-up

Tel: 0181 725 2773 (Tues, Thurs, Fri)

Rebecca Walker: Researcher Patient recruitment & liaison with practices. "Jog" phone calls.

Tel: 0181 725 5664 (Mon, Tues, Wed)

If you have any queries, please do not hesitate to contact a member of the research team who will be happy to help.

The project also has a steering group:

Prof Sean Hilton: Head of Dept of General Practice.

Dr Derek Dundas: Consultant Radiologist

Dr Sangeeta Patel: GP lecturer

Latest Research.

The NHS R&D Health and Technology Assessment Programme who fund our project here at St George's, are also responsible for funding two other randomised trials for low back pain.

G.Ps in the Nottinghamshire area are being invited to take part in a randomised trial of lumbar spine x-rays for patients who have had low back pain for more than 6 weeks. Patients are being identified from the practice computers using READ codes and then invited to take part in the trial. This study is approximately half way through patient recruitment and will finish recruiting in Dec 98.

In the Newcastle area a trial is just beginning of lumbar spine x-rays for patients who are employed and are being given a certificate for absence from work.

We are in regular contact with these other projects and hope that, at a later stage, further collaboration may be possible.

68. I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all	[ ]
Occasionally	[ ]
Quite often	[ ]
Very often	[ ]

69. I have lost interest in my appearance:

Definitely	[ ]
I don't take so much care as I should	[ ]
I may not take quite as much care	[ ]
I take just as much care as ever	[ ]

70. I feel quite restless as if I have to be on the move:

Very much indeed	[ ]
Quite a lot	[ ]
Not very much	[ ]
Not at all	[ ]

71. I look forward with enjoyment to things:

As much as ever I did	[ ]
Rather less than I used to	[ ]
Definitely less than I used to	[ ]
Hardly at all	[ ]

72. I get sudden feelings of panic:

Very often indeed	[ ]
Quite often	[ ]
Not very often	[ ]
Not at all	[ ]

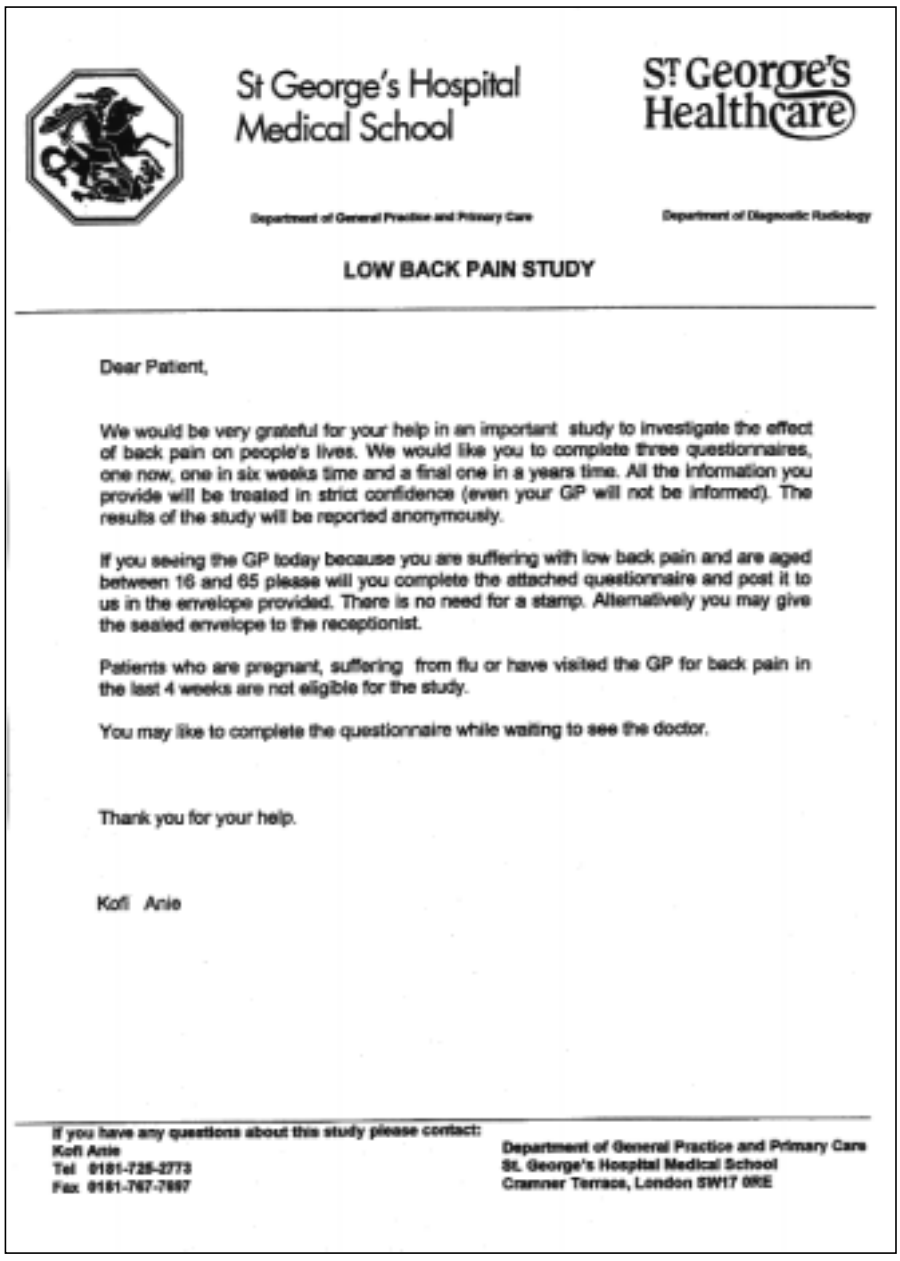
73. I can enjoy a good book or radio or TV programme:

Often	[ ]
Sometimes	[ ]
Not often	[ ]
Very seldom	[ ]

NOW PLEASE CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS AND SEND THE QUESTIONNAIRE BACK TO US IN THE PREPAID ENVELOPE PROVIDED

Appendix 3

Patient invitation letter, consent form and initial questionnaire for observational study



St George's Hospital Medical School

St George's Healthcare

Department of General Practice and Primary Care

Department of Diagnostic Radiology

LOW BACK PAIN STUDY

Dear Patient,

We would be very grateful for your help in an important study to investigate the effect of back pain on people's lives. We would like you to complete three questionnaires, one now, one in six weeks time and a final one in a years time. All the information you provide will be treated in strict confidence (even your GP will not be informed). The results of the study will be reported anonymously.

If you seeing the GP today because you are suffering with low back pain and are aged between 16 and 65 please will you complete the attached questionnaire and post it to us in the envelope provided. There is no need for a stamp. Alternatively you may give the sealed envelope to the receptionist.

Patients who are pregnant, suffering from flu or have visited the GP for back pain in the last 4 weeks are not eligible for the study.

You may like to complete the questionnaire while waiting to see the doctor.

Thank you for your help.

Kofi Anie

If you have any questions about this study please contact:
Kofi Anie
Tel 0181-725-2773
Fax 0181-767-7897

Department of General Practice and Primary Care
St. George's Hospital Medical School
Cranmer Terrace, London SW17 0RE

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St George's Hospital Medical School

Department of General Practice and Primary Care

St George's Healthcare

Department of Diagnostic Radiology

Low Back Pain Study

Consent Form

Please indicate whether you agree to be contacted by the research workers in connection with the Low Back Pain Study.

Please delete

I agree to be contacted by the research worker

I do not wish to be contacted

Name..... Signed.....

Address.....

.....

Telephone Number.....
(Day time preferable)

Date.....

General Practitioner.....

St George's Hospital Medical School

Department of General Practice and Primary Care

St George's Healthcare

Department of Diagnostic Radiology

LOW BACK PAIN STUDY

Initial Questionnaire

Some of the questions are very similar. Please be patient and answer all the questions by ticking the most appropriate box.

First, we would like to ask you some questions about yourself.

1. Name:.....Patient No:.....

   Address:.....

   .....Tel No.:.....

2. Age:..... Date:.....

3. Sex:.....

Is the pain in your back at or below your waist? a. Yes [ ] b. No [ ]

Are you pregnant? a. Yes [ ] b. No [ ]

Are you suffering from 'flu or other feverish illness at the moment? a. Yes [ ] b. No [ ]

Have you visited your GP about your back in the last 4 weeks? a. Yes [ ] b. No [ ]

4. Are you? *(Please tick one)*

a. Employed	[ ]
b. Self Employed	[ ]
c. Unemployed	[ ]
d. Retired	[ ]
e. Student	[ ]
f. Looking after the house	[ ]

If you have any questions about this study please contact:
Kofi Anie
Tel 0181-725-2773
Fax 0181-767-7697

Department of General Practice and Primary Care
St. George's Hospital Medical School
Cranmer Terrace, London SW17 0RE

5. If you are employed, are you working? a. Full-Time [ ] b. Part-Time [ ]

6. What is your Occupation?.....
(Please give last occupation if not working at the moment)

7. If you are in paid employment, are you off at the moment because of your back? a. Yes [ ] b. No [ ]

8. How many days have you been off work in the last month, because of your back?.....

We would also like to ask you about the problem with your back.

9. How long have you had the present back pain episode?.....

10. Have you had similar back pain in the past? a. Yes [ ] b. No [ ]

11. If yes, how many times?.....

12. How long did the worst back pain episode last?.....

13. Did your GP refer you to hospital for an X-ray today? a. Yes [ ] b. No [ ]

14. If yes, which hospital?.....

15. Have you ever had an X-ray of your back before today? a. Yes [ ] b. No [ ]

When your back hurts, you may find it difficult to do some of the things you normally do.

*This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **today**. As you read the list, think of yourself **today**.*

When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one.

*Remember, only tick the sentence if you are sure that it describes you **today**.*

16. I stay at home most of the time because of my back. [ ]

17. I change position frequently to try and get my back comfortable. [ ]

18. I walk more slowly than usual because of my back. [ ]

19. Because of my back I am not doing any of the jobs that I usually do around the house. [ ]

20. Because of my back, I use a handrail to get upstairs. [ ]

21. Because of my back, I lie down to rest more often. [ ]

22. Because of my back, I hold on to something to get out of an easy chair. [ ]

23. Because of my back, I try to get other people to do things for me. [ ]

24. I get dressed more slowly than usual because of my back. [ ]

25. I only stand up for short periods of time because of my back. [ ]

26. Because of my back, I try not to bend or kneel down. [ ]

27. I find it difficult to get out of a chair because of my back. [ ]

28. My back is painful almost all the time. [ ]

29. I find it difficult to turn over in bed because of my back. [ ]

30. My appetite is not very good because of my back pain. [ ]

31. I have trouble putting on my socks (or stockings) because of the pain in my back. [ ]

32. I only walk short distances because of my back pain. [ ]

33. I sleep less well because of my back. [ ]

34. Because of my back pain, I get dressed with help from someone else. [ ]

35. I sit down for most of the day because of my back. [ ]

36. I avoid heavy jobs around the house because of my back. [ ]

37. Because of my back pain, I am more irritable and bad tempered with people than usual. [ ]

38. Because of my back, I go upstairs more slowly than usual. [ ]

39. I stay in bed most of the time because of my back. [ ]

Now we want you to give us an idea of just how bad your back pain is at the moment.

40. Here is a thermometer with various grades of pain from "no pain at all" at the bottom to "the pain is almost unbearable" at the top. We want you to put a cross by the words that describe your pain best. Remember, we want to know how bad your pain is ***at the moment****.*

We would like to know the reason for visiting the GP today.

41. When you attended the surgery today, which of the following did you expect from your GP? *(Please tick any that apply).*

a. Prescription	[ ]
b. Advice	[ ]
c. Referral for X-ray	[ ]
d. Certificate off work	[ ]
e. Referral to Specialist (eg. Consultant, Physiotherapist)	[ ]

42. How satisfied were you with your GP's approach? *(Please tick one).*

a. Very Satisfied	[ ]
b. Satisfied	[ ]
c. Indifferent	[ ]
d. Dissatisfied	[ ]
e. Very Dissatisfied	[ ]

We would like to ask you about your health in general and 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.

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

Excellent	[ ]
Very good	[ ]
Good	[ ]
Fair	[ ]
Poor	[ ]

44. Compared to one year ago, how would you rate your health in general now?:

Much better now than one year ago	[ ]
Somewhat better now than one year ago	[ ]
About the same	[ ]
Somewhat worse now than one year ago	[ ]
Much worse now than one year ago	[ ]

45. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much? *(Please tick one box on each line).*

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	[ ]	[ ]	[ ]
Moderate activities, such as moving a table, pushing 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	[ ]	[ ]	[ ]
Walking half a mile	[ ]	[ ]	[ ]
Walking 100 yards	[ ]	[ ]	[ ]
Bathing and dressing yourself	[ ]	[ ]	[ ]

46. 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.

	Yes	No
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 (eg. it took extra effort)	[ ]	[ ]

47. 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)?

	Yes	No
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	[ ]	[ ]

48. 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?

Not at all	[ ]
Slightly	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

49. How much bodily pain have you had during the past 4 weeks?

None	[ ]
Very mild	[ ]
Mild	[ ]
Moderate	[ ]
Severe	[ ]
Very Severe	[ ]

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

Not at all	[ ]
A little bit	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

*These questions are about how you feel and how things have been with you during **the past 4 weeks**. (For each question please indicate the one answer that comes the closest to the way you have been feeling).*

51. How much time during the past 4 weeks: *(Please tick one box on each line)*

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
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?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

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

All of the time	[ ]
Most of the time	[ ]
Some of the time	[ ]
A little of the time	[ ]
None of the time	[ ]

53. How true or false is each of the following statements for you? *(Please tick one box on each line)*

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
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	[ ]	[ ]	[ ]	[ ]	[ ]

By placing a tick in one box in each group below, please indicate which statements best describe your own health state <u>today</u>.

54. Mobility

I have no problems in walking about	[ ]
I have some problems in walking about	[ ]
I am confined to bed	[ ]

55. Self-Care

I have no problems with self-care	[ ]
I have some problems washing or dressing myself	[ ]
I am unable to wash or dress myself	[ ]

56. Usual Activities

I have no problems with performing my usual activities (eg. work, study, housework, family or leisure activities)	[ ]
I have some problems with performing my usual activities	[ ]
I am unable to perform my usual activities	[ ]

57. Pain / Discomfort

I have no pain or discomfort	[ ]
I have moderate pain or discomfort	[ ]
I have extreme pain or discomfort	[ ]

58. Anxiety / Depression

I am not anxious or depressed	[ ]
I am moderately anxious or depressed	[ ]
I am extremely anxious or depressed	[ ]

59.

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 you can imagine is marked by 0.

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

Your own health state today

*We would like to ask you about how you are feeling. Read each item and tick the reply which comes closest to how you have been feeling in **the past week**. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.*

60. I feel tense or 'wound up':
- Most of the time [ ]
- A lot of the time [ ]
- From time to time [ ]
- Not at all [ ]

61. I still enjoy the things I used to enjoy:
- Definitely as much [ ]
- Not quite so much [ ]
- Only a little [ ]
- Hardly at all [ ]

62. I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly [ ]
- Yes, but not too badly [ ]
- A little, but it does not worry me [ ]
- Not at all [ ]

63. I can laugh and see the funny side of things:
- As much as I always could [ ]
- Not quite so much now [ ]
- Definitely not so much now [ ]
- Not at all [ ]

64. Worrying thoughts go through my mind:
- A great deal of the time [ ]
- A lot of the time [ ]
- From time to time, but not too often [ ]
- Only occasionally [ ]

65. I feel cheerful:
- Not at all [ ]
- Not often [ ]
- Sometimes [ ]
- Most of the time [ ]

66. I can sit at ease and feel relaxed:
- Definitely [ ]
- Usually [ ]
- Not often [ ]
- Not at all [ ]

67. I feel as if I am slowed down:
- Nearly all the time [ ]
- Very often [ ]
- Sometimes [ ]
- Not at all [ ]

68. I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all [ ]
- Occasionally [ ]
- Quite often [ ]
- Very often [ ]

69. I have lost interest in my appearance:
- Definitely [ ]
- I don't take so much care as I should [ ]
- I may not take quite as much care [ ]
- I take just as much care as ever [ ]

70. I feel quite restless as if I have to be on the move:
- Very much indeed [ ]
- Quite a lot [ ]
- Not very much [ ]
- Not at all [ ]

71. I look forward with enjoyment to things:
- As much as ever I did [ ]
- Rather less than I used to [ ]
- Definitely less than I used to [ ]
- Hardly at all [ ]

72. I get sudden feelings of panic:
- Very often indeed [ ]
- Quite often [ ]
- Not very often [ ]
- Not at all [ ]

73. I can enjoy a good book or radio or TV programme:
- Often [ ]
- Sometimes [ ]
- Not often [ ]
- Very seldom [ ]

NOW PLEASE CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS AND SEND THE QUESTIONNAIRE BACK TO US IN THE PREPAID ENVELOPE PROVIDED

Appendix 4

Patient information leaflet

The Low Back Pain Study

Information for patients

This leaflet answers some of the questions that patients commonly ask about the study

This appendix has been reproduced by scanning in copies of the original, which were printed on coloured paper, and therefore the quality may not be excellent. If you need to see the originals, please contact the authors.

Thank you very much for taking part in this study.

Please complete and send back your questionnaire as soon as possible if you have not already done so.

Thank you

The research team

Sally Kerry
Project Manager
(0181) 725 2722

Kafi Anie
(0181) 725 2773

Rebecca Walker
(0181) 725 5664

Please ring us if you have any problems concerning the questionnaires, or with any other aspect of the study.

The Dept. of General Practice & Primary Care
St. George's Hospital Medical School
Cranmer Terrace
Tooting
SW17 0RE

The Low Back Pain Study

Information for patients

This leaflet answers some of the questions that patients commonly ask about the study

"What do I have to do?"

Your GP has given you a questionnaire to fill in and send back to us. Please do this as soon as you can.

We will send you two more questionnaires, one in 6 weeks time and another in a year's time. Please fill these in as soon as you get them and send them back to us in the FREEPOST envelope provided.

There is no need for you to visit St. George's Hospital or the Medical School.

"I can't answer all the questions."

The form will be useful even if you cannot complete all the questions.

"I don't feel the questions quite fit my circumstances."

Answer the questions as best you can. If you would like to give further information please add it to the questionnaire.

"Why so many questions?"

Because everyone is different and back pain affects people in lots of different ways. We are interested in how back pain restricts your everyday activities and how this affects the way you feel and your quality of life.

"What about confidentiality?"

The reason we need your name and address is so we can post new questionnaires to you. We assure you that all information will be treated with the strictest of confidence.

"Why are you doing the research?"

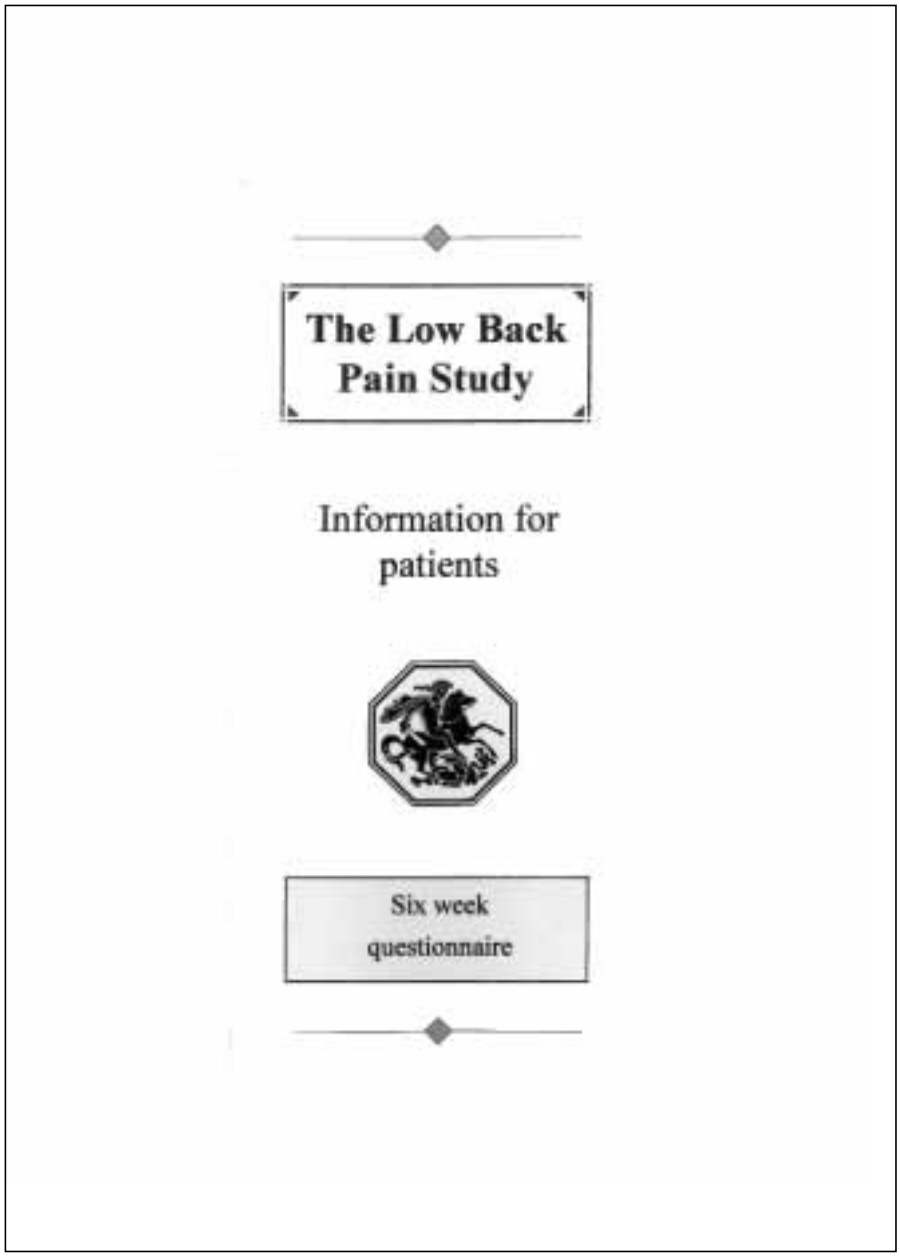
Although back pain is very common we do not always know the best way to treat it or what tests are necessary. This study will show us how doctors are treating back pain and which patients will benefit from further investigations.

"What happens to the results?"

The results of this study will be published in medical journals read by doctors and other people interested in back pain. We hope this will benefit people like yourself by improving doctors' understanding and treatment of back pain.

Appendix 5

6-week patient information leaflet



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Thank you very much for taking part in this study.

Please help us by returning your yellow form as soon as possible.

The research team

Sally Kerry
Project Manager
(0181) 725 2722

Kofi Anie
(0181) 725 2773

Rebecca Walker
(0181) 725 5664

Please ring us if you have any problems concerning the questionnaires, or with any other aspect of the study.

The Dept. of General Practice & Primary Care
St. George's Hospital Medical School
Cranmer Terrace
Tooting
SW17 0RE

The Low Back Pain Study

Information for patients

Six week questionnaire

Thank you for taking part in this study and completing your green questionnaire.

We are now sending you another questionnaire to see how your back pain has changed. Please fill in this yellow questionnaire and send it back to us as soon as possible.

It is important to our research that we find out what happens to people after they first visit their GP with back pain. This is why we are sending out this questionnaire. In about 10 months time you will recieve another final questionnaire which will be pink.

"Who can I ask about the study."

Please ring us if you have any questions about the study or filling in the questionnaire questionnaires. We are available on the following days during office hours.

Sally Kerry 0181-725-2785
Tuesday,Wednesday am, Friday

Rebecca Walker 0181-725-5664
Monday,Tuesday,Wednesday am

Kofi Anie 0181-725-2773
Tuesday,Thursday,Friday

"I've answered these questions before."

Some of the questions are the same or similar to the ones on the green questionnaire you answered before. This is because we are interested in how your answers have changed in the six weeks since you filled in your first questionnaire.

"I went to see someone else about my back pain."

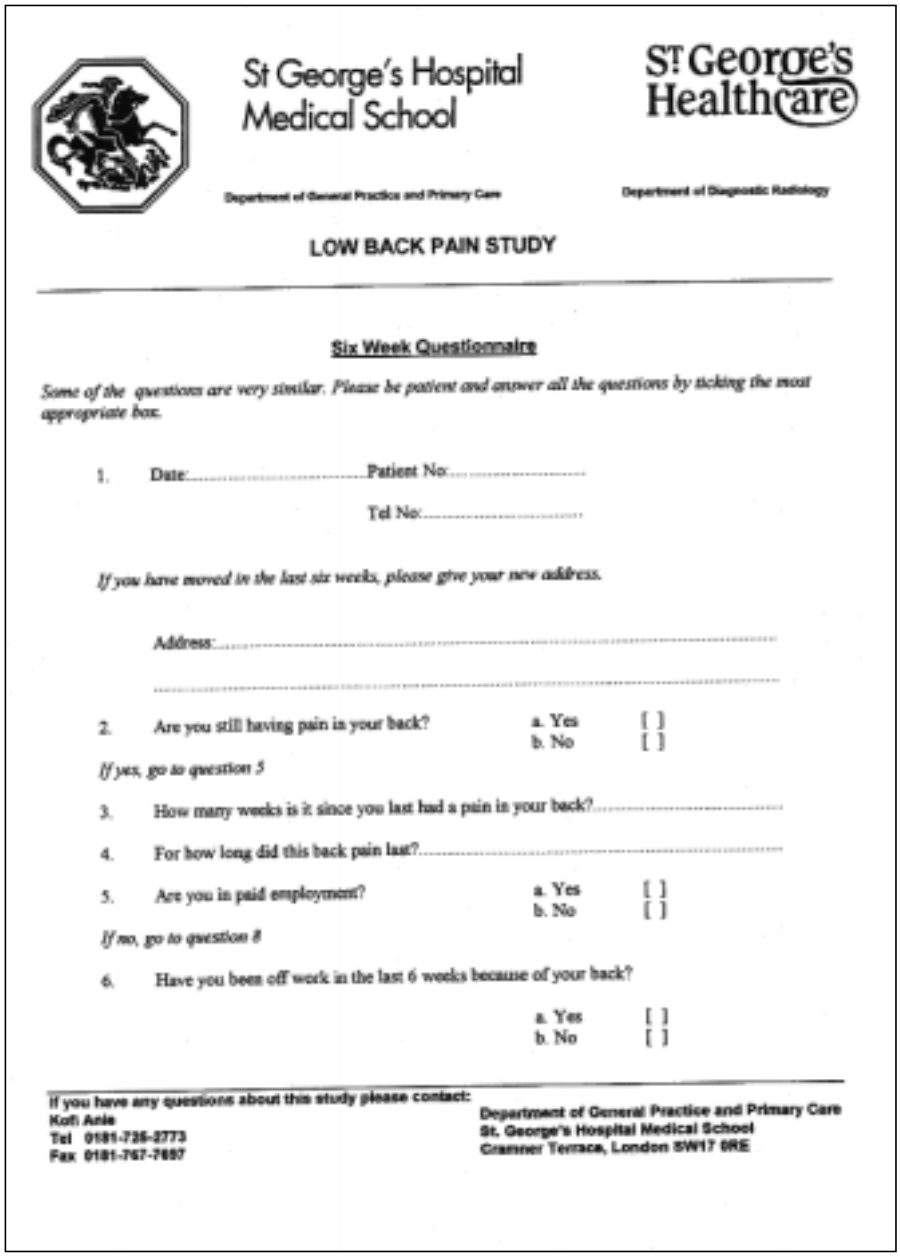
Many people consult health professionals other than their GP for back pain. We are interested in all kinds of treatment for back pain, for example physiotherapy, chiropractice or osteopathy whether this was arranged by your GP or not. Your replies are completely confidential and will not be

"I can't answer all the questions."

The form will still be useful even if you cannot complete all the questions

Appendix 6

Follow-up questionnaires at 6 weeks and 1 year for all patients



St George's Hospital Medical School

Department of General Practice and Primary Care

St George's Healthcare

Department of Diagnostic Radiology

LOW BACK PAIN STUDY

Six Week Questionnaire

Some of the questions are very similar. Please be patient and answer all the questions by ticking the most appropriate box.

1. Date:.....Patient No:.....

   Tel No:.....

If you have moved in the last six weeks, please give your new address.

Address:.....

.....

2. Are you still having pain in your back? a. Yes [ ] b. No [ ]

If yes, go to question 5

3. How many weeks is it since you last had a pain in your back?.....

4. For how long did this back pain last?.....

5. Are you in paid employment? a. Yes [ ] b. No [ ]

If no, go to question 8

6. Have you been off work in the last 6 weeks because of your back? a. Yes [ ] b. No [ ]

If you have any questions about this study please contact:
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7. How many days have you been off work in the last six weeks, because of your back?.....

8. How satisfied were you with your GP's management of your back pain? *(Please tick one).*

a. Very Satisfied [ ]
b. Satisfied [ ]
c. Indifferent [ ]
d. Dissatisfied [ ]
e. Very Dissatisfied [ ]

If you are not satisfied, please give reasons:

9. .....

.....

.....

.....

10. Have you been referred by your GP to any other health professionals in the last 2 months? *(Please give number of visits).*

		Were these consultations? *(Please tick)*	
	Number of Visits	NHS	Private
a. Physiotherapist			
b. Osteopath			
c. Chiropractor			
d. Hospital Consultant			
e. Other (Please specify)			

11. Have you consulted any other health professionals in the last 2 months? *(Please give number of visits).*

		Were these consultations? *(Please tick)*	
	Number of Visits	NHS	Private
a. Physiotherapist			
b. Osteopath			
c. Chiropractor			
d. Hospital Consultant			
e. Other (Please specify)			

12. Did these visits involve you taking time off work? a. Yes [ ] b. No [ ]

13. If yes, how much time have you taken off work for these visits?.....

14. Did anyone else have to take time off work to accompany you on these visits? a. Yes [ ] b. No [ ]

15. If yes, how much time have they taken off work to accompany you?.....

16. Has your GP referred you for an X-ray in the last 2 months? a. Yes [ ] b. No [ ]

17. If yes, which hospital?.....

18. Did you have to take time off work for the X-ray? a. Yes [ ] b. No [ ]

19. If yes, how many hours?.....

20. Did anyone else have to take time off work to accompany you for the X-ray? a. Yes [ ] b. No [ ]

21. If yes, how many hours have they taken off work to accompany you?.....

When your back hurts, you may find it difficult to do some of the things you normally do.

*This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **today**. As you read the list, think of yourself **today**.*

*When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure that it describes you **today***

22. I stay at home most of the time because of my back. [ ]
23. I change position frequently to try and get my back comfortable. [ ]
24. I walk more slowly than usual because of my back. [ ]
25. Because of my back I am not doing any of the jobs that I usually do around the house. [ ]
26. Because of my back, I use a handrail to get upstairs. [ ]
27. Because of my back, I lie down to rest more often. [ ]
28. Because of my back, I hold on to something to get out of an easy chair. [ ]
29. Because of my back, I try to get other people to do things for me. [ ]
30. I get dressed more slowly than usual because of my back. [ ]
31. I only stand up for short periods of time because of my back. [ ]
32. Because of my back, I try not to bend or kneel down. [ ]
33. I find it difficult to get out of a chair because of my back. [ ]
34. My back is painful almost all the time. [ ]
35. I find it difficult to turn over in bed because of my back. [ ]
36. My appetite is not very good because of my back pain. [ ]
37. I have trouble putting on my socks (or stockings) because of the pain in my back. [ ]
38. I only walk short distances because of my back pain. [ ]
39. I sleep less well because of my back. [ ]
40. Because of my back pain, I get dressed with help from someone else. [ ]
41. I sit down for most of the day because of my back. [ ]
42. I avoid heavy jobs around the house because of my back. [ ]
43. Because of my back pain, I am more irritable and bad tempered with people than usual. [ ]
44. Because of my back, I go upstairs more slowly than usual. [ ]
45. I stay in bed most of the time because of my back. [ ]

Now we want you to give us an idea of just how bad your back pain is at the moment.

46. *Here is a thermometer with various grades of pain from "no pain at all" at the bottom to "the pain is almost unbearable" at the top. We want you to put a cross by the words that describe your pain best. Remember, we want to know how bad your pain is **at the moment***

We would like to ask you about your health in general and 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.

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

Excellent	[ ]
Very good	[ ]
Good	[ ]
Fair	[ ]
Poor	[ ]

48. Compared to one year ago, how would you rate your health in general now?:

Much better now than one year ago	[ ]
Somewhat better now than one year ago	[ ]
About the same	[ ]
Somewhat worse now than one year ago	[ ]
Much worse now than one year ago	[ ]

49. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much? *(Please tick one box on each line).*

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	[ ]	[ ]	[ ]
Moderate activities, such as moving a table, pushing 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	[ ]	[ ]	[ ]
Walking half a mile	[ ]	[ ]	[ ]
Walking 100 yards	[ ]	[ ]	[ ]
Bathing and dressing yourself	[ ]	[ ]	[ ]

50. 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.

	Yes	No
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 (eg. it took extra effort)	[ ]	[ ]

51. 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)?

	Yes	No
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	[ ]	[ ]

52. 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?

Not at all	[ ]
Slightly	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

53. How much bodily pain have you had during the past 4 weeks?

None	[ ]
Very mild	[ ]
Mild	[ ]
Moderate	[ ]
Severe	[ ]
Very Severe	[ ]

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

Not at all	[ ]
A little bit	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

*These questions are about how you feel and how things have been with you during **the past 4 weeks**. (For each question please indicate the one answer that comes the closest to the way you have been feeling).*

55. How much time during the past 4 weeks: *(Please tick one box on each line)*

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
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?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

56. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives etc.)?

All of the time	[ ]
Most of the time	[ ]
Some of the time	[ ]
A little of the time	[ ]
None of the time	[ ]

57. How <u>true</u> or <u>false</u> is each of the following statements for you? *(Please tick one box on each line)*

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
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	[ ]	[ ]	[ ]	[ ]	[ ]

By placing a tick in one box in each group below, please indicate which statements best describe your own health state <u>today</u>.

58. Mobility

I have no problems in walking about	[ ]
I have some problems in walking about	[ ]
I am confined to bed	[ ]

59. Self-Care

I have no problems with self-care	[ ]
I have some problems washing or dressing myself	[ ]
I am unable to wash or dress myself	[ ]

60. Usual Activities

I have no problems with performing my usual activities (eg. work, study, housework, family or leisure activities)	[ ]
I have some problems with performing my usual activities	[ ]
I am unable to perform my usual activities	[ ]

61. Pain / Discomfort

I have no pain or discomfort	[ ]
I have moderate pain or discomfort	[ ]
I have extreme pain or discomfort	[ ]

62. Anxiety / Depression

I am not anxious or depressed	[ ]
I am moderately anxious or depressed	[ ]
I am extremely anxious or depressed	[ ]

63.

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 you can imagine is marked by 0.

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

Your own health state today

*We would like to ask you about how you are feeling. Read each item and tick the reply which comes closest to how you have been feeling in **the past week**. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.*

64. I feel tense or 'wound up':
- Most of the time [ ]
- A lot of the time [ ]
- From time to time [ ]
- Not at all [ ]

65. I still enjoy the things I used to enjoy:
- Definitely as much [ ]
- Not quite so much [ ]
- Only a little [ ]
- Hardly at all [ ]

66. I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly [ ]
- Yes, but not too badly [ ]
- A little, but it does not worry me [ ]
- Not at all [ ]

67. I can laugh and see the funny side of things:
- As much as I always could [ ]
- Not quite so much now [ ]
- Definitely not so much now [ ]
- Not at all [ ]

68. Worrying thoughts go through my mind:
- A great deal of the time [ ]
- A lot of the time [ ]
- From time to time, but not too often [ ]
- Only occasionally [ ]

69. I feel cheerful:
- Not at all [ ]
- Not often [ ]
- Sometimes [ ]
- Most of the time [ ]

70. I can sit at ease and feel relaxed:
- Definitely [ ]
- Usually [ ]
- Not often [ ]
- Not at all [ ]

71. I feel as if I am slowed down:
- Nearly all the time [ ]
- Very often [ ]
- Sometimes [ ]
- Not at all [ ]

72. I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all [ ]
- Occasionally [ ]
- Quite often [ ]
- Very often [ ]

73. I have lost interest in my appearance:
- Definitely [ ]
- I don't take so much care as I should [ ]
- I may not take quite as much care [ ]
- I take just as much care as ever [ ]

74. I feel quite restless as if I have to be on the move:
- Very much indeed [ ]
- Quite a lot [ ]
- Not very much [ ]
- Not at all [ ]

75. I look forward with enjoyment to things:
- As much as ever I did [ ]
- Rather less than I used to [ ]
- Definitely less than I used to [ ]
- Hardly at all [ ]

76. I get sudden feelings of panic:
- Very often indeed [ ]
- Quite often [ ]
- Not very often [ ]
- Not at all [ ]

77. I can enjoy a good book or radio or TV programme:
- Often [ ]
- Sometimes [ ]
- Not often [ ]
- Very seldom [ ]

NOW PLEASE CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS AND SEND THE QUESTIONNAIRE BACK TO US IN THE PREPAID ENVELOPE PROVIDED

St. George's Hospital Medical School

Department of General Practice and Primary Care

St George's Healthcare

Department of Diagnostic Radiology

LOW BACK PAIN STUDY

One year Questionnaire

Some of the questions are very similar. Please be patient and answer all the questions by ticking the most appropriate box.

1. Date:..... Patient No:.....

2. Are you still having pain in your back? a. Yes [ ] b. No [ ]

3. If no, how long is it since you last had a pain in your back?.....

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you today. As you read the list, think of yourself today.
When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure that it describes you today.

4. I stay at home most of the time because of my back. [ ]
5. I change position frequently to try and get my back comfortable. [ ]
6. I walk more slowly than usual because of my back. [ ]
7. Because of my back I am not doing any of the jobs that I usually do around the house. [ ]
8. Because of my back I use a handrail to get upstairs. [ ]
9. Because of my back I lie down to rest more often. [ ]
10. Because of my back I hold on to something to get out of an easy chair. [ ]
11. Because of my back I try to get other people to do things for me. [ ]
12. I get dressed more slowly than usual because of my back. [ ]

If you have any questions about this study please contact:
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13. I only stand up for short periods of time because of my back. [ ]
14. Because of my back I try not to bend or kneel down. [ ]
15. I find it difficult to get out of a chair because of my back. [ ]
16. My back is painful almost all the time. [ ]
17. I find it difficult to turn over in bed because of my back. [ ]
18. My appetite is not very good because of my back pain. [ ]
19. I have trouble putting on my socks (or stockings) because of the pain in my back. [ ]
20. I only walk short distances because of my back pain. [ ]
21. I sleep less well because of my back. [ ]
22. Because of my back pain I get dressed with help from someone else. [ ]
23. I sit down for most of the day because of my back. [ ]
24. I avoid heavy jobs around the house because of my back. [ ]
25. Because of my back pain I am more irritable and bad tempered with people than usual. [ ]
26. Because of my back I go upstairs more slowly than usual. [ ]
27. I stay in bed most of the time because of my back. [ ]

28. *Here is a thermometer with various grades of pain from "no pain at all" at the bottom to "the pain is almost unbearable" at the top. We want you to put a cross by the words that describe your pain best. Remember, we want to know how bad your pain is at the moment.*

29. Are you in paid employment? a. Yes [ ] b. No [ ]

If no, please go to question 32

30. Have you been off work in the last year **because of your back**? a. Yes [ ] b. No [ ]

31. How much time have you been off work in the last year **because of your back**?.....

32. Has your GP referred you for an X-ray in the last year? a. Yes [ ] b. No [ ]

33. If yes, which hospital?.....

34. Did you have to take time off work for the X-ray? a. Yes [ ] b. No [ ]

35. If yes, how many hours?.....

36. Did anyone else have to take time off work to accompany you for the X-ray? a. Yes [ ] b. No [ ]

37. If yes, how many hours have they taken off work to accompany you?.....

38. Have you been referred by your GP to any other health professionals in the last year? *(Please give number of visits).*

			Were these consultations on the NHS or private? *(Please tick)*	
	Number of Visits	Please tick if waiting for first appointment	NHS	Private
a. Physiotherapist				
b. Osteopath				
c. Chiropractor				
d. Hospital Consultant				
e. Other (Please specify)				

39. Have you consulted any **other** health professionals in the last 12 months? *(Please give number of visits).*

		Were these consultations on the NHS or private? *(Please tick)*	
	Number of Visits	NHS	Private
a. Physiotherapist			
b. Osteopath			
c. Chiropractor			
d. Hospital Consultant			
e. Other (Please specify)			

40. Did these visits involve you taking time off work? a. Yes [ ] b. No [ ]

41. If yes, how much time have you taken off work for these visits?.....

42. Did anyone else have to take time off work to accompany you on these visits? a. Yes [ ] b. No [ ]

43. If yes, how much time have they taken off work to accompany you?.....

We would like to ask you about your health in general and 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.

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

Excellent [ ]
Very good [ ]
Good [ ]
Fair [ ]
Poor [ ]

45. Compared to one year ago how would you rate your health in general now?:

Much better now than one year ago [ ]
Somewhat better now than one year ago [ ]
About the same [ ]
Somewhat worse now than one year ago [ ]
Much worse now than one year ago [ ]

46. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much? *(Please tick one box on each line)*

	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities such as running, lifting heavy objects, participating in strenuous sports	[ ]	[ ]	[ ]
Moderate activities such as moving a table, pushing 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	[ ]	[ ]	[ ]
Walking half a mile	[ ]	[ ]	[ ]
Walking 100 yards	[ ]	[ ]	[ ]
Bathing and dressing yourself	[ ]	[ ]	[ ]

47. 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

	Yes	No
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 (eg. it took extra effort)	[ ]	[ ]

48. 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)?

	Yes	No
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	[ ]	[ ]

49. 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?

Not at all	[ ]
Slightly	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

50. How much bodily pain have you had during the past 4 weeks?

None	[ ]
Very mild	[ ]
Mild	[ ]
Moderate	[ ]
Severe	[ ]
Very Severe	[ ]

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

Not at all	[ ]
A little bit	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

*These questions are about how you feel and how things have been with you during **the past 4 weeks**. (For each question please indicate the one answer that comes the closest to the way you have been feeling).*

52. How much time during the past 4 weeks *(Please tick one box on each line)*

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
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?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

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

All of the time	[ ]
Most of the time	[ ]
Some of the time	[ ]
A little of the time	[ ]
None of the time	[ ]

54. How true or false is each of the following statements for you? *(Please tick one box on each line)*

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
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	[ ]	[ ]	[ ]	[ ]	[ ]

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

55. Mobility

I have no problems in walking about	[ ]
I have some problems in walking about	[ ]
I am confined to bed	[ ]

56. Self-Care

I have no problems with self-care	[ ]
I have some problems washing or dressing myself	[ ]
I am unable to wash or dress myself	[ ]

57. Usual Activities

I have no problems with performing my usual activities (eg. work, study, housework, family or leisure activities)	[ ]
I have some problems with performing my usual activities	[ ]
I am unable to perform my usual activities	[ ]

58. Pain / Discomfort

I have no pain or discomfort	[ ]
I have moderate pain or discomfort	[ ]
I have extreme pain or discomfort	[ ]

59. Anxiety / Depression

I am not anxious or depressed	[ ]
I am moderately anxious or depressed	[ ]
I am extremely anxious or depressed	[ ]

60.

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 you can imagine is marked by 0.

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

Your own health state today

We would like to ask you about how you are feeling. Read each item and tick the reply which comes closest to how you have been feeling in the past week. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response.

61. I feel tense or 'wound up':
- Most of the time [ ]
- A lot of the time [ ]
- From time to time [ ]
- Not at all [ ]

62. I still enjoy the things I used to enjoy:
- Definitely as much [ ]
- Not quite so much [ ]
- Only a little [ ]
- Hardly at all [ ]

63. I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely and quite badly [ ]
- Yes, but not too badly [ ]
- A little, but it does not worry me [ ]
- Not at all [ ]

64. I can laugh and see the funny side of things:
- As much as I always could [ ]
- Not quite so much now [ ]
- Definitely not so much now [ ]
- Not at all [ ]

65. Worrying thoughts go through my mind:
- A great deal of the time [ ]
- A lot of the time [ ]
- From time to time, but not too often [ ]
- Only occasionally [ ]

66. I feel cheerful:
- Not at all [ ]
- Not often [ ]
- Sometimes [ ]
- Most of the time [ ]

67. I can sit at ease and feel relaxed:
- Definitely [ ]
- Usually [ ]
- Not often [ ]
- Not at all [ ]

68. I feel as if I am slowed down:
- Nearly all the time [ ]
- Very often [ ]
- Sometimes [ ]
- Not at all [ ]

69. I get a sort of frightened feeling like 'butterflies' in the stomach:
- Not at all [ ]
- Occasionally [ ]
- Quite often [ ]
- Very often [ ]

70. I have lost interest in my appearance:
- Definitely [ ]
- I don't take so much care as I should [ ]
- I may not take quite as much care [ ]
- I take just as much care as ever [ ]

71. I feel quite restless as if I have to be on the move:
- Very much indeed [ ]
- Quite a lot [ ]
- Not very much [ ]
- Not at all [ ]

72. I look forward with enjoyment to things:
- As much as ever I did [ ]
- Rather less than I used to [ ]
- Definitely less than I used to [ ]
- Hardly at all [ ]

73. I get sudden feelings of panic:
- Very often indeed [ ]
- Quite often [ ]
- Not very often [ ]
- Not at all [ ]

74. I can enjoy a good book or radio or TV programme:
- Often [ ]
- Sometimes [ ]
- Not often [ ]
- Very seldom [ ]

NOW PLEASE CHECK THAT YOU HAVE ANSWERED ALL THE QUESTIONS AND SEND THE QUESTIONNAIRE BACK TO US IN THE PREPAID ENVELOPE PROVIDED. Thank you.

Appendix 7

Information collected from practices

PRACTICE INFORMATION

During the period of the back pain study
did your practice have an on site physiotherapy service,/alternative therapy service/Consultant Specialist service?

YES NO

If yes, please state which service or services are available.

Which hospital do you normally refer your patients to for routine spinal x-rays? If more than one hospital is used on a regular basis please state both.

Approximate travel times in minutes to and from the most convenient hospital.

By car

0-10 ☐	10-20 ☐	20-30 ☐	30+ ☐	DK ☐

On foot

0-10 ☐	10-20 ☐	20-30 ☐	30+ ☐	DK ☐

By bus

0-30 ☐	30+ ☐	DK ☐

Is your practice in receipt of deprivation payments?

YES ☐ NO ☐

Is your practice fundholding?

YES NO

If yes, please give date.

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GP INFORMATION

PRACTICE CODE	GP NAME	
QUALIFICATION		YEAR OF QUALIFICATION
SEX	MALE ☐	FEMALE ☐
TRAINER	YES ☐	NO ☐
	FULL TIME ☐	PART TIME ☐

GP INFORMATION

PRACTICE CODE	GP NAME	
QUALIFICATION		YEAR OF QUALIFICATION
SEX	MALE ☐	FEMALE ☐
TRAINER	YES ☐	NO ☐
	FULL TIME ☐	PART TIME ☐

Back Pain: GP note search 12 months after recruitment to trial

Patient Number		Patient D o B	
Patient Name		GP Name	
Patient Address		GP address	

Group	O	N	X	Randomisation checked with GP Yes / No	Sticker seen Yes / No

Date of consent		Tick here if No consent date ☐
Date of questionnaire		

	DATE	Number of Back pain consultations since date	Number of Other Consultations since date
Recruitment date			
If notes indicate that there was no consultation for back pain on recruitment date: proxy date			
Recruit date less 12 months			
Recruit date less 4 weeks			
Recruit date + 4 weeks			
Recruit date + 12 months			

Flu symptoms at recruitment?	No	Yes

On sickness certificate at recruitment? No Yes	If Yes: Date Circle Reason: BP Not BP Not spec
N of sickness certificates in 12 months since recruitment	BP ☐ Not BP ☐ Not spec ☐
Date of 1st certificate for back pain	N of days certificated on 1st certificate ☐
N of days certificated for low back pain in 12 months since recruitment	
Continuous Intermittent certification?	

X-ray history

X-ray referral	Y / N	Referral Date	Which Hospital?	Recording GP? Y/N	Request from in patient? Y/N	Reason(verbatim from form if poss)	Date of X-ray	Result (verbatim from form if poss) Inc Serious pathology
in five years prior to recruitment?								
at recruitment?		X		X				
In 12 months following recruitment?								

In 12 months since recruitment

MRI								
CT SCAN								

Prescription in 12 months after recruitment for low back pain (Write "none" if no prescription)

Date	Item	Dose	Duration	Date	Cost

Referrals in 12 months after recruitment for low back pain (Write "none" if no referrals)

Date	Profession	NHS Y/N/UK	Comments

Relevant past medical history

	In all correspondence Does last mentioned prior to recruitment	In notes in 12 months prior to recruitment Date
Cancer		
HIV/AIDS		
TB		
Osteoporosis		
Spondylolisthesis/ spondylitis		
TB		
Arthritis		
Neurological signs		
Use of steroids		

Eg sciatica, weakness, pain & sensation, abnormal reflexes, Tplegia
Eg prolapsed intervertebral disc, thrombosis, haemorrhage, stenosis, hydrocephalus

Now Diagnosis within 12 months of recruitment _____

PATIENT IDENTIFICATION FORM

Practice ID		Patient Number	3/	Recruitment Period	
Practice Name & Address		Patient's Name		Patient's Address	
Date of Birth		Sex		Male ☐ Female ☐	
Method used to identify patient e.g. which key words used					
Date of first 'new consultation					
Seen within 4 weeks				Yes ☐ No ☐	
Pregnant				Yes ☐ No ☐	
G P Consulted					
Already identified				Yes ☐ No ☐	
If yes give number in main study					

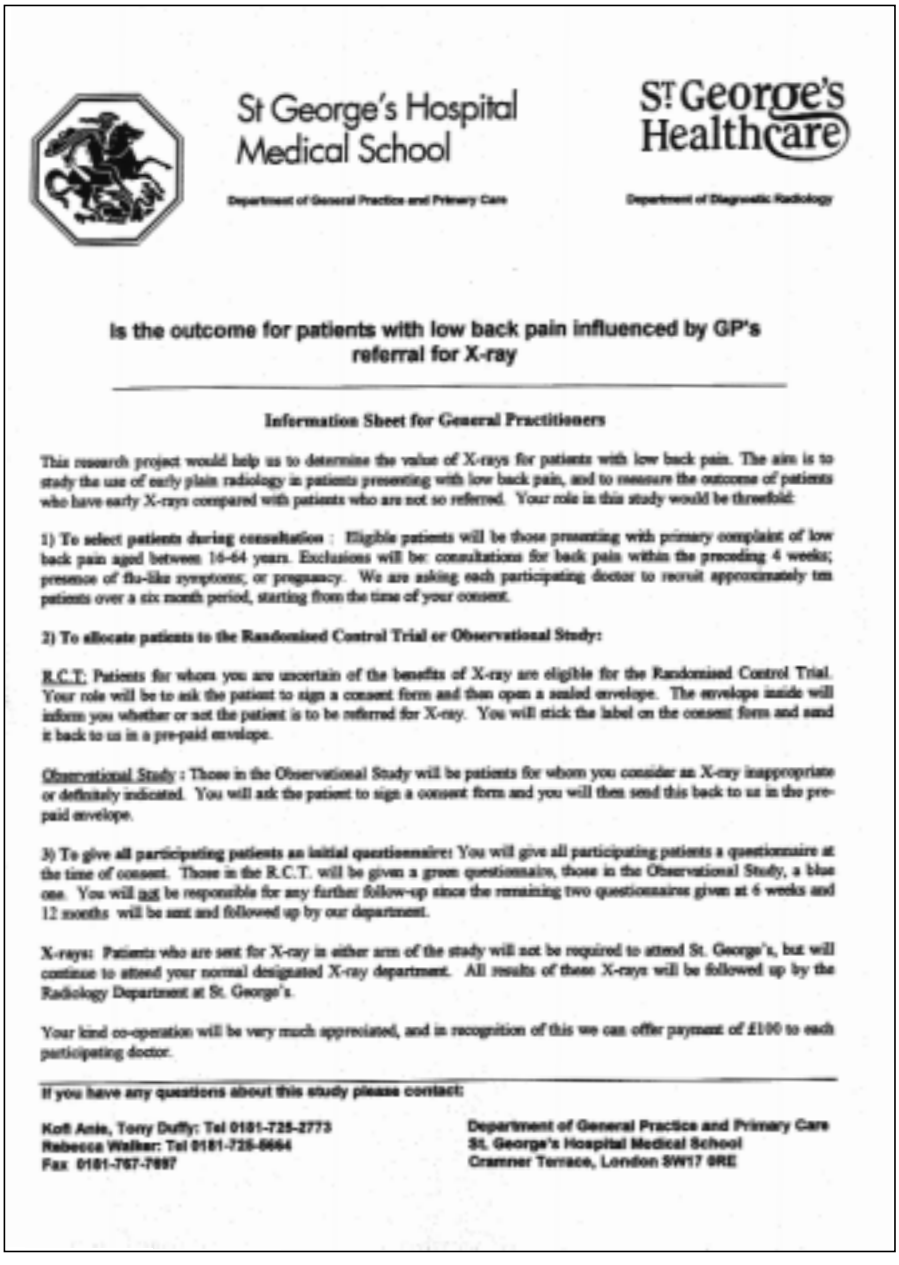
Appendix 8

Project milestones

	Original	**Revised**
Pilot study	15 November 1995 to 15 February 1996	No separate pilot study
GP recruitment	100 GPs in 6 months to 31 September 1996 from practices referring to St George's Healthcare Trust	229 GPs in 20 months to 31 August 1997 from four Health Authorities
Patient recruitment	300 patients to RCT 2000 patients to observational study (500 to be followed up) in 12 months from 15 March 1996 to 15 March 1997	153 patients to RCT 506 patients to observational study (all followed up) in 26 months from 15 January 1996 to 15 March 1998
6-week questionnaires	To 30 April 1997	To 30 April 1998
12-month questionnaires	To 15 March 1998	To 15 March 1999
12-month note search	To 15 March 1998	To 15 March 1999
Study end date	15 October 1998	30 June 1999

Appendix 9

Information sheet mailed to GPs with invitation letter



St George's Hospital Medical School

Department of General Practice and Primary Care

St George's Healthcare

Department of Diagnostic Radiology

Is the outcome for patients with low back pain influenced by GP's referral for X-ray

Information Sheet for General Practitioners

This research project would help us to determine the value of X-rays for patients with low back pain. The aim is to study the use of early plain radiology in patients presenting with low back pain, and to measure the outcome of patients who have early X-rays compared with patients who are not so referred. Your role in this study would be threefold:

1) **To select patients during consultation** : Eligible patients will be those presenting with primary complaint of low back pain aged between 16-64 years. Exclusions will be: consultations for back pain within the preceding 4 weeks; presence of flu-like symptoms; or pregnancy. We are asking each participating doctor to recruit approximately ten patients over a six month period, starting from the time of your consent.

2) To allocate patients to the Randomised Control Trial or Observational Study:

R.C.T: Patients for whom you are uncertain of the benefits of X-ray are eligible for the Randomised Control Trial. Your role will be to ask the patient to sign a consent form and then open a sealed envelope. The envelope inside will inform you whether or not the patient is to be referred for X-ray. You will stick the label on the consent form and send it back to us in a pre-paid envelope.

Observational Study : Those in the Observational Study will be patients for whom you consider an X-ray inappropriate or definitely indicated. You will ask the patient to sign a consent form and you will then send this back to us in the pre-paid envelope.

3) **To give all participating patients an initial questionnaire:** You will give all participating patients a questionnaire at the time of consent. Those in the R.C.T. will be given a green questionnaire, those in the Observational Study, a blue one. You will not be responsible for any further follow-up since the remaining two questionnaires given at 6 weeks and 12 months will be sent and followed up by our department.

X-rays: Patients who are sent for X-ray in either arm of the study will not be required to attend St. George's, but will continue to attend your normal designated X-ray department. All results of these X-rays will be followed up by the Radiology Department at St. George's.

Your kind co-operation will be very much appreciated, and in recognition of this we can offer payment of £100 to each participating doctor.

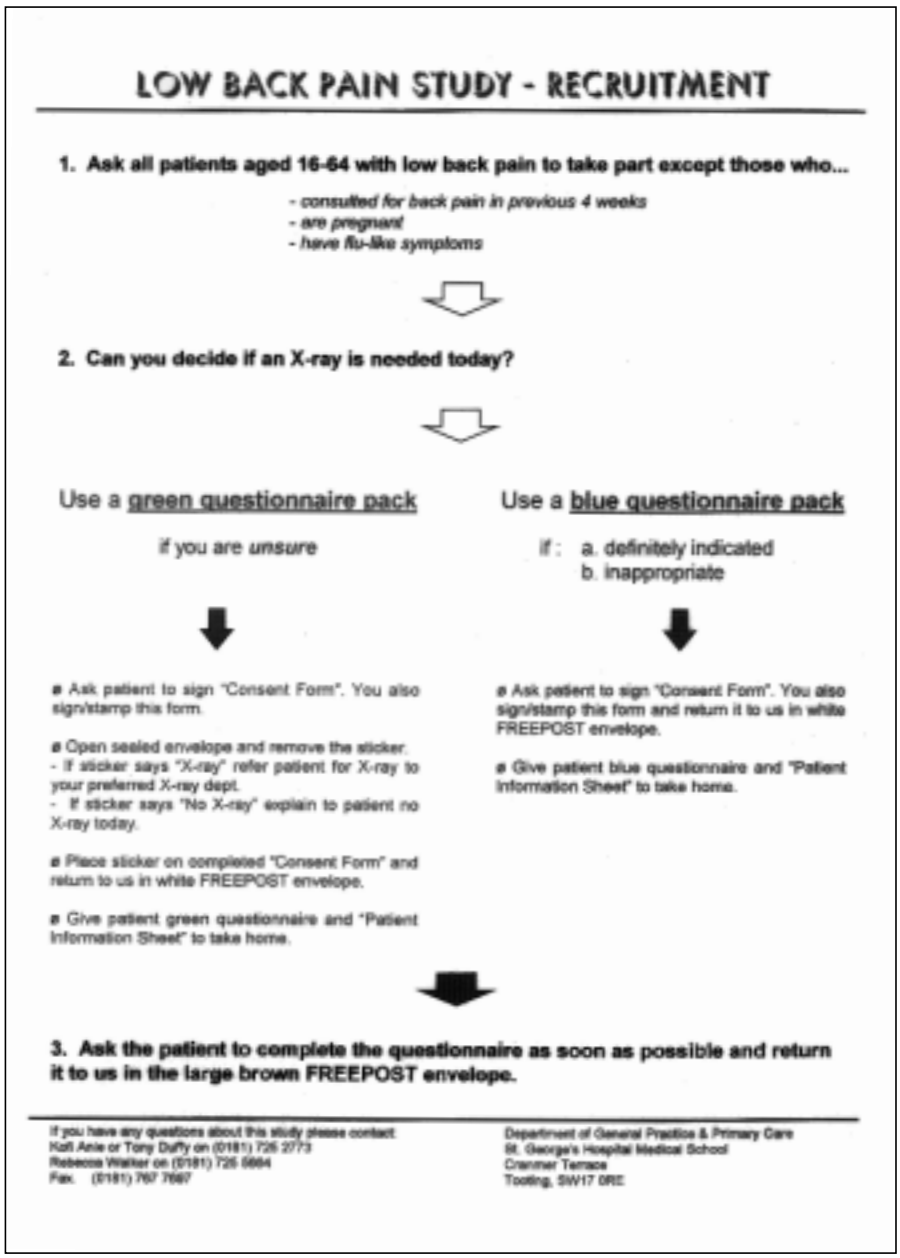
If you have any questions about this study please contact:

Kofi Anie, Tony Duffy: Tel 0181-725-2773
Rebecca Walker: Tel 0181-725-5664
Fax 0181-767-7697

Department of General Practice and Primary Care
St. George's Hospital Medical School
Cranmer Terrace, London SW17 0RE

Appendix 10

Flow chart (laminated) for doctors desk



LOW BACK PAIN STUDY - RECRUITMENT

1. Ask all patients aged 16-64 with low back pain to take part except those who...

- *consulted for back pain in previous 4 weeks*
- *are pregnant*
- *have flu-like symptoms*

2. Can you decide if an X-ray is needed today?

Use a green questionnaire pack

if you are *unsure*

- Ask patient to sign "Consent Form". You also sign/stamp this form.
- Open sealed envelope and remove the sticker.
  - If sticker says "X-ray" refer patient for X-ray to your preferred X-ray dept.
  - If sticker says "No X-ray" explain to patient no X-ray today.
- Place sticker on completed "Consent Form" and return to us in white FREEPOST envelope.
- Give patient green questionnaire and "Patient Information Sheet" to take home.

Use a blue questionnaire pack

if : a. definitely indicated
b. inappropriate

- Ask patient to sign "Consent Form". You also sign/stamp this form and return it to us in white FREEPOST envelope.
- Give patient blue questionnaire and "Patient Information Sheet" to take home.

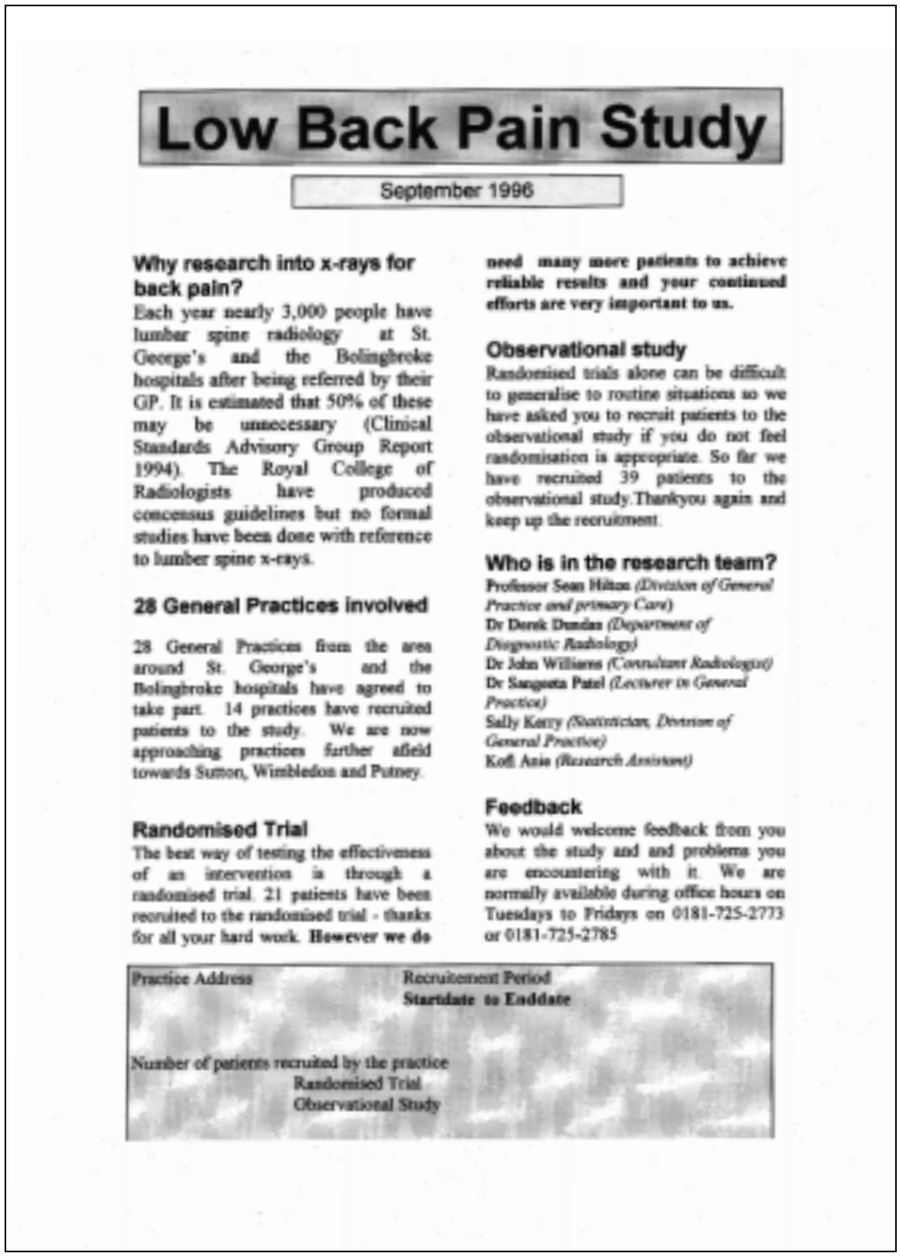
3. Ask the patient to complete the questionnaire as soon as possible and return it to us in the large brown FREEPOST envelope.

If you have any questions about this study please contact:
Kath Anie or Tony Duffy on (0181) 726 2773
Rebecca Walker on (0181) 726 6864
Fax. (0181) 767 7697

Department of General Practice & Primary Care
St. George's Hospital Medical School
Cranmer Terrace
Tooting, SW17 0RE

Appendix 11

First GP newsletter, September 1996



Low Back Pain Study

September 1996

Why research into x-rays for back pain?

Each year nearly 3,000 people have lumbar spine radiology at St. George's and the Bolingbroke hospitals after being referred by their GP. It is estimated that 50% of these may be unnecessary (Clinical Standards Advisory Group Report 1994). The Royal College of Radiologists have produced concensus guidelines but no formal studies have been done with reference to lumber spine x-rays.

28 General Practices involved

28 General Practices from the area around St. George's and the Bolingbroke hospitals have agreed to take part. 14 practices have recruited patients to the study. We are now approaching practices further afield towards Sutton, Wimbledon and Putney.

Randomised Trial

The best way of testing the effectiveness of an intervention is through a randomised trial. 21 patients have been recruited to the randomised trial - thanks for all your hard work. **However we do need many more patients to achieve reliable results and your continued efforts are very important to us.**

Observational study

Randomised trials alone can be difficult to generalise to routine situations so we have asked you to recruit patients to the observational study if you do not feel randomisation is appropriate. So far we have recruited 39 patients to the observational study.Thankyou again and keep up the recruitment.

Who is in the research team?

Professor Sean Hilton *(Division of General Practice and primary Care)*
Dr Derek Dundas *(Department of Diagnostic Radiology)*
Dr John Williams *(Consultant Radiologist)*
Dr Sangeeta Patel *(Lecturer in General Practice)*
Sally Kerry *(Statistician, Division of General Practice)*
Kofi Asie *(Research Assistant)*

Feedback

We would welcome feedback from you about the study and and problems you are encountering with it. We are normally available during office hours on Tuesdays to Fridays on 0181-725-2773 or 0181-725-2785

Practice Address

Recruitement Period
Startdate to Enddate

Number of patients recruited by the practice
Randomised Trial
Observational Study

Appendix 12

Second GP newsletter, September 1997

The Low Back Pain Study

Volume 1 Issue 2 September 1997

The story so far.....

The Low Back Pain Study invited all practices in Merton, Sutton and Wandsworth, Croydon, Kingston & Richmond and East Surrey to take part in the study. In total, 123 practices kindly agreed to take part, of whom 53 (114 GPs) are still active. The remaining practices have finished their recruitment period, withdrawn or have yet to recruit.

So far, we have recruited 118 patients to the Randomised trial and 295 patients to the observational study. Given that we are aiming for 190 patients in the Randomised trial and 400 patients in the observational study by the end of the year, we feel very pleased with this recruitment and hopeful that we will reach this target. Please keep up the good work, December is not far off!

Thank you for all your hard work and continuing support!

Ideas to boost recruitment.

Take the Plunge

For some GPs getting round to recruiting the first patient is the most difficult. It may not be as difficult as you think it's going to be.

Screen Savers

How about using your screen saver to remind you about the study? Call Rebecca if you would like help with this.

Jog Calls

Some GPs have found a weekly or fortnightly call extremely helpful in jogging their memory about the project amidst a hectic schedule. It only takes a minute, or if you prefer, we can leave a message with the receptionist. If you think this

might be helpful please let us know.

E-mail

If you are a regular e-mail user, you might prefer us to send messages in this way. Simply send us your e-mail address as soon as possible to:

skerry@sghms.ac.uk

Any Questions.....?

In view of the likely questions that patients may ask you with regard to the questionnaire, we have devised a short coloured leaflet which we send to all patients when we have received their consent form. This answers some of their "most asked questions" and reminds them to send their questionnaires back. In particular, it also explains that if they have difficulty filling out all of the questionnaire they should simply fill in as much as they are able to. We enclose a copy for your interest.

Who's who in the Team.

Sally Kerry: Project Manager and Principal investigator.

Tel: 0181 725 2785 (Tue, Wed, Fri)

Kofi Anie: Researcher Practice recruitment and patient follow-up

Tel: 0181 725 2773 (Tues, Thurs, Fri)

Rebecca Walker: Researcher Patient recruitment & liaison with practices. "Jog" phone calls.

Tel: 0181 725 5664 (Mon, Tues, Wed)

If you have any queries, please do not hesitate to contact a member of the research team who will be happy to help.

The project also has a steering group:

Prof Sean Hilton: Head of Dept of General Practice.

Dr Derek Dundas: Consultant Radiologist

Dr Sangeeta Patel: GP lecturer

Latest Research.

The NHS R&D Health and Technology Assessment Programme who fund our project here at St George's, are also responsible for funding two other randomised trials for low back pain.

G.Ps in the Nottinghamshire area are being invited to take part in a randomised trial of lumbar spine x-rays for patients who have had low back pain for more than 6 weeks. Patients are being identified from the practice computers using READ codes and then invited to take part in the trial. This study is approximately half way through patient recruitment and will finish recruiting in Dec 98.

In the Newcastle area a trial is just beginning of lumbar spine x-rays for patients who are employed and are being given a certificate for absence from work.

We are in regular contact with these other projects and hope that, at a later stage, further collaboration may be possible.

Appendix 13

Drug costs

TABLE 42 *Unit costs of prescribed medications*

BNF code	Medication name	Units	Units per DDD	Mean DDDs per prescription	Cost per unit (£)	Cost per DDD (£)
D01.3.1	Ranitidine (np)	150 mg	2.00	30	0.46	0.97
D04.1.1	Temazepam	10 mg	2.00	21	0.02	0.04
D04.1.1	Zopiclone (Zimovane®)	7.5 mg	1.00	28	0.16	0.17
D04.1.2	Diazepam	2 mg	5.00	10.7	0.00	0.02
D04.1.2	Diazepam	5 mg	2.00	7.4	0.00	0.01
D04.3.1	Dothiepin	75 mg	2.00	30	0.12	0.24
D04.3.1	Dothiepin (Prothiaden®)	25 mg	6.00	56	0.05	0.31
D04.3.3	Setraline (Lustral®)	50 mg	1.00	28	0.95	0.99
D04.6.9	Prochlorperazine	5 mg	3.75	8	0.02	0.09
D04.7.1	Paracetamol	500 mg	6.00	8	0.02	0.14
D04.7.1	Co-Codamol (np)	8 mg/500 mg	6.00	16	0.03	0.18
D.04.7.1	Co-Codamol (Kapake®)	30 mg/500 mg	6.00	18	0.08	0.47
D04.7.1	Solpadol®	30 mg/500 mg	6.00	9.5	0.08	0.49
D04.7.1	Tylex®	30 mg/500 mg	6.00	18.2	0.09	0.54
D04.7.1	Co-dydramol (np)	10 mg/500 mg	6.00	18	0.01	0.09
D04.7.1	Co-proxamol (np)	32.5 mg/325 mg	6.00	14.1	0.01	0.07
D04.7.2	Tramadol	50 mg	6.00	25	0.18	1.11
D04.7.2	Tramadol (Zydol®)	50 mg	6.00	17.7	0.18	1.11
D04.7.2	Tramadol (Zydol®)	100 mg	3.00	30	0.32	0.99
D04.7.2	Tramadol (Zydol®)	150 mg	2.00	15	0.64	1.33
D04.7.2	Codeine phosphate (np)	30 mg	3.33	7	0.02	0.07
D04.7.2	Dihydrocodeine	30 mg	6.00	28	0.03	0.17
D10.1.1	Flurbiprofen (Froben®)	100 mg	2.00	26.7	0.16	0.33
D10.1.1	Indomethacin (Indocid®) m/r	75 mg	1.33	30	0.17	0.23
D10.1.1	Ketoprofen (Oruvail®)	200 mg	0.75	23.1	0.58	0.45
D10.1.1	Meloxicam (Mobic®)	7.5 mg	2.00	14	0.33	0.69
D10.1.1	Meloxicam (Mobic®)	15 mg	1.00	29	0.46	0.48
D10.1.1	Nabumetone (Relifex®)	500 mg	2.00	23.1	0.32	0.67
D10.1.1	Naproxen (np)	250 mg	2.00	23.1	0.09	0.18
D10.1.1	Naproxen (np)	500 mg	1.00	22.2	0.18	0.19
D10.1.1	Naproxen (Naprosyn® enteric coated)	250 mg	2.00	14	0.12	0.25
D10.1.1	Naproxen (Naprosyn® enteric coated)	500 mg	1.00	19.5	0.24	0.25
D10.1.1	Feldene (Piroxicam®) capsules	10 mg	2.00	20	0.11	0.22
D10.1.1	Piroxicam (np)	20 mg	1.00	25	0.13	0.14
D10.1.1	Ibuprofen (np)	200 mg	6.00	15.1	0.01	0.04
D10.1.1	Ibuprofen (np)	400 mg	3.00	22.5	0.01	0.05
D10.1.1	Ibuprofen (np)	600 mg	2.00	19.4	0.03	0.05

continued

TABLE 42 contd *Unit costs of prescribed medications*

BNF code	Medication name	Units	Units per DDD	Mean DDDs per prescription	Cost per unit (£)	Cost per DDD (£)
D10.1.1	Ibuprofen (Brufen®)	200 mg	6.00	23.1	0.03	0.19
D10.1.1	Ibuprofen (Brufen Retard®)	800 mg	1.50	29	0.21	0.33
D10.1.1	Aceclofenac (Preservex®)	100 mg	2.00	30	0.25	0.52
D10.1.1	Diclofenac sodium	25 mg	4.00	24.3	0.04	0.17
D10.1.1	Diclofenac sodium	50 mg	2.00	24	0.08	0.16
D10.1.1	Diclofenac sodium (Voltarol®)	25 mg	4.00	19.4	0.09	0.39
D10.1.1	Diclofenac sodium (Voltarol®)	50 mg	2.00	18.1	0.18	0.38
D10.1.1	Diclomax®	75 mg	1.33	23.61	0.23	0.32
D10.1.1	Diclomax Retard®	100 mg	1.00	34.8	0.33	0.35
D10.1.1	Diclofenac sodium (Voltarol® SR)	75 mg	1.33	18	0.31	0.43
D10.1.1	Diclofenac sodium (Voltarol® Retard)	100 mg	1.00	14	0.45	0.47
D10.1.1	Diclofenac sodium and misoprostol (Arthrotec® 50)	50 mg/ 200 mcg	2.00	20.1	0.25	0.52
D10.1.1	Diclofenac sodium and misoprostol (Arthrotec® 75)	75 mg/ 200 mcg	1.33	29	0.29	0.41
D10.2.2	Methocarbamol (Robaxin®)	750 mg	4.00	84	0.11	0.46
D10.1.1	Diclofenac sodium (Voltarol® injection)	3 ml ampoule	1	1	0.83	0.86
D10.1.2	Adcortyl injection	1ml ampoule	1	1	1.02	1.06
D10.3.2	Intralgin® gel	50 g	1	1	0.49	0.51
D10.3.2	Voltarol Emulgel®	100 mg	1	1	7.00	7.28

Health Technology Assessment panel membership

This report was identified as a priority by the Diagnostics and Imaging Panel.

Acute Sector Panel

Current members

Chair:
Professor Francis H Creed
University of Manchester

Professor Clifford Bailey
University of Leeds

Ms Tracy Bury
Chartered Society of Physiotherapy

Professor Collette Clifford
University of Birmingham

Dr Katherine Darton
M.I.N.D.

Mr John Dunning
Papworth Hospital, Cambridge

Mr Jonathan Earnshaw
Gloucester Royal Hospital

Mr Leonard Fenwick
Freeman Group of Hospitals, Newcastle-upon-Tyne

Professor David Field
Leicester Royal Infirmary

Ms Grace Gibbs
West Middlesex University Hospital NHS Trust

Dr Neville Goodman
Southmead Hospital Services Trust, Bristol

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MRC Institute of Hearing Research, University of Nottingham

Professor Robert Hawkins
University of Manchester

Dr Duncan Keeley
General Practitioner, Thame

Dr Rajan Madhok
East Riding Health Authority

Dr John Pounsford
Frenchay Hospital, Bristol

Dr Mark Sculpher
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Dr Iqbal Sram
NHS Executive, North West Region

Mrs Joan Webster
Consumer member

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Professor Senga Bond
University of Newcastle-upon-Tyne

Professor Ian Cameron
Southeast Thames Regional Health Authority

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Mid-Kent Health Care Trust

Professor Cam Donaldson
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Mr Ian Hammond
Bedford & Shires Health & Care NHS Trust

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Queen Elizabeth Hospital, Birmingham

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University of Dundee

Professor Kenneth Taylor
Hammersmith Hospital, London

* Previous Chair

continued

continued

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University of Leeds

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Leeds Teaching Hospitals NHS Trust

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Dr Barry Cookson
Public Health Laboratory Service, Colindale

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Association of Cytogeneticists, Oxford

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RDRD, Trent Regional Health Authority

Ms Julia Davison
St Bartholomew's Hospital, London

Professor MA Ferguson-Smith
University of Cambridge

Dr Mansel Haeney
University of Manchester

Professor Sean Hilton
St George's Hospital Medical School, London

Mr John Hutton
MEDTAP International Inc., London

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St Bartholomew's Hospital, London

Dr Ian Reynolds
Nottingham Health Authority

Professor Colin Roberts
University of Wales College of Medicine

Miss Annette Sergeant
Chase Farm Hospital, Enfield

Professor John Stuart
University of Birmingham

Dr Ala Szczepura
University of Warwick

Mr Stephen Thornton
Cambridge & Huntingdon Health Commission

Dr Jo Walsworth-Bell
South Staffordshire Health Authority

Methodology Group

Current members

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Health Economics Research Group, Brunel University

Professor Doug Altman
ICRF/NHS Centre for Statistics in Medicine, University of Oxford

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Guy's, King's & St Thomas's School of Medicine & Dentistry, London

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MRC Health Services Research Collaboration, University of Bristol

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Centre for Health Economics, University of York

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We look forward to hearing from you.

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