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Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain

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Abstract

Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain

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Objectives: To test whether patients with persistent non-specific low back pain, when offered access to traditional acupuncture care alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost. Safety and acceptability of acupuncture care to patients, and the heterogeneity of outcomes were also tested.
Design: A pragmatic, two parallel group, randomised controlled trial. Patients in the experimental arm were offered the option of referral to the acupuncture service comprising six acupuncturists. The control group received usual care from their general practitioner (GP). Eligible patients were randomised in a ratio of 2:1 to the offer of acupuncture to allow between-acupuncturist effects to be tested.
Setting: Three non-NHS acupuncture clinics, with referrals from 39 GPs working in 16 practices in York, UK.
Participants: Patients aged 18–65 years with non-specific low back pain of 4–52 weeks' duration, assessed as suitable for primary care management by their general practitioner
Interventions: The trial protocol allowed up to ten individualised acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need.
Main outcome measures: The Short Form 36 (SF-36) Bodily Pain dimension (range 0–100 points), assessed at baseline, and 3, 12 and 24 months. The study was powered to detect a 10-point difference between groups at 12 months post-randomisation. Cost–utility analysis was conducted at 24 months using the EuroQoL 5 Dimensions (EQ-5D) and a preference-based single index measure derived from the SF-36 (SF-6D). Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, and safety and acceptability of acupuncture care.
Results: A total of 159 patients were in the 'acupuncture offer' arm and 80 in the 'usual care' arm. All 159 patients randomised to the offer of acupuncture care chose to receive acupuncture treatment, and received an average of eight acupuncture treatments within the trial. Analysis of covariance, adjusting for baseline score, found an intervention effect of 5.6 points on the SF-36 Pain dimension [95% confidence interval (CI) –1.3 to 12.5] in favour of the acupuncture group at 12 months, and 8 points (95% CI 0.7 to 15.3) at 24 months. No evidence of heterogeneity of effect was found for the different acupuncturists. Patients receiving acupuncture care did not report any serious or life-threatening events. No significant treatment effect was found for any of the SF-36 dimensions other than Pain, or for the PPI or the ODI. Patients receiving acupuncture care reported a significantly greater reduction in worry about their back pain at 12 and 24 months compared with the usual care group. At 24 months, the acupuncture care group was significantly more likely to report 12 months pain free and less likely to report the use of medication for pain relief. The acupuncture service was found to be cost-effective at 24 months; the estimated cost per quality-adjusted (QALY) was £4241 (95% CI £191 to £28,026) using the SF-6D scoring algorithm based on responses to the SF-36, and £3598 (95% CI £189 to £22,035) using the EQ-5D health status instrument. The NHS costs were greater in the acupuncture care group than in the usual

care group. However, the additional resource use was less than the costs of the acupuncture treatment itself, suggesting that some usual care resource use was offset. **Conclusions:** Traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific low back pain. Acupuncture care and usual care were both associated with clinically significant improvement at 12- and 24-month follow-up. Acupuncture care was significantly more effective in reducing bodily pain than usual care at 24-month follow-up. No benefits relating to function or disability were identified. GP referral to a service providing traditional acupuncture care offers a cost-effective intervention for reducing low back pain over a 2-year period. Further research is needed to examine many aspects of this treatment including its impact compared with other possible short-term packages of care (such as massage, chiropractic or physiotherapy), various aspects of cost-effectiveness, value to patients and implementation protocols.

Contents

Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases, usage differs in the literature, but the term has a constant meaning throughout this review.

Glossary

Allocation to 'acupuncture care' Patients in this group were randomised to the offer of up to ten acupuncture treatments. Acupuncture care was delivered in private practice by a qualified traditional acupuncturist and paid for by York Health Authority. Acupuncturists were not restricted to needling; each practitioner offered a package of individualised care, comparable to their practice under non-trial conditions. Patients received auxiliary and adjunctive treatments (moxa, cupping, massage, acupressure and Chinese herbs) as indicated, as well as advice on exercise and diet. GPs were advised that they could offer these patients any additional care that they felt was needed.

Allocation to 'usual care' Patients in this group were randomised to receive pragmatic GP management, with no restrictions on the care they received.

Traditional acupuncture A holistic approach to health based on over 2000 years of developments in East Asia and more recent refinements in the West. Fine needles are sensitively inserted at empirically derived locations to trigger the body's natural self-healing mechanisms. This healing process can be explained either in terms of harnessing the body's energy (qi), or in terms of neurophysiological processes. As well as treating a wide range of illnesses, traditional acupuncture can be used to improve a patient's overall well-being. Emphasis is also placed on lifestyle management and the wider issues that may relate to a patient's condition.

Traditional acupuncture diagnosis Grounded careful observation of patient's signs and symptoms, which are then grouped together in syndromes or patterns of disharmony. Treatment is then directed towards restoring balance and harmony by needling relevant acupuncture points.

De qi The sensation experienced by the patient when the needle 'obtains the qi'. It is felt locally at the site of the needle as a dull ache, distending sensation or numbness.

Moxibustion (moxa) An adjunctive technique used by acupuncturists to warm a needle or area of the body to help to correct an underlying disharmony. The herb *Artemesia vulgaris* (mugwort) is burned slowly near the skin such that the warmth gently penetrates the body's surface.

Acupressure Application of finger pressure to acupuncture points to create the same sort of changes that can be generated by inserting needles.

Massage An adjunctive technique that can be used immediately before acupuncture to localise the area of pain, assist in the movement of qi and identify the most appropriate acupuncture points to use. It also serves the secondary functions of relaxing the patient and strengthening the therapeutic relationship.

Cupping A technique used by acupuncturists as an adjunct to help to treat specific patterns. It involves heating the air inside a glass cup and applying the cup to the skin, creating a partial vacuum as the air cools.

continued

Glossary *continued*

Chinese herbs Chinese herbal medicine uses the same theoretical and diagnostic framework as acupuncture. A prescription of herbs is designed to correct underlying imbalances in the patient's condition, thereby acting as a catalyst in facilitating the body's natural healing mechanisms. Chinese herbs and acupuncture can be used in conjunction for the same patient.

Persistent low back pain An episode of pain lasting for at least 4 weeks and less than a whole year.

Individualised care Treatment plans shaped according to patient characteristics, individualised diagnosis and patient responses to treatment.

List of abbreviations

AACP	Acupuncture Association of Chartered Physiotherapists
A&E	accident and emergency
ANCOVA	analysis of covariance
ANOVA	analysis of variance
AUC	area under the curve
BAAB	British Acupuncture Accreditation Board
BAcC	British Acupuncture Council
BMAS	British Medical Acupuncture Society
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
CSAG	Clinical Standards Advisory Group
EQ-5D	EuroQol 5 Dimensions
ICER	incremental cost-effectiveness ratio
ITT	intention-to-treat
LBP	low back pain
MBPSR	multidisciplinary biopsychosocial rehabilitation
NICE	National Institute for Clinical Excellence
NSAID	non-steroidal anti-inflammatory drug
ODI	Oswestry Pain Disability Index
OR	odds ratio
PPI	McGill Present Pain Index
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SF-36	Short Form 36 General Health Status Profile
SF-6D	a preference-based single index measure derived from the SF-36
SPSS	Statistical Package for the Social Sciences
STRICTA	STandards for Reporting Interventions in Controlled Trials of Acupuncture
TCM	traditional Chinese medicine
TENS	transcutaneous electrical nerve stimulation

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

Executive summary

Objectives

The primary objective was to test the hypothesis that a population of patients with persistent non-specific low back pain, when offered access to traditional acupuncture care alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost. Secondary objectives were to monitor the safety and acceptability of acupuncture care to patients, and to assess the evidence for an 'acupuncturist effect' by testing the heterogeneity of outcomes for the six acupuncturists participating in the trial.

Methods

Design

The study was a pragmatic, two parallel group, randomised controlled trial (n = 241). Patients in the experimental arm were offered the option of referral to the acupuncture service comprising six acupuncturists. The control group received usual care from their general practitioner (GP). Eligible patients were randomised in a ratio of 2:1 to the offer of acupuncture to allow between-acupuncturist effects to be tested.

Setting

The study was conducted in three non-NHS acupuncture clinics, with referrals from 39 GPs working in 16 practices in York, UK.

Subjects

The subjects were patients aged 18–65 years with non-specific low back pain of 4–52 weeks' duration, assessed as suitable for primary care management by their GP.

Interventions

The trial protocol allowed up to ten individualised acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need. Acupuncture patients received needling using disposable acupuncture needles, and adjunctive treatments including massage and advice on diet, rest and exercise. Usual care commonly entailed a mixture of physiotherapy, medication and recommended back exercises. Patients receiving acupuncture care continued to have access to usual care for their back pain at the discretion of their GP.

Main outcome measures

The primary outcome measure was the Short Form 36 (SF-36) Bodily Pain dimension (range 0–100 points), assessed at baseline, and 3, 12 and 24 months. The study was powered to detect a 10-point difference between groups at 12 months post-randomisation. Cost–utility analysis was conducted at 24 months using the EuroQoL 5 Dimensions (EQ-5D) and a preference-based single index measure derived from the SF-36 (SF-6D). Secondary outcomes included the McGill Present Pain Index (PPI), Oswestry Pain Disability Index (ODI), all other SF-36 dimensions, medication use, pain-free months in the past year, worry about back pain, satisfaction with care received, and safety and acceptability of acupuncture care.

Results

The trial successfully recruited 241 patients via referrals from 39 GPs. Two patients withdrew immediately, leaving 159 in the 'acupuncture offer' arm and 80 in the 'usual care' arm. All 159 patients randomised to the offer of acupuncture care chose to receive acupuncture treatment, and received an average of eight acupuncture treatments within the trial.

Analysis of covariance, adjusting for baseline score, found an intervention effect of 5.6 points on the SF-36 Pain dimension [95% confidence interval (CI) –1.3 to 12.5] in favour of the acupuncture group at 12 months, and 8 points (95% CI 0.7 to 15.3) at 24 months. No evidence of heterogeneity of effect was found for the different acupuncturists. Patients receiving acupuncture care did not report any serious or life-threatening events. Sixteen patients dropped out of acupuncture treatment, four of whom mentioned specific minor adverse events, such as pain at the site of needling.

No treatment effect was found for any of the SF-36 dimensions other than Pain, or for the ODI. Patients receiving acupuncture care reported a significantly greater reduction in worry about their back pain at 12 and 24 months compared with the usual care group. At 24 months, the acupuncture care group was significantly more likely to report 12 months pain free and less likely to report the use of medication for pain relief.

The acupuncture service was found to be cost-effective at 24 months; the estimated cost per quality-adjusted (QALY) was £4241 (95% CI £191 to £28,026) using the SF-6D scoring algorithm based on responses to the SF-36, and £3598 (95% CI £189 to £22,035) using the EQ-5D health status instrument. The NHS costs were greater in the acupuncture care group than in the usual care group. However, the additional resource use was less than the costs of the acupuncture treatment itself, suggesting that some usual care resource use was offset.

Conclusions

Traditional acupuncture care delivered in a primary care setting was safe and acceptable to patients with non-specific low back pain. Acupuncture care and usual care were both associated with clinically significant improvement at 12- and 24-month follow-up. Acupuncture care was significantly more effective in reducing bodily pain than usual care at 24-month follow-up. No benefits relating to function or disability were identified. GP referral to a service providing traditional acupuncture care offers a cost-effective intervention for reducing low back pain over a 2-year period.

Implications for healthcare

Based on the study's findings, commissioners of musculoskeletal services would be justified in considering making GP referral to a short course of traditional acupuncture care available for a typical population of primary care attendees with persistent non-specific low back pain.

Recommendations for research

The following recommendations are suggested for further research.

- Trials are needed to assess the impact of traditional acupuncture on the persistence and recurrence of low back pain compared with other possible short-term packages of care (such as massage, chiropractic or physiotherapy), delivered in an episode of non-acute low back pain.
- The cost-effectiveness of different types of acupuncture offered as short-term packages of care, delivered in an episode of non-acute low back pain, could be assessed.
- Research is needed into the optimum timing for an acupuncture treatment package in a patient episode of low back pain, and to assess the value of repeated courses of acupuncture for patients experiencing recurrent episodes of low back pain.
- Further studies with more patients per acupuncturist are warranted to explore differences between acupuncturists. No significant difference between acupuncturists was found in this study. However, this lack of evidence of heterogeneity does not mean that there is no heterogeneity.
- Exploration is needed of the underlying causes and mechanisms involved in the continued improvement over time of patients with low back pain receiving a short course of traditional acupuncture.
- Qualitative investigation is needed into the meaning to patients of the substantial reported reduction in worry about back pain found in the acupuncture care group, but not in the usual care group, its relationship to patient coping strategies and its implications for the care and management of this group of patients.
- There is a need for the distillation of a protocol for traditional acupuncture treatment for low back pain that allows individualised treatment to be delivered while defining a package of care that represents value for money, which can be commissioned reliably and safely.
- Acupuncture may be delivered in a number of different ways. This trial examined traditional acupuncture delivered by qualified practitioners. There is a case for research to look at the comparative cost-effectiveness of different modes of acupuncture offered as short-term packages of care, delivered in an episode of non-acute low back pain, for example acupuncture care delivered by physiotherapists in a primary care setting.
- Qualitative work is indicated to assess the relative value placed on process utilities by patients, such as feelings of relaxation and support during treatment, and the possibility of trade-off between these and conventional pain outcomes should be explored using standard methods for preference elicitation such as conjoint analysis.
- Methodological work is needed to guide the research community about the best way to proceed with missing data in clinical trials with longer term outcomes.

Chapter 1
Background

Introduction

In a national survey, 40% of the adult population in Britain reported that they had experienced back pain in the previous 12 months. Nearly 40% of these consulted their GP for help with back pain, and 10% visited a practitioner of complementary medicine (osteopath, chiropractor or acupuncturist).[1] The annual cost of back pain to the NHS is estimated at £480 million, with the annual cost to a GP practice with a list of 10,000 patients estimated at £88,000 in 1994.[2] The majority of back pain episodes are managed in primary care, with conservative (non-surgical) treatments favoured for chronic and subacute low back pain. Cochrane reviews exist for as many as 13 such treatments[3–15] (Appendix 1). The evidence to support the individual interventions is mixed, in terms of both quality and clarity of conclusions.[16,17] The Clinical Standards Advisory Group (CSAG) report on low back pain provided a model for the identification and treatment of simple back pain within primary care and recommended management to include the use of alternative therapies, such as chiropractic and osteopathy, following a period of GP-only care and before considering referral to secondary care.[2]

Acupuncture use and provision in the UK

Acupuncture is used by an estimated 2% of the adult general population in a 12-month period for a range of conditions, including back pain.[18] While access to acupuncture is most often through self-referral to a private practitioner, an estimated 10% of treatments is provided within the NHS and a growing number of GP practices in England offer their patients access to acupuncture.[19,20]

Acupuncture and the treatment of chronic pain

Acupuncture is best recognised by the public for its use in treating bodily pain. Reports of the use of acupuncture for a wide range of pain conditions exist in the acupuncture literature. How the process of pain relief is accomplished through acupuncture is not clear-cut, but many theories based on scientific principles exist. In 1985, a review of the research evidence on acupuncture and pain control concluded that the evidence from larger uncontrolled studies on mixed groups of chronic pain patients suggests that acupuncture can offer clinically significant short-term pain relief for 50–70% of patients, compared with the 30–35% that might be expected on the basis of a placebo effect alone.[21]

A subsequent review included 51 controlled clinical studies on the effectiveness of acupuncture in chronic pain. These studies were reviewed using predefined methodological criteria relating to comparability of prognosis, adequacy of intervention, adequacy of effect measurement and data presentation. The quality of the studies was deemed to be mediocre by these criteria. The review concluded that the results from the better studies are highly contradictory, and the efficacy of acupuncture in the treatment of chronic pain therefore remains doubtful.[22]

The most recent review of acupuncture for chronic pain also included 51 studies. In this review, results were positive in 21 studies, negative in three and neutral in 27. Three-quarters of the studies received a low-quality score, and low-quality trials were significantly associated with positive results ($p = 0.05$). Six or more acupuncture treatments were found to be significantly associated with positive outcomes ($p = 0.03$) even after adjusting for study quality. The authors conclude that there is limited evidence that acupuncture is more effective than no treatment for chronic pain, and inconclusive evidence that acupuncture is more effective than placebo, sham acupuncture or standard care.[23]

Acupuncture for low back pain: clinical and cost-effectiveness evidence

The literature on back pain and acupuncture shows evidence of short-term relief. An early review concluded that the evidence from studies comparing acupuncture treatment with no treatment, normal management or an alternative

treatment suggests that the effects of acupuncture may diminish substantially over time. The authors of this review comment that the use of non-standardised outcome measures, lack of statistical power, and variability in the type and duration of intervention make it hard to draw any useful conclusions regarding the comparative clinical effectiveness of acupuncture for pain relief in this group of patients.[21] Since the trial described in this report was commissioned, three further reviews of acupuncture for back pain have been published.[24–26]

Based on 12 trials, the first of these reviews reported a paucity of good-quality evidence. However, using meta-analysis techniques the authors present an odds ratio (OR) of improvement with acupuncture compared with a control intervention (not sham acupuncture) of 2.30 [95% confidence interval (CI) 1.28 to 4.13]. The authors concluded that acupuncture is superior to various control interventions, although there is insufficient evidence to state whether it is superior to placebo. The review concludes that the clinical effectiveness of acupuncture needs to be investigated further.[24] Commentary on this review included the observation that perhaps the biggest problem in this group of trials is that they have avoided the hard question of longer term outcomes.[27]

A Cochrane review, published in the following year and also based on 12 trials, found that the data were statistically and clinically too heterogeneous to allow meta-analysis of the findings. The authors concluded that the evidence did not clearly indicate that acupuncture is effective in the management of back pain and advocated more high-quality randomised controlled trials (RCTs).[25]

The most recent review examined 20 trials of acupuncture for back pain and concluded that, as the quality of the studies was generally poor, the effectiveness of acupuncture for treating acute or chronic back pain remains unclear.[26]

To date, there have been no cost-effectiveness studies of an acupuncture service for low back pain.

Issues in the evaluation of an acupuncture service for low back pain

Definition of acupuncture/acupuncturist

Acupuncture is practised in a number of different ways, stemming from different traditions and training. In particular, there is an important distinction to be made between practitioners using acupuncture as their main therapeutic intervention, and those who are using acupuncture as an adjunct to their mainstream clinical practice, for example GPs or physiotherapists. In the UK there are three major practitioner groups delivering acupuncture to patients. All three groups have a membership in the region of 2000–2500:

- The British Acupuncture Council (BAcC):[28] registered membership of this professional association is restricted to practitioners who have completed a recognised 3-year training course entailing 3600 hours, of which there is a minimum of 1200 contact hours of education. Membership of BAcC is open to qualified acupuncture practitioners with and without conventional medical qualifications.
- British Medical Acupuncture Society (BMAS):[29] most medical doctors who use acupuncture are members of the BMAS. For a Certificate in Basic Competence in acupuncture, the course is two weekends. A Certificate of Accreditation in acupuncture requires 100 hours' education and training in acupuncture.
- The Acupuncture Association of Chartered Physiotherapists (AACP):[30] membership is open to physiotherapists who are required to have undertaken a minimum of 20 hours of acupuncture training. Styles of acupuncture are likely to show greater variation between these groups of practitioners than within them.

Acupuncture treatment can focus on a holistic, energy-based approach to the patient or it can use a more disease-orientated diagnostic and treatment model. In practice, the approach taken is likely to reflect the training and background of individual practitioners. In particular, BAcC members are likely to claim that they are delivering a substantially different package of care because it includes diagnosis and treatment according to traditional Chinese medicine (TCM) principles.

Treatment protocol

Within a trial, a restricted protocol for acupuncture treatment has the advantage of strengthening the internal validity of the study. However, such an approach would not be compatible with the individualised treatment plans and care delivered by traditional acupuncture practitioners.[31,32]

Service delivery

NHS GPs and physiotherapists can offer acupuncture to their patients as part of usual care. In contrast, few TCM practitioners are currently

employed within the NHS. Evaluating the care they can deliver to NHS patients therefore entails identifying or setting up a service that is practical within NHS arrangements, acceptable to patients and to GPs, and allows safe and appropriate referrals to be made.

Patient preferences

There is a growing recognition that patients' preferences may have an effect in trials, either by influencing the outcome of the treatment (positive attitude to treatment may result in better health outcomes) or by 'dissatisfied' patients dropping out of treatment regimens.[33,34] With acupuncture, there is the additional issue of the technology itself, which is unfamiliar to many people and potentially unacceptable to some patients (e.g. needle phobia).

Identification of an appropriate control or comparison group

Placebo acupuncture is not straightforward.[35] A commonly used control group is sham acupuncture, using techniques that are not intended to stimulate known acupuncture points. However, there is disagreement on correct needle placement. Also, particularly in the studies on pain, sham acupuncture often seems to have either intermediate effects between the placebo and 'real' acupuncture points or effects similar to those of the 'real' acupuncture points. Placement of a needle in any position elicits a physiological response that complicates the interpretation of studies involving sham acupuncture. Thus, there is substantial controversy over the use of sham acupuncture in control groups.[36,37] In addition, acupuncture treatment does not lend itself easily to practitioner or patient blinding. Practitioner blinding is not possible, and patient blinding may jeopardise the treatment integrity and external reliability of the results.[31] For example, attempts to enhance patient blinding by using only 'acupuncture-naive' patients may be increasingly restrictive, when lifetime use of acupuncture is estimated to be 7% for the general population, and the majority of these patients present with musculoskeletal problems.[18]

Homogeneity of patient group

In research studies, non-specific low back pain is commonly classified using a temporal definition, with acute pain defined as that of less than 4 weeks' duration, subacute as 4–12 weeks' duration, and chronic pain as that of more than 12 weeks' duration.[38] However, these classifications may not relate straightforwardly to clinical care, and the CSAG report recommended management strategies that came into play at 6 weeks.[2] Trial interventions need to follow customary classifications to allow cross-study comparisons to be made, while acknowledging that treatment choices may not reflect these temporal classifications. Systematic reviews of interventions for chronic low back pain tend to include studies in which patients report pain that has lasted from 4 to 12 weeks as well as those with pain that has lasted for more than 12 weeks.[38] An alternative classification places all episodes of more than 4 weeks' duration in the 'persistent' category, saving the term chronic for low back pain in which the notion of 'episode' has been lost and the pain is seen as a long-term problem, regardless of severity.[39] In this classification, pain duration of a whole year or more is offered as a possible subcategory.

The natural history of low back pain

Studies of low back pain interventions are particularly susceptible to effects arising from a regression to the mean; patients will tend to seek help at the point when the pain is at its worst or least bearable, and the natural history of the condition is that the pain will reduce substantially for most people within a single episode. Non-specific low back pain has been characterised as an "intermittent, recurrent, episodic problem".[39] The episodic natural history of low back pain suggests that long-term outcomes are needed to identify interventions that, when offered relatively early, result in a reduction in recurrence and persistence of symptoms.[39]

Acupuncture or acupuncturist effect?

Acupuncture is delivered within the context of a consultation involving extensive interaction with the practitioner. This raises the question of how much the effects observed after an intervention are attributable to the practitioner and how much to the treatment itself. This question has mostly been asked in relation to trials of surgical procedures,[40] but has relevance across all technologies where the practitioner is a key part of the delivery of the intervention. An important dimension of this issue is the relative effectiveness of different acupuncturists who, like all practitioners, apply lessons from their cumulative clinical experience when treating patients, and use different interpersonal skills within the therapeutic relationship.

Rationale for proposed design of present study

Increased use of acupuncture in primary care will

place a demand on NHS resources. There is a need for clinical and economic evaluations to ascertain the appropriate use of acupuncture in this context. The present study is designed to contribute to the evidence available regarding the effectiveness of the use of acupuncture for the treatment of pain, as well as to inform purchasers of the circumstances in which an acupuncture service might represent a cost-effective addition to existing services for patients consulting specifically with low back pain.

Pragmatic design

The study is a pragmatic RCT. Patients in the experimental arm were offered the option of referral from their GP to the acupuncture service. The control group received normal management from their GP. To maximise participation in the trial, and to test the intervention as it might be delivered in practice, eligible patients were randomised to the offer of acupuncture, rather than to acupuncture itself. This recognises the fact that acupuncture is likely to be offered on the NHS as an option within normal management, and that uptake will depend in part on patient preferences.[41] It was also recognised that GPs will exercise preferences in terms of their willingness to refer patients for acupuncture. The study therefore aimed to recruit a range of GPs from the York area who were willing to consider acupuncture referral for patients with low back pain, and willing to participate in the trial.

Individualised care

The study focused on the largest group of acupuncturists, who used acupuncture as their main therapeutic intervention. All acupuncturists in the trial were members of BAcC, working to standards of training, competency and safety set and monitored by the British Acupuncture Accreditation Board (BAAB), and a minimum of 3 years' postqualification experience. One advantage of using acupuncturists with homogeneous methods of practice is that the results will be generalisable to practitioners registered with BAcC nationally. Following the principles of pragmatic trial design, the intervention was designed to be as close to real-world care as possible. GPs participating in the study made referrals to community-based acupuncturists who were reimbursed directly by the Health Authority on a fee-for-service basis. Acupuncture practitioners are free to devise individualised care plans, and not be restricted by a formalised treatment protocol. All treatments given were recorded on a patient basis.

Inclusion criteria for persistent pain

Eligible patients entered the study at the point at which the GP was considering active treatment, short of hospital referral. Patients with back pain persisting for 4 weeks or more were eligible, unless their current episode of pain had lasted for more than a whole year. This patient group can be defined with ease, is relatively large and places a significant burden on the resources of the NHS. The intention behind not accepting patients with a current episode lasting for more than 52 weeks was to reduce the likelihood of including those patients who were no longer working because of their back pain.

Outcome measures

The study was designed in response to a call for research into the longer term effects of acupuncture for pain. Clinical outcomes were measured by the Bodily Pain dimension of the General Health Status Profile Short Form 36 (SF-36)[42,43] the Present Pain Intensity Scale of the McGill Pain Questionnaire[44] and the Oswestry Pain Disability Index (ODI).[45,46] In addition, the SF-36 measures seven other dimensions of perceived health, including mental health. These measures had all been previously piloted with this group of patients.[47] SF-36 Pain dimension was chosen as the primary outcome, as the pilot data had shown that this measure was responsive to change in patients with low back pain receiving traditional acupuncture, and further studies have shown evidence of the validity and responsiveness of this measure among back pain patients in a primary care setting.[48]

Long-term follow-up

The majority of back pain patients are likely to report clinically significant short-term benefits following acupuncture.[21] An uncontrolled pilot study conducted by the applicants confirmed a highly significant post-treatment improvement that was maintained at 6 months.[47] To assess the potential for longer term benefits, the study as designed measured outcomes at 3 months postrandomisation, and again at 12 months. A 24-month follow-up was added after the start of the trial to enhance the assessment of longer term effects (see section 'Deviations from original protocol', p. 5).

Intention-to-treat analysis

Analysis of primary outcomes is undertaken on an intention-to-treat basis. In this study this means that all cases followed up successfully were analysed according to allocation group, whether they received their allocated treatment or not.

That is, the benefits reported by those patients who received the offer of acupuncture treatment were compared to those reported by patients randomised not to receive this offer. The precise level of take-up from patients offered acupuncture could not be specified in advance, but the analysis compared the population-level benefits of offering acupuncture to this group of clinically defined patients. Numbers permitting, subgroup analysis was planned comparing the two patient groups (those who accepted the offer of acupuncture and those who did not) within the intervention arm. This analysis also allowed a comparison of outcomes between those patients choosing and receiving acupuncture and those choosing normal management.

Testing for heterogeneity between acupuncturists

Technical interpretation of the apparently simple question of whether it is the acupuncture or the acupuncturists that are effective is not easy. This study took an indirect but pragmatic approach, and tested for a difference in effectiveness between acupuncturists. If there is a difference then there is an acupuncturist effect, albeit a variable one. If effects are homogeneous, then there may or may not be an acupuncturist effect as well as an acupuncture effect, although pragmatically this is not important.

Study aims and hypotheses

The primary objective was to test the hypothesis that a population of patients with persistent non-specific low back pain, when offered access to traditional acupuncture alongside conventional primary care, gained more long-term relief from pain than those offered conventional care only, for equal or less cost.

Secondary objectives were to monitor the safety and acceptability of acupuncture to patients, and to assess the evidence for an acupuncturist effect by testing the heterogeneity of outcomes for the six acupuncturists participating in the trial.

Deviations from original protocol

- The required number of patients was revised to allow for between-acupuncturist effects to be tested. The number of patients offered acupuncture was increased from 100 to 160, and the number in the normal management group was decreased from 100 to 80 without loss of power in the main comparison.
- The study began with a core group of 12 GPs and was later expanded to include 43 interested GPs in the York area, to facilitate the recruitment of patients and increase the representativeness of participating GPs.
- Interim analysis on the first 160 patients suggested that a difference might be found between the two groups in pain reduction at 12 months. To improve the relevance of the cost-effectiveness analysis, and on the advice of the external chair of the trial advisory group, further funding was applied for and secured to allow 24-month follow-up data to be collected.

Chapter 2
Methods

Basic design

The study was a pragmatic, parallel design, RCT. Patients in the experimental arm were offered the option of referral to acupuncture care, whereas the control group received normal management from their GP (*Figure 1*). All participants were patients of GPs in the York area, and all participating acupuncturists practised in the city itself. York Health Authority funded the treatment costs of the acupuncture. The study was carried out collaboratively between researchers at the University of Sheffield and the Foundation for Traditional Chinese Medicine, and was supported by a trial advisory group with an external chair and a patient representative. The study design incorporated a pilot study of outcomes for low back pain following acupuncture, undertaken by the Foundation.[47]

Ethical approval

Ethics approval for the study was obtained from York Local Research Ethics Committee.

Recruitment methods

Recruitment of Acupuncturists

Suitable local acupuncturists were identified by the Foundation for Traditional Chinese Medicine. Six acupuncturists were required for the trial. One acupuncturist left the UK soon after the start of the trial and was replaced. Each of the seven participating acupuncturists practised at one of three acupuncture clinics in York: the teaching clinic at the Northern College of Acupuncture, the York Clinic and the Healing Clinic. All three clinics have established links with the Foundation for Traditional Chinese Medicine. The acupuncturists in the study had all completed the training required to register with BAcC. They each had between 5 and 18 years' experience of acupuncture practice at the start of the trial. All practitioners had full professional indemnity insurance. Practitioners were to be paid a set fee per visit. Retrospective claims for fees were to be made to the Health Authority via the study team.

Recruitment of GPs

The study began with a core group of 12 GPs and was later expanded to include all interested GPs in the York area to facilitate the recruitment of patients. A local GP acted as advisor to the study. This GP (MR) was involved in the development of the protocol and took on the role of briefing other GPs about the trial. The GP advisor organised a meeting with continuous medical education (CME) credits to inform interested GPs about the trial, and established initial contacts with 28 of the 126 GPs in York. The remaining 98 GPs were each sent a letter of introduction from the study team inviting them to participate in the trial. The researcher followed up all expressions of interest with a personal visit. Detailed study information packs were given out at these meetings, as well as desktop leaflet dispensers containing patient referral forms for the trial.

Recruitment of patients

Patients were recruited to the trial over an 18-month period from August 1999 to January 2001. Patients were recruited prospectively. GPs used broad study entry criteria to identify eligible patients during consultations for low back pain. Full eligibility was established at a later stage by the researcher. GPs were asked to: (1) tell the patients that the practice was participating in an NHS-funded trial that might involve the offer of acupuncture; (2) obtain the patient's consent to pass on contact details to the researcher; (3) provide patients with an information sheet concerning the study (Appendix 2) and (4) record the patient's contact details on a patient referral form should they be interested in participating. Where suitable patients declined to take part in the study at this point, GPs were asked to complete the referral form indicating their reason for refusal. GPs faxed completed patient referral forms to the research office as soon as possible after the consultation.

Inclusion and exclusion criteria

Eligibility criteria were applied by the researcher, who contacted patients by telephone, usually within 24 hours of receiving the patient referral form.

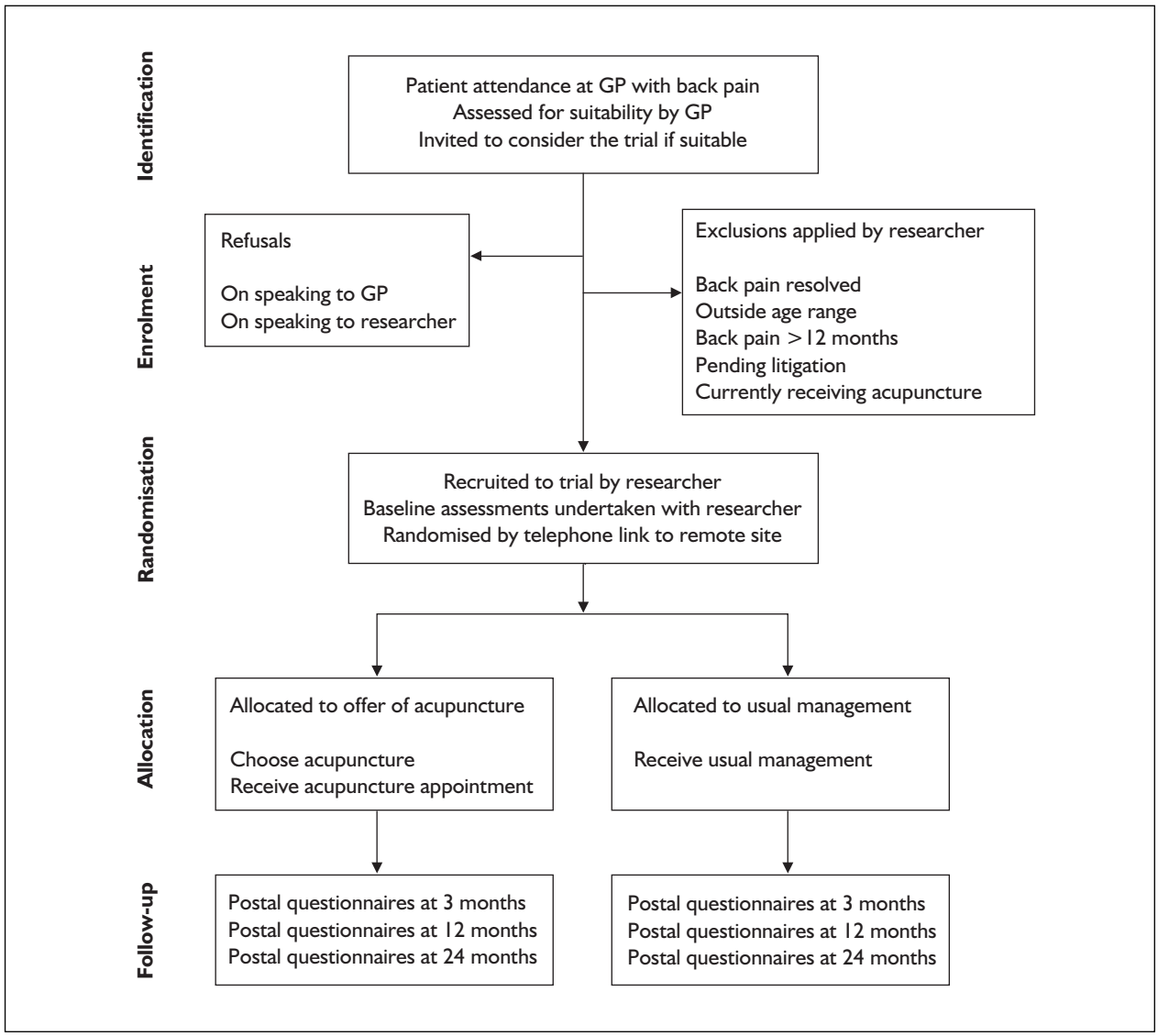

FIGURE 1 *Patients' progress through the stages of the trial*

Inclusion criteria

- Aged of 20–65 years
- presenting with low back pain
- assessed as suitable for primary care management according to CSAG guidelines
- current episode of low back pain of at least 4 weeks' duration and no longer than 12 months.

Exclusion criteria

- Possible spinal pathology (e.g. carcinoma)
- severe or progressive motor weakness or central disc prolapse
- past spinal surgery
- pending litigation
- bleeding disorders (e.g. haemophilia)
- currently receiving acupuncture treatment.

Consent

Eligible and interested patients received a home visit to discuss the study in more detail. The researcher ensured that the patient had received a patient information sheet, and gave a verbal explanation of the study to make sure the patient understood what was involved. If patients were eligible and agreed to participate in the study, a consent form was completed and signed by the patient and the researcher.

Baseline assessment and outcome measures

Baseline assessment was undertaken in the presence of the study researcher. Clinical assessments

TABLE 1 *Outcome measures and data collection tools*

Measure	Administration
Bodily Pain dimension of the General Health Status Profile SF-36 administered as part of the full SF-36 questionnaire[42,43]	Baseline, 3, 12 and 24 months
Present Pain Intensity scale of the McGill Pain Questionnaire[44]	Baseline, 3, 12 and 24 months
Oswestry Low Back Pain Disability Questionnaire[45,46]	Baseline, 3, 12 and 24 months
Short Form 36 Health-related Quality of Life Measure (SF-36). The SF-36 measures seven other dimensions of perceived health besides pain, including physical functioning, mental health and vitality[43,48]	Baseline, 3, 12 and 24 months
SF-6D:[49,50] a preference-based single index measure derived from the SF-36	Baseline, 3, 12 and 24 months
EuroQol 5D (EQ-5D):[51] included for economic analysis purposes	Baseline, 3, 12 and 24 months
Background and demographic questions (Appendix 3)	Baseline
Back pain experience questions (Appendix 4)[91]	Baseline, 3, 12 and 24 months
Patient satisfaction with overall care (Appendix 5)	3 months
Patient satisfaction with acupuncture care (Appendix 6)	3 months
Patient responses to acupuncture treatment questionnaire (Appendix 7)	3 months
Resource-use questionnaire (Appendix 8)	12 and 24 months

included the SF-36, Present Pain Intensity (PPI) scale from the McGill Pain Questionnaire, and the ODI. In addition, patients were asked to complete the EuroQol 5 Dimensions (EQ-5D), demographic questions and questions about their low back pain experience. The full range of outcome measures used is described in *Table 1*.

Randomisation procedure

A computer-generated, blocked randomisation sequence (nine cases per block) was provided by the study statistician (MC). The randomisation sequence was held by the principal investigator (KJT). Every effort was made to ensure the concealment of the randomisation sequence from the researcher doing the patient recruitment; the sequence was held in a secure location at the university, the researcher was not aware of the number of cases in each randomisation block, and individual patient allocation was conducted remotely via mobile telephone, once consent and baseline assessment had been obtained. The study researcher informed GPs by letter of each patient's allocation.

Interventions

Patients randomised to the offer of acupuncture and choosing to receive treatment were offered an appointment as soon as possible, to suit their commitments and available appointments. Study acupuncturists were informed that care should comprise an initial consultation and treatment, followed by up to nine further treatments. The precise number of treatments received was determined by clinical need, as judged by the acupuncturist. The initial consultation entailed a full history-taking and a diagnosis, made in terms of differentiation of syndromes in accordance with traditional acupuncture. This diagnosis guided the individual treatment to be offered to patients. Only disposable acupuncture needles were used. Other treatments, such as heat lamp, moxa and massage, were permitted and advice on rest and exercise was offered as appropriate. Treatment process notes, including TCM diagnosis, were completed at each session by the acupuncturists. The standardised treatment record pro forma was developed by a practitioner researcher (HMcP) and reflected the range of information that would usually be recorded in a traditional acupuncture session (Appendix 9). Patients were not offered a second course of free acupuncture care.

Patients receiving acupuncture continued to have access to normal management for their back pain, at the discretion of their GP. Patients choosing not to have acupuncture continued to receive normal management from their GP. Patients randomised to usual care continued to receive care organised by their own GP. The use of acupuncture treatment outside the trial by patients in either arm of the trial was monitored at follow-up.

Follow-up assessments

Baseline measures were to be completed immediately before randomisation in the presence of the researcher, at 3 months postrandomisation, and again at 12 and 24 months postrandomisation. Follow-up at all time-points was undertaken by post. To minimise the loss to follow-up, non-responders were followed up with up to two postal reminders and then offered a home visit by the researcher to complete the measures. If this failed, key outcome data were sought from non-responders by telephone.

Sample size and study power

The primary outcome measure was the difference between the baseline and 12-month score on the Bodily Pain dimension of the SF-36. The pilot study found a mean change in pain score of 35 points at 6 months (SD 19.3). A difference, or change, of between 5 and 10 points on SF-36 dimension scores is widely thought to represent a clinically significant benefit.[42]

Allowing for a 10–15% dropout rate, the prestudy power calculation indicated that 100 patients were needed in each group to detect a difference in outcome between the groups of 10 points (SD 19.3) for the SF-36 Pain score at 12 months, at 90% power and a 5% significance level. This was estimated to give a power of 90% to detect a difference of 0.5 points on the PPI scale of McGill Pain Questionnaire. A difference of 1 point is generally considered to be clinically significant on this scale. In the pilot study, changes in the other dimensions of the SF-36 were found to have both larger and smaller standard deviations, though broadly similar, and hence the power to detect differences in the other SF-36 dimensions will vary around the values for the Bodily Pain dimension.

The required number of patients was subsequently revised to allow for between-acupuncturist effects to be tested. This assumed a mean acupuncture plus acupuncturist effect of 10 points on the SF-36 pain score, and between-acupuncturist SD = 7.8 (so that 90% of acupuncturists have an effect >0.0 assuming a normal distribution of effect sizes). With these assumptions, using the method of Day and Graham,[52] it was calculated that there would be an approximately 85% chance of detecting heterogeneity between acupuncturists with six therapists each treating 20 patients. Assuming some variability between acupuncturists in the numbers each actually treated, the chance of detecting significant heterogeneity in effectiveness of acupuncturists was expected to be around 80%, with six acupuncturists treating a total of 120 patients.

The number of patients offered acupuncture increased to 160, and the number in the normal management group was decreased from 100 to 80 without loss of power in the main comparison.

Clinical data analysis

Primary clinical outcomes were assessed at 12 and 24 months by comparing mean scores on the SF-36 Bodily Pain dimension in the two randomisation groups, with all patients offered acupuncture comprising the intervention group. Data were entered into Statistical Package for the Social Sciences (SPSS) PC data sets and checked using random double entry to ensure accuracy.

Missing data

Item-level missing data were imputed where appropriate, using the methods recommended by Ware and Sherbourne.[42] Some patient loss to follow-up is inevitable in any trial. This will be even more likely in trials located in primary care, and those seeking to measure longer term outcomes. The major undesirable effects of missing data in clinical trials are the introduction of biases and the loss of efficiency due to reduced sample size.[53] A comprehensive analysis was undertaken of the known characteristics of patients lost to follow-up to test for evidence of any difference between the randomisation groups. Data imputation was not undertaken as there is currently no standard method for handling missing longitudinal data in clinical trials.

Analysis methods

The allocation method produced two groups of patients: those randomised to the offer of acupuncture and those randomised to receive usual GP care. At recruitment, patients were told that the decision to have acupuncture, if offered, was theirs. The expectation was that some of the patients allocated to the offer of acupuncture would choose not to receive it. The main analysis was planned comparing the two randomisation groups, with all patients offered acupuncture comprising the intervention group. In the event, all patients offered acupuncture chose to receive it, although nine patients in the acupuncture offer arm did not attend for any treatment because their pain resolved before the first appointment.

Data were analysed using SPSS PC 11.5 and STATA V8. The analysis was performed on an ITT basis, with SF-36 Pain scores as the primary outcome at 12 and 24 months. Analysis of covariance (ANCOVA) was undertaken for 12- and 24-month outcomes, with baseline SF-36 Pain scores as a covariate. Analysis of the primary outcome was undertaken blind to treatment allocation by a statistician with no prior involvement in the trial (SW). Sensitivity analysis was undertaken using a regression model developed on the 3-month data (Appendix 10). Exploratory analysis was also undertaken excluding 11 cases who reported being unable to work owing to their low back pain at recruitment. The trial exclusion criterion of back pain for less than 12 months was intended to restrict patients in this category, and all 11 cases were randomised to the offer of acupuncture (of these 11 patients, ten were followed up at 12 months and eight at 24 months).

The adjusted estimated effect size and 95% confidence intervals are reported for all results. Subgroup analysis was performed according to the protocol, to test for heterogeneity between acupuncturists. Additional subgroup analysis was undertaken for hypothesis generation only.

Economic analysis methods

The economic analysis was designed as a cost-effectiveness study with the main outcome measure being the SF-6D.[49,50] The EQ-5D[51] was used as a secondary outcome measure. The incremental cost-effectiveness ratio (ICER) for a series of acupuncture treatments compared with normal treatment for lower back pain was estimated. Both an NHS and a societal perspective were adopted for the estimation of costs, with NHS treatment costs, private sector treatment costs and costs due to lost productivity considered.

Costs

NHS treatment costs included all NHS contacts with primary and secondary healthcare services and treatments and medications administered. Private sector treatment costs included all healthcare purchased privately by the patients in the trial. Details of healthcare utilisation were collected from two main sources, GP notes and a resource-use questionnaire to individual trial patients. GP notes were examined for all patients to collect information on the number and type of GP and practice nurse contacts and drugs prescribed. Other healthcare usage over the 24-month period was collected by means of a self-completion questionnaire, which was administered to all patients included in the trial at two time-points, 12 months and 24 months. Information was collected on hospitalisations, outpatient visits (pain clinic, for physiotherapy, and other visits), physiotherapy based at general practice, chiropractic and osteopathy services during the preceding 12 months.

Patient self-reports may be criticised on the basis that they may be subject to recall bias. However, it was considered that, at a practical level, this method offered an appropriate and efficient mechanism for obtaining this information. To minimise the risk of recall bias in relation to hospital episodes in relation to low back pain, the date and duration of hospital inpatient stays were collected from the resource-use questionnaire and cross-referenced directly with the hospital concerned. Patients were also asked to document their use of private healthcare treatments (physiotherapy, acupuncture, osteopathy, chiropractic services and other services or products).

The resource-use questionnaire also included questions relating to the estimation of costs due to lost productivity, including employment status and time lost from work due to lower back pain.

To promote generalisability in the findings of economic evaluation studies in healthcare it is advisable to use national sources for unit cost data. Local unit costs may be used in the absence of national costs, but these are often specific to the area under consideration and hence are not easily transferable to other geographical areas. Unit costs for all resources used by trial patients were obtained for the financial year 2001–02 and were obtained using national sources wherever possible, including the Personal Social Services Research Unit Database,[54] NHS Reference Costs[55] and the British National Formulary.[56] Where national costs were unavailable, local unit costs were obtained from the healthcare centres in the trial location (Appendix 11). Time lost from work due to lower back pain was valued using age- and gender-adjusted daily wage rates from the Office for National Statistics, New Earnings Survey of 2003.[57]

Health outcome measures

The EQ-5D and SF-6D were used to assess health-related quality of life. Patients in the trial were surveyed at baseline, and at 3, 12 and 24 months. The responses to the EQ-5D were converted into utility scores using the tariff of values generated

from the York Measurement and Valuation of Health (MVH) project.[58] The SF-36 was transformed into the SF-6D, a single preference-based measure of health, using the algorithm derived by Brazier and colleagues.[50] The utilities generated from each measurement instrument were plotted against time, and the quality-adjusted life-year (QALY) gain for each patient was calculated using area under the curve methods.[59]

Statistical techniques

The sample size for the study was based on expected differences in the pain dimension of the SF-36, which was the main clinical outcome measure for the clinical trial. All clinical and economic analyses were carried out on an ITT basis. Resource use, costs and health outcomes data were analysed using SPSS version 10.0. Despite the potential skewness of cost data, the arithmetic mean and standard *t*-test-based confidence intervals are considered appropriate for comparing mean costs between two groups and the most relevant statistics for informing decision-making.[60] The validity of the results was confirmed using bootstrapping, where the original data were used to provide an empirical estimate of the sampling distribution through repeated resampling from the observed data.[61] The primary analysis reflected a comparison of costs to the NHS and QALYs measured using the SF-6D for the 24-month period of the trial. The cost-effectiveness of the intervention to the NHS was assessed bearing in mind the recent guidance from the National Institute for Clinical Excellence (NICE) relating to the acceptability of a new technology. The guidance indicates that a ceiling ratio of £20,000 per QALY represents the threshold of what the NHS can afford to pay for additional QALYs, unless there are other arguments for adopting the technology.[62]

A secondary analysis was conducted using the EQ-5D to calculate QALYs. Where EQ-5D data were missing owing to a failure to administer the instrument at 0 and 3 months, values were imputed based on an ordinary least squares regression model estimated using the observed EQ-5D score as the dependent variable and the responses to the individual items of the SF-36 at 0 and 3 months, respectively, as the independent variables. Subsequent analyses were conducted using social costs and excluding the 11 patients who were permanently unable to work as a consequence of their low back pain. Both costs and outcomes occurring during the 12–24-month period were discounted at 3.5%, the current recommended rate for public sector projects.[63]

Chapter 3

Recruitment and treatment processes

GP recruitment

A total of 43 GPs from 18 different practices agreed to participate, and 39 GPs from 16 practices referred patients into the trial. Recruitment was not practice based; not all GPs from these 16 practices referred patients. The 39 GPs referred an average of 7 patients into the trial.

Patient recruitment

Over an 18-month recruitment period, 289 patients were identified by GPs as suitable for the trial. Of these, 281 met the formal study inclusion criteria when applied by the researcher, and 241 (85.8%) were recruited into the trial. Eight patients failed to meet the inclusion criteria for the trial at the point of telephone screening: five of these patients were outside the age range for the trial, one patient had pending litigation relating to their low back pain, one patient had suffered from their current episode of low back pain for longer than the 12-month cut-off period, and one patient was currently receiving acupuncture at one of the clinics involved.

A further 40 patients identified by GPs were not recruited into the trial: 12 patients (4.3%) had back pain which resolved between referral and randomisation, and 13 patients (4.6%) invited to participate in the trial by their GP declined to do so. The most frequent reason recorded by GPs was that they did not want acupuncture. A further 15 patients (5.3%) decided not to participate after learning more about the trial from the researcher, most often because they did not feel that they had time to participate.

In total, 241 patients were recruited into the study (85.8%); 160 were randomised to the offer of acupuncture and 81 to usual GP management (*Figure 2*).

Factors which encouraged or reduced recruitment

Many trials conducted in primary care experience difficulties with GP and patient recruitment and fail to achieve the required target. This trial succeeded in reaching its target, with a variable response from individual GPs. A survey of participating GPs was conducted after patient recruitment to the study had ceased and achieved a 73% response rate (Appendix 12). Responses indicated that the factors that encouraged GPs to refer patients into the trial were: a belief in the potential benefits of acupuncture, a wish to support the research project, the fact that the intervention provided an additional treatment option, and positive feedback from patients who had received acupuncture. The main factors that reduced GPs' willingness to participate in the trial included: other ongoing treatment modalities, the fact that only 66% of patients would be allocated to the offer of acupuncture, and concerns about time constraints within the consultation.

All responding GPs reported that they found the entry requirements 'clear', most found them 'easy to apply' and 80% reported that the requirements were 'easy to remember'.

None of the participating GPs estimated that they had discussed the trial with all eligible patients; most estimated that they had done so with 40–60% of eligible patients. The main reasons given for not discussing the trial with appropriate patients were: simple forgetfulness (mentioned by 75% of responding GPs), time constraints (mentioned by 52%) and co-morbidity or patient distress (also mentioned by 52%). The best estimate is that the trial recruited 50% of the potential demand for the acupuncture service from the participating practices.

Baseline characteristics of patients

Table 2 gives the demographic characteristics of the entire sample of 241 patients. The mean age of the participants was 42.6 years and 60.7% were women. Almost all of the sample described their ethnic origin as 'white'. At baseline, 79% were working either full or part time, and 21% reported having left full-time education after the age of 18 years. Fifteen patients reported that they were permanently unable to work for health reasons, 11 of these because of low back pain. Just over a

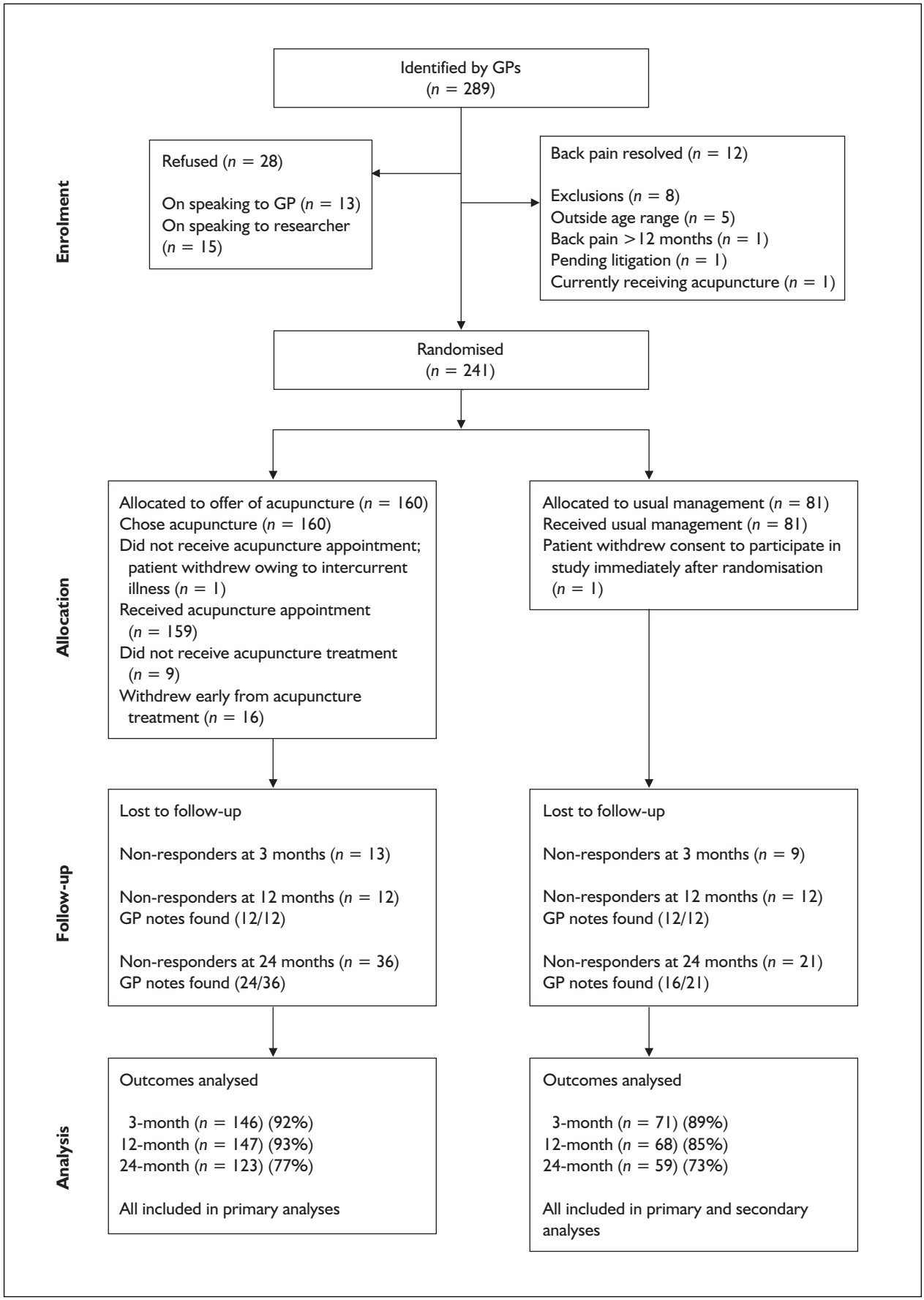

FIGURE 2 *Patients progress through the trial: CONSORT flowchart*

TABLE 2 *Demographic profiles of 241 cases at baseline*

Characteristic		Entire sample (n = 241)	
Age (years)			
	Mean (SD)	42.6	(10.7)
	Range	20–64	
		n	**(%)**
Gender			
	Male	96	(39.8)
	Female	145	(60.2)
Ethnicity			
	White	239	(99.2)
	Non-white	2	(0.8)
Work status			
	Working full-time	128	(53.1)
	Working part-time	63	(25.9)
	Housewife	20	(8.4)
	Retired	11	(4.6)
	Student	4	(1.7)
	Permanently unable to work owing to LBP	11	(4.6)
	Permanently unable to work for other health reasons	4	(1.7)
Education: age (years) on leaving full-time education			
	<19	191	(79.5)
	≥19	50	(20.5)
Ever used acupuncture before			
	Yes	64	(26.6)

LBP, low back pain.

quarter of the sample reported ever having used acupuncture before.

Treatment allocation

Patients were randomised in a 2:1 ratio in favour of the intervention: 160 patients (66.4%) were randomised to the offer of up to ten acupuncture treatments delivered in private practice by a qualified acupuncturist and paid for by York Health Authority, and 81 patients (33.6%) were randomised to receive pragmatic GP management with no restrictions on the care received ('usual care'). Two patients withdrew from the study after randomisation, providing no data: one withdrew from acupuncture because of intercurrent illness, and the other after learning that they had been randomised to usual care, despite full prior understanding that this might be the case.

This resulted in a total of 239 patients: 159 in the 'acupuncture offer' arm, and 80 in the 'usual care' arm. All patients randomised to the offer of acupuncture chose to receive acupuncture. First appointments were usually made within 2 weeks of allocation (median 10 days, interquartile range 7 to 15 days).

Comparison of patient characteristics by allocation group

There were no major differences between randomised groups at baseline with respect to most demographic characteristics: history, location and severity of low back pain; patient expectations regarding their low back pain before randomisation, the presence of co-morbidity, baseline clinical assessments, or known aspects of their previous management of low back pain (*Tables 3–7*). None of the differences was significant apart from the fact that patients allocated to the acupuncture group were more likely to report that they were permanently unable to work for health reasons (*Table 3*).

Patient follow-up rates

Acceptable follow-up rates were achieved in both groups at 3, 12 and 24 months (*Figure 2*). Follow-

TABLE 3 *Demographic profiles at baseline by allocation group*

Characteristic		Acupuncture (*n* = 159)	Usual care (*n* = 80)
Age (years)			
	Mean (SD)	42.0 (10.8)	44.0 (10.4)
	Range	20–64	26–64
		***n* (%)**	***n* (%)**
Gender			
	Male	60 (37.7)	34 (42.5)
	Female	99 (62.3)	46 (57.5)
Ethnicity			
	White	159 (100)	78 (97.5)
	Non-white	0 (0)	2 (2.5)
Work status			
	Working full-time	82 (51.6)	45 (56.3)
	Working part-time	40 (25.2)	22 (27.5)
	Housewife	13 (8.2)	7 (8.8)
	Retired	7 (4.4)	4 (5.0)
	Student	3 (1.9)	1 (1.3)
	Permanently unable to work owing to low back pain	11 (6.9)	–
	Permanently unable to work for other health reasons	3 (1.9)	1 (1.3)
Education: age (years) on leaving full-time education			
	<19	123 (77.4)	67 (83.8)
	≥19	36 (22.6)	13 (16.3)

TABLE 4 *Baseline characteristics by allocation group: history, location and severity of low back pain*

Characteristic		Acupuncture (*n* = 159)	Usual care (*n* = 80)
No. of weeks with back pain			
	Mean (SD)	17.1 (13.5)	16.7 (14.6)
	Range	4–48	4–48
		***n* (%)**	***n* (%)**
No. of previous episodes			
	None previously	25 (15.7)	13 (16.3)
	1–5 episodes	57 (35.8)	23 (28.8)
	>5 episodes	77 (48.4)	44 (55.0)
Presence of leg pain			
	Yes	106 (66.7)	59 (73.8)
	No	53 (33.3)	21 (26.3)
Frequency of back pain in past week			
	Every day	140 (88.1)	68 (85.0)
	Occasionally/never	19 (11.9)	12 (15.0)
Frequency of leg pain in past week			
	Every day	65 (40.9)	32 (40.0)
	Occasionally/never	94 (59.1)	48 (60.0)
Bothersomeness of back pain in past week			
	Extremely/very	89 (56.0)	45 (56.3)
	Moderately/slightly	68 (42.8)	32 (40.0)
	Not at all	2 (1.3)	3 (3.8)
Bothersomeness of leg pain in past week			
	Extremely/very	41 (25.8)	17 (21.3)
	Moderately/slightly	51 (32.1)	34 (42.5)
	Not at all	67 (42.1)	29 (36.3)

TABLE 5 *Patients' expectations and priorities before randomisation by allocation group*

Expectation		Acupuncture (*n* = 159)	Usual care (*n* = 80)
If you had to spend the rest of your life with your back as it is now how would you feel?			
	Terrible/unhappy	126 (79.3)	63 (78.8)
Importance of reducing your back pain?			
	Very important	137 (86.2)	66 (82.5)
Importance of increasing your activities?			
	Very important	126 (79.2)	57 (71.3)
Importance of reducing your medication?			
	Very important	97 (61.0)	48 (60.0)
Expectation of back pain in 6 months time?			
	Better	80 (50.3)	30 (37.5)
	Same/worse	78 (49.0)	49 (61.3)
	Don't know	1 (0.7)	1 (1.2)
Do you think acupuncture can work (in general)?			
	Yes	129 (81.1)	65 (81.3)
	No	1 (0.6)	0
	Don't know	29 (18.2)	15 (18.8)
Do you think your back pain will be helped by acupuncture?			
	Yes	111 (69.8)	51 (63.8)
	No	2 (1.3)	0
	Don't know	46 (28.9)	29 (36.2)

TABLE 6 *Baseline characteristics by allocation group: previous management of low back pain, co-morbidity and prior use of acupuncture*

Characteristic		Acupuncture (*n* = 159)	Usual care (*n* = 80)
Used medicine for LBP in past 4-weeks			
	Yes	140 (88.1)	72 (90.0)
	No	19 (11.9)	8 (10.0)
Taken days off work for back pain over last 4 weeks			
	Yes	49 (30.8)	26 (32.5)
Days off work for those who took time off	Mean (range)	10.2 (1 to 28)	11.2 (1 to 28)
Ever received injections into back for LBP			
	Yes	29 (18.2)	11 (13.8)
	No	130 (81.8)	69 (86.3)
Ever received disability benefits for LBP			
	Yes	15 (9.4)	5 (6.3)
	No	144 (90.6)	75 (93.8)
Have any other major health problem(s) in addition to back pain?			
	Yes	44 (27.7)	25 (31.3)
	No	115 (72.3)	55 (68.8)
Ever used acupuncture (for any reason)			
	Yes, private	20 (12.6)	7 (8.8)
	Yes, NHS	21 (13.2)	15 (18.8)

TABLE 7 *Baseline clinical assessments by allocation group*

Assessment results	Acupuncture offer Mean (SD)	Usual care Mean (SD)
SF-36 Bodily Pain Score	30.8 (16.1)	30.4 (18.0)
PPI	2.6 (1.0)	2.7 (1.0)
ODI	33.7 (15.4)	31.4 (14.2)
SF-36 Physical Function	55.5 (25.2)	60.0 (21.8)
SF-36 Social Functioning	61.2 (27.0)	65.4 (30.5)
SF-36 Role-Physical	21.7 (31.9)	23.8 (34.0)
SF-36 Role-Emotional	64.3 (43.9)	65.8 (43.1)
SF-36 Mental Health	66.6 (17.9)	68.6 (16.1)
SF-36 Vitality	45.7 (19.4)	46.8 (20.7)
SF-36 General Health Perceptions	63.5 (17.8)	63.8 (20.1)
SF-36 Health Transition	44.7 (21.5)	42.5 (20.0)

TABLE 8 *Data availability for 239 patients (excluding two patients who withdrew from the study immediately after randomisation)*

Measure	Baseline		3-month follow-up		12-month follow-up		24-month follow-up	
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Assessment data								
SF-36	239	(100)	17	(90.8)	15	(90.0)	182	(76.2)
PPI	239	(100)	216	(90.4)	192	(80.3)	162	(67.8)
ODI	239	(100)	217	(90.8)	193	(80.8)	163	(68.2)
EQ-5D	137[a]	(57.3)	138	(57.7)	211	(88.3)	163	(68.2)
Satisfaction with care received			208	(87.0)				
Worry about back pain			216	(90.4)	192	(80.2)	161	(67.4)
Back pain-free months in past year at 24 months							147	(61.5)
Medical record data					***Months 1–12***			
Comprehensive medical records					227	(95.0)		
Limited notes					12	(5.0)		
							Months 13–24	
Comprehensive medical records							215	(90.0)
Limited notes							7	(2.9)
No notes available							17	(7.1)
Acupuncture treatment booklets			150	(100)				
Patient interview data for sample of patients in the acupuncture arm interviewed at 3 months			12	(100)				
Practitioner interview data completed after the treatment phase			6	(100)				

[a] EQ-5D was included for the purposes of the cost-effectiveness analysis. Owing to an administrative oversight, the EQ-5D was not included in the patient booklets from the outset. As a result 102 patients do not have baseline EQ-5D scores, and 79 are missing 3-month EQ-5D scores. All patients have SF-36 scores, from which it is possible to impute EQ-5D scores (see Chapter 5, section 'Cost-effectiveness analysis', p. 47).

up data were obtained at 3 months for 92% (146/159) and 92% (71/80) of patients in the acupuncture group and usual care group, respectively. At 12 months the response rates were similar: follow-up data were obtained for 93% (147/159) of the acupuncture offer group and 85% (68/80) of the usual care group. As anticipated, the follow-up rate at 24 months was lower. However, the follow-up rate was similar in both groups: 77% 123/159) in the acupuncture group and 73% (59/80) in the usual care group.

If postal reminders and visits failed to produce completed outcome questionnaires, patients were

requested to give verbal responses over the telephone to a limited set of key outcome questions: 11.6% of all responses were completed by telephone at 12 months and 9.9% at 24 months. The numbers of responses available for analyses assessing outcomes are shown in *Table 8*.

Characteristics of patients lost to follow-up

Tables 9–12 show the characteristics of patients lost to follow-up compared with those who remained in the study at 12 and 24 months. At 12 months the numbers lost to follow-up in both groups were small (acupuncture =12, usual care = 12) and there was no evidence of any difference between those followed up and those lost to follow-up, apart from in their ages: those lost to follow-up at 12 months were younger than those who completed follow-up ($p = 0.02$). This was observed in both randomisation groups and so there was no evidence of any difference in ages between randomisation groups with respect to loss to follow-up ($p = 0.62$).

Inevitably, more patients were lost to follow-up at 24 months (acupuncture = 36, usual care = 21). Those who were lost to follow-up were younger than those who completed follow-up ($p = 0.02$) and seemed to have poorer SF-36 pain scores at 3 months ($p = 0.05$). Once again, this pattern was observed in both randomisation groups, indicating that there was no evidence of any difference between the randomisation groups in those lost to follow-up ($p = 0.39$ and $p = 0.89$ respectively).

Follow-up of those not completing acupuncture care

Within the acupuncture group, there was evidence that those lost to follow-up at 12 months had received fewer acupuncture treatments ($p = 0.004$). This effect was not observed at 24 months. Nine patients randomised to receive acupuncture did not receive any treatment because their back pain resolved before their first appointment; eight of these were followed up at 12 months and six were followed up at 24 months. A further 16 patients withdrew from treatment before they had received the full number of treatments advised by the acupuncturist, 13 of whom were followed up at 12 months and ten at 24 months.

Process of acupuncture treatment

The process and content of the acupuncture treatment delivered in the trial are described in this section according to the international Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) guidelines.[64] Further details of the acupuncture diagnosis and treatment received have been published elsewhere.[65] For definitions of the terms used in acupuncture, see the Glossary.

Practitioner details

Background data on the six acupuncturists, who treated at least 20 patients each, are shown in *Table 13*. A seventh practitioner treated two trial patients before relocating and leaving the trial.

Number of treatments received

Information on acupuncture treatment was collected using a standard form completed by practitioners at each appointment (Appendix 9), and by semistructured interviews with each practitioner undertaken after all trial treatment was completed. The trial protocol allowed for up to ten treatments per patient, the precise number being agreed between patient and practitioner. Nine patients randomised to the offer of acupuncture and choosing to have acupuncture did not receive any treatment. In total, 1285 treatments were provided, an average of 8.1 treatments per patient in the acupuncture intervention arm (range 0–10) and 8.6 (range 1–10) among the 150 patients who received acupuncture treatment. More than half the patients received the maximum of ten treatments (*Table 14*). In most cases, patient treatment was completed within 3 months of entering the trial.

Termination of acupuncture therapy

Fifty-six per cent of patients received the maximum allowable ten treatments. Acupuncturists were asked the reason for the termination of acupuncture treatment if fewer than ten treatments were given. In most cases where the patient received less than ten treatments this was by agreement between the practitioner and the patient, where further treatment was not felt to be necessary. Sixteen patients withdrew from treatment. Patients cited the following reasons for withdrawal: being 'too busy' ($n = 4$), lack of response to treatment ($n = 3$), adverse events ($n = 4$) or a mixture of these reasons ($n = 5$). Seventeen patients in the acupuncture group paid for further private acupuncture treatment in the 12 months following randomisation.

Traditional acupuncture diagnosis

Practitioners recorded a traditional acupuncture diagnosis at the first consultation using a standardised form (Appendix 9). The presenting

TABLE 9 *Characteristics of patients followed up and those lost to follow-up (12 months)*

Characteristic	Acupuncture		Usual care		Logistic regression for difference between groups	
	Followed up (%)	Lost to follow-up (%)	Followed up (%)	Lost to follow-up (%)	*p*-Value comparing follow-up groups	*p*-Value for interaction[a]
At baseline	(*n* = 147)	(*n* = 12)	(*n* = 68)	(*n* = 12)		
Gender = male	37.4	41.7	42.6	41.7	0.77	0.8
Presence of leg pain at entry	67.3	58.3	75.0	66.7	0.79	0.98
Other major health problem reported at entry	28.6	16.7	29.4	41.7	0.26	0.23
Thinks acupuncture may help their back problem at entry	71.4	50.0	64.7	58.3	0.25	0.23
At 3 months	(*n* = 134)	(*n* = 6)	(*n* = 61)	(*n* = 7)		
Dissatisfied with overall care received	12.0	16.7	19.7	42.9	0.72	0.38
Happy to try acupuncture again	91.3	83.3			0.56	

[a] This assesses the hypothesis that the pattern of loss to follow-up is the same in the two randomisation groups.

TABLE 10 *Clinical characteristics of patients followed up and those lost to follow-up (12 months)*

Characteristic	Acupuncture		Usual care		Two-way ANOVA for difference between groups	
	Followed up Mean (SD)	Lost to follow-up Mean (SD)	Followed up Mean (SD)	Lost to follow-up Mean (SD)	*p*-Value comparing follow-up groups	*p*-Value for interaction[a]
At baseline	(*n* = 147)	(*n* = 12)	(*n* = 68)	(*n* = 12)		
No. of acupuncture treatments received	8.3 (2.7)	5.8 (4.6)			0.004	
Age (years)	42.4 (10.7)	35.9 (10.6)	44.6 (10.5)	40.4 (9.2)	0.02	0.62
Weeks with back pain	17.1 (13.5)	17.3 (14.3)	16.1 (14.5)	20.2 (14.8)	0.48	0.52
Past episodes of low back pain	2.4 (0.7)	2.0 (0.7)	2.4 (0.8)	2.6 (0.7)	0.70	0.07
SF-36 Physical Function score	55.8 (25.6)	51.7 (20.9)	60.1 (21.1)	58.8 (26.6)	0.60	0.79
SF-36 Pain score	30.9 (16.4)	28.7 (12.9)	30.7 (18.1)	28.7 (18.0)	0.56	0.97
At 3 months	(*n* = 134)	(*n* = 6)	(*n* = 61)	(*n* = 7)		
SF-36 Pain score	61.3 (23.2)	50.0 (16.9)	56.4 (26.0)	47.2 (20.4)	0.13	0.87

[a] This assesses the hypothesis that the pattern of loss to follow-up is the same in the two randomisation groups.
ANOVA, analysis of variance.

TABLE 11 *Characteristics of patients followed up and those lost to follow-up (24 months)*

Characteristic	Acupuncture		Usual care		Logistic regression for difference between groups	
	Followed up (%)	Lost to follow-up (%)	Followed up (%)	Lost to follow-up (%)	*p*-Value comparing follow-up groups	*p*-Value for interaction[a]
At baseline	(*n* = 123)	(*n* = 36)	(*n* = 59)	(*n* = 21)		
Gender = male	35.8	44.4	39.0	52.4	0.85	0.78
Presence of leg pain at entry	57.7	57.7	78.0	62.9	0.42	0.25
Other major health problem reported at entry	26.0	33.3	28.8	38.1	0.77	0.92
Thinks acupuncture may help their back problem at entry	70.7	66.7	67.8	52.4	0.79	0.49
At 3 months	(*n* = 134)	(*n* = 6)	(*n* = 61)	(*n* = 7)		
Dissatisfied with overall care received	412.4	11.1	17.0	40.0	0.69	0.32
Happy to try acupuncture again	91.2	88.5			0.73	

[a] This assesses the hypothesis that the pattern of loss to follow-up is the same in the two randomisation groups.

TABLE 12 *Clinical characteristics of patients followed up and those lost to follow-up (24 months)*

Characteristic	Acupuncture		Usual care		Two-way ANOVA for difference between groups	
	Followed up Mean (SD)	Lost to follow-up Mean (SD)	Followed up Mean (SD)	Lost to follow-up Mean (SD)	*p*-Value comparing follow-up groups	*p*-Value for interaction[a]
At baseline	(*n* = 123)	(*n* = 36)	(*n* = 59)	(*n* = 21)		
No. of acupuncture treatments received	8.2 (2.7)	7.5 (3.6)			0.20	
Age (years)	42.5 (10.7)	39.9 (11.2)	45.5 (10.6)	40.0 (8.9)	0.02	0.39
Weeks with back pain	17.0 (13.3)	17.3 (14.1)	16.0 (14.1)	18.7 (15.9)	0.50	0.58
Past episodes of low back pain	2.3 (0.7)	2.3 (0.7)	2.4 (0.8)	2.4 (0.7)	0.88	0.94
SF-36 Physical Function score	56.3 (24.9)	52.7 (26.3)	59.9 (20.8)	60.0 (25.0)	0.66	0.63
SF-36 Pain score	30.8 (16.6)	30.9 (14.6)	29.9 (18.7)	31.7 (16.2)	0.73	0.75
At 3 months	(*n* = 118)	(*n* = 28)	(*n* = 55)	(*n* = 9)		
SF-36 Pain score	62.3 (22.4)	54.8 (24.9)	57.4 (26.9)	48.6 (18.5)	0.05	0.89
At 12 months	(*n* = 123)	(*n* = 24)	(*n* = 59)	(*n* = 16)		
SF-36 Pain score	64.6 (25.3)	61.1 (27.8)	58.9 (22.2)	54.3 (22.5)	0.87	0.9
At 24 months	(*n* = 120)	(*n* = 27)	(*n* = 57)	(*n* = 18)		
GP visits for back pain	1.3 (1.7)	0.7 (0.8)	1.1 (1.3)	0.4 (0.9)	0.24	0.11
Medication costs for LBP (£)	12.0 (35.2)	6.0 (11.8)	6.2 (16.0)	4.4 (13.5)	0.46	0.66

[a] This assesses the hypothesis that the pattern of loss to follow-up is the same in the two randomisation groups.

TABLE 13 *Characteristics of acupuncturists and treatment given*

	Practitioner						Mean for all practitioners
	A	B	C	D	E	F	
Duration of initial training (years)	3	3	5	3	2	3	3.2
Location of initial training	UK	UK	China	UK	UK	UK	–
Years in practice	5	18	18	9	18	9	12.8
No. of patients treated	26	21	20	27	29	25	24.7
Mean no. of needles used per treatment	9.1	12.0	9.8	10.4	10.4	6.0	9.6

TABLE 14 *Number of acupuncture treatments per patient*

No. of treatments	Frequency	Valid (%)
0	9	5.7
1	3	1.9
2	1	0.6
3	2	1.3
4	3	1.9
5	7	4.4
6	15	9.4
7	9	5.7
8	5	3.1
9	16	10.1
10	89	56.0
Total	159	100.0

syndromes show that the predominant primary syndrome was qi and blood stagnation, followed by kidney deficiency and then bi syndrome. Fifty-eight per cent of patients were diagnosed as having both a primary and a secondary syndrome. The predominant secondary syndrome was kidney deficiency. The majority of patients (88%) received a diagnosis of qi and blood stagnation either as a primary or a secondary syndrome, 28% of bi syndrome and 53% of kidney deficiency. A further diagnostic category of 'other' was also included as an option: a total of 20 patients had other syndromes diagnosed, most commonly liver qi stagnation. For analysis purposes, traditional acupuncture diagnosis has been used to classify patients into two broad groups that have meaning in TCM terms: those with kidney deficiency (53%) and those without kidney deficiency (46%).

Acupuncture needling

Practitioners customised the treatment time for individual patients, usually 10–30 minutes (range 5–40 minutes). All practitioners attempted to attain de qi most of the time. However, de qi was not always sought, and not always attained. In sensitive patients, needles were sometimes inserted without obtaining de qi. Acupuncturists used an average of 9.6 needles per treatment (range 6–12).

A total of 177 different acupuncture points was used throughout the trial. Certain points were used sufficiently often to constitute at least 2% of the total (*Table 15*). Points were used both bilaterally and unilaterally. Needles used were normally 25 or 40 mm long and between 0.20 and 0.30 mm in diameter.

Points from the bladder and the gallbladder channels were much used, 38.4% and 14.9% respectively, as well as huatuojiaji points (22.9%). The most commonly used points were BL-23 and the two lowest huatuojiaji points.

Points selected were often a combination of local points (such as BL-23, BL-26, BL-53, BL-54 and GB-30 as well as lower lumbar huatuojiaji points) and distal points (such as BL-40, BL-60, GB-34 and GB-40). Practitioners aimed to balance these points with others, focused on underlying diagnostic categories, such as bi syndrome and kidney deficiency, key points for the latter being BL-23 and KID-3.

Association between diagnosis and needling treatment

Whether diagnosis determined treatment was assessed for one specific relationship: that between a diagnosis of kidney deficiency and the use of the point kidney 3, which is strongly indicated for kidney deficiency. Analysis using the χ^2 test showed a highly significant association ($p < 0.01$). For the other two syndromes, qi and blood stagnation and bi syndrome, the primary points used would be expected to be local to the area of pain, and therefore not amenable to tests of association with the syndromes.

Auxiliary treatments

Auxiliary treatments were used by all practitioners, but to varying degrees. Moxa was used in 17.7% of treatments. Practitioners reported using moxa to target cold bi or kidney yang deficiency. Other commonly used adjuncts to needling were massage (42.2%), acupressure (12.8%), cupping (4.5%) and

TABLE 15 *Acupuncture points used on at least 2% of all occasions*

	Practitioner						Total
	A	B	C	D	E	F	
Bladder channel points							
BL-23	106	152	4	117	6	64	449
BL-26	118	4	–	3	157	7	289
BL-32	43	50	8	12	57	39	209
BL-40	76	41	28	31	143	19	338
BL-53	43	31	3	8	191	52	328
BL-54	62	63	17	23	67	11	243
BL-60	47	50	17	33	70	11	228
Total	663	747	193	344	868	288	3103 (38.4%)
Gallbladder channel points							
GB-30	34	46	2	98	128	21	329
GB-34	16	28	84	71	155	7	361
Total	105	153	165	285	343	150	1201 (14.9%)
Kidney channel points							
KID-3	17	89	9	19	33	71	238
All	19	96	10	20	33	82	260 (3.2%)
Huatuojiaji points							
Huatuojiaji-L3	73	10	37	63	72	–	255
Huatuojiaji-L4	103	42	110	68	162	1	486
Huatuojiaji-L5	104	12	91	47	220	1	475
All	418	164	293	435	526	12	1848 (22.9%)
Ahshi points							
All	22	15	15	91	90	2	235 (2.9%)
Shiqizhuxia (extra point)							
All	52	40	1	46	71	–	210 (2.6%)
All other points							
All	171	165	236	309	132	205	1218 (15.1%)

Chinese herbs (3.4%). Practitioners reported using massage and acupressure briefly and early on in the treatment session, to enable accurate localisation of the back pain, to refine point selection and to build a stronger therapeutic relationship with the patient.

Adjunctive treatments received from acupuncturists

Acupuncturists also reported giving self-help advice to patients, most commonly diet (11.3%), yoga exercises (3.3%), other specific exercises (3.0%) and relaxation exercises (2.6%). Practitioners reported prescribing yoga or stretching exercises to move a patient's low back qi, relaxation exercises to calm the shen, and dietary change to strengthen the spleen, tonify the qi and help to clear damp bi.

Usual care received

Information on the care received by all patients in the trial was collected from the patients at 3 months.

Treatments reported during 3 months from recruitment

The profile of treatments reported by group allocation is shown in *Figure 3*. For patients in the trial, usual care commonly entailed a mixture of physiotherapy, medication and recommended back exercises. One in five patients randomised to usual care reported no treatment during the first 3 months of the trial. Eight patients in the control group reported that they had received acupuncture during the first 3 months of the trial. Further investigation revealed that this was

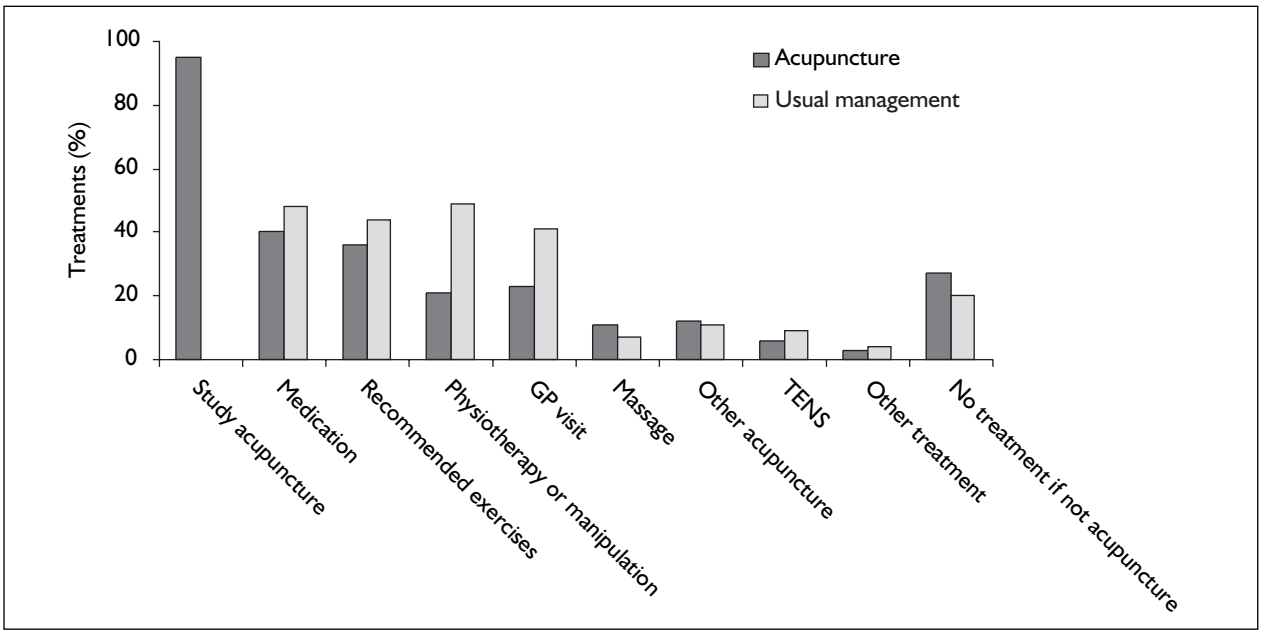

FIGURE 3 *Treatments received during 3 months from recruitment. TENS, transcutaneous electrical nerve stimulation*

TABLE 16 *Number of patients receiving additional acupuncture treatment during the trial period*

	Private acupuncture		NHS-delivered acupuncture	
	n	**(%)**	***n***	**(%)**
Months 1–12[a]				
Acupuncture group	17	(11.6)	5	(3.4)
Usual care group	2	(2.9)	10	(14.7)
Months 13–24[b]				
Acupuncture group	10	(8.1)	6	(4.9)
Usual care group	2	(3.4)	5	(8.5)

[a] Denominators = 147 for acupuncture group and 68 for usual care group.
[b] Denominators = 123 for acupuncture group and 59 for usual care group.

obtained as an adjunct treatment from a physiotherapist. None of the control group received traditional acupuncture treatment during this time.

Comparison of allocation groups by treatments received during acupuncture treatment phase

The treatment protocol for patients randomised to the acupuncture offer arm of the trial allowed additional treatment to be offered by their GP. These patients received similar treatments to the patients in the control group, but used them to a lesser extent (*Figure 3*). The implications of this use of additional care are considered further in the clinical and cost-effectiveness analyses. Nine patients randomised to the offer of acupuncture and choosing to have acupuncture did not receive any treatment. All these patients reported a resolution of their symptoms following randomisation and before taking up their first acupuncture appointment. Sixteen patients (20%) in the usual care group reported no treatment in the first 3 months of care.

Acupuncture treatment received outside the trial

The trial protocol allowed up to ten individualised acupuncture treatments per patient. No further NHS treatments with these practitioners were possible for these patients. Usual care commonly entailed a mixture of physiotherapy, medication and recommended back exercises. As this was a pragmatic trial, neither group was told not to

access acupuncture from other sources. During the treatment phase, a small proportion of patients in both groups received NHS-delivered acupuncture that was not part of the study, from either a physiotherapist or a GP offering a limited acupuncture intervention alongside other care (*Figure 3*). In addition, a number of patients reported having received private acupuncture during the trial follow-up period of 2 years. In the acupuncture group, this sometimes entailed continued treatment from the study acupuncturist, paid for directly by the patient. This was reported by a minority of patients, and was less common in the second year of the trial than in the first year (*Table 16*).

Chapter 4

Patient outcomes

SF-36 Bodily Pain

Mean SF-36 Pain scores increased significantly between baseline and 3 months in both groups ($p < 0.001$). This increased score was maintained or improved in both groups at 12 and 24 months (*Table 17*).

Tables 18–20 give the estimated between-group effects for SF-36 Pain scores at 3, 12 and 24 months.

A simple ANCOVA, with baseline bodily pain as covariate, based on 215 subjects, comparing bodily pain at 12 months between the two groups gave a (non-significant) estimated effect of 5.6 points (95% CI –1.3 to 12.5). A more complex ANCOVA, adjusted for relevant confounding variables was also performed, based on 212 subjects, with bodily pain at 12 months as the outcome or dependent variable. This gave a (non-significant) estimated effect between the groups of 6.0 points (95% CI –0.6 to 12.6, $p = 0.07$). Further analysis was

TABLE 17 *Mean SF-36 Pain scores at baseline, and 3, 12 and 24 months*

Period	Unadjusted mean scores					
	Acupuncture			Usual care		
	n	Mean	(SD)	*n*	Mean	(SD)
Baseline	159	30.8	(16.2)	80	30.4	(18.0)
3 months	146	60.9	(23.0)	71	55.4	(25.4)
12 months	147	64.0	(25.6)	68	58.3	(22.2)
24 months	123	67.8	(24.0)	59	59.5	(23.4)
	Difference			Difference		
	n	Mean	Standardised effect size[a]	*n*	Mean	Standardised effect size[a]
From baseline to 3 months	146	+29.3	1.8	71	+24.9	1.4
From baseline to 12 months	147	+33.0	2.0	68	+27.6	1.5
From baseline to 24 months	123	+37.0	2.3	59	+29.6	1.6

[a]Calculated here as the difference divided by the standard deviation of the baseline score.

TABLE 18 *Effect of intervention on SF-36 Pain scores at 3 months*

Model	Adjusted means				Estimated effect	95% CI	*p*-Value
	Acupuncture		Usual care				
	n	Mean	*n*	Mean			
All cases (adjusted for baseline SF-36 Pain score)	146	60.8	71	55.7	+5.1	–1.5 to 11.6	0.129
All cases (adjusted for baseline SF-36 and other baseline covariates[a])	144	60.7	70	55.2	+5.5	–0.7 to 11.7	0.079
Excluding cases permanently unable to work owing to back pain at baseline (adjusted for baseline SF-36 Pain score)	136	62.3	71	55.8	+6.5	0.02 to 13.0	0.050

[a] Duration of current episode of LBP in weeks, Expectations of back pain in 6 months, SF-36 Physical Functioning, reported pain in legs as well as back (see Appendix 13).

TABLE 19 *Effect of intervention on SF-36 Pain scores at 12 months*

Model	Adjusted means				Estimated effect	95% CI	*p*-Value
	Acupuncture		Usual care				
	n	Mean	*n*	Mean			
All cases (adjusted for baseline SF-36 Pain score)	147	64.0	68	58.4	+5.6	–1.3 to 12.5	0.111
All cases (adjusted for baseline SF-36 and other baseline covariates[a])	145	63.9	67	57.8	+6.0	–0.6 to 12.6	0.074
Excluding cases permanently unable to work owing to back pain at baseline (adjusted for baseline SF-36 Pain score)	137	65.5	68	58.5	+7.0	0.13 to 13.8	0.046

[a] Duration of current episode of LBP in weeks, Expectations of back pain in 6 months, SF-36 Physical Functioning, reported pain in legs as well as back (see Appendix 13).

TABLE 20 *Effect of intervention on SF-36 Pain scores at 24 months*

Model	Adjusted means				Estimated effect	95% CI	*p*-Value
	Acupuncture		Usual care				
	n	Mean	*n*	Mean			
All cases (adjusted for baseline SF-36 Pain score)	123	67.7	59	59.7	+8.0	0.7 to 15.3	0.032
All cases (adjusted for baseline SF-36 and other baseline covariates[a])	121	67.7	58	58.7	+9.0	1.8 to 16.2	0.015
Excluding cases permanently unable to work owing to back pain at baseline (adjusted for baseline SF-36 Pain score)	115	70.1	59	59.7	+10.4	3.2 to 17.6	0.005

[a] Duration of current episode of LBP in weeks, Expectations of back pain in 6 months, SF-36 Physical Functioning, reported pain in legs as well as back (see Appendix 13).

performed excluding those cases reporting their employment status as 'permanently unable to work due to low back pain' at the start of the trial, based on 205 subjects. This gave an estimated effect of 7.0 points at 12 months (95% CI 0.13 to 13.8, $p = 0.046$).

Similar analyses were performed on 24-month outcome data (*Table 20*). A simple ANCOVA, based on 182 subjects, comparing bodily pain at 24 months between the two groups gave an estimated effect of 8.0 points (95% CI 0.7 to 15.3, $p = 0.032$). The more complex ANCOVA, based on 179 subjects, gave an estimated effect of 9.0 points (95% CI 1.8 to 16.2, $p = 0.015$). Excluding the patients permanently unable to work owing to their low back pain at the start of the trial gave an estimated effect of 10.4 points at 24 months (95% CI 3.2 to 17.6, $p = 0.005$).

Summary of primary outcome results

In summary, there was marginal statistical evidence ($0.05 < p < 0.10$) of a difference in bodily pain at 12 months between the groups after adjustment for baseline pain score, with the acupuncture group achieving a better pain score than those allocated to usual care, but this effect of 6.0 points may not be statistically reliable. Sensitivity analysis, excluding ten patients with follow-up who were permanently unable to work owing to their low back pain at the start of the trial, increased the effect to 7.0 points, but did not alter the overall finding. At 24 months postrandomisation, the results showed a statistically significant difference between the groups, with higher (better) pain scores in the acupuncture group, and an estimated effect of 8.0 points, rising to 10.4 points when eight patients with follow-up who were permanently unable to

work owing to their low back pain at the start of the trial were excluded. A difference of at least 5 points in the mean score of the SF-36 Pain subscale is considered to represent a clinically significant benefit.[42]

Heterogeneity of acupuncturist effect

Analysis methods

Heterogeneity of acupuncturist effect was assessed by comparing outcomes for six acupuncturists each of whom treated a minimum of 15 patients. The analysis was a nested ANCOVA, whereby acupuncturists are nested within the acupuncture group and baseline SF-36 Pain score is the covariate. The variance between allocation groups is split into that due to acupuncture as a main effect, and that due to the acupuncturist. The analysis excluded those patients who were permanently unable to work owing to low back pain as they were unevenly distributed between practitioners. Using this restricted data set, residuals from the model suggested only moderate skewness, with no outliers.

Results for individual acupuncturists

Results for the six acupuncturists are shown in *Table 21* and *Figures 4–6*. The effect is shown with confidence intervals and adjustment for individual baseline pain scores.

Statistical analysis of heterogeneity

Tests for heterogeneity show that the practitioners contribute 35% of the variability of the treatment effect at 12 months (1171/3372). However, there is no significant difference between practitioners, since their residual variation is less than the residual from the model (*Table 22*).

At 24 months the effect of acupuncture is greater, and there is no evidence of any difference between the practitioners selected for the study (*Table 23*). Practitioners contribute just 2% of the variability of the treatment effect at 24 months (74/4265).

To investigate whether the increasing homogeneity observed over time was due to patient dropout or to the effect of acupuncture, heterogeneity in the subgroup of cases with SF-36 Pain scores was assessed at each follow-up (n = 182).

Figure 7 shows individual acupuncturist effects for this subgroup compared with all cases. The data suggest that the increasing homogeneity observed cannot be explained by patient dropout, and the results observed suggest that the effect of acupuncture care increased over time.

Subgroup analyses

No subgroup analysis was specified in the protocol except for looking at the outcomes for subjects randomised to the offer of acupuncture who chose not to have treatment. As all patients offered acupuncture chose to receive it, there is no such subgroup to analyse. The rationale for subgroup analysis within a trial is strictly hypothesis generation and exploration, and therefore four subgroups were analysed where there was a clear a priori case for anticipating that a difference might be observed.[66]

Acute, subacute and chronic low back pain

The patient group for this trial was specified pragmatically. That is, a population was chosen that was believed to represent the group of back pain patients to whom a GP might decide to offer active care, short of a hospital referral. As a result, the population spanned the traditional classification of 'subacute' cases (current episode of 4–12 weeks' duration) and 'chronic' cases (12–48 weeks' duration). Therefore, differences between subgroups were explored according to the commonly used cut-off of 12 weeks' duration. The results for SF-36 Pain scores at 24 months indicate no evidence of a difference in the treatment effect for these two groups (p-value for interaction 0.34) and no overall effect for chronicity. It is possible that the subacute group was more actively managed in the acupuncture arm than in usual care, resulting in a larger treatment effect (*Table 24*).

Patient expectations for low back pain

The psychological antecedents and sequelae of low back pain have been well documented, including the impact of expectations regarding prognosis.[67] Therefore, Pain outcomes at 24 months were compared for patients grouped according to their baseline expectations of change in their low back pain in the next 6 months ('much better'/'better'; 'same'; 'much worse'/'worse'). There was some weak evidence of a difference in the treatment effect for these three groups at 24 months (p-value for interaction 0.10) and a similar effect over the whole trial group (p = 0.12). The data suggest a possible reinforcement of initial optimism within the acupuncture care group (*Table 24*).

TABLE 21 *Estimated effect by practitioner: individual practitioner outcomes compared with control group* (n = *71, 68, 59*)

***n* = 228**	**Practitioner**											
	1		**2**		**3**		**4**		**5**		**6**	
	Estimated effect		**Estimated effect**		**Estimated effect**		**Estimated effect**		**Estimated effect**		**Estimated effect**	
	n	**(95% CI)**	***n***	**(95% CI)**	***n***	**(95% CI)**	***n***	**(95% CI)**	***n***	**(95% CI)**	***n***	**(95% CI)**
3 months	28	7.3 (–2.5 to 17.1)	26	3.2 (–6.9 to 13.2)	20	3.6 (–7.6 to 14.7)	24	12.0* (1.6 to 22.4)	15	–0.6 (–13.1 to 11.9)	21	13.7* (2.3 to 24.7)
12 months	27	14.8* (4.5 to 25.2)	26	0.1 (–10.4 to 10.7)	20	7.7 (–3.9 to 19.3)	24	11.8* (1.0 to 22.6)	17	5.5 (–6.9 to 17.9)	21	7.1 (–4.4 to 18.5)
24 months	25	14.5* (3.9 to 25.2)	21	12.6* (1.3 to 24.0)	15	13.5* (0.6 to 26.5)	19	5.9 (–5.9 to 17.7)	14	12.2 (–1.2 to 25.5)	19	11.6 (–0.2 to 23.5)

* Significant at 95% level.

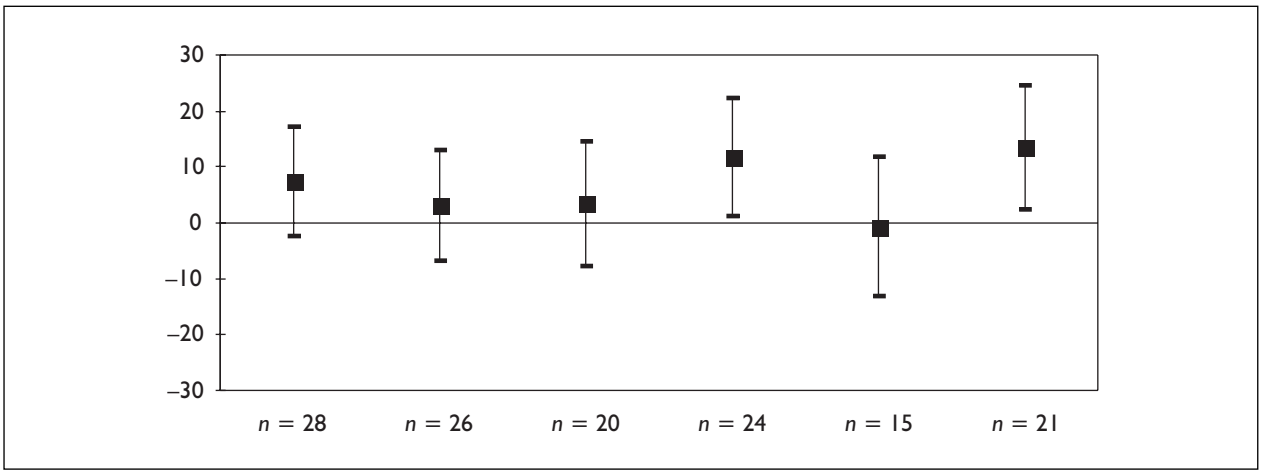

FIGURE 4 *Practitioner effect size compared with controls at 3 months* (n = *215)*

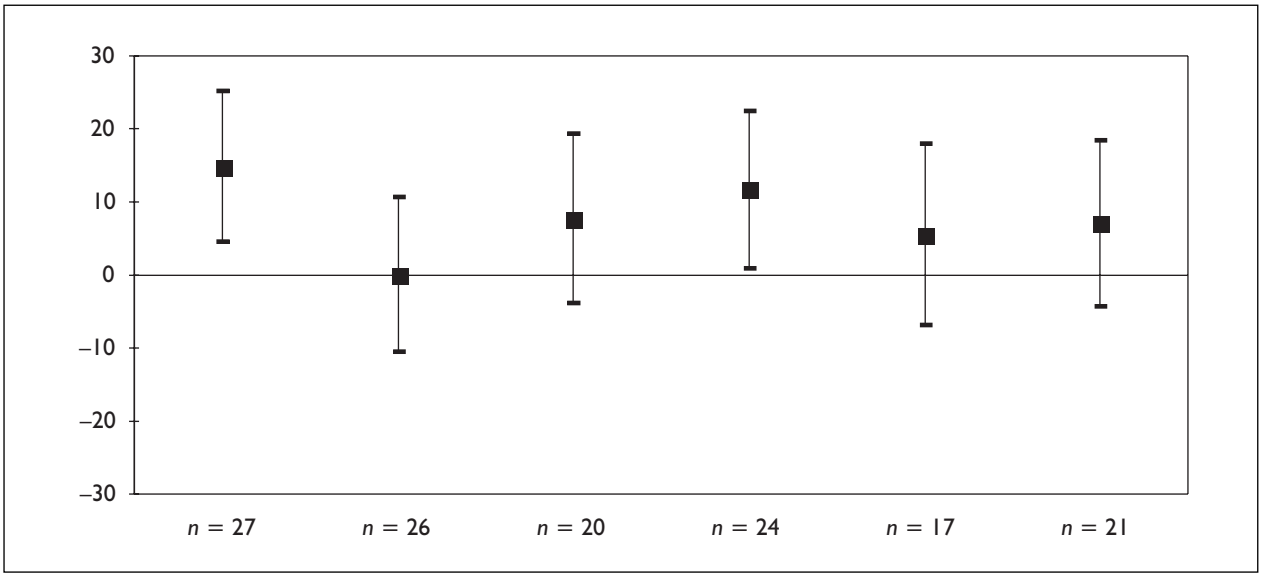

FIGURE 5 *Practitioner effect size compared with controls at 12 months* (n = *203)*

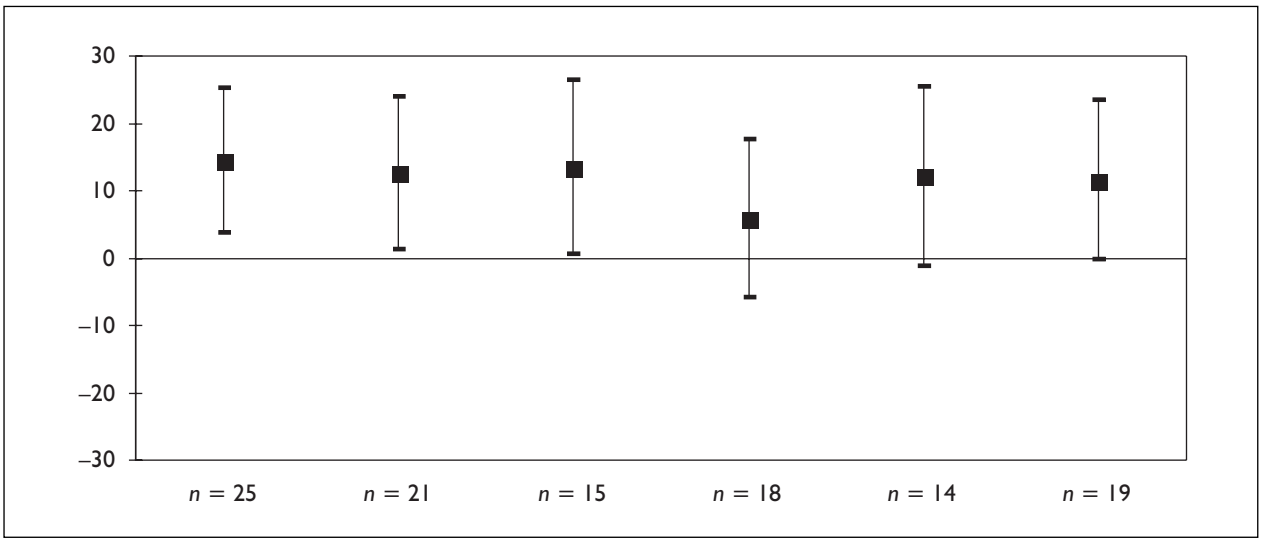

FIGURE 6 *Practitioner effect size compared with controls at 12 months* (n = *171)*

TABLE 22 *Analysis of practitioner effects in SF-36 Pain scores at 12 months*

ANOVA	Sums of squares	df	Mean square	MS ratio
Baseline pain	6298	1	6298	
Treatment	3372	6	562	
Acupuncture	(2201)	(1)	(2201)	3.98 ($p = 0.04$)
Practitioners	(1171)	(5)	(234.2)	<1
Residual	109097	197	553.8	
Total	118767	204		

TABLE 23 *Analysis of practitioner effects in SF-36 Pain scores at 24 months*

ANOVA	Sums of squares	df	Mean square	MS ratio
Baseline pain	3053	1	3053	
Treatment	4265	6	710	
Acupuncture	(4191)	(1)	(4191)	7.92 ($p = 0.005$)
Practitioners	(74)	(5)	(14.8)	<1
Residual	87866	166	529	
Total	95184	173		

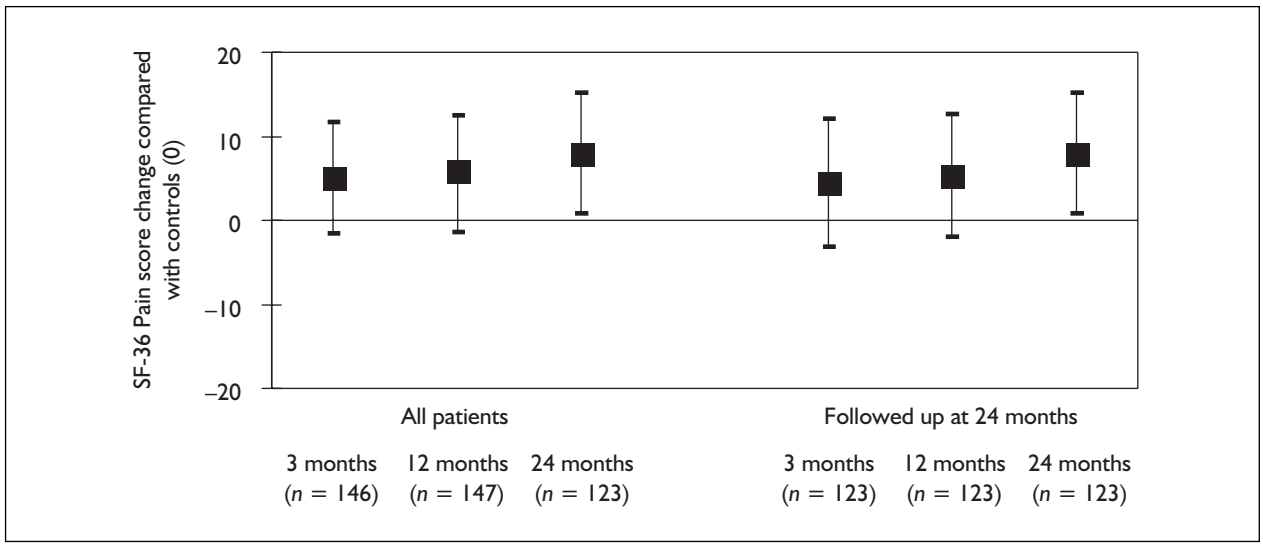

FIGURE 7 *Acupuncture effect over time: practitioner effect compared with controls at 3, 12 and 24 months; all patients compared with those with follow-up at 24 months (mean difference and 95% CI for difference)*

Patient expectations of acupuncture treatment

Belief in the possibility that acupuncture will help has been cited as a possible mechanism for non-specific effects observed in acupuncture trials. A comparison was made of groups classified according to beliefs, stated before randomisation, about whether acupuncture could help with their back pain ('yes'; 'don't know/no'). There was weak evidence of a difference in the treatment effect for these two groups (p-value for interaction 0.07), and no evidence of an effect over the whole trial group ($p = 0.54$). The data suggest that patients without a prior belief in the effectiveness of acupuncture did better in the acupuncture group. This may be associated with negative beliefs at entry followed by a positive 'mind shift' associated with acupuncture care; a benefit that would not be available to those patients receiving acupuncture who already believed that it offered a therapeutic option that could improve their low back pain (*Table 24*).

TCM diagnosis

Finally, groups within the acupuncture arm were compared according to their allocated TCM

TABLE 24 *Subgroup analyses for SF-36 Pain scores at 24 months*

Characteristic	Subgroup	No. in subgroup	Adjusted means for 24 months		Estimated treatment effect[a]	*p*-Value for effect of subgroup characteristic	*p*-Value for interaction
			Acupuncture	Usual care			
Duration of LBP episode at baseline	Up to 12 weeks	*105*	68.1	57.1	**10.7**	0.47	0.34
	More than 12 weeks	*77*	67.3	63.6	**3.6**		
Expectations re LBP in 6 months	Much/better	*81*	73.1	56.9	**16.3**	0.12	0.10
	Same	*69*	65.7	62.8	**1.4**		
	Much/worse	*26*	54.2	55.6	**–2.7**		
Belief that acupuncture can help their LBP	Yes	*127*	66.4	62.8	**3.3**	0.54	0.07
	Don't know[b]	*55*	71.0	52.6	**18.2**		
TCM diagnosis of kidney deficiency (acupuncture group only)	Absence	*54*	70.0		**4.0**[c]	0.38	
	Presence	*62*	66.0				

[a] Effect adjusted for baseline pain score.
[b] Only one patient stated 'no'.
[c] This is the estimated subgroup effect comparing patients with a TCM diagnosis of 'kidney deficiency' to those without this diagnosis.

diagnosis regarding the presence or absence of 'kidney deficiency'. Most acupuncturists would expect patients without kidney deficiency to do better. There was no statistical evidence of an effect relating to a diagnosis of 'kidney deficiency' (*Table 24*).

Secondary outcomes

SF-36 dimensions

The SF-36 Pain dimension score was the primary outcome measure for this study. SF-36 has an additional seven dimensions that were all measured at baseline, and 3, 12 and 24 months (*Figures 8* and *9*). SF-36 Pain scores have been included in the figures for completeness.

Changes over time

Between recruitment and 3 months, four of the SF-36 dimensions other than Pain (Role–Physical, Physical Functioning, Social Functioning, and Role–Emotional) showed clinically significant change in both randomisation groups (range 8–35 points) (*Figures 10–14*). Smaller change was observed in the Vitality/Energy dimension (*Figure 15*). SF-36 scores for Mental Health and General Health Perceptions were similar at each of the four time-points at which measures were taken, in both groups (*Figures 16* and *17*). At 12 months gains observed at 3 months in Physical Functioning, Role–Physical, Social Functioning and Role–Emotional were sustained in both groups. Scores observed at 12 months were sustained at 24 months, with a small additional improvement observed in the Role–Physical dimension in both randomisation groups (*Figures 10–17*).

Differences between groups

The between-groups effect for change between baseline and 12-month outcome did not reach statistical significance for any of the SF-36 dimensions other than Pain.

McGill PPI and ODI

The McGill PPI measures pain intensity in the past week. No treatment effect was found for this measure at 12 or 24 months. The ODI measures pain and its impact on functioning. Better outcomes were observed in the acupuncture intervention group for both these measures, but no significant effect was found at any time-point except for McGill Present Pain score at 3 months (*Table 25*).

Pain-free months and medication use at 24 months

At 24 months, a difference between allocation groups was seen for two subsidiary, pain-related outcomes (*Table 26*). The number of months

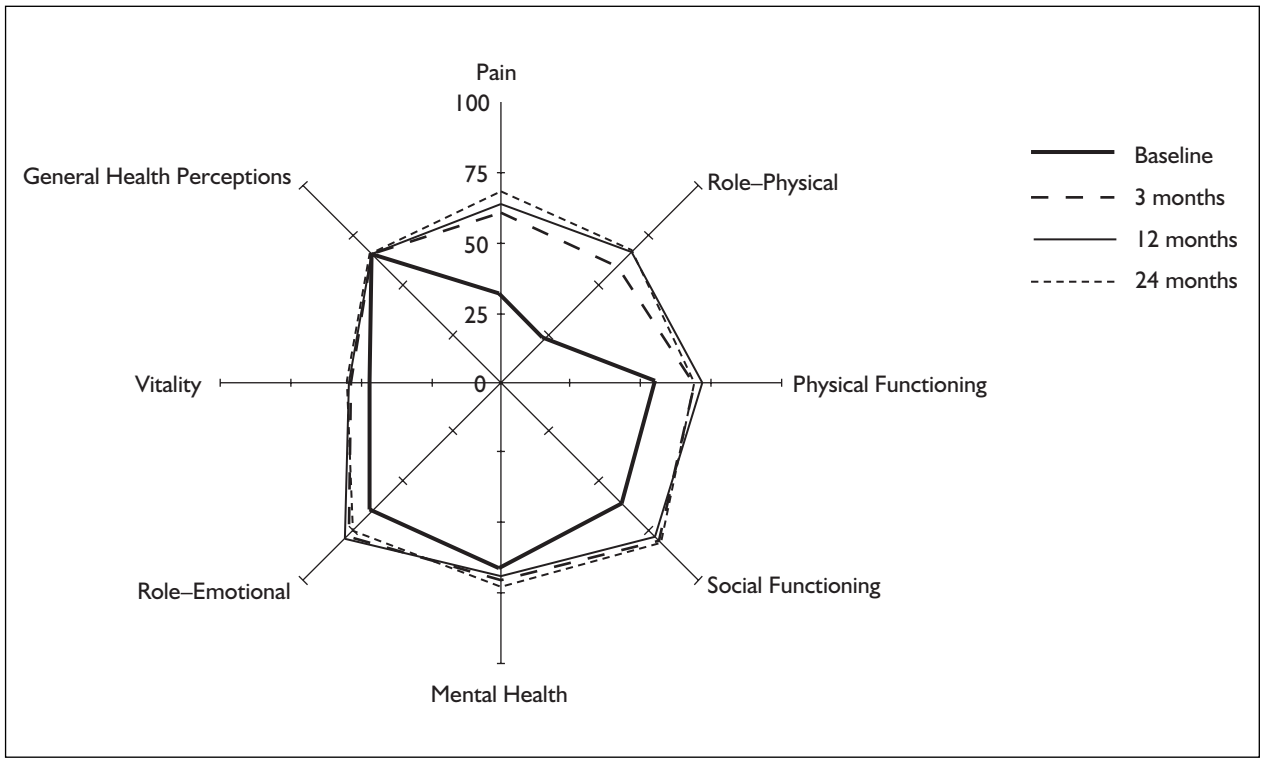

FIGURE 8 *SF-36 dimension scores for the acupuncture group at baseline, 3, 12 and 24 months*

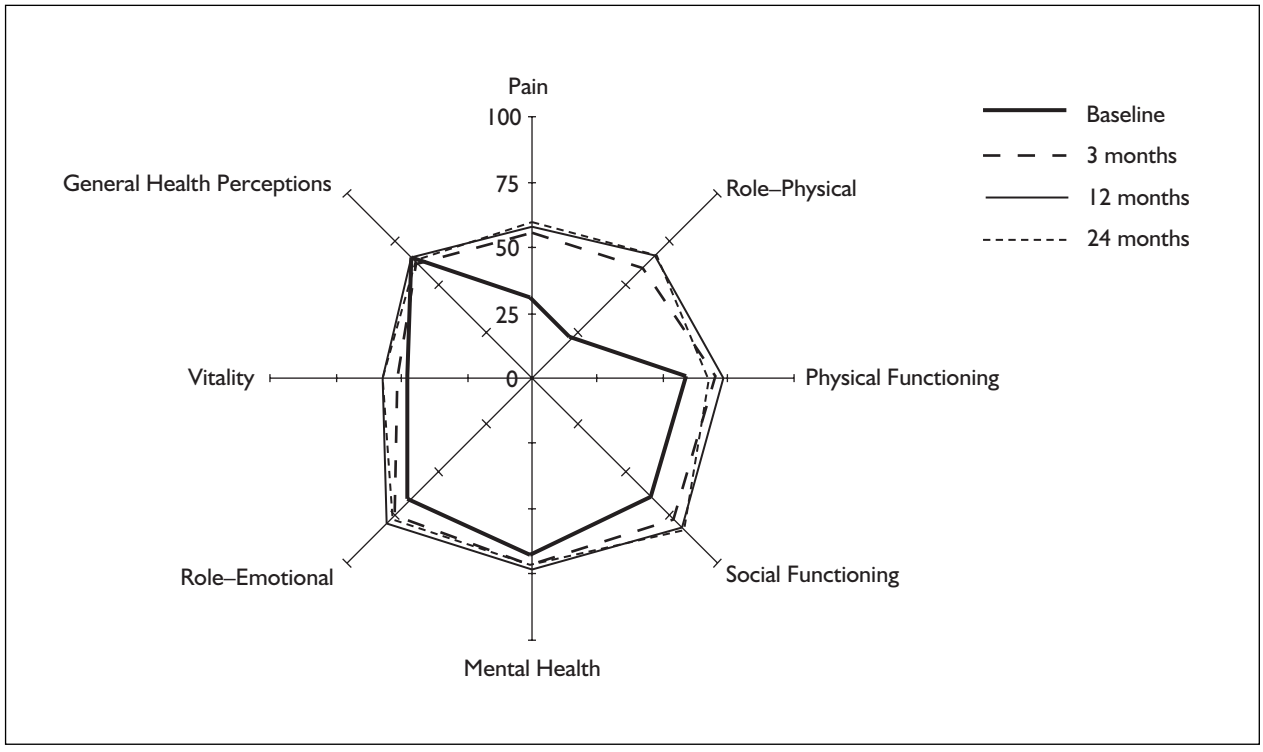

FIGURE 9 *SF-36 dimension scores for the usual care group at baseline, 3, 12 and 24 months*

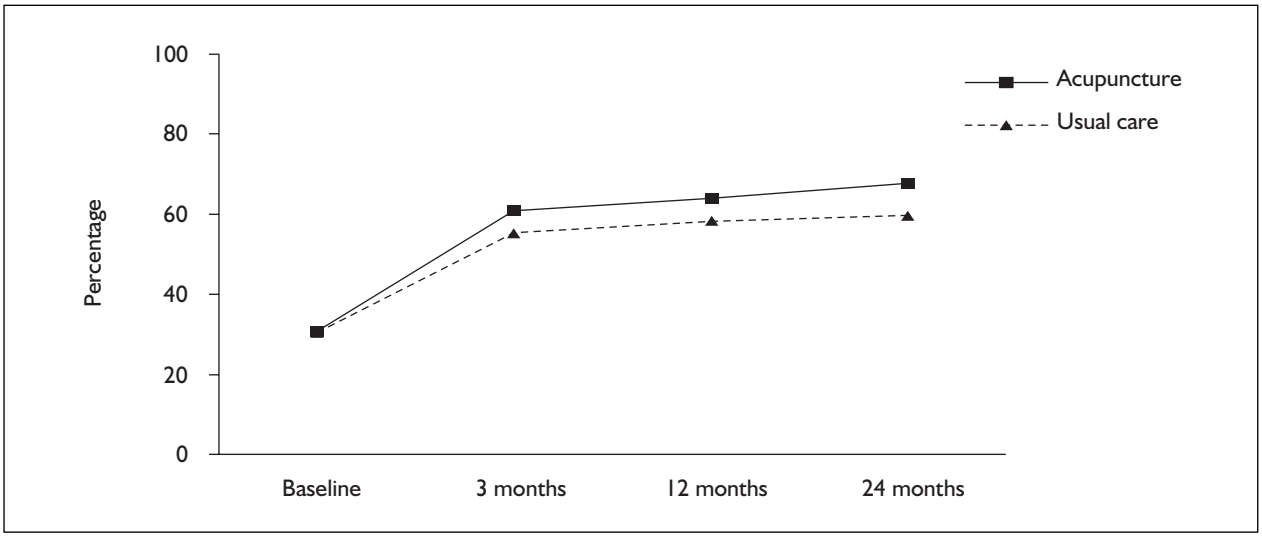

FIGURE 10 *Between-groups effects for SF-36 Bodily Pain*

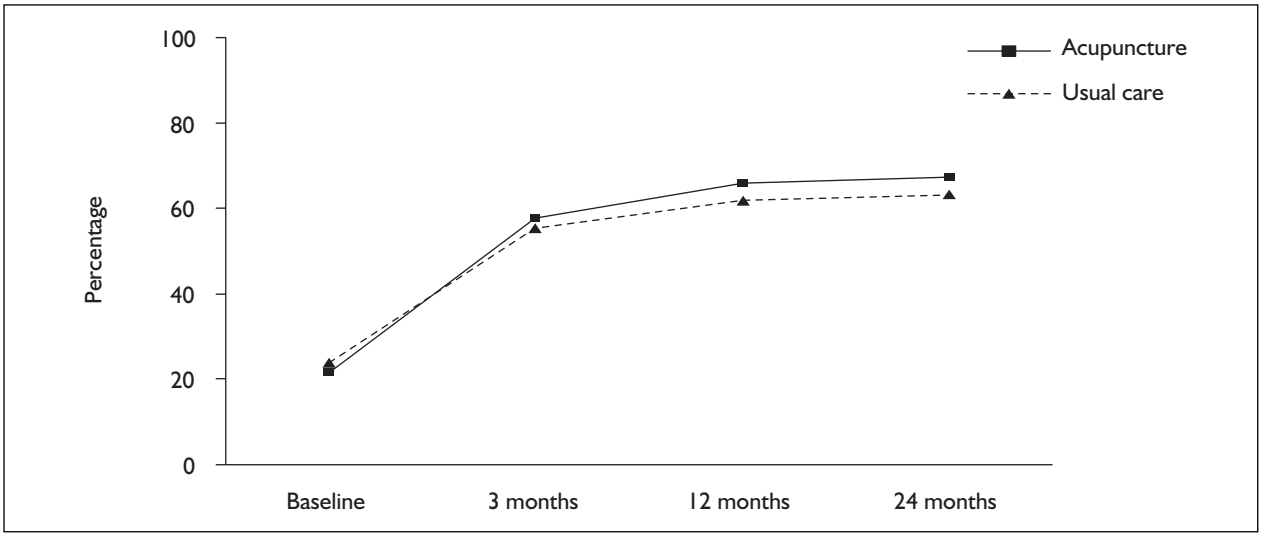

FIGURE 11 *Between-groups effects for SF-36 Role–Physical*

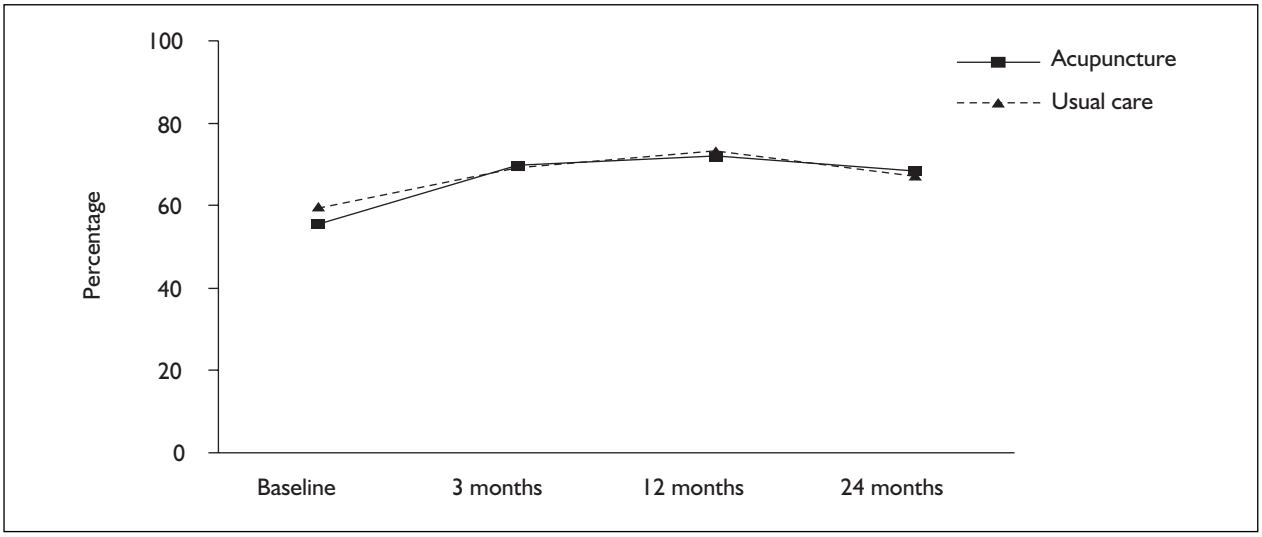

FIGURE 12 *Between-groups effects for SF-36 Physical Functioning*

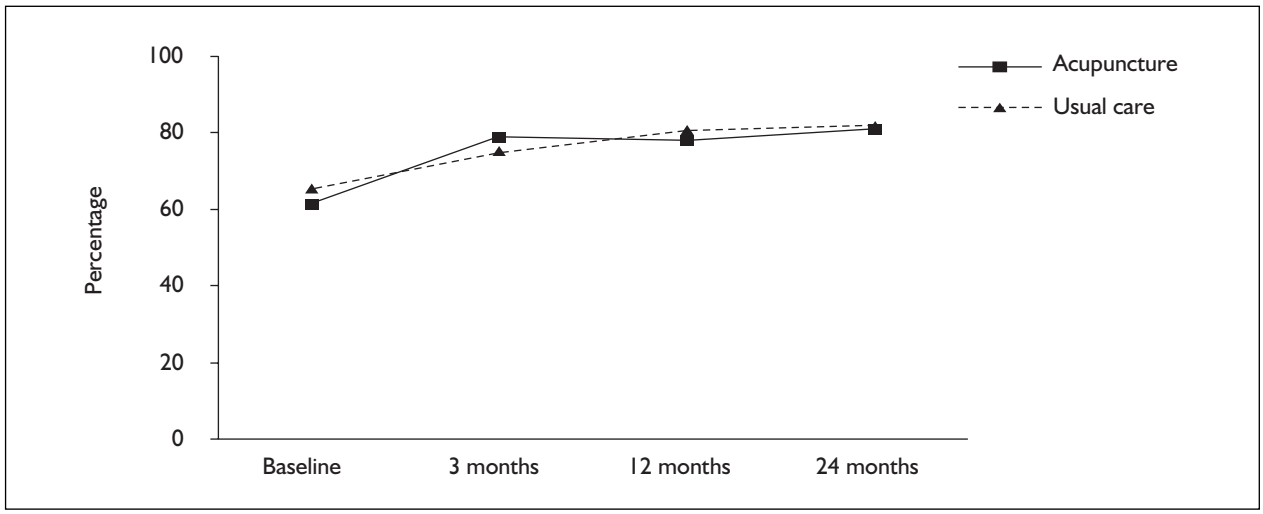

FIGURE 13 *Between-groups effects for SF-36 Social Functioning*

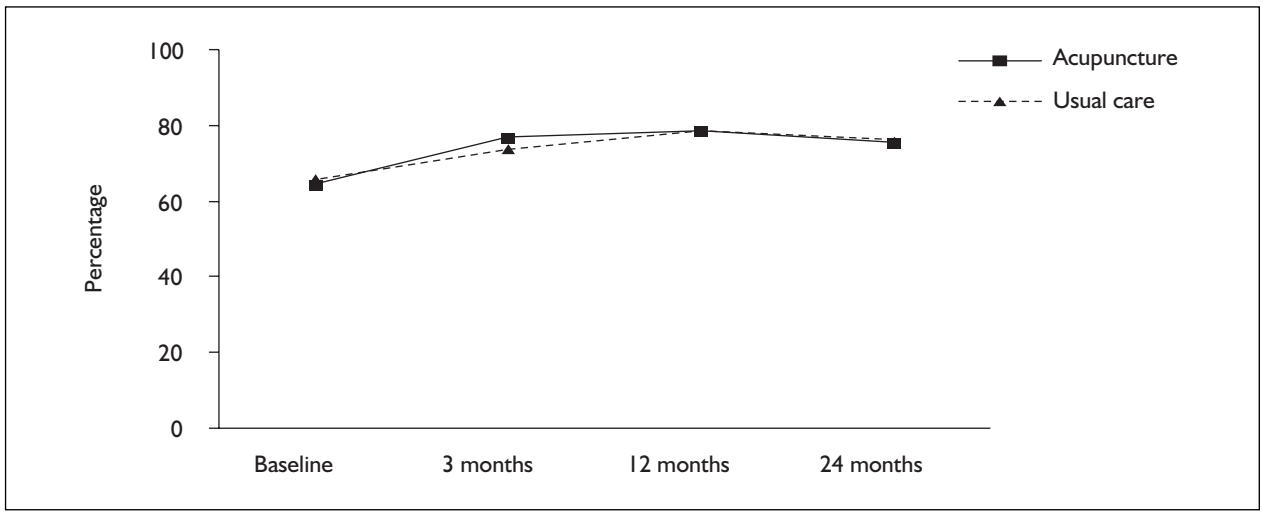

FIGURE 14 *Between-groups effects for SF-36 Role–Emotional*

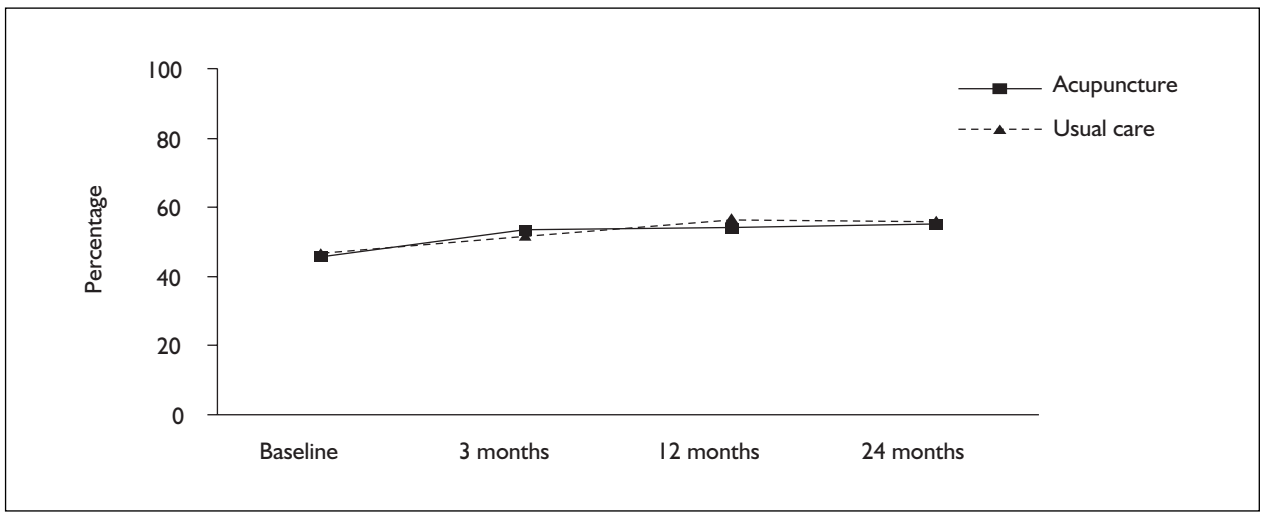

FIGURE 15 *Between-groups effects for SF-36 Vitality*

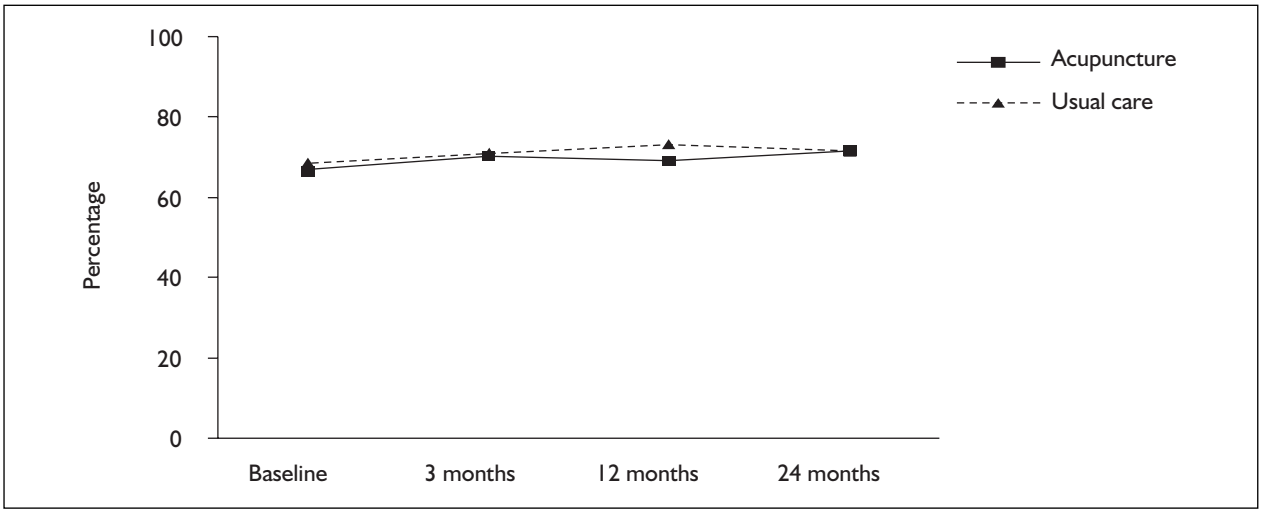

FIGURE 16 *Between-groups effects for SF-36 Mental Health*

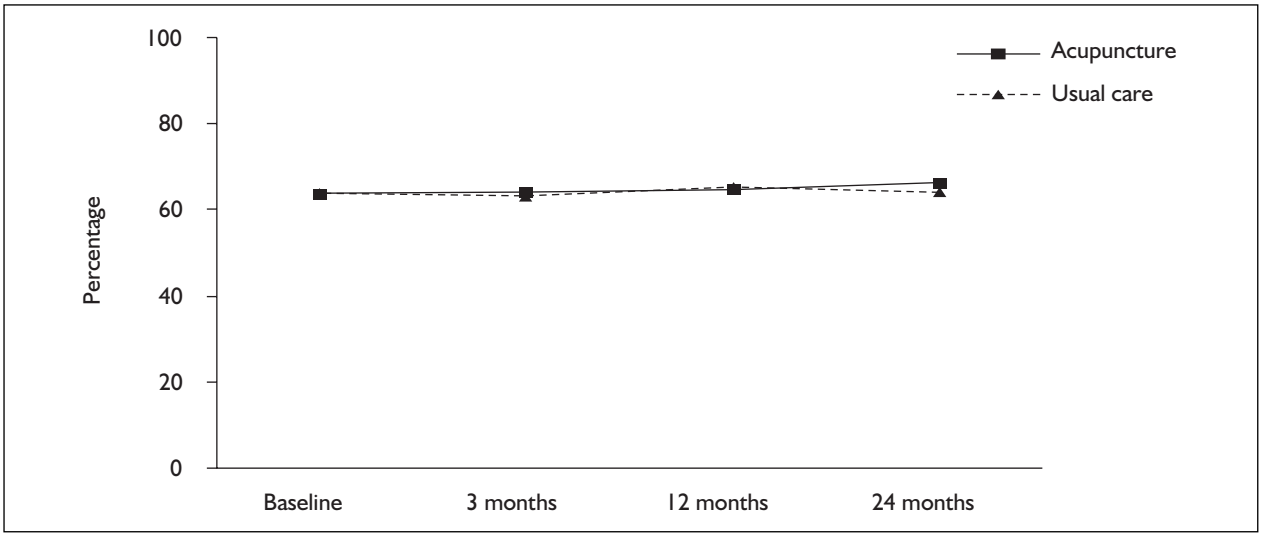

FIGURE 17 *Between-groups effects for SF-36 General Health Perceptions*

TABLE 25 *Effect of intervention on PPI and ODI at 3, 12 and 24 months*

Outcome point	Acupuncture		Usual care		Estimated effect[a]	95% CI	*p*-Value
	n	Adjusted mean	*n*	Adjusted mean			
PPI							
3 months (adjusted for baseline PPI)	145	2.43	71	2.77	–0.34	–0.62 to –0.07	0.02
12 months (adjusted for baseline PPI)	135	2.44	57	2.51	–0.07	–0.38 to 0.25	0.67
24 months (adjusted for baseline PPI)	113	2.44	49	2.67	–0.23	–0.59 to 0.13	0.21
ODI							
3 months (adjusted for baseline ODI score)	146	20.4	71	23.3	–2.9	–6.7 to 0.9	0.15
12 months (adjusted for baseline ODI score)	134	20.1	57	20.6	–0.5	–5.1 to 4.2	0.85
24 months (adjusted for baseline ODI score)	113	18.3	49	20.7	–3.4	–7.8 to 1.0	0.21

[a] A negative effect implies an improved outcome.

TABLE 26 *Additional outcomes at 24 months*

Outcome		Acupuncture		Usual care	
		n	(%)	*n*	(%)
Low back pain or leg pain in past 12 months?					
	Yes	93	(81.6)	46	(92.0)
	No	21	(18.4)	4	(8.0)
	Difference between groups $p = 0.06$ (χ^2, 1 df)				
Use of medication for back pain in past 4 weeks					
	Yes	45	(39.8)	29	(59.2)
	No	68	(60.2)	20	(40.8)
	Difference between groups $p = 0.03$ (χ^2, 1 df)				
Compared to how you felt when you came into the study, how worried are you about your low back pain?					
	Much less worried	43	(38.4)	8	(16.3)
	Less worried	36	(32.1)	11	(22.4)
	Same	21	(19.8)	21	(45.7)
	More worried	6	(5.4)	7	(14.3)
	Much more worried	5	(4.5)	0	
	Difference between groups $p < 0.001$ (χ^2, 4 df)				

reported free of low back pain in the past year was higher in the acupuncture group (mean for acupuncture group 2.9, mean for usual care group 1.2, $p = 0.03$). More patients in the acupuncture group reported 12 months pain free compared with those in usual care (18.4 versus 8.0%). Reported medication use for low back pain was higher in the usual care group in the past month (59 versus 40%).

Retrospective assessments of benefit

All patients in the trial were asked to assess their relative level of 'worry about their back pain' at 3, 12 and 24 months compared with baseline. At 24 months, more patients in the acupuncture group reported being 'much less' or 'less' worried (*Table 26*). A similar pattern was also observed at 3 months and at 12 months (*Figures 18–20*).

Figure 21 shows patients' assessments of their health, compared with 1 year ago, using the SF-36 'Health Transition' item. This shows differences between the allocation groups at three months that are sustained at 12 and 24 months. At 24 months, patients in the acupuncture group were more likely ($p < 0.001$) to attribute perceived benefit to their initial treatment package compared with those receiving usual care (*Table 27*).

Satisfaction with care received

Patients in both groups were asked to rate their satisfaction with care at 3 months postrandomisation. Questions were asked about satisfaction with information received about their low back pain, treatment received and satisfaction with overall care for their low back pain. *Table 28* compares the proportion of patients in each response category by allocation group, for those providing data at 3 months.

A higher proportion of patients in the acupuncture group reported being 'very satisfied' or 'somewhat satisfied' with their treatment and overall care. Similar proportions were satisfied with the information that they received about their low back pain. Recent research suggests that information is lost following the common practice of collapsing these two categories, qualitative research having shown that there is considerable dissatisfaction in all groups except for those selecting 'very satisfied'.[68] Comparisons of the proportion 'very satisfied' in the two allocation groups indicate that patients in the acupuncture group were significantly more likely to be 'very satisfied' with their treatment ($p = 0.01$) and their overall care ($p = 0.04$), but showed no difference in satisfaction with information received ($p = 0.43$).

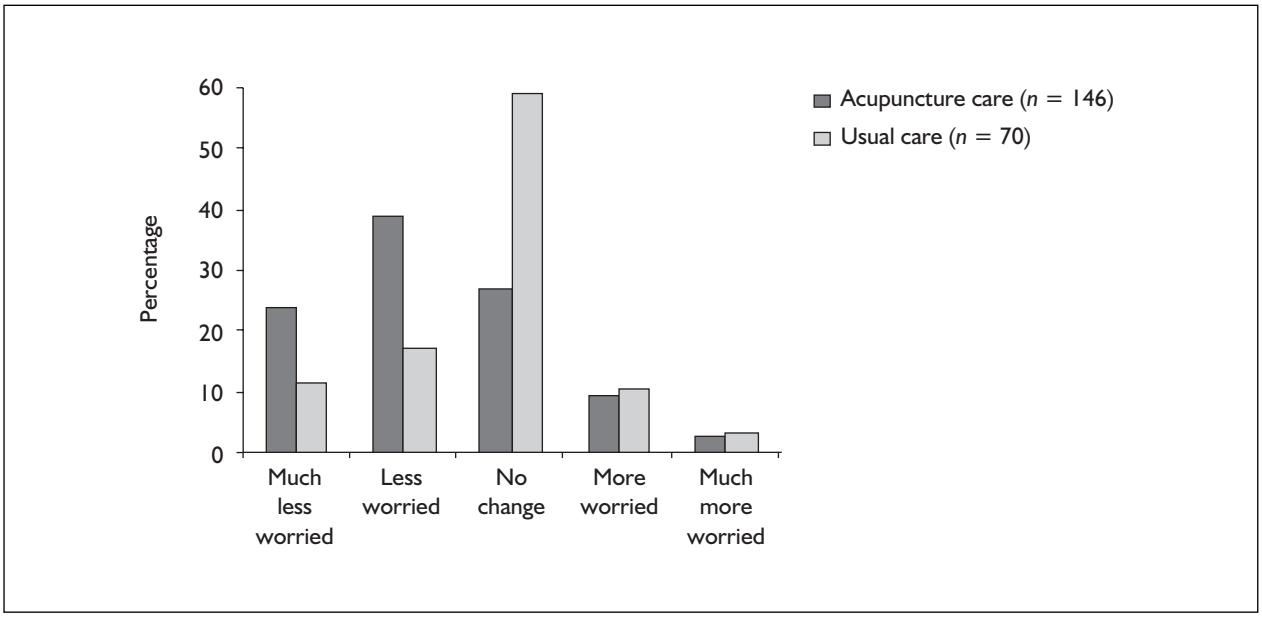

FIGURE 18 *Worry about low back pain: compared with the worry you felt when you previously completed a questionnaire, how worried are you now about your back problem? (At 3 months)*

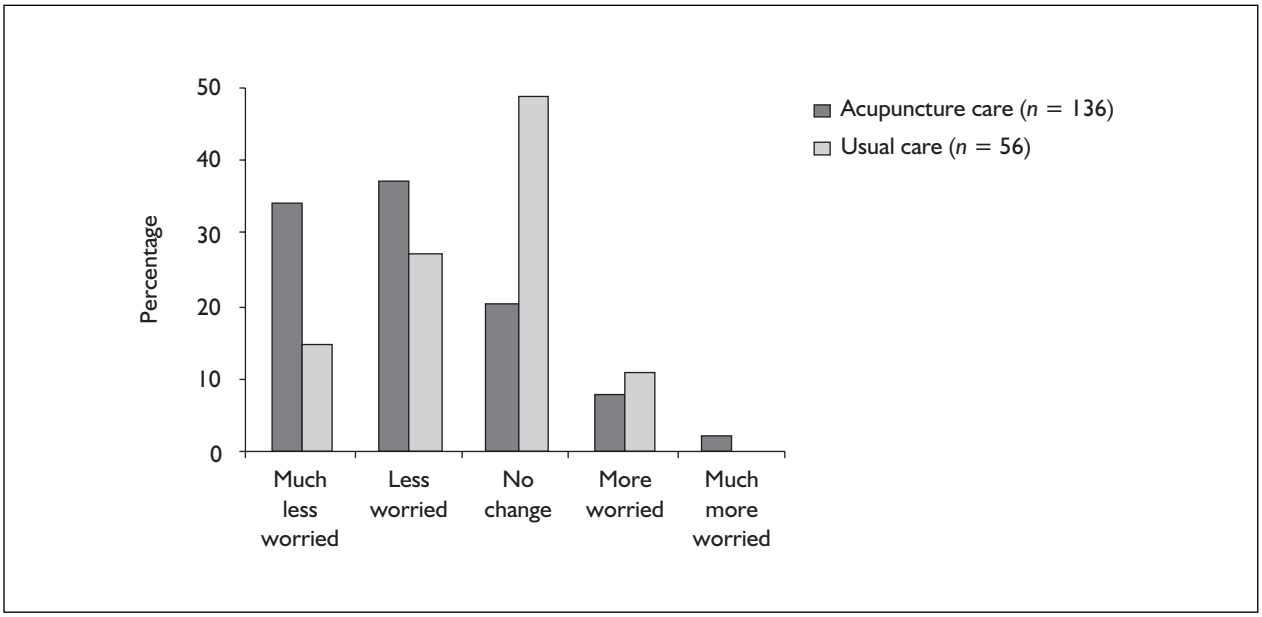

FIGURE 19 *Worry about low back pain: compared with the worry you felt when you previously completed a questionnaire, how worried are you now about your back problem? (At 12 months)*

Safety and adverse events

Adverse event data was collected for the acupuncture group only. No serious adverse events (defined as an event resulting in hospitalisation and/or permanent disability or death) were reported by patients receiving acupuncture during the trial. One patient visited the accident and emergency (A&E) department following treatment, with symptoms of a panic attack. The doctor she saw concluded that her symptoms were not due to her treatment, and her GP was happy for her to continue with acupuncture treatment, which she elected to do.

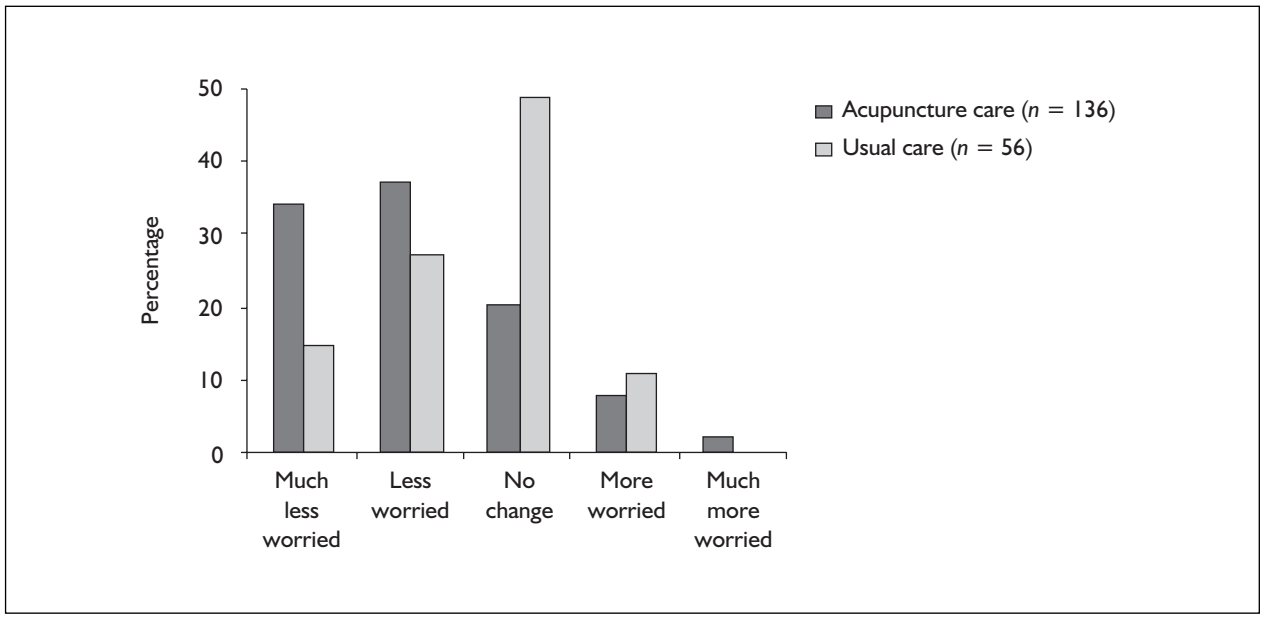

FIGURE 20 *Worry about low back pain: compared with the worry you felt when you previously completed a questionnaire, how worried are you now about your back problem? (At 12 months)*

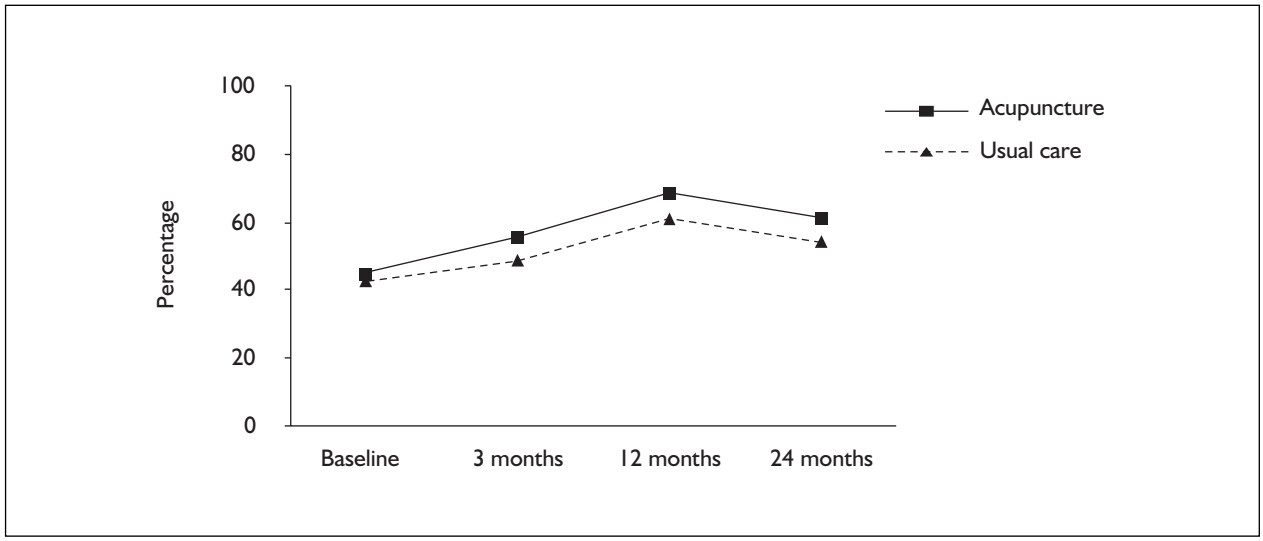

FIGURE 21 *Assessment of health now, compared with 1 year ago*

TABLE 27 *Do you think the treatment package you were allocated to at the beginning of the study has helped your back pain? Assessment at 24 months*

		Acupuncture		Usual care		All	
		n	(%)	*n*	(%)	*n*	(%)
Did it help?							
	Yes	90	(81.1)	23	(52.3)	113	(72.9)
	No	21	(18.9)	21	(47.7)	42	(27.1)
Difference between groups $p = < 0.001$ (χ^2, 1 df)							

TABLE 28 *Reported satisfaction with care at 3 months*

Satisfaction dimension	Response category	Acupuncture (*n* = 146)		Usual care (*n* = 71)	
		n	(%)	*n*	(%)
Information received	Very satisfied	45	(32.1)	21	(30.9)
	Somewhat satisfied	52	(37.1)	17	(25.0)
	Neither satisfied or dissatisfied	26	(18.6)	16	(23.5)
	Somewhat dissatisfied	12	(8.6)	12	(17.6)
	Very dissatisfied	5	(3.6)	2	(2.9)
	Missing	6		3	
Treatment received	Very satisfied	61	(43.6)	18	(26.5)
	Somewhat satisfied	46	(32.9)	21	(30.9)
	Neither satisfied or dissatisfied	16	(11.4)	14	(20.6)
	Somewhat dissatisfied	13	(9.3)	12	(17.6)
	Very dissatisfied	4	(2.9)	3	(4.4)
	Missing	6		3	
Overall care received	Very satisfied	52	(37.1)	17	(25.0)
	Somewhat satisfied	52	(37.1)	24	(35.3)
	Neither satisfied or dissatisfied	18	(12.9)	13	(19.1)
	Somewhat dissatisfied	15	(10.7)	11	(16.2)
	Very dissatisfied	3	(2.1)	3	(4.4)
	Missing	6		3	

TABLE 29 *Transient responses to acupuncture treatment*

(*n* = 133) Missing = 6	Patients with response after any acupuncture treatment		Patients rating response as moderate or severe		Patients reporting being bothered quite a lot or a great deal by response at the time		Patients with response that they were not prepared to experience again	
Response	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)
Temporary worsening of symptoms	84	(63.2)	69	(51.9)	30	(22.6)	10	(7.5)
Feeling tired/ drowsy	65	(50.0)	22	(16.5)	4	(3.0)	7	(5.3)
Feeling dizzy/light-headed	36	(27.3)	7	(5.3)	5	(3.8)	5	(3.8)
Feeling energised	50	(40.0)	32	(24.1)	5	(3.8)	1	(<1)
Feeling relaxed	112	(85.5)	79	(59.4)	7	(5.3)	2	(1.5)
Feeling hungry	10	(7.6)	3	(2.3)	1	(<1)	1	(<1)
Other response (including painful needling)	9	(18.8)	6	(4.5)	4	(3.0)	4	(3.0)
Any response	133	(100)	78	(58.6)	36	(27.1)	17	(12.8)

Of the patients who had received at least one acupuncture treatment, and who provided data at 3 months, a high proportion (63%) reported experiencing a temporary worsening of low back symptoms. A smaller proportion (23% of all patients receiving acupuncture) stated that this bothered them 'a lot' or 'a great deal' at the time (*Table 29*).

Seventeen patients reported at least one response to treatment that they were not prepared to experience again. Most frequently this was an exacerbation of their low back pain (7.5% of patients). The next most frequently reported category was tiredness/drowsiness. One in 20 patients had experienced at least one episode of unacceptable drowsiness following a treatment. Additional information on the questionnaires suggests that this might be linked to the need to drive immediately following treatment.

TABLE 30 *Results from univariate analysis using 'Would you be happy to try acupuncture again?' as the dependent variable (n = 133)*

Variable	*p*-Value
Tiredness/drowsiness	0.65
Dizziness/light-headed	0.62
Temporary worsening of symptoms	0.33
Bothersome aggravations	0.36
Gender of patient	0.96
Age of patient	0.65
Practitioner seen	0.26
Feeling energised	<0.05
Feeling relaxed	<0.01
Reassurance and support from acupuncturist	<0.001
Prepared to have response again	<0.001
Difference in SF-36 pain score at 3 months	<0.001

Adherence to treatment

Dropout from acupuncture treatment once it had started was relatively uncommon (16/160). Five patients chose to discontinue early in the course of treatment, because they could not find the time for treatment. Patients who dropped out later in the course of treatment cited lack of treatment efficacy, adverse events, or a mixture of these two factors. Four patients dropped out of treatment citing a particular adverse event as the primary cause: worsening of symptoms ($n = 1$), painful needling ($n = 2$) and nosebleeds attributed to the treatment ($n = 1$) (*Appendix 13*).

Acceptability of acupuncture treatment

All patients reported at least one transient response to treatment, and many reported more than one (*Table 29*). The most frequently reported response was feeling relaxed (85%). With the exception of symptom exacerbation, few patients reported being bothered by these responses. Of those reporting feelings of relaxation and tiredness, or dizziness, some described problems relating to their ability to return to work or to drive immediately following treatment. Seventeen patients had a response to treatment that they were not prepared to experience again, but only 13 patients stated that they were not willing to try acupuncture again. Taking willingness to try acupuncture again as a proxy for acceptability of treatment experience, univariate analysis, with 'would you be happy to try acupuncture again?' as the dependent variable, was used to establish variables with an independent influence on acceptability from the patient's perspective.

Negative transitory responses to treatment, including a worsening of symptoms and 'bothersome responses', were not independently associated with willingness to try acupuncture again. Nor was the practitioner seen, or the age or gender of the patient. Factors that independently influenced patients included not being prepared to have a particular response again, not experiencing feelings of relaxation following treatment, the level of perceived reassurance and

TABLE 31 *What predicts unwillingness to try acupuncture again? Regression model using 'Would you be happy to try acupuncture again?' as the dependent variable (n = 133)*

		OR	95% CI
Prepared to have treatment response again (Reference category 'Yes')	'No'	40.4	(4.3 to 377.5)
Perceived support from acupuncturist (Reference category 'Excellent')	'Poor or fair'	23.7	(1.5 to 369.7)
	'Good'	5.9	(0.9 to 70.7)
	'Very good'	1.3	(0.1 to 22.0)
SF36 pain score at 3 months (Reference category 'Better')	'Same or worse'	16.7	(1.9 to 150.8)
Feeling relaxed after at least one session (Reference category 'Yes')	'No'	13.9	(1.4 to 133.2)
$R^2 = 0.65$.			

TABLE 32 *Patient assessments of acupuncture care*

***n* = 139** **How would you rate …**	**Poor (%)**	**Fair (%)**	**Good (%)**	**Very good (%)**	**Excellent (%)**
Friendliness and courtesy of acupuncturist	0	0.7	9.4	21.6	68.3
Respect shown to you and attention to your privacy	0	0.7	12.2	20.9	66.2
Personal interest taken in you and your problems	0.7	2.9	16.5	26.6	52.5
Reassurance and support offered to you by the acupuncturist	0.7	3.6	21.6	25.2	48.9
Attention given to what you have to say	0	3.6	15.1	33.1	48.2
The amount of time you had with the acupuncturist at each visit	0	4.3	16.5	34.5	44.6
Explanations of acupuncture treatment procedures	0.7	9.4	18.0	38.1	33.8
Advice given about ways of avoiding illness and staying healthy	3.6	10.1	28.1	38.8	19.4

support from the acupuncturist, and SF-36 Pain score at 3 months (*Table 30*).

Logistic regression was used to identify the best predictors of a patients being unwilling to use acupuncture again. A regression model was developed which suggested a reasonably good fit. This model identifies four strong influences on the decision not to want to try acupuncture again, correctly classifying 65% of the group. However, the confidence intervals for the effect are wide (*Table 31*).

Patient evaluations of acupuncture care

An assessment of satisfaction with specific aspects of acupuncture care was also sought at 3 months. Patient ratings indicate high levels of acceptability for the experience of acupuncture as delivered by the study acupuncturists to this group of primary care patients, especially in the areas of interpersonal care and reassurance and support (*Table 32*).

Chapter 5
Economic analysis

Methods

The economic analysis was designed as a cost-effectiveness study with the main outcome measure being the SF-6D.[49,50] The EQ-5D[51] was used as a secondary outcome measure. The ICER for a series of acupuncture treatments compared with normal treatment for low back pain was estimated. Both an NHS and a societal perspective were adopted for the estimation of costs, with NHS treatment costs, private sector treatment costs and costs due to lost productivity considered. Detailed methods are given in Chapter 2.

Costs

Tables 33 and *34* detail the resources used during the periods 0–12 and 12–24 months, respectively. The sample sizes for each period are reduced relative to the total trial population, reflecting the response rates to the 12-month and 24-month patient resource-use questionnaires. Missing values for number of visits to a healthcare professional, where some contact had been recorded, were replaced with median values for all patients using that service. During the 0-12-month period the only statistically significant differences in resource use were for private acupuncture, with the acupuncture care group recording greater use of this facility. During the 12–24-month period there were statistically significant differences in hospital pain clinic visits, with the control group recording more frequent attendances.

Table 35 documents the mean NHS costs of healthcare resource use for treatment for lower back pain during the period of the trial. As

TABLE 33 *Mean resource use for each group over 0–12 months*

Type of care	Acupuncture group (mean) (n = 147)	Control group (mean) (n = 68)	Difference in means	(95% CI)
Secondary care				
Days in hospital	0.007	0.044	–0.037	(–0.1 to 0.029)
A&E visit	0.020	0.029	–0.009	(–0.053 to 0.035)
Hospital outpatients visits (generic)	0.265	0.235	0.030	(–0.320 to 0.380)
Hospital pain clinic visits	0.312	0.441	–0.121	(–0.614 to 0.371)
Hospital physiotherapy visits	2.704	1.154	1.550	(–0.092 to 3.192)
Primary care				
Acupuncture study	8.083	0	8.08	(7.648 to 8.941)
Other NHS acupuncture visits	0.367	1.132	–0.765	(–1.594 to 0.064)
NHS chiropractic visits	0.068	0	0.068	(–0.129 to 0.265)
NHS osteopathy visits	0	0		
GP visits for LBP	1.635	1.800	–0.165	(–0.951 to 0.622)
GP visits not for LBP	3.371	3.250	0.121	(–1.047 to 1.289)
Practice nurse visits for LBP	0.96	0.91	0.049	(–0.54 to 0.64)
Practice nurse visits not for LBP	0.0063	0.079	–0.019	(–0.057 to 0.020)
Physiotherapy at GP surgery	0.674	1.088	–0.415	(–1.151 to 0.322)
Other NHS therapist visits	3.017	2.103	0.914	(–1.437 to 3.265)
Private care				
Private acupuncture visits	1.762	0.118	1.644 *	(0.267 to 3.021)
Private physiotherapy visits	0.503	0.765	–0.261	(–1.165 to 0.643)
Private chiropractic visits	0.602	1.074	–0.471	(–1.302 to 0.359)
Private osteopathy visits	0.150	0.147	0.003	(–0.304 to 0.309)
Other private therapist visits	3.446	2.243	1.203	(–0.556 to 2.962)

* Significant difference between means ($p < 0.05$).

TABLE 34 *Mean resource use for each group over 12–24 months*

Type of care	Acupuncture group (mean) (*n* = 123)	Control group (mean) (*n* = 59)	Difference in means	(95% CI)
Secondary care				
Days in hospital	0.024	–	0.024	(–0.016 to 0.064)
A&E visit	0.081	–	0.081	(–0.036 to 0.198)
Hospital outpatients visits (generic)	0.148	0.31	–0.163	(–0.476 to 0.150)
Hospital pain clinic visits	0.082	0.475	–0.393*	(–0.694 to –0.091)
Hospital physiotherapy visits	0.459	0.78	–0.321	(–0.961 to 0.320)
Physiotherapy at GP surgery	0.317	0.559	–0.242	(–0.809 to 0.324)
Primary care				
Acupuncture study	–	–	–	
Other NHS acupuncture visits	0.192	0.793	–0.601*	(–1.170 to –0.334)
NHS chiropractic visits	–	–	–	
NHS osteopathy visits	–	–	–	
GP contacts for LBP	1.33	1.12	0.2 0	(–0.29 to 0.70)
GP contacts not for LBP	2.96	3.28	–0.32	(–1.64 to 1.00)
Practice nurse for LBP	–	–	–	
Practice nurse not for LBP	1.08	1.07	0.01	(–0.77 to 0.78)
Other NHS therapist visits	0.75	1.34	–0.589	(–1.468 to 0.290)
Private care				
Private acupuncture	0.429	0.155	0.273	(–0.282 to 0.829)
Private physiotherapy	0.35	0.339	0.011	(–0.529 to 0.550)
Private chiropractic service	0.287	0.305	–0.018	(–0.505 to 0.469
Private osteopathy	0.049	0.051	0.017	(–0.158 to 0.154)
Other private therapist visits	1.009	0.862	0.146	(0.763 to 1.056)

* Significant difference between means ($p < 0.05$).

TABLE 35 *Mean NHS costs (£) of healthcare resource use for treatment for low back pain (0–24 months)*

	Acupuncture group Mean (SD) (*n* = 123)	Control group Mean (SD) (*n* = 59)	Difference in means	(95% CI)
Acupuncture				
Acupuncture, study *	214.01 (68.49)	–	214.01*	(196.38 to 231.62)
Acupuncture, other NHS	9.26 (83.27)	31.46 (120.44)	–22.20	(–52.45 to 82.06)
Hospitalisations (days)	2.22 (24.62)	18.32 (99.66)	–16.10	(–35.07 to 2.49)
Other healthcare visits				
GP	78.15 (66.89)	88.07 (95.08)	–9.92	(–34.43 to 14.59)
Outpatient	48.00 (167.30)	84.78 (256.59)	–36.78	(–99.42 to 25.86)
Other NHS	87.89 (52.97)	95.93 (55.99)	–8.04	(–24.91 to 8.82)
Medication for LBP	34.12 (114.94)	16.47 (27.33)	17.65	(–12.31 to 47.61)
Total NHS costs (discounted)	471.10 (341.61)	332.24 (426.50)	138.86*	(22.91 to 254.82)

n = sample size.
* Significant difference between means ($p < 0.05$).

TABLE 36 *Total social costs (£) of treatment for low back pain (0–24 months)*

Item	Acupuncture group Mean (SD) per patient	Control group Mean (SD) per patient	Difference in means	(95% CI)
Total NHS costs	**£471.10 (£341.61) (*n* = 123)**	**£332.24 (£426.50) (*n* = 59)**	**£138.86***	**(£22.91 to £254.82)**
Private healthcare expenditure	£77.10 (£205.52) (*n* = 109)	£93.83 (£338.85) (*n* = 54)	–£16.72	(–£101.24 to £67.79)
Total direct healthcare costs	**£525.30 (£601.29) (*n* = 109)**	**£367.16 (£492.28) (*n* = 54)**	**£158.14**	**(–£28.23 to £319.58)**
Total days taken off work owing to LBP	16.086 (43.271) (*n* = 106)	20.134 (53.739) (*n* = 54)	–4.048	(–19.265 to 11.169)
Total productivity costs	£1679.99 (£4812.54) (*n* = 106)	£2321.68 (£6011.38) (*n* = 54)	–£641.69	(–£2130.62 to £1299.52)
Total social costs (undiscounted)	**£2201.25 (£4167.80) (*n* = 97)**	**£2511.09 (£4097.94) (*n* = 52)**	**–£309.84**	**(–£1611.79 to 1168.59)**
Total social costs (discounted)	**£2135.39 (£3798.45) (*n* = 97)**	**£2469.09 (£3618.97) (*n* = 52)**	**–£333.70**	**(–£1601.92 to £1179.81)**

* Significant difference between means ($p < 0.05$).

expected, there were statistically significant differences between groups in the costs of initial acupuncture treatment. The total mean NHS costs of treatment for the acupuncture care group (£471.10) were higher than for the control group (£332.24) and the difference was statistically significant. However, the initial acupuncture treatment accounted for approximately 45% of the total NHS costs of treatment for the acupuncture care group.

The results from the analysis of social costs are presented in *Table 36*. Social costs include NHS treatment costs, private sector treatment costs, and costs due to lost productivity as a consequence of time taken off work owing to low back pain by individuals in the trial. Individuals in the control group incurred greater private healthcare expenditure for low back pain, although the difference between the groups was not statistically significant. Productivity costs were higher in the control group, reflecting a higher reported absence from work within this group. Total mean (discounted) social costs were lower for the acupuncture group (£2135.39) than for the control group (£2469.09), although the difference in social costs was not statistically significant.

Health outcomes

The results from the analysis of both the SF-6D (*Table 37* and *Figure 22*) and the EQ-5D (*Tables 38* and *39*, *Figures 23* and *24*) indicate considerable improvements in health status from baseline to 3 months, and reduced improvements from 3 to 12 months and from 12 to 24 months for both groups. Both the SF-6D and the EQ-5D indicate that the QALY gain for the acupuncture care group was slightly higher than for the control group over the 24-month trial period and the difference in QALY gain was statistically significant where missing values for the EQ-5D were imputed using regression analyses based on responses to the SF-36.

Cost-effectiveness analysis

The results of the cost-effectiveness analysis for those patients with complete data on NHS costs and SF-6D outcomes are presented in *Table 40*. There were some differences in both costs and outcomes between acupuncture and control groups. Over the period of the trial it was found that acupuncture care was associated with a higher cost but with a slight increase in QALYs gained. As a consequence the mean ICER for acupuncture in low back pain was positive (point estimate £4241). To gain an understanding of the uncertainty surrounding this ICER, a cost-effectiveness acceptability curve (CEAC) was estimated using a bootstrap method. The percentiles from the bootstrap repetitions were used to produce a CEAC. This shows the percentage of bootstrap repetitions that are cost-

TABLE 37 *SF-36 scores translated into SF-6D*

	Acupuncture care group Mean (SD)	Control care group Mean (SD)	Difference in means	(95% CI)
Baseline	0.597 (0.115) (n = 158)	0.607 (0.132) (n = 80)	–0.010	(–0.045 to 0.024)
3 months	0.713 (0.138) (n = 146)	0.699 (0.150) (n = 70)	0.013	(–0.027 to 0.054)
12 months	0.725 (0.151) (n = 134)	0.730 (0.125) (n = 56)	–0.005	(–0.047 to 0.037)
24 months	0.742 (0.141) n = 113	0.729 (0.126) n = 50	0.013	(–0.033, 0.059)
Change from 0 to 24 months	0.139 (0.139) n = 112	0.118 (0.153) n = 50	0.020	(–0.028, 0.068)
Area under curve from 0 to 24 months (undiscounted)	1.448 (0.249) n = 112	1.421 (0.213) n = 50	0.027	(–0.053, 0.107)
Area under curve from 0 to 24 months (undiscounted)	1.419 (0.244) n = 112	1.398 (0.208) n = 50	0.027	(–0.051, 0.104)

AUC, area under the curve.

TABLE 38 *EQ-5D scores*

	Acupuncture group Mean (SD)	Control group Mean (SD)	Difference in means	(95% CI)
Baseline	0.534 (0.293) (n = 91)	0.532 (0.284) (n = 46)	0.002	(–0.102 to 0.106)
3 months	0.753 (0.189) (n = 96)	0.655 (0.274) (n = 42)	0.099*	(0.006 to 0.192)
12 months	0.739 (0.265) (n = 145)	0.726 (0.207) (n = 68)	0.012	(–0.060 to 0.084)
24 months	0.757 (0.228) (n = 113)	0.732 (0.196) (n = 50)	0.003	(–0.048 to 0.098)
Change from 0 to 24 months	0.202 (0.261) (n = 62)	0.209 (0.270) (n = 28)	–0.007	(–0.126 to 0.112)
AUC, 0–24 months (undiscounted)	1.516 (0.352) (n = 60)	1.354 (0.412) (n = 27)	0.163	(–0.092 to 0.334)
AUC, 0–24 months (discounted)	1.500 (0.348) (n = 60)	1.340 (0.412) (n = 27)	0.161	(–0.087 to 0.331)

* Significant difference between means ($p < 0.05$).

effective, assuming different ceiling values for the cost per QALY. Assuming an implicit threshold maximum willingness to pay value of £30,000 for a QALY, *Figure 25* illustrates that the probability of the cost per QALY of acupuncture for low back pain falling below this threshold value is very close to 1.0.

The distribution of the ICER estimates resulting from the bootstrap repetitions is shown in *Figure 26*. The majority of observations indicate that acupuncture treatment for low back pain results in increased costs and improved effectiveness relative to a situation in which acupuncture care is not provided.

TABLE 39 *EQ-5D scores including imputed missing data values*

	Acupuncture group Mean (SD)	Control group Mean (SD)	Difference in means	(95% CI)
Baseline	0.541 (0.253) (n = 149)	0.533 (0.243) (n = 78)	0.007	(–0.062 to 0.076)
3 months	0.745 (0.167) (n = 157)	0.671 (0.225) (n = 75)	0.074*	(0.023 to 0.126)
12 months	0.732 (0.256) (n = 154)	0.728 (0.196) (n = 77)	0.003	(–0.062 to 0.069)
24 months	0.753 (0.207) (n = 146)	0.737 (0.182) (n = 66)	0.015	(–0.043 to 0.074)
Change from 0 to 24 months	0.214 (0.289) (n = 137)	0.209 (0.296) (n = 64)	–0.005	(–0.082 to 0.092)
AUC, 0–24 months (undiscounted)	1.492 (0.299) (n = 133)	1.390 (0.261) (n = 56)	0.102*	(0.011 to 0.192)
AUC, 0–24 months (discounted)	1.467 (0.293) (n = 133)	1.366 (0.259) (n = 56)	0.101*	(0.012 to 0.190)

* Significant difference between means ($p < 0.05$).

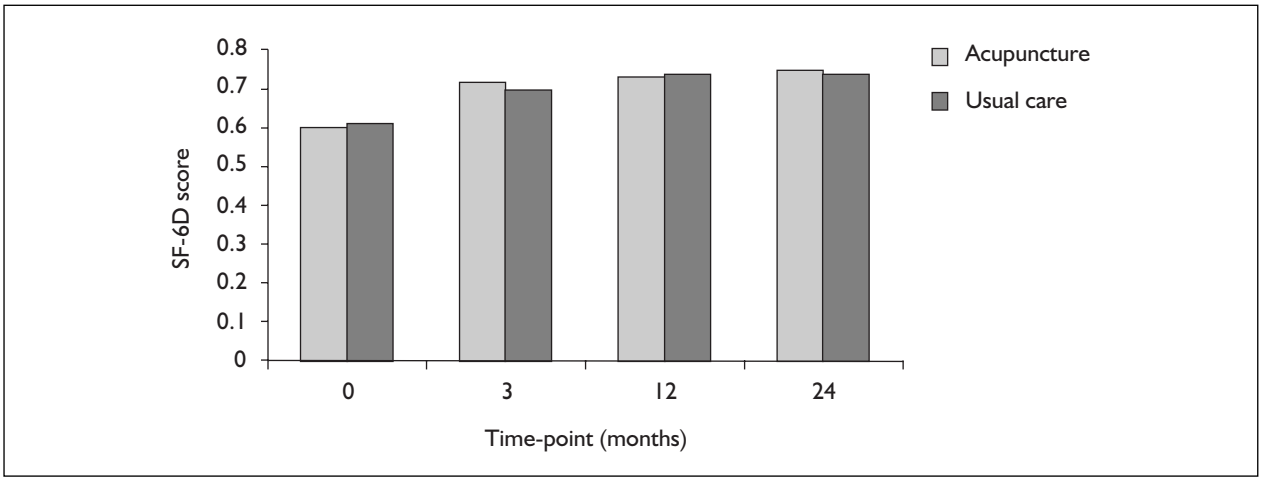

FIGURE 22 *SF-6D scores over time*

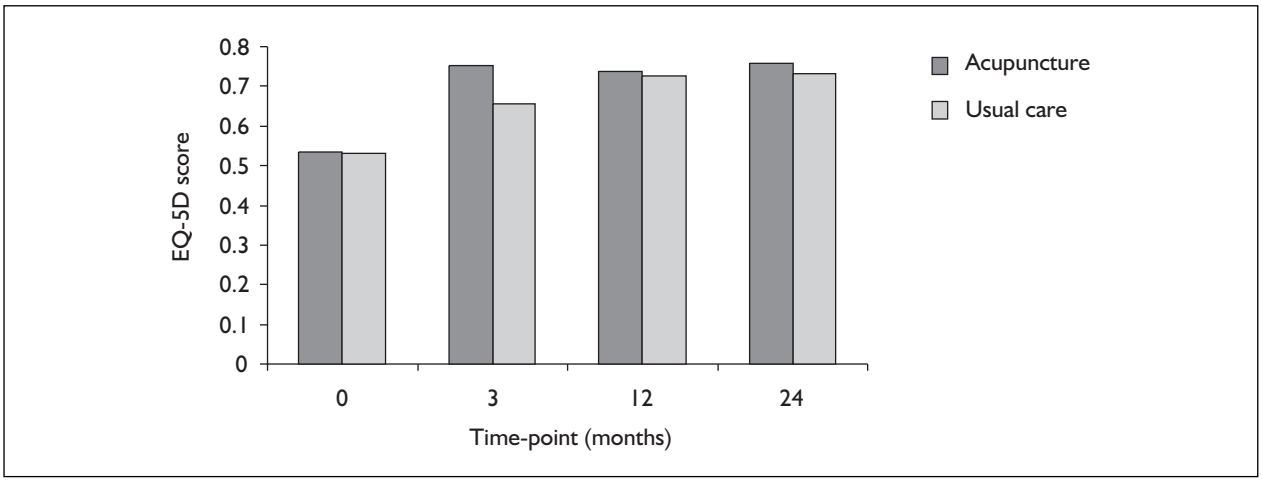

FIGURE 23 *EQ-5D scores over time*

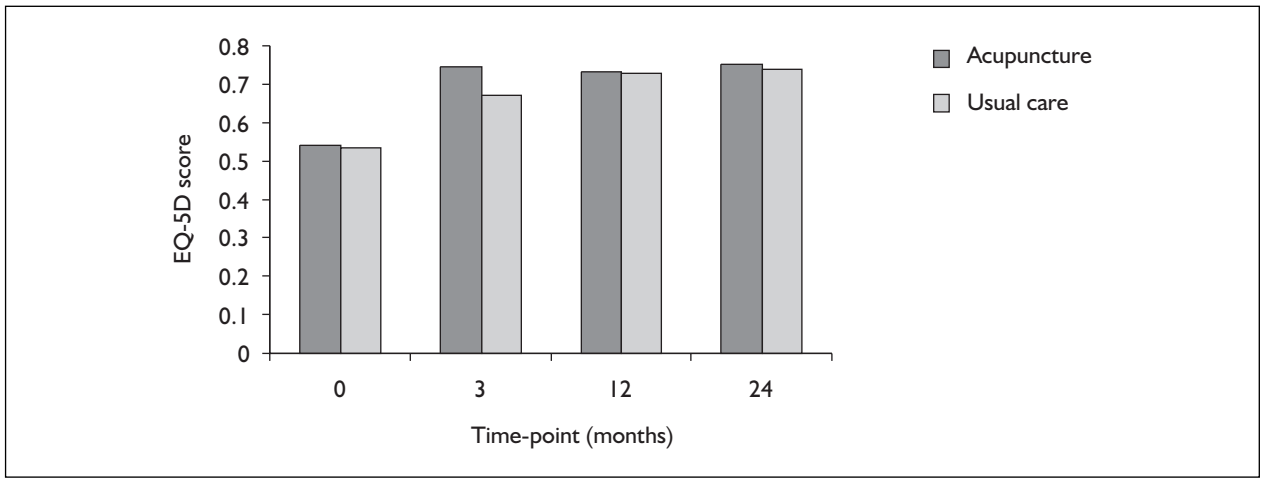

FIGURE 24 *EQ-5D scores over time including imputed missing data values*

TABLE 40 *Summary of outcome and NHS costs using SF-6D*

	Acupuncture care group Mean (SD) (*n* = 78)	**Usual care group Mean (SD) (*n* = 44)**	**Difference in means**	**(95% CI)**
Mean NHS cost over 24 months (discounted)	£459.70 (£376.39)	£345.21 (£550.44)	£114.50	(–£39.74, £268.73)
AUC using SF-6D, 0–24 months (discounted)	1.453 (0.248)	1.426 (0.191)	0.027	(–0.056, 0.110)
ICER		**£4241**		**£191 to £28,026**[a]

[a] Estimated using the 5th and 95th percentiles of the bootstrap repetition ICER values.

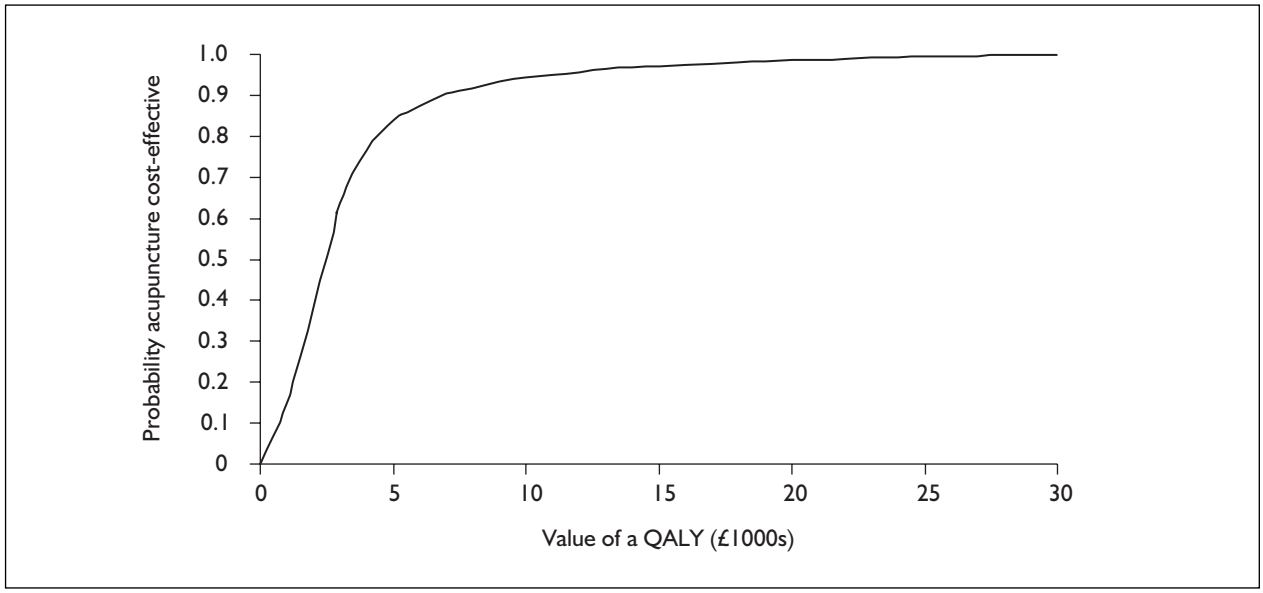

FIGURE 25 *Cost-effectiveness acceptability curve*

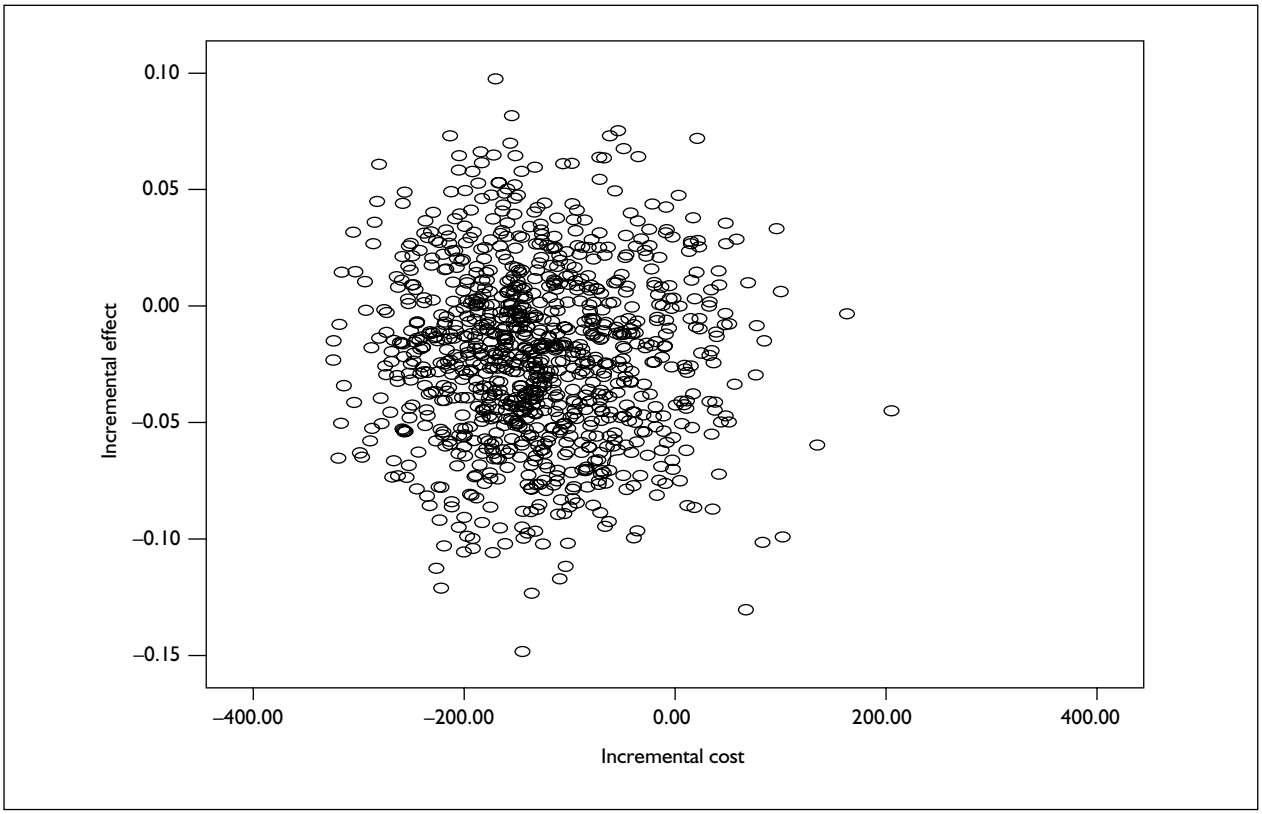

FIGURE 26 *Plot of distribution of bootstrapped ICER estimates*

Alternative cost-effectiveness analyses

Several alternative analyses of cost-effectiveness were carried out to test assumptions made in the main analysis and to improve the generalisability of the results. The results of these analyses are provided in Appendix 14. None of the alternative assumptions had a significant impact and the ICER values obtained were similar to the ICER value obtained from the base-case analysis.

Handling missing data in the primary analysis

The results of the primary data analysis relating to cost-effectiveness previously presented contained only those cases with complete data on NHS costs and SF-6D outcomes for the 24-month period of the trial. As a consequence, the total sample size for estimating cost-effectiveness was reduced markedly in comparison to the total number of individuals included in the trial. To assess the impact of the missing data on the results obtained, the statistical technique of multiple imputation was used to impute missing data values relating to NHS costs and SF-6D outcomes. The main advantage of using multiple imputation relative to other simpler mechanisms for handling missing data (e.g. last observation carried forward or mean imputation) is that it uses a formal statistical model for handling missing values which includes uncertainty in the prediction of the missing values themselves.[69] Multiple imputation of missing values uses Monte Carlo simulation techniques to replace missing values with a set of plausible estimates drawn from their predictive distribution which, at the same time, reflect the uncertainty in the data due to missing variables.[70] The number of estimates required is determined by the rate of missing information for the quantity being estimated. In this study the rate of missing information relating to NHS costs and SF-6D outcomes determined that five estimates were required. The missing data relating to NHS costs and SF-6D scores were estimated taking into account the time-point of questionnaire administration and the characteristics of each of the non-responders (including their age and gender) and matching them to equivalent individuals in the group of responders. Each completed data set was then analysed separately using complete data statistics, and the results (mean estimates and standard deviations) were combined using

TABLE 41 *Summary of outcome and costs using SF-6D: missing values imputed using multiple imputation technique*

	Acupuncture care group Mean (SD) (*n* = 159)	Usual care group Mean (SD) (*n* = 80)	Difference in means	(95% CI)
Mean NHS cost over 24-months (discounted)	£460.20 (£338.67)	£338.14 (£421.38)	£122.07	(£22.61, £221.52)
AUC using SF-6D, 0–24 months (discounted)	1.459 (0.247)	1.430 (0.208)	0.029	(–0.034, 0.092)
ICER		**£4209**		**(£182 to £27,899)**

* Significant difference between means ($p < 0.05$).

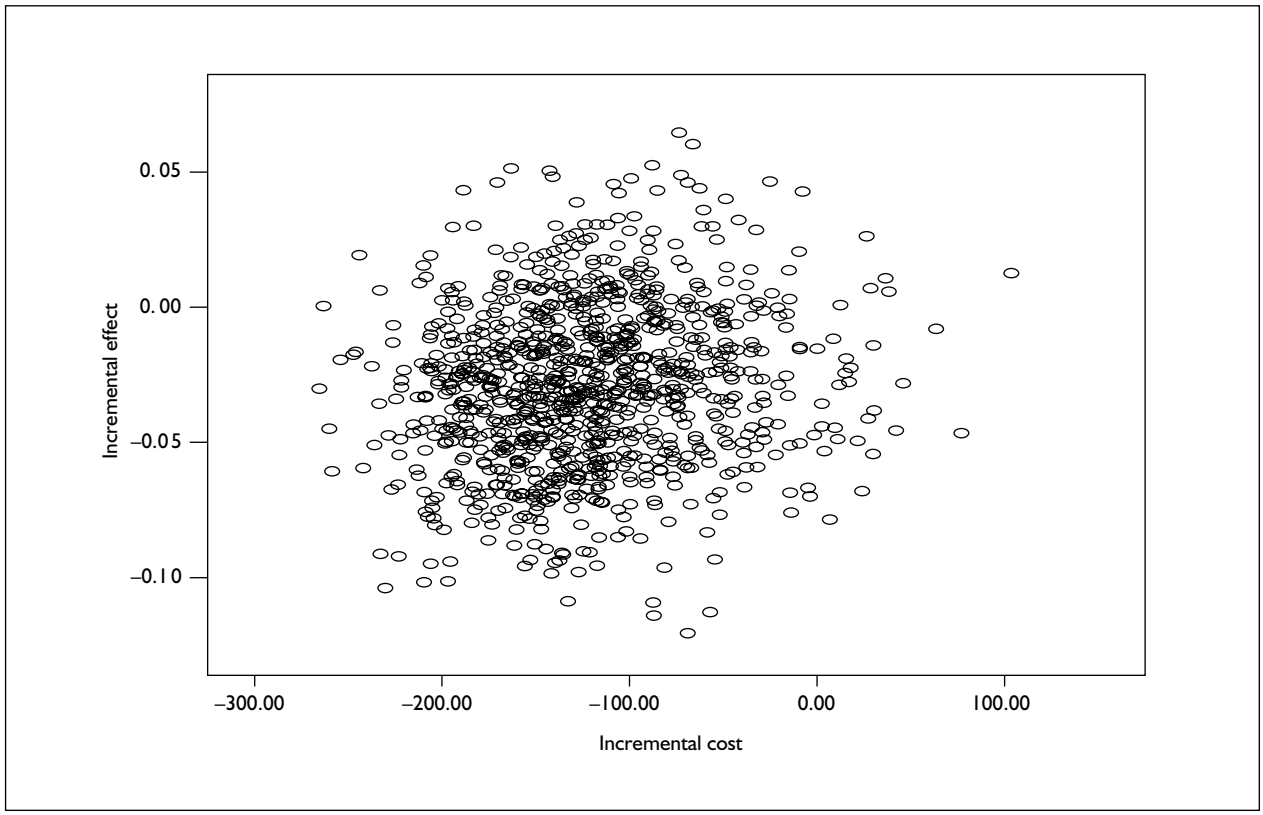

FIGURE 27 *Plot of distribution of bootstrapped ICER estimates including results of multiple imputation*

simple rules developed by Rubin to produce overall mean estimates and standard deviations reflecting missing data uncertainty due to non-response.[70]

The results are presented in *Table 41*. It can be seen that the results are very similar to the complete case analysis, in that acupuncture care is associated with a higher cost but with a slight increase in QALYs gained. As a consequence, the mean ICER for acupuncture in low back pain is positive (point estimate £4209).

The distribution of the ICER estimates resulting from the bootstrap repetitions is shown in *Figure 27*. As in the complete case analysis, the majority of observations indicate that acupuncture treatment for low back pain results in increased costs and improved effectiveness relative to a situation in which acupuncture care is not provided.

Conclusions

Apart from the initial acupuncture course, the only significant difference found between the groups in resource use during the first 12 months was a greater number of additional visits for private acupuncture in the acupuncture group. During months 13–24, patients in the usual care group reported significantly more visits for NHS acupuncture and significantly more visits to NHS pain clinics. The economic component of the study indicates that acupuncture care for the treatment of low back pain confers a modest health benefit for a relatively minor extra NHS cost relative to normal treatment. These conclusions hold regardless of the elicitation technique used to calculate QALYs, and whether the analysis is conducted including or excluding those individuals included in the trial who were permanently unable to work.

When societal rather than NHS costs are considered acupuncture care is the dominant therapy, although the wide confidence interval around the point estimate for cost differences means that this result must be interpreted with caution. From the perspective of the NHS, even assuming a maximum acceptable cost-effectiveness ratio to the NHS of £20,000,[62] acupuncture care for the treatment of low back pain appears highly cost-effective.

Chapter 6
Discussion

Clinical and economic findings of the present study will be considered in relation to previously published trials of acupuncture and other conservative treatments for persistent low back pain and offer recommendations for further research. The discussion will conclude with a review of the strengths and weaknesses of the design and analysis of the present study, and the research issues arising from these considerations.

Clinical outcomes

This pragmatic study assessed the outcome of a single course of NHS-delivered acupuncture. An effect was found of 5.6 points on the primary outcome SF-36 Pain dimension (95% CI –0.6 to 12.6) in favour of the acupuncture group at 12 months, and 8 points (95% CI 1.8 to 16.2) at 24 months.

Two systematic reviews of acupuncture for low back pain have reported mixed results, and reached different conclusions regarding effectiveness.[15,24] The difficulty in drawing firm conclusions can be explained in terms of the variability of the nature of the acupuncture intervention, the study design and the quality of the individual studies. Two placebo-controlled trials, assessed as better quality by the authors of the first review,[15] have shown positive short-term benefits for acupuncture, measured in terms of pain intensity/reduction.[71,72] The short-term results in the present study did not show a positive effect for acupuncture at 3-month follow-up; however, the results may not be directly comparable, owing to the experimental and standardised nature of the interventions in the placebo-controlled trials.

Four trials of acupuncture for back pain have been published since these reviews.[73–76] The design and patient populations in these trials make direct comparison with the present results difficult: two trials did not assess traditional acupuncture[73,74] and a third excluded patients with a history of less than 6 months of back pain.[76] The fourth trial, a three-arm open trial of traditional acupuncture, massage and self-care, by Cherkin and colleagues, was closest to the present study in design.[75] The design of the Cherkin trial was similar to the present study in that it involved seven traditional acupuncturists offering up to ten treatments, and measured longer term outcomes at 12 months. It focused on 'persistent back pain' and included patients with a history of at least 6 weeks of back pain, but excluded 297/431 of the patients identified in primary care, including those with symptoms below a certain threshold. The trial by Cherkin and colleagues also differed with respect to the primary outcome measure (modified Roland Disability Scale) and the fact that a more restrictive protocol was followed by the acupuncturists, which did not allow them to offer Chinese massage or herbs to patients. This high-quality study found no evidence of an acupuncture effect at 12 months measured in terms of the modified disability scale, but did find evidence of a massage effect.[75]

Evidence from a meta-analysis of RCTs of acupuncture for low back pain has shown that individualising the selection of points, and courses of acupuncture involving four or more treatments were associated with larger effect sizes.[24] The results of this trial provide support to these findings.

A recent health needs assessment concluded that there is an urgent need for more evidence of the longer term impact of discrete, short-term interventions, delivered earlier in an episode of persistent low back pain.[39] The present study provides such evidence for an acupuncture intervention compared with usual care. Further studies are needed to assess the relative benefit of acupuncture on the persistence and recurrence of low back pain compared with other short-term packages of care, delivered in an episode of non-acute low back pain.

Cost-effectiveness

The estimated cost-effectiveness of the acupuncture service is likely to be considered favourable by health services commissioners; the estimated cost per QALY was £4241 (95% CI £191 to £28,026) using the SF-6D scoring algorithm based on responses to the SF-36, and £3598 (95% CI £189 to £22,035) using the EQ-5D health status

instrument. The NHS costs were greater in the acupuncture care group than in the usual care group. However, the costs of the acupuncture treatment itself made up 45% of the total NHS costs in the acupuncture group. No other studies on the costs or cost-effectiveness of acupuncture care for low back pain have been published to date. Further studies assessing the cost-effectiveness of acupuncture care compared with other short-term packages of care, delivered in an episode of non-acute low back pain, are needed to show the relative cost-effectiveness of acupuncture care, and to inform decision-making regarding appropriate services for this patient group.

Optimum timing for an acupuncture treatment package

Patients in this trial were recruited with a current episode of low back pain of between 4 and 52 weeks' duration. This was chosen for pragmatic reasons to mirror the point at which GPs might offer patients active treatment. Analysis showed a benefit for all patients in this group. However, the results suggest that episode duration at recruitment was negatively associated with better outcome. Further investigation of the optimum timing for an acupuncture treatment package in a patient episode of low back pain may be warranted to target the intervention more effectively, and to aid decisions regarding cost-effective service delivery.

Safety and acceptability of acupuncture

All patients randomised to the offer of acupuncture chose to receive it. It is possible that patients with negative feelings about acupuncture screened themselves out of the trial. Information was available on a small proportion of patients, 13/289 (4.5%), assessed as suitable for the trial by their GP who declined to enter the trial. For the majority of these, a lack of interest in having acupuncture was given as the reason by the GP. Adverse event data were collected for the acupuncture group only. No serious adverse events (defined as an event resulting in hospitalisation and/or permanent disability or death) were reported by patients receiving acupuncture during the trial. However, a high proportion of patients (63%) reported experiencing a temporary worsening of their low back symptoms following acupuncture treatment. A smaller proportion (23% of all patients receiving acupuncture), stated that this bothered them 'a lot' or 'a great deal' at the time. Data from this trial suggest that this experience did not reduce the acceptability of acupuncture to the majority of patients. Further evidence of the acceptability of acupuncture to patients with low back pain was seen in the high levels of satisfaction reported compared with usual care, and 90% of patients in the acupuncture group stated at 3 months that they would be willing to have acupuncture again.

A regression model identified four strong influences on the decision not to want to try acupuncture again: having an unacceptable response to treatment, support from the acupuncturist that was perceived to be less than 'excellent', a pain score that was the same or worse than at entry, and not experiencing a feeling of relaxation during treatment sessions. Patients commonly reported positive experiences of the process of treatment, such as feeling supported and relaxed. Although positively valued by patients, such 'process utilities' may not be taken into account in a conventional cost-effectiveness analysis if they do not translate directly into health outcomes.[77] Further work is needed to assess the relative value placed on these utilities by patients, and the possibility of trade-off between these and conventional pain outcomes.

Internal validity

The trial outcomes were analysed on an ITT basis using complete case analysis and a two-group comparison because all patients allocated to the offer of acupuncture chose to receive it. Primary outcomes were analyses using ANCOVA methods with adjustment for baseline scores only. Further analysis was undertaken adjusted for potential baseline confounders. Additional analysis was undertaken excluding those cases identified at baseline as permanently unable to work owing to low back pain. These patients were not intended to be included in the study as the 12-month exclusion criteria for a current episode of low back pain were expected to identify such cases. In the event, 11 such cases were included in the trial, all of whom were allocated to the acupuncture group. These 11 cases had considerably poorer reported health status at baseline and poorer pain outcomes, and therefore had the potential to impact on the results. A further analysis, undertaken excluding these cases, altered the 12-month outcome, but not the 24-month results or the economic analysis. However, as a pragmatic trial, it may be argued that the true results should include these cases.

Five further issues relate to the internal validity of the trial: prior patient expectations, the choice of outcomes, the timing of the outcome measures used, the use of non-trial acupuncture by either allocation group, and the handling of missing data.

Patient prior expectations of treatment

This study adopted a pragmatic open design to assess the delivery of acupuncture care that mirrored everyday practice as closely as possible. One advantage of an open trial design is that the process of acupuncture does not need to be compromised by the process of blinding patients.[41] However, open trials may be vulnerable to confounding or bias owing to prior patient expectations of treatment, especially where subjectively assessed outcome measures, such as perceived pain, are used. Previous reports of the impact on trial outcome measures of positive prior beliefs about complementary therapies in general have shown no association, positive or negative.[78,79] However, one of these studies found that patient expectations for benefit from a specific complementary therapy were associated with improved levels of function at 10 weeks among patients with low back pain.[79] The present trial did not measure strength of beliefs, but it did explore the impact of certainty in patient expectations regarding the likely benefit of acupuncture on pain outcomes. Patients who responded positively were compared with those who were not sure or responded negatively. An association was found between the absence of a positive prior belief that acupuncture can help low back pain and an increased effect at 24 months in the acupuncture arm of the trial. Conversely, in the control group, patients with no positive prior belief in the value of acupuncture for their low back pain had poorer outcomes than those who thought it might help. This evidence does not support the argument that the benefits of acupuncture depend on prior belief. The association found in the acupuncture group may be associated with negative beliefs at entry, followed by a positive 'mind shift' associated with acupuncture care, a benefit that would not be available to those patients receiving acupuncture who already believed that it offered a therapeutic option that could improve their low back pain. Further research in this area is warranted.

Choice of outcomes

The primary and secondary outcomes used in this study conform to the internationally developed recommendations for low back pain research.[80] The primary outcome measure was reported pain in the past month, and this was measured using the pain dimension of the SF-36 health status instrument, which has been validated for use in trials. Several secondary measures were included, including two validated pain outcome measures: the McGill PPI (which measures pain in the past week) and the ODI. These validated secondary outcome measures showed mixed effects. The ODI, which measures the impact of pain on daily living, showed an immediate effect in both groups, but did not show much change at 12 or 24 months. A similar pattern was seen for the PPI. Detailed analysis of item responses to SF-36, PPI and ODI may help to identify the specific impact of acupuncture on low back pain.[81]

In contrast, other secondary outcomes measured suggest that acupuncture patients may experience a number of additional benefits, including a significant reduction in 'worry' about their back pain compared with the usual care group, which increased at each time-point measured. Possible reasons for this reduction in reported worry include a reduced expectation of another episode of pain, or a reduction in fear of another episode stemming from a belief that acupuncture offers an effective management strategy. The present data do not enable this to be explored further, and it was not possible to test how this reduced worry interacts with reduced pain scores. A qualitative investigation is indicated to explore the meaning to patients of a reported reduction in worry about back pain following acupuncture, and its implications for the care and management of this group of patients.

Timing of outcome measurement

This study found evidence for a long-term effect for acupuncture due to the continued improvement in the acupuncture group. This resulted in increased homogeneity between acupuncturist effects over time. The evidence of a long-term clinical effect of acupuncture, beyond the source of treatment, is not unique to this trial. Increasing benefits post-treatment have been demonstrated in a number of trials of acupuncture. For example, a trial of acupuncture for migraine monitored pain and medication scores at baseline, 6 weeks (after six weekly treatments), 4 months and 12 months. Mean scores for pain showed a significant difference between the true and sham acupuncture groups at 6 weeks, and that this difference grew at 4 months, and again at 12 months.[82] Similarly, in a trial of acupuncture for stroke, patients were monitored on a number of stroke-related outcome measures at inclusion, 6 weeks (after 6 weeks of treatment)

and 12 months. Results showed that the acupuncture group improved significantly more than controls at 6 weeks and again even more at 12 months.[83] It has been suggested that the effects of acupuncture can be divided into two components, acupuncture analgesia and therapeutic acupuncture, and several hypotheses have been suggested for the mechanisms of therapeutic acupuncture that may explain these longer term effects, including some sort of physiological relearning that is triggered by the acupuncture.[84,85] Further research is indicated to explore the underlying causes and mechanisms involved in the continued improvement over time of patients with low back pain receiving a short course of acupuncture.

Use of non-study acupuncture

The trial protocol allowed up to ten individualised acupuncture treatments per patient. No further NHS treatments with these practitioners were possible for these patients. Usual care commonly entailed a mixture of physiotherapy, medication and recommended back exercises. As this was a pragmatic trial, neither group was told not to access acupuncture from other sources. A small proportion of patients in both groups received NHS-delivered acupuncture that was not part of the study, usually from a physiotherapist or GP offering a limited acupuncture intervention. In addition, a number of patients reported having received private acupuncture during the trial follow-up period of 2 years. This use was more common in the acupuncture group, but even in this group, over 90% of patients followed up at 24 months reported no additional private acupuncture in the past 12 months.

Handling missing data

Some patient loss to follow-up is inevitable in any trial. This will be even more likely in trials located in primary care, and those seeking to measure longer term outcomes. This study achieved a high follow-up rate at 12 months (93% and 85% in the acupuncture and usual care groups, respectively), but lost a higher proportion of patients at the 24-month follow-up (77% and 73% follow-up in the acupuncture and usual care groups, respectively). The major undesirable effects of missing data in clinical trials are the introduction of biases and the loss of efficiency due to reduced sample size.[53] A comprehensive analysis of the known characteristics of patients showed that those who were lost to follow-up were younger than those who completed follow-up ($p = 0.02$) and seemed to have poorer SF-36 Pain scores at 3 months ($p = 0.05$). However, this pattern was observed in both randomisation groups, indicating that there was no evidence of any difference between the randomisation groups in those lost to follow-up. The analysis of clinical outcomes proceeded on this assumption. An alternative approach would have been to consider data imputation to maximise the available data. Taking the outcome for the last observation made and carrying this forward to the next outcome point if that is missing (last observation carried forward) is a commonly used technique for handling missing data where there are multiple outcome points. Alternatively, assuming that the values are missing at random one can impute missing values, and so analyse the data for the complete cohort and not just for those completed at each occasion.[86] The use of last observation carried forward methods has been criticised, and imputed data may produce either conservative or anti-conservative results.[87,88] Nevertheless, a sensitivity analysis to investigate the effect of missing values on the primary outcomes reported in this study may be indicated.[89]

Despite the growing interest in multiple imputation techniques, there is currently no standard method for handling missing longitudinal data in clinical trials. Methodological work is needed to guide the research community about the best way to investigate the effect of missing values on primary outcomes in clinical trials.

A stronger consensus is developing among health economists regarding the best methods of handling missing data.[69] Multiple imputation techniques were used in the present cost-effectiveness analysis, to assess the impact of missing data. Sensitivity analysis using imputed data demonstrated the robustness of the cost–utility findings.

External validity

The key issue for external validity in a pragmatic trial is the extent to which the results are relevant to other settings, given the lack of standardisation inherent in the process. In this trial, the issue of transferability is further complicated by the acupuncture intervention being delivered on an individualised basis, and by the pragmatic definition of the relevant patient population.

Type of acupuncture

The study focused on the largest group of acupuncturists, who use acupuncture as their main therapeutic intervention. All acupuncturists in the trial were members of the BAcC, working to

standards of training, competency and safety set and monitored by the BAAB. One advantage of using acupuncturists with homogeneous methods of practice is that the results are relevant to practitioners registered with BAcC nationally. The degree to which the results are generalisable to this group of practitioners is limited by the sample of six practitioners in the present study. However, since in many previous trials of acupuncture the intervention was delivered by a single practitioner, the present design represents a substantial improvement in this respect and was able to demonstrate acceptable homogeneity of effects for these practitioners. The results are not generalisable to other types of acupuncture as practised by members of the BMAS and the AACP. This question would need to be addressed through studies designed specifically to measure the comparative efficacy of different types of acupuncture.

Study location

For practical purposes, the study was located in York, with GPs recruited from within the boundaries of York Health Authority as it was constituted at the time of the trial. It cannot be assumed that these GPs are identical to those in other parts of the country with respect to their willingness to refer patients to acupuncturists. However, there is good evidence to suggest that, nationally, many GPs are positive about the potential contribution of acupuncture in primary care.[20] Although York is unusual in having an acupuncture training college and a research foundation for TCM, the availability of traditional acupuncturists is not exceptional in York. The professional register of the BAcC shows that qualified traditional acupuncturists are well distributed across the country. In the present study, the acupuncture service was provided by six acupuncturists and made available to GPs in 18 practices, and a similar ratio of registered acupuncturists per GP practice exists nationally.

Patient population

A retrospective survey of GPs participating in the trial suggested that approximately 50% of the eligible patients seen during the recruitment period were included. No systematic pattern of exclusion was identified; GPs reported that most of these patients were missed because of time constraints in the consultation. However, it is not known how many of these patients would have been suitable for referral to the acupuncture service, or whether the results obtained would apply to them. The transferability of the results rests in part on any new service accepting referrals that are similar to those in this trial. Patients in this trial represent those who GPs considered for active treatment, and span the traditional subacute and chronic categories. The transferability of the results of this trial rests, in part, on the assumption that the referring behaviour of the 43 participating GPs mirrors usual practice.

Eleven patients were referred into the trial who reported that they were permanently unable to work owing to their low back pain. These patients had relatively poor outcomes with respect to pain reduction. As all 11 were in the acupuncture group, their presence in the study reduced the observed difference between the two groups. In practice, it can be assumed that, if an acupuncture service was available, similar patients might be referred by GPs, and their inclusion is therefore appropriate in a pragmatic trial. Further research on the potential benefits of acupuncture for this group of patients may be warranted.

Heterogeneity of acupuncturist effect

The transferability of the results also depends on the possibility of providing a similar intervention or service. The acupuncturists in this study were selected on the basis of their qualifications, training and experience. These are criteria that can be replicated, but it is still possible that the acupuncturists in the trial practised differently to each other and obtained different levels of success. Therefore, a test was done for heterogeneity of acupuncturist effect, comparing outcomes for the six acupuncturists, each of whom treated a minimum of 15 patients. Tests for heterogeneity showed no significant difference between practitioners for 12- or 24-month pain outcomes. At 24 months, practitioners contributed just 2% of the variability of the treatment effect. This suggests that, for this group of acupuncturists, the acupuncture effect is much greater than the acupuncturist effect. The authors know of no other studies of acupuncture that have explored this issue within the context of a pragmatic trial.

The intervention as delivered

The trial protocol allowed up to ten individualised acupuncture treatments per patient. The acupuncturist determined the content and the number of treatments according to patient need. Detailed information was collected on the intervention as delivered and reported in accordance with the international STRICTA guidelines.[54] More than half of the patients received the maximum number of treatments allowed. Practitioners customised the treatment time for individual patients, usually 10–30 minutes

(range 5–40 minutes). All practitioners attempted to attain de qi most of the time, and acupuncturists used an average of 9.6 needles per treatment (range 6–12). While a total of 177 different acupuncture points were used throughout the trial, certain points were used sufficiently often to constitute at least 2% of the total. The range of points used reflects the individualised nature of a traditional acupuncture approach to diagnosis and treatment. Auxiliary treatments including massage and advice on diet, rest and exercise were also used by the study practitioners to varying degrees. Using the experience of acupuncture as delivered in this trial, the authors suggest that there is scope for a flexible treatment protocol for the use in trials of acupuncture for low back pain, one that allows practitioners to address normal patient variation (Appendix 15).

Further research is needed to support the distillation of a protocol for acupuncture treatment for low back pain that allows individualised treatment to be delivered while defining a package of care that can be commissioned reliably and safely.

Chapter 7
Conclusions

Implications for low back pain management in primary care

Results from the present study suggest that GP referral to a brief course of traditional acupuncture is associated with greater long-term clinical benefit, compared with usual GP care. Over a 24-month period, an intervention comprising an average of eight sessions of traditional acupuncture care produces costs that are slightly higher than those associated with usual care (i.e. GP management with advice on exercise, medication and referral to physiotherapy for some patients). Given the additional benefits observed in this trial, the service is cost-effective at 24 months.

Based on the study's observed superiority in long-term clinical and economic outcomes of acupuncture compared with usual GP care, and the acceptability of traditional acupuncture care to patients in this study, commissioners of musculoskeletal services would be justified in making GP referral to a short course of traditional acupuncture available to primary care attendees with persistent non-specific low back pain at the point when their GP considers active treatment. Access to such a service would depend on patient and GP preferences. The experimental service assessed in the present study worked well, but delivery mechanisms for future provision would need further consideration.

Relevance to consumers

Most traditional acupuncture is accessed via the private sector[18] and the results from this trial will be of interest to consumers within and outside the NHS. Patients should have access to the findings regarding both benefits and adverse events. This study provides evidence that traditional acupuncture was acceptable to patients with low back pain, with high levels of satisfaction reported. Acupuncture patients also reported a significantly greater reduction in worry about their back pain at 12 and 24 months compared with the usual care group, and this may also be seen as a valuable outcome by patients. At 24 months, 81% of acupuncture patients stated that their allocated treatment had helped their back pain, compared with 52% in the usual care group. Four patients dropped out of treatment citing an adverse event as their primary reason, but almost one in four patients reported a temporary exacerbation of their back pain during treatment that bothered them 'a lot' or 'a great deal' at the time. Patients considering traditional acupuncture for low back pain should be informed about the relatively high likelihood that they will experience a temporary aggravation of their symptoms.

Recommendations for further research: clinical issues

Comparison with other short-term packages of care

Acupuncture appears to offer a useful therapeutic option for patients with low back pain, showing significant longer term benefits compared with usual care. Patients in this trial reported high levels of satisfaction with their acupuncture care. However, other short-term packages of care may offer similar longer term benefits. Comparative studies are needed to assess the longer term clinical outcomes and patient acceptability of different types of care (e.g. massage, chiropractic or physiotherapy) delivered as discrete and limited packages, early in an episode of low back pain.

Specific effects of traditional acupuncture

This trial showed an effect for referral to a service offering traditional acupuncture on the reduction of reported pain that increased over time. No effect was found for reported pain-related disability as measured. Further work is indicated, including a detailed analysis of item responses to SF-36 and Oswestry questionnaires, to explore both the specific impact of acupuncture on low back pain, and the underlying causes and mechanisms involved in the continued improvement over time of patients with low back pain receiving a short course of traditional acupuncture.

Acupuncture may be delivered in a number of ways. This trial examined traditional acupuncture delivered by qualified practitioners. There is a case for research to look at the comparative cost-

effectiveness of different modes of acupuncture offered as short-term packages of care, delivered during an episode of non-acute low back pain, for example acupuncture delivered by physiotherapists in a primary care setting.

Relevance of reduced worry about back pain

Acupuncture patients reported a substantial reduction in worry about their back pain that was not observed in the usual care group. A qualitative investigation is needed to explore the meaning to patients of this reduction in worry, its relationship to patient coping strategies and its implications for the care and management of this group of patients.

A protocol for traditional acupuncture treatment for low back pain

A treatment protocol has been proposed for the evaluation of traditional acupuncture for low back pain. Further work is needed to develop a protocol for practice that allows individualised treatment to be delivered while defining a package of care that can be commissioned reliably and safely, and which represents value for money. Exploration of the optimum timing of a primary care acupuncture intervention, and the issue of repeat courses of treatment need to be considered.

Recommendations for further research: economic issues

Traditional acupuncture care was found to be cost-effective in this trial compared with usual care. Further research is indicated that looks at the cost-effectiveness of acupuncture compared with other short-term packages of care delivered in episodes of non-acute low back pain.

Recommendations for further research: methodological issues

Patient expectations

Much has been made of the possibility that trials of complementary therapies reflect patient expectations of treatment. This trial adds to the growing body of evidence by suggesting that this is not the case, with no significant relationship found between positive expectations of acupuncture and treatment outcome. Subgroup analysis suggests that the opposite effect may be possible, as an association was found between the absence of a positive prior belief that acupuncture can help low back pain and an increased effect at 24 months in the acupuncture arm. Conversely, in the control group, patients with no positive prior belief in the value of acupuncture for their low back pain had poorer outcomes than those who thought that it might help. This evidence does not support the argument that the benefits of acupuncture depend on prior belief. Further research in this area is warranted.

Process utilities

Patients commonly reported positive experiences of the process of treatment, such as feeling supported and relaxed. Although positively valued by patients, such 'process utilities' may not be taken into account in a conventional cost-effectiveness analysis if they do not translate directly into health outcomes. Further work is indicated to assess the relative value placed on these utilities by patients, and the possibility of trade-off between these and conventional pain outcomes.

Handling missing data

Missing data at follow-up are a risk in any community-based trial, and the risk is increased by a design that calls for long-term follow-up. The major undesirable effects of missing data in clinical trials are the introduction of biases and the loss of efficiency due to reduced sample size. Following a thorough exploration of known characteristics, which found no evidence of any difference between the randomisation groups in those lost to follow-up, complete case analysis was undertaken on the clinical outcome measures in this trial. Alternative analysis strategies are gaining popularity, particularly those using techniques of multiple imputations. There appears to be a growing consensus regarding the use of these techniques in cost-effectiveness analysis, but no similar consensus regarding the best way to handle missing longitudinal data in clinical trials. Methodological work appears to be needed to guide the research community about the best way to investigate the effect of missing values on primary outcomes in clinical trials.

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Contribution of authors

KJ Thomas (Deputy Director, Medical Care Research Unit) was principal investigator and grantholder, and was jointly responsible for the conception and design of the study, the analysis of the clinical data and the interpretation of the clinical and economic findings.

H MacPherson (Senior Research Fellow) was lead clinical (acupuncture) researcher, and was jointly responsible for the conception and design of the study and the analysis and interpretation of the clinical data.

L Thorpe (Research Fellow) was trial researcher and manager, contributed to the design of the study and the analysis and interpretation of the clinical data, and revised the final report.

J Ratcliffe (Senior Research Fellow in Health Economics) was lead economic researcher, and was jointly responsible for the analysis and interpretation of the economic data.

J Brazier (Professor of Health Economics) supervised the economic evaluation, and was responsible for the design of the economic evaluation and jointly responsible for the analysis and interpretation of the economic data.

M Campbell (Professor of Medical Statistics) was the trial statistician, was jointly responsible for the design of the study, the analysis and the interpretation of the clinical data, and analysed the acupuncturist heterogeneity data.

M Fitter (Chartered Psychologist) was the acupuncture research advisor, and was jointly responsible for the conception and design of the study. M Roman (General Practitioner) was GP advisor, and was jointly responsible for the conception and design of the study.

S Walters (Senior Lecturer in Medical Statistics) undertook independent statistical analysis and interpretation of the primary clinical outcome data. JP Nicholl (Director, Medical Care Research Unit) supervised the trial design and data analysis, and was jointly responsible for the design of the study, and the analysis and interpretation of the clinical data.

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Appendix 1

Cochrane reviews of conservative treatments for low back pain

TABLE 42 *Cochrane reviews*

Intervention	Patients	First author	No. of trials	Authors' quality assessment of trials	Results	Comments
Back schools	Non-specific LBP	van Tulder[3]	15	Low	Moderate evidence that back schools have better short-term effects than other treatments for chronic LBP. Moderate evidence that back schools in an occupational setting are more effective than 'placebo' or waiting list controls	Back schools may be effective for patients with recurrent and chronic LBP. Little is known about the cost-effectiveness of back schools
Bed rest	Acute LBP or sciatica	Hagen[4]	9	Mixed	High-quality studies comparing bed rest with advice to stay active found no difference in pain intensity or functional status at follow-up	Bed rest compared with advice to stay active will at best have small effects, and at worst may have small harmful effects on acute LBP
Behavioural treatment	Chronic non-specific LBP	van Tulder[5]	20	Low	Behavioural treatment has a moderate positive effect on pain intensity of chronic LBP patients compared with waiting list controls or no treatment	Behavioural treatment is an effective treatment for chronic LBP patients, but it is unknown what type of patients benefit most from what type of behavioural treatment
Exercise therapy	Non-specific LBP	van Tulder[13]	39	Mixed	Exercise therapy is not more effective than inactive or other active treatments for acute LBP. Conflicting evidence exists on the effectiveness of exercise therapy compared with inactive treatments for chronic LBP	There is no evidence to suggest that specific exercises are effective for the treatment of acute LBP. Exercises may be helpful for chronic LBP patients to increase return to work and normal daily activities
Injection therapy	Benign LBP lasting longer than 1 month	Nelemans[14]	21	Low	Facet joint, epidural and local injection therapy has not yet been shown to be effective, nor has it been shown to be ineffective	Convincing evidence is lacking on the effects of injection therapies for LBP. More well-designed explanatory trials are needed
Lumbar supports	Non-specific LBP	van Tulder[6]	13	Low	There is limited evidence that lumbar supports are more effective than no treatment. It remains unclear whether lumbar supports are more effective than other interventions for treatment of LBP	There is a need for high-quality randomised trials on the effectiveness of lumbar supports

continued

TABLE 42 *Cochrane reviews (cont'd)*

Intervention	Patients	First author	No. of trials	Authors' quality assessment of trials	Results	Comments
Massage	Non-specific LBP	Furlan[7]	8	Mixed	Massage was inferior to manipulation and TENS, equal to corsets and exercise, and superior to relaxation therapy, acupuncture, self-care education and sham laser	Massage may be beneficial for patients with subacute and chronic non-specific LBP
MBPSR	Chronic LBP	Guzmán[8]	10	Mixed	There was strong evidence that MBPSR with a functional restoration approach improved function when compared with inpatient or outpatient non-multidisciplinary treatments, and moderate evidence that it improved pain when compared with outpatient non-multidisciplinary rehabilitation or usual care	Intensive MBPSR with a functional restoration approach improves pain and function
Muscle relaxants	Non-specific LBP	van Tulder[9]	30	High	There is strong evidence that any of the muscle relaxants are more effective than placebo for patients with acute LBP on short-term pain relief	Muscle relaxants are effective in the management of non-specific LBP
NSAIDs	Non-specific LBP	van Tulder[10]	51	Mixed	The placebo-controlled studies suggest that NSAIDs are effective in improving global improvement in patients with acute LBP. There is conflicting evidence that NSAIDs are more effective than paracetamol, and moderate evidence that NSAIDs are not more effective than other drugs for acute LBP	NSAIDs are slightly effective for short-term global improvement in patients with acute LBP
Radiofrequency denervation	Chronic musculoskeletal pain	Niemisto[11]	7	High		There is conflicting evidence on the short-term effect of radiofrequency lesioning on pain and disability in chronic LBP of zygapophyseal joint origin; and limited evidence that intradiscal radiofrequency thermocoagulation is not effective for chronic discogenic LBP

continued

TABLE 42 *Cochrane reviews (cont'd)*

Intervention	Patients	First author	No. of trials	Authors' quality assessment of trials	Results	Comments
TENS	Chronic LBP	Milne[12]	5	Low	In all trials there was no statistically significant difference between the active TENS group and the placebo TENS group for any outcome measures	There is no evidence to support the use of TENS in the treatment of LBP
Acupuncture	Non-specific LBP	van Tulder[15]	11	Low	There was no evidence showing acupuncture to be more effective than no treatment; moderate evidence indicating that acupuncture is not more effective than trigger-point injection or TENS; and limited evidence that acupuncture is not more effective than placebo or sham acupuncture for the management of LBP	There is a need for more high-quality RCTs with large samples, using valid acupuncture treatment, with both a short-term and a long-term follow-up

MBPSR, multidisciplinary biopsychosocial rehabilitation; NSAID, non-steroidal anti-inflammatory drug.

Appendix 2

Patient information leaflet

Chronic Low Back Pain Study: clinical and economic benefits of an offer of acupuncture treatment

Patient Information – please read carefully and ask if you have any questions

What is the purpose of the study?

Many people with Persistent Low Back Pain try alternative medicine, including acupuncture, in their search for relief from their symptoms.

At present most of this treatment is provided privately. Some people believe that this form of treatment should be available for NHS patients via a referral from their General Practitioner.

At present, there is no clear answer to the question whether patients offered acupuncture report more relief from their pain symptoms than those receiving usual care only. We wish to answer this question. It is also important to find out about the relative costs of offering an acupuncture service to NHS patients in this way.

The study will involve a total of 240 patients, and is funded by the NHS Executive. It will ask whether the provision of a GP referral to an acupuncture service improves the health of people with Chronic Low Back Pain. In particular it will look at whether they receive as much or more benefit as those receiving usual care from their GP, for the same or less cost.

Acupuncture

Acupuncture aims to help a person achieve improvements in health by stimulating the body's own tendency to heal itself. It has been used in China for two thousand years. It is claimed that many kinds of illnesses, for example, arthritis, migraine and depression are treatable by acupuncture.

Traditional Chinese acupuncture involves the insertion of very fine needles just under the skin. Sometimes the needles are removed immediately, sometimes they are left in place for a few minutes. The insertion of the needle creates a brief pricking sensation, but most patients do not report that this is painful. Traditional Chinese acupuncture sometimes involves the application of heat to the needles to stimulate activity. This is experienced as warmth and is not painful. Sometimes, after acupuncture, people experience a temporary worsening of symptoms, or a temporary return of symptoms of a past illness. However, these 'aggravations' pass within a few days and are seen by an acupuncturist as an indication that the body's self-healing mechanism has been stimulated by the treatment.

What will be involved if I agree to take part in the study?

It is important to make sure that everyone in the study should be equally likely to get offered acupuncture or to receive usual care from the GP. If you agree to take part in the study, then you will be allocated at random to one of two groups – one group will be offered a referral to one of two acupuncture clinics in York, and one group will continue to receive usual care from their GP. You will not be able to choose which group you are in.

If I am offered acupuncture

If you are offered acupuncture, you can choose whether or not to accept this offer. You will have the opportunity to discuss what will be involved further with the researcher. As part of the study, you will attend an acupuncture clinic in York for treatment. The acupuncturists have all completed the training required to register with the British Acupuncture Council. They have between 3 and 15 years' experience of acupuncture practice. The first treatment session with an acupuncturist will be organised by the researcher at a time which is convenient for you. The first appointment will last about one hour. The number of subsequent treatments (up to a maximum of nine) will be decided by the acupuncturist. The times will be arranged directly between you and the clinic. They will last about half an hour. **The costs of the acupuncture treatment, but not the travel to the clinic, will be met by the study.** Once the study has finished, neither the study nor your GP will be able to fund continuing acupuncture treatment. If you wish to continue with acupuncture treatment, it will be up to you to make arrangements to pay for this.

If I am <u>not</u> offered acupuncture

If you are in the group which is not offered acupuncture, you will continue to receive usual care from your GP and we will monitor your care and health over the next 12 months.

Can I withdraw from the study at any time?

Yes. You are free to decide not to join the study, and may withdraw at any time or choose not to answer certain questions. You will continue to receive the same quality of care from your GP if you decide not to take part in the study.

Will there be any effects on my treatment?

If you take part in the study your care will continue to be at the discretion of your GP. If you decide to take part, are offered acupuncture and <u>accept</u> this offer, your GP may decide not to refer you for another type of treatment (e.g. physiotherapy) while you are receiving acupuncture.

What information will be collected in the study?

Once you've agreed to take part in the study, you will be asked by the researcher to complete a few questionnaires designed to record your overall state of health, your pain symptoms and the treatment you receive. This will take approximately 20 minutes. Three months after starting treatment, and again at 12 months after starting treatment, you will be asked to complete these same questionnaires. This will allow us to record the changes in your state of health during and after the treatment period. You will be contacted at home, sent similar questionnaires and provided with a stamped, addressed envelope for their return. In addition to this, information may be collected via your GP about any consultations, prescriptions and referrals recorded during the study period. The researcher may also need access to your hospital records if you have had a referral to hospital for back pain during this period.

Will the information obtained in the study be confidential?

Anything you say will be treated in complete confidence, no names will be mentioned in any reports of the study and care will be taken so that individuals cannot be identified from details in reports of the results of the study. All information about you, including your replies to questionnaires, is subject to legal requirements, including the Data Protection Act. Any information stored on computers will remain anonymous and will not be disclosed to any one other than the investigators.

Will anyone else be told about my participation in the study?

With your agreement, we will inform your GP that you are helping with this study.

What if I wish to complain about the way in which this study has been conducted?

If you have *any* cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study. In addition, the complaints mechanisms of the British Acupuncture Council are available to you.

If you have any complaints or concerns please contact the project co-ordinator: –

Kate Thomas, Medical Care Research Unit, School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent St., Sheffield S1 4DA. Telephone: 0114-222-0753

In the event of a complaint concerning the professional conduct of an acupuncturist who treats you, you can also contact: The Ethics Secretary, Preliminary Investigation Committee, British Acupuncture Council, Park House, 206–208 Latimer Road, London W10 6RE.

What if I am harmed?

If you are harmed by your participation in this study, there are no *special* compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action.

All acupuncturists treating patients in the research programme are insured for professional practice. Insurance policies cover malpractice, public liability and products liability.

Appendix 3

Baseline background and demographic questions

To end with I would just like to ask you a few background questions about yourself.

1. Can you tell me how old you were when you left full-time education?

   ..... years

   (*Patient still in full time education, tick here, skip to Qu.3*) ☐

2. (a) <u>*Working patients only*</u>
   (*If in Qu.9 patients said they were working*)

   You said previously that you were working. Do you work:

   (1) Full-time
   (2) Part-time

   What is the name and title of your job?

   Occupation: .....

   Industry: .....

   (b) <u>*Unemployed patients only*</u>
   (*If in Qu.9 patients said they were not working at the moment*)

   You said previously that you were not working at the moment. Can I ask which of the following applies to you?

   (1) Are you looking for work?
   (2) Are you permanently unable to work?
   (3) Are you out of work because of back pain?
   (4) Are you retired?
   (5) Are you looking after the home or family?
   (6) Other, please specify .....

3. Do you feel you have any other <u>major</u> health problem apart from your back pain?

   .....

4. Have you ever had a health problem for which you have seen any of the following?

	NHS	Private	Over counter
1. Osteopath/Chiropractor – or received osteopathy/ chiropractic treatment?			
2. Acupuncturist – or received acupuncture treatment? When did you have it? ..... Where?			
3. Homeopath – or received homeopathic treatment?			
4. Hypnotherapist – or received hypnotherapy?			
5. Medical herbalist – or been given a herbal prescription?			
6. Other specialist in alternative or complementary medicine?			

5. Do you think acupuncture can work? (*In general*)
   (1) Yes
   (2) No
   (3) Don't know

   Other comments? .....

6. Do you think your back problem may be able to be helped by acupuncture?
   (1) Yes
   (2) No
   (3) Don't know

   Other comments? .....

7. Have you ever previously been invited to enter the trial and declined?

   (1) Yes (*specify GP who invited the patient, and date of invitation*)

   .....

   (2) No

   .....

Appendix 4

Back pain experience questions

YOUR VIEWS ABOUT YOUR LOW BACK PAIN AND/OR LEG PAIN[91]

Please answer every question by circling the appropriate number, or ticking the relevant box(es). If you are unsure about how to answer a question, please give the best answer you can and make a comment in the left margin.

1. <u>During the past week</u>, how often have you had each of the following symptoms?
(*circle one number in each row*)

	Never	Occasionally	Every day	Many times a day	All the time
a. Low back pain	1	2	3	4	5
b. Leg pain (sciatica)	1	2	3	4	5
c. Numbness or tingling in leg, foot, or groin	1	2	3	4	5
d. Weakness in leg or foot (e.g. difficulty lifting foot)	1	2	3	4	5

2. <u>During the past week</u>, how bothersome have each of the following symptoms been?
(*circle one number in each row*)

	Not at all	Slightly	Moderately	Very	Extremely
a. Low back pain	1	2	3	4	5
b. Leg pain (sciatica)	1	2	3	4	5
c. Numbness or tingling in leg, foot, or groin	1	2	3	4	5
d. Weakness in leg or foot (e.g. difficulty lifting foot)	1	2	3	4	5

3. Do you usually work or go to college?

○ Yes (*specify work or college*) .....
○ No

If yes:
<u>During the past four weeks</u>, how many days did low back pain or leg pain (sciatica) keep you from going to work/college?

.....

4. <u>During the past four weeks</u>, how many days did low back pain or leg pain (sciatica) keep you in bed all or most of the day?

.....

5. During the past four weeks, have you used any medicine for low back pain or leg pain (sciatica)?

○ Yes
○ No (*skip to question 6*)

If yes:
Please list all medications taken for low back pain or leg pain (sciatica) during the past four weeks (please include no. of tablets and dosage, e.g. paracetamol, 2 tablets, 3 times daily):

.....

6. If you had to spend the rest of your life with your back condition as it is now, how would you feel about it?

(*tick one*)
○ Terrible
○ Unhappy
○ Mostly dissatisfied
○ Mixed (about equally satisfied and dissatisfied)
○ Mostly satisfied
○ Pleased
○ Delighted

7. Compared with the worry you felt when you previously completed a questionnaire, how worried are you now about your back problem or leg pain (sciatica)?

(*tick one*)
○ Much less worried
○ Less worried
○ No change
○ More worried
○ Much more worried

Additional questions asked at 3 months only

1. During the last three months, have you applied for disability benefits for low back pain or leg pain (sciatica)?
○ No
○ Yes

2. During the last three months, did you receive any of the following for low back pain or leg pain (sciatica)?
Tick all applicable
○ Recommended exercises
○ Physiotherapy
○ GP consultation
○ Traction
○ Low back surgery
○ Injections into spine (e.g. epidural)
○ Acupuncture (which was not part of the study treatment)
○ TENS unit (transcutaneous electrical nerve stimulation)
○ Recommended to bed rest
○ Spinal manipulation (by chiropractor/osteopath/GP)
○ Massage therapy
○ Overnight hospitalisation
○ Outpatient hospital visit
○ Other, *please specify* .....

Additional questions asked at 24 months only

1. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you had low back pain or leg pain (sciatica)?

○ Yes
○ No (*Please go to question 2*)

If yes:

a) Please state how many times you have had low back pain or leg pain (sciatica) in the last twelve months:
(*Count episodes that lasted at least one day, but eventually went away completely*)

.....

b) Thinking about your most recent episode of low back pain or leg pain (sciatica), in which month did this episode start:

.....

c) Thinking about your most recent episode of low back pain or leg pain (sciatica) please state how many days this episode lasted:
If your most recent episode is still ongoing please tick here. ○

.....

2. In the twenty-four months since you joined the study have you made any changes in your day to day life in order to take care of your back?

○ Yes
○ No

If yes:
Please indicate the changes you have made:
(*circle any that apply*)

	Increased	Decreased
a. Rest	1	2
b. Heed early warning signs of back problem	1	2
c. General physical activity/exercise	1	2
d. Specific exercises for your back	1	2
e. Relaxation methods (e.g. tapes, yoga, meditation)	1	2
f. Care when lifting	1	2
g. Taking on new activities/challenges	1	2
h. Other, please specify:		

Do you think the treatment package you were allocated to at the beginning of the study (referral for acupuncture/usual care) has helped your back pain?

○ Help
○ No help

Acupuncture group only

Would you recommend acupuncture to others?

- ○ Yes
- ○ No

Would you be happy to try acupuncture again?

- ○ Yes
- ○ No

Appendix 5

Satisfaction with care received

<u>Over the past three months</u>, how satisfied were you with:

(*circle one number in each row*)

	Very satisfied	**Somewhat satisfied**	**Neither satisfied nor dissatisfied**	**Somewhat dissatisfied**	**Very dissatisfied**
a. The information you were given about your low back pain or leg pain (*sciatica*)?	1	2	3	4	5
b. The treatment for your low back pain or leg pain (*sciatica*)?	1	2	3	4	5
c. Your overall care for low back pain or leg pain (*sciatica*)?	1	2	3	4	5

Appendix 6

Patient satisfaction with acupuncture care

YOUR TREATMENT FROM THE ACUPUNCTURIST

Thinking about your own health care, how would you rate the following?

(*please circle one number on each line*)

a. Explanations of acupuncture treatment procedures?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5
b. Attention given to what you have to say?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5
c. Advice you were given about ways of avoiding illness and staying healthy?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5
d. Friendliness and courtesy shown to you by the acupuncturist?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5
e. Personal interest in you and your problems?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5
f. Respect shown to you, attention to your privacy?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5
g. Reassurance and support offered to you by the acupuncturist?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5
h. Amount of time you had with the acupuncturist during each visit?	Poor	Fair	Good	Very Good	Excellent
	1	2	3	4	5

Appendix 7

Patient responses to acupuncture treatment questions

Please complete the form for any that apply to you.

Response	**Did you experience this?**	***If yes*, How would you describe the strength of your response? (*circle one*)**			***If yes*, How much did this response bother you at the time? (*circle one*)**				***If yes*, Would you be prepared to experience it again?**
A. Temporary worsening of symptoms	Yes No	Mild	Moderate	Severe	Not at all	A bit	Quite a lot	A great deal	Yes No
B. Dizziness/light headedness	Yes No	Mild	Moderate	Severe	Not at all	A bit	Quite a lot	A great deal	Yes No
C. Tiredness/drowsiness	Yes No	Mild	Moderate	Severe	Not at all	A bit	Quite a lot	A great deal	Yes No
D. Energised	Yes No	Mild	Moderate	Severe	Not at all	A bit	Quite a lot	A great deal	Yes No
E. Relaxed	Yes No	Mild	Moderate	Severe	Not at all	A bit	Quite a lot	A great deal	Yes No
F. Hungry	Yes No	Mild	Moderate	Severe	Not at all	A bit	Quite a lot	A great deal	Yes No
G. Other, *please specify*: ……	Yes No	Mild	Moderate	Severe	Not at all	A bit	Quite a lot	A great deal	Yes No

Appendix 8

Resource use questionnaire

ABOUT YOUR USE OF HEALTH SERVICES AND YOUR EMPLOYMENT IN THE LAST 12 MONTHS

In this last section we would like you to think about your use of health services and about your employment in the last 12 months. We understand that it is difficult to remember things that happened 12 months ago but please try to answer these questions as best you can.

Part A: Use of hospital services

1. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you been admitted to hospital because of low back pain?

○ Yes
○ No

If yes, please give the following details of your most recent admission.

Name of hospital .....

Approximate date .....

2. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended an accident and emergency department because of low back pain?

○ Yes
○ No

If yes, please state number of visits .....

3. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended hospital outpatients for low back pain? Please do not include attendances for physiotherapy.

○ Yes
○ No

If yes, please state number of attendances .....

4. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended hospital pain clinic (or back pain clinic) for low back pain?

○ Yes
○ No

If yes, please state number of attendances .....

Part B: Use of physiotherapy services

5. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended hospital outpatients for physiotherapy for low back pain?

○ Yes
○ No

If yes, please state number of attendances .....

6. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended your GP surgery for physiotherapy for low back pain?

○ Yes
○ No

If yes, please state number of attendances .....

7. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended a private physiotherapist for low back pain?

○ Yes
○ No

If yes, please state number of attendances .....

Part C: Use of other therapies in the last 12 months

8. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended a chiropractic service for low back pain, that was paid for by the NHS?

○ Yes
○ No

If yes, please state number of attendances .....

9. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended a chiropractic service for low back pain, that you paid for yourself?

○ Yes
○ No

If yes, please state number of attendances .....

10. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended an osteopathy service for low back pain, that was paid for by the NHS?

○ Yes
○ No

If yes, please state number of attendances .....

11. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended an <u>osteopathy</u> service for low back pain, that you paid for yourself?

○ Yes
○ No

If yes, please state number of attendances .....

12. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended an <u>acupuncture</u> service for low back pain, that was paid for by the NHS? (Please do <u>not</u> include acupuncture sessions that were part of this study)

○ Yes
○ No

If yes, please state number of sessions .....

13. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended an <u>acupuncture</u> service for low back pain that you paid for yourself?

○ Yes
○ No

If yes, please state number of sessions .....

14. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you attended <u>any other therapists</u>, for low back pain that were <u>not</u> mentioned above?

○ Yes
○ No

If yes, please give details .....

15. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you <u>purchased any medical devices or appliances</u> for low back pain? For example, a TENS machine, a back support corset, or medication that was <u>not</u> a prescription?

○ Yes
○ No

If yes, please give details .....

<u>Part D: About your work</u>

16. Are you in paid employment?

○ Yes
○ No (*Please go to question 18*)

If yes, please indicate whether you are in full time or part time paid employment.

○ Full time
○ Part time

17. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you needed to take time off work because of low back pain?

○ Yes
○ No

If yes, please state the number of days .....

18. In the last 12 months (since you completed the twelve-month follow-up questionnaire) have you ceased employment because of low back pain?

○ Yes
○ No

Appendix 9

Acupuncture diagnosis and treatment form

SYNDROME FORM

ID …… Office use only

Date ……..

Fill in primary (1º) and secondary (2º) syndromes at first session only.

1º	2º	SYNDROMES		AETIOLOGY
☐	☐	☐ **QI & BLOOD STAGNATION**		
		☐ low back pain	☐ no improvement with rest	☐ accident or injury (recent)
		☐ low back stiffness	☐ better for gentle activity	☐ accident or injury (old)
		☐ sudden onset after injury/strain	☐ wiry pulse	☐ heavy lifting
		☐ sudden re-occurrence (from old injury/trauma)	☐ purple tongue	☐ other (specify)
			☐ other (specify)	
☐	☐	☐ **BI SYNDROME**		
		☐ low back pain		☐ exposure to weather
		☐ low back stiffness		☐ living environment cold/damp
		☐ worse with rest		☐ diet
		☐ eases with movement		☐ other (specify)
		☐ **Damp Bi pattern**	☐ **Cold Bi pattern**	
		☐ worse with damp	☐ worse for cold	
		☐ heaviness	☐ tight muscles	
		☐ numbness	☐ better for warmth	
		☐ tiredness	☐ pale tongue	
		☐ greasy tongue	☐ tight or wiry pulse	
		☐ slippery pulse	☐ other (specify)	
		☐ other (specify)		
☐	☐	☐ **KIDNEY XU**		
		☐ chronic low back pain	☐ better with rest	☐ constitution
		☐ no stiffness	☐ worse with too much activity	☐ old age
		☐ bilateral pain	☐ other (specify)	☐ overwork
		☐ gradual onset		☐ other (specify)
		☐ **Yin Xu: empty heat**	☐ **Yang Xu: empty cold**	
		☐ sensation of heat	☐ feeling cold	
		☐ restless	☐ better with warmth	
		☐ anxious	☐ dull ache	
		☐ worse in p.m.	☐ tiredness, low energy	
		☐ thready pulse	☐ depressed	
		☐ red tongue or tip	☐ deep pulse	
		☐ other (specify)	☐ pale tongue	
			☐ other (specify)	
		☐ **OTHER PATTERN**	(list symptoms)	(list aetiology)

TREATMENT FORM

(*To be completed at every session*)

Date ……..…

Treatment no ……..…

Acupuncture interventions:

List acupuncture points used: (indicate unilateral or bilateral)

Notes: attaining *de qi*, needle technique, etc

Moxa interventions:

☐ moxa ☐ sparrow-pecking ☐ moxa box

Approximate location:

Other interventions:

☐ massage
☐ cupping
☐ electro-acupuncture
☐ Chinese herbs ☐ to be taken internally ☐ for external use
☐ other (specify)

Home-based self treatments prescribed:

☐ Specific physical exercises
☐ Tai chi
☐ Yoga
☐ Self massage
☐ Relaxation exercises
☐ Other (specify)

Facilitating and supporting lifestyle change:

☐ Dietary advice
- ☐ low dairy
- ☐ low wheat
- ☐ ensure food is warm and cooked
- ☐ avoid wine & spirits
- ☐ stop coffee
- ☐ other dietary advice (specify)

☐ Non dietary change
- ☐ stop smoking
- ☐ take more exercise
- ☐ take more rest
- ☐ protect from cold and damp
- ☐ other (specify)

☐ General support and empowerment (describe):

Please Turn Page Over

REACTIONS TO TREATMENT

Type 1: Reactions to normal treatment, which could be positive indicators (but could be experienced as adverse by newer patients), and are communicated spontaneously by the patient during or after treatment, or at the next visit:

☐ light-headedness
☐ energised
☐ tired
☐ relaxed
☐ hungry
☐ drowsy
☐ other (specify)

Type 2: Reactions to normal treatment which result in an aggravation of symptoms followed by a significant improvement (better than before treatment) as a result of asking if the patient had any reactions to the previous treatment:

list symptoms that worsened:
when starting after treatment?:
for how long did symptoms last?:
any other details:

Type 3: Adverse events:

☐ fainting
☐ fit (convulsions)
☐ vomiting
☐ skin reactions
☐ unacceptable bruising
☐ unacceptable bleeding
☐ unacceptable pain at a point from needling
☐ unacceptable worsening of symptoms
☐ forgotten needle
☐ broken needle
☐ moxa burn
☐ pneumothorax
☐ cross infection
☐ other (specify)

Please write about the incident in some detail:

Appendix 10

Regression model for estimating treatment effects

The regression model was developed using the 3-month data and applied to the 12- and 24-month results. The potential effect modifiers in *Table 43* were entered into the regression model one at a time with baseline pain score, and excluded if the resulting error mean square was larger than with baseline pain score alone. This process left four variables in the model, in addition to baseline SF-36 Pain score (*Table 44*).

TABLE 43 *Potential effect modifiers*

Variable	Error mean square
Baseline pain score	**536**
Duration of LBP in weeks	514
SF-36 Physical Functioning	494
Expectations re LBP	513
Pain in the legs	533
SF-36 Vitality	536
Previous episodes of LBP	538
Age (years)	539
Gender	540
SF-36 Mental Health	544
Expectations of acupuncture re LBP	552

TABLE 44 *Impact of individual factors in the regression model on the effect size, based on 3-month SF-36 Pain scores*

Model	No. of cases	Significance for randomisation	Adjusted mean, acupuncture group	Adjusted mean, usual management group	Adjusted mean difference
Randomisation	212	0.102	63.8	57.9	5.8
Items					
Randomisation +SF-36 Bodily Pain at baseline	212	0.096	63.8	57.9	5.9
Randomisation +SF-36 Physical Functioning at baseline	212	0.034	64.3	56.9	7.4
Randomisation + leg pain	212	0.141	63.6	58.3	5.3
Randomisation +Expectations at baseline	212	0.125	63.7	58.2	5.5
Full model Randomisation +SF-36 Bodily Pain at baseline +SF-36 Physical Functioning at baseline +Leg pain +Expectations at baseline +Duration of LBP in weeks	212	0.079	60.7	55.2	5.5

Appendix 11
Unit costs

TABLE 45 *Unit costs*

Cost component	Unit cost (£)	Source	Details *
Acupuncture			
Study acupuncture first visit (1 hour)	34.00	York Primary Health Care Trust	Primary care clinic visit to study acupuncturist
Study acupuncture subsequent visits (45 minutes)	24.00		
Non-study NHS acupuncture visit	24.00	York Primary Health Care Trust	Vast majority of private acupuncture sessions were for additional treatment following study acupuncture
Private acupuncture visit	24.00		Mean cost per inpatient day (generic)
Hospital inpatient day	273.00	Netten and Curtis, 2003[90]	Mean cost per outpatient attendance (generic)
NHS visits			
Hospital outpatient visit	82.00	Netten and Curtis, 2003[90]	Assumes 9.36-minute consultation
Hospital pain clinic	82.00	Netten and Curtis, 2003[90]	Assumes 30-minute clinic visit
GP	20.00	Netten and Curtis, 2003[90]	Primary care clinic visit to chiropractor or osteopath
Physiotherapy	18.00	Netten and Curtis, 2003[90]	
Chiropractor or osteopath	25.00	York Primary Health Care Trust	
Other costs			
Private healthcare visits	Various	Trial data	Patients reported individual costs
Over-the-counter medication	Various	Trial data	Patients reported individual costs
Prescription drugs	Various	BNF, September 2002[56]	Specified by dosage and pack size
Cost of a day off sick	88.86	Office for National Statistics[57]	One-fifth of average weekly earnings weighted by age and gender

[a] All NHS visit costs include salary, on-costs, qualifications, overhead and capital costs.

Appendix 12

Survey of GPs participating in the trial

Please answer with reference to the YACBAC low back pain and acupuncture project

1. Were there any factors that reduced your willingness to participate in the trial?
(*Tick all applicable*)

- ☐ Patients had only 66.6% chance of being allocated to the acupuncture group
- ☐ Your personal time constraints within the consultation
- ☐ Your uncertainty of the benefits of acupuncture
- ☐ Your uncertainty about the acupuncture service itself
- ☐ Other ongoing treatment modalities
- ☐ Difficulty for patients attending clinics (?travel)
- ☐ Other factors (please specify): .....

  .....

2. Were there any factors which increased your willingness to participate in the trial?
(*Tick all applicable*)

- ☐ Your belief in the potential benefits of acupuncture
- ☐ Wish to support this research project
- ☐ The involvement of a GP advisor
- ☐ Positive feedback from patients who have received acupuncture
- ☐ Acupuncture provided an additional treatment option
- ☐ Other factors (please specify): .....

  .....

3. Is there anything else we could have done to encourage you to identify patients?

Please comment: .....

.....

4. Did you find the main entry requirements for patients into the study:
(*circle one number on each line*)

	YES	NO
a. Clear	1	2
b. Easy to apply	1	2
c. Easy to remember	1	2

5. Can you give your best estimate of the proportion of eligible patients seen by you personally with whom you discussed the trial (whether or not they agreed to participate)?
(*Tick one response*)

☐ 100%
☐ 80%–99%
☐ 60%–79%
☐ 40%–59%
☐ 20%–39%
☐ < 20%

6. What do you think were your reasons for not discussing the trial with individual patients?
(*Tick all applicable*)

☐ Time constraints
☐ Patient co-morbidity
☐ Patient distress (e.g. life events)
☐ Just forgot!
☐ Other (please give details): .....

7. Do you make referrals to the Acute Back Pain Service at the York District Hospital?

☐ Yes
☐ No

8. Does your practice have a current contract with a private physiotherapist, or other service (e.g. acupuncturist, osteopath) related to back care?

☐ Yes
☐ No

If yes, please give details: .....

9. Has your management of back pain changed over the last 3 years?

☐ Yes
☐ No

If yes, then please indicate in what way:
(*circle one number on each line*)

	Increased	**Decreased**
a. Prescription of Analgesics	1	2
b. Prescription of Anti-inflammatories	1	2
c. Prescription of Physiotherapy	1	2
d. Advised Exercise	1	2
e. Advised Rest	1	2
f. Other, please specify …	1	2

10. Over the course of the project we have tried to maintain a high profile with you. Has this been effective?

☐ Yes
☐ No

Do you recall:
(*circle one number on each line*)

	Yes	**No**
a. Phone calls from the study researcher	1	2
b. Patient acknowledgement letters	1	2
c. Patient discharge letters	1	2
d. Project reminder letters	1	2
e. Project updates	1	2
f. Trial information posters for surgery waiting rooms	1	2
g. YACBAC logo	1	2

11. If a similar acupuncture service was to be set up in York would you consider referring appropriate patients?

☐ Yes
☐ No

How would you see such a service being funded ?
(*Tick all applicable*)
☐ GP contract with acupuncture clinics
☐ PCG contract with acupuncture clinics
☐ Patients self-funding

STUDY RESULTS

We are interested in how you would like to receive feedback about the study results. The study is ongoing until February 2002 so results will be made available soon after this date. Below are a few suggestions on obtaining feedback. Please feel free to provide your own suggestions in the space provided.

(*Please tick any*)
☐ Summary of results to be sent out to study GPs
☐ Full report to be sent out to study GPs
☐ Feedback meeting for interested GPs

☐ Other (please give details)

We are very grateful for your participation in this project and would welcome any further comments you may wish to make (e.g. with respect to the design, management and execution of the project).

COMMENTS

Thank you for filling in this questionnaire.

We are very keen to have your comments on this project and intend to place the names of each GP returning completed questionnaires in an end of project Prize Draw, the winner receiving a bottle of champagne.

Appendix 13

Treatment dropout and patient follow-up in the acupuncture group

TABLE 46 *Dropout and follow-up (acupuncture group)*

No. of treatments	All patients	Self-discharged	Reason given for self-discharge	12-month follow-up	24-month follow-up
10 (max.)	89	0		126	107
7 to 9	30	2	Treatment not working + adverse events	Y	N
			Treatment not working + adverse events	Y	Y
5 or 6	22	9	Treatment not working	Y	N
			Treatment not working	Y	N
			Treatment not working + adverse events	Y	Y
			Treatment not working + adverse events	Y	Y
			Made back pain worse	Y	Y
			Needles painful	Y	Y
			Needles painful	Y	Y
			Nosebleeds	Y	Y
			Too busy to attend	Y	Y
2–4	6	3	Treatment not working + adverse events	Y	Y
			Too busy looking after poorly father	Y	Y
			Too busy with children	N	N
1	3	2	Too busy to attend	N	N
			Too busy/lazy – could not be bothered	N	N
		16		13	10
None	9	NA	Stayed in study to 12/24 months	8	6
Total	159[a]			147	123

[a] One patient withdrew from trial before treatment owing to concurrent illness.
NA, not applicable; Y, yes; N, no.

Appendix 14

Alternative cost-effectiveness analyses

When the EQ-5D was used to calculate QALYs the overall impact on the ICER was similar to the results obtained when using the SF-6D. It was found that excluding the 11 people in the trial who were permanently unable to work owing to their back pain reduced the value of the ICER, implying improved cost-effectiveness for acupuncture treatment. When societal costs rather than NHS costs were used as the numerator for estimating the ICER, then acupuncture treatment became dominant in that it was less expensive and conferred greater health benefits (measured using either the SF-6D or EQ-5D) than the control therapy. However, where patient plus productivity loss costs are considered, these results should be interpreted with caution as the confidence interval around the point estimate for societal costs is very large.

TABLE 47 *Summary of results of alternative analyses*

Analysis	Cost difference (95% CI)	QALY difference (95% CI)	ICER (95% CI)
NHS costs			
Using EQ-5D to calculate QALYs (n = 85)	£255.47* (£202.61, £387.49)	0.071 (–0.036, 0.178)	£3598 (£188 to £22,149)
Excluding those permanently unable to work (n = 142)	£82.06 (–£61.85, £225.96)	0.039 (–0.021, 0.121)	£2104 (£128 to £19,340)
Imputation of QALYs and cost (see *Table 41*) (n = 239)	£122.07* (£22.61, £221.52)	0.29 (–0.034, 0.092)	£4209 (£182 to £27,899)
Societal costs			
Inclusion of patient costs (n = 142)	132.18* (£19.35, £253.08)	0.043 (–0.012, 0.121)	**Acupuncture dominant**
Inclusion of patient plus lost productivity costs (n=149)	–247.98 (£–1203.94, £1102.19)	0.058 (–0.011, 0.157)	**Acupuncture dominant**

* Significant difference between means ($p < 0.05$).

Appendix 15

Proposed acupuncture treatment protocol for use in trials of acupuncture for low back pain

From the recorded data and the practitioner interviews it is known that point prescriptions often combined local and adjacent points (such as BL-23, BL-26, BL-53, BL-54 and GB-30, as well as the hua-tuo lower lumbar points) and distal points (such as BL-40, BL-60, GB-34 and GB-40). Other local points used at the site of pain, were the 'ahshi!' or 'that's it!' points. In traditional acupuncture, a prescription of points should ideally contain a balance across local, adjacent and distal points, as well as zang fu organ points. For example, with kidney deficiency, key points used were often BL-23 and KID-3, both of which strengthen the kidneys, and a zang fu organ point directly associated with the low back. The authors suggest that there is scope for a treatment protocol for the use in trials of acupuncture for low back pain. The suggested protocol takes into account the acupuncture practice described in the trial, while allowing flexibility to address normal patient variation (*Box 1*).

BOX 1 *Treatment protocol*

Between six and 12 needles should be used for most patients.
The prescription of points will depend on the location of the pain.
The final selection to be a balanced prescription drawn from:

1. Bladder and gallbladder channel points:
   (a) local points
   (b) adjacent points, especially BL-23, BL-26, BL-53 and GB-30
   (c) distal points, especially BL-40 and GB-34
   These points will make up the majority of points selected.
2. Additional local points: huatuojiaji points, ahshi points and shiqizhuxia (extra).
3. Kidney syndrome points: especially BL-23 and KID-3.
4. Additional points: selected according to individual patient's presenting symptoms.
5. Auxiliary treatments and home-based self-help: at the practitioner's discretion.

Given the data of this trial, a total of 85% of the points used would have been within the scope of the first three items in the above treatment protocol, with the following breakdown: bladder channels (38%), gallbladder channels (15%), kidney channels (3%), huatuojiaji points (23%), ahshi points (3%) and shiqizhuxia (extra) points (3%).

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We look forward to hearing from you.

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