

Evaluating Acupuncture and Standard care for pregnant women with Back pain (EASE Back): a feasibility study and pilot randomised trial

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**National Institute for
Health Research**

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Abstract

Evaluating Acupuncture and Standard carE for pregnant women with Back pain (EASE Back): a feasibility study and pilot randomised trial

Nadine E Foster,^{1*} Annette Bishop,¹ Bernadette Bartlam,¹ Reuben Ogollah,¹ Panos Barlas,¹ Melanie Holden,¹ Khaled Ismail,² Sue Jowett,³ Christine Kettle,⁴ Jesse Kigozi,³ Martyn Lewis,¹ Alison Lloyd,¹ Jackie Waterfield¹ and Julie Young¹

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Background: Many pregnant women experience low back pain. Acupuncture appears to be a safe, promising intervention but evidence is needed about its clinical effectiveness and cost-effectiveness.

Objectives: To assess the feasibility of a future large randomised controlled trial (RCT) testing the additional benefit of adding acupuncture to standard care (SC) for pregnancy-related back pain.

Design: Phase 1: a questionnaire survey described current care for pregnancy-related back pain. Focus groups and interviews with midwives, physiotherapists and pregnant women explored acceptability and feasibility of acupuncture and the proposed RCT. Phase 2: a single-centre pilot RCT. Participants were identified using six methods and randomised to SC, SC plus true acupuncture or SC plus non-penetrating acupuncture.

Participants: Phase 1: 1093 physiotherapists were surveyed and 15 midwives, 21 physiotherapists and 17 pregnant women participated in five focus groups and 20 individual interviews. Phase 2: 125 women with pregnancy-related back pain participated.

Interventions: SC: a self-management booklet and onward referral for one-to-one physiotherapy (two to four sessions) for those who needed it. SC plus true acupuncture: the self-management booklet and six to eight treatments with a physiotherapist comprising true (penetrating) acupuncture, advice and exercise. SC plus non-penetrating acupuncture: the self-management booklet and six to eight treatments with a physiotherapist comprising non-penetrating acupuncture, advice and exercise.

Main outcome measures: Pilot RCT outcomes included recruitment rates, treatment fidelity, follow-up rate, patient-reported pain and function, quality of life and health-care resource use. Birth and neonatal outcomes were also assessed. Staff overseeing outcome data collection were blind to treatment allocation.

Results: Phase 1: 629 (57.5%) physiotherapists responded to the survey, 499 were experienced in treating pregnancy-related back pain and reported 16 advice and 18 treatment options. Typical treatment comprised two to four individual sessions of advice and exercise over 6 weeks. Acupuncture was reported by 24%. Interviews highlighted the impact of back pain and paucity of effective interventions. Women and midwives strongly supported a RCT and expressed few concerns. Physiotherapists' concerns about acupuncture in pregnancy informed a training programme prior to the pilot RCT. Phase 2: We recruited 125 of 280 potentially eligible women (45%) in 6 months and randomised 41 to SC and 42 each to the SC plus true acupuncture and SC plus non-penetrating acupuncture arms. Analysis was conducted with 124 participants (41, 42 and 41, respectively) as one participant was randomised in error. Three of six recruitment methods were the most successful. In total, 10% of women ($n = 4$) randomised to SC alone accessed one-to-one physiotherapy and received an average of two treatments. The average number of treatments was six for both SC plus true acupuncture and SC plus non-penetrating acupuncture. Treatments were in line with protocols. Eight-week follow-up was 74%. Patient-reported outcomes (pain, function and quality of life) favoured the addition of acupuncture. There was no evidence of serious adverse events on mothers or birth and neonatal outcomes. The Pelvic Girdle Questionnaire was found to be an appropriate outcome measure for a future trial.

Conclusions: A future main RCT is feasible and would be welcomed by women and clinicians. Longer-term follow-up and further follow-up efforts are recommended for a main trial.

Trial registration: Current Controlled Trials ISRCTN49955124.

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List of abbreviations

ACPWH	Association of Chartered Physiotherapists in Women's Health	PGQ	Pelvic Girdle Questionnaire
BMI	body mass index	PI	principal investigator
BNF	<i>British National Formulary</i>	PIL	patient information leaflet
CARE	Childbirth And REproductive health	PSS	Personal Social Services
CI	confidence interval	QALY	quality-adjusted life-year
CLRN	Comprehensive Local Research Network	RCT	randomised controlled trial
CRF	case report form	REC	Research Ethics Committee
CTU	Clinical Trials Unit	ROC	receiver operating characteristic
EASE Back	Evaluating Acupuncture and Standard carE for pregnant women with Back pain study	RS	responsiveness statistic
EQ-5D	European Quality of Life-5 Dimensions	SAE	serious adverse event
GP	general practitioner	SAP	statistical analysis plan
HTA	Health Technology Assessment	SC	standard care
IQR	interquartile range	SD	standard deviation
MCID	minimum clinically important difference	SES	standardised effect size
MDC	minimum data collection	SF-12	Short Form questionnaire-12 items
NIHR	National Institute of Health Research	SRM	standardised response mean
NRS	Numeric Rating Scale	SSOPT	Staffordshire and Stoke-on-Trent Partnership Trust
ODI	Oswestry Disability Index	TCM	traditional Chinese medicine
PGP	pelvic girdle pain	TENS	transcutaneous electrical nerve stimulation
		TSC	Trial Steering Committee
		UHNS	University Hospital of North Staffordshire

Plain English summary

Many pregnant women have back pain that impacts on their activities, work and sleep. Acupuncture is a promising intervention already used by physiotherapists in the NHS, but we do not know if it is better than standard care (SC).

Based on information from a survey of almost 500 physiotherapists across the UK and from interviews with 17 pregnant women, 15 midwives and 21 physiotherapists, we found that SC varies a lot and more needs to be done to help these women. We discovered that pregnant women are keen to take part in a study to find out if acupuncture is better than SC. Pregnant women and their midwives had few concerns about acupuncture although physiotherapists expressed some concerns and training needs that helped us design a brief training programme for them.

We performed a small study with 125 women to test whether or not acupuncture offers additional benefit over SC. We found that almost half of pregnant women with back pain agreed to join the study and three-quarters gave us information 8 weeks later. The results show that a much larger study in the NHS is possible and desirable but we need to make some minor changes to the ways we recruit and follow up women after treatment.

This prepares the way for a larger study involving three hospitals and linked physiotherapy services over several years. When it is finished we will know whether or not women with low back pain during pregnancy should be offered acupuncture in addition to SC.

Scientific summary

Background

More than two-thirds of pregnant women experience low back pain that interferes with everyday activities, work and sleep. Most women do not receive much in the way of treatment but are advised to self-manage and only those with the most severe problems are referred to NHS physiotherapists. Acupuncture appears to be a safe, promising intervention used by some NHS physiotherapists, but there are no high-quality trial data regarding its clinical effectiveness or cost-effectiveness, in comparison with standard care (SC).

We wish to investigate the short- and long-term clinical effectiveness and cost-effectiveness of acupuncture in a future randomised controlled trial (RCT). Before this can be done, a feasibility and pilot trial was needed. Our main concerns were whether or not pregnant women would find the offer of acupuncture acceptable and if they could be recruited and retained in a RCT, whether or not physiotherapists would be willing to provide acupuncture for this indication, and whether or not we could design a credible SC intervention; we also wanted to determine the most suitable primary outcome measure and to estimate the sample size needed for a future full RCT.

Aim and objectives

The overall aim was to assess the feasibility of a future RCT testing the additional benefit of acupuncture to SC in women with pregnancy-related low back pain [with and without pelvic girdle pain (PGP)]. The Evaluating Acupuncture and Standard care for pregnant women with Back pain (EASE Back) feasibility and pilot trial, funded over 24 months by the National Institute of Health Research (NIHR) Health Technology Assessment, was conducted in two phases.

Phase 1: pre-pilot work

The objectives were to:

- provide data on current UK SC and acupuncture treatment for low back pain in pregnant women
- explore the views of pregnant women with back pain on the acceptability of the proposed interventions, the content and delivery of participant information, the outcomes most important to them and the most appropriate timing of outcome measurement
- optimise trial information, recruitment and consent procedures by learning what works best from the perspectives of pregnant women with low back pain, midwives and physiotherapists
- investigate the views of NHS health professionals regarding (1) the acceptability and feasibility of referring women with back pain in pregnancy to physiotherapists for acupuncture, (2) the proposed trial design and interventions and (3) ways in which to maximise recruitment and retention to a trial.

Phase 2: pilot randomised controlled trial

The objectives were to:

- test the trial procedures, training programme for health professionals, interventions and short-term outcomes with pregnant women with back pain; provide data on recruitment and follow-up rates, treatment fidelity, outcome completion rates; and estimate the between-group difference on key outcomes
- bring the above findings together, with experts in SC, acupuncture and trial design, in a consensus conference to finalise the design, interventions, primary outcome measure, sample size and operational aspects of a future main trial.

Methods

Phase 1: pre-pilot work

Phase 1 consisted of exploratory mixed methods, using survey research and qualitative interviews conducted between June and November 2012.

Current UK standard care and acupuncture practice

A cross-sectional postal survey of 1093 chartered physiotherapists described current SC and acupuncture treatment for women with pregnancy-related low back pain.

Experiences and views of pregnant women with low back pain, midwives and physiotherapists

Qualitative semistructured focus groups and individual interviews were conducted with midwives, physiotherapists and pregnant women to explore current care and attitudes towards acupuncture in pregnancy, and to inform the recruitment methods, patient information materials and interventions for the pilot RCT. Results also informed the development of a training programme for physiotherapists participating in the pilot RCT.

Optimise the information, recruitment and consent procedures for the pilot trial

Findings from the focus groups and interviews were used to develop the patient information leaflet, recruitment methods, screening and consent procedures and finalise the timing and content of outcome assessments in the pilot RCT. Findings from the survey and interviews informed the development of the self-management booklet *Managing Your Back and Pelvic Girdle Pain in Pregnancy* used in the pilot RCT.

Phase 2: pilot randomised controlled trial

A single-centre, three-arm parallel pilot RCT was performed in one NHS hospital trust and surrounding NHS community trust between May 2013 and April 2014. Potentially eligible participants were identified using six methods. If women appeared eligible during a brief screening telephone call, they were invited for a face-to-face full eligibility screen with a research midwife or nurse. We audio-recorded and analysed a sample of 30 of these face-to-face screening and consent meetings.

Women were included if they had pregnancy-related low back pain (with or without PGP), were under the care of participating NHS sites and general practitioner practices, were 18 years and over, were at 13 to 31 weeks' gestation, were naive to acupuncture treatment, were able to read and communicate in English and were willing to participate. Women were excluded if they had ever had any form of acupuncture previously, were at high risk of miscarriage or pre-term labour, had pre-eclampsia, had previous history of surgery to the spine or pelvis, had contraindications to the treatments or had a particularly high fear of needles, pain in the anterior pelvic region only or a current urinary tract infection.

Eligible women who gave written informed consent to participate were randomised in a 1 : 1 : 1 ratio, stratified by gestational weeks, to receive SC alone, SC plus a course of true acupuncture or SC plus a course of non-penetrating acupuncture, delivered by physiotherapists.

Standard care: SC comprised a posted copy of the EASE Back study self-management booklet and onward referral for one-to-one physiotherapy for those women who needed it, in negotiation with their community midwife. The treatment protocol for physiotherapy was between two and four sessions of advice, education and exercise.

Standard care plus true acupuncture: participants received the same EASE Back study self-management booklet and were offered a course of between six and eight treatment sessions with a physiotherapist comprising true (penetrating) acupuncture at between 12 and 20 agreed acupuncture points, as well as advice, education and exercise.

Standard care plus non-penetrating acupuncture: participants received the same EASE Back study self-management booklet and were offered a course of between six and eight treatment sessions with a physiotherapist comprising non-penetrating acupuncture at eight agreed acupuncture points, as well as advice, education and exercise.

Patients were followed up at 8 weeks after randomisation using patient-reported outcome measures for pain and function [Oswestry Disability Index (ODI), Pelvic Girdle Questionnaire (PGQ) and Pain Numeric Rating Scale (NRS)] and quality of life (Short Form questionnaire-12 items and European Quality of Life-5 Dimensions). Patients were also asked to report pain before going to bed at night and ability to sleep through the night.

Consideration of outcome measures and sample size for a full randomised controlled trial

We reviewed the data from the pilot RCT on three potential primary outcome measures for a full RCT (ODI, PGQ and Pain NRS), and considered missing data, floor and ceiling effects and responsiveness to change. We used information on minimum clinically important difference, effect size and standard deviation (SD) to estimate the sample size needed for a future full RCT.

Results

Phase 1: pre-pilot work

There was a 57.5% ($n = 629$) response to the survey, with 499 physiotherapists experienced in treating pregnancy-related back pain included in the analysis. A total of 16 advice and 18 treatment options were reported, most frequently advice on posture (98%) and work (88%), home exercise (94%), postural exercise (93%), support belts (48%) and manual therapy (48%). A typical course of treatment was two to four one-to-one treatment sessions over 6 weeks. Acupuncture was reported by 24%.

A total of 53 individuals (17 pregnant women, 15 midwives and 21 physiotherapists) were interviewed in five focus groups and 20 individual interviews. Results highlighted the extensive impact of moderate to severe back pain and the paucity of effective interventions. Despite many physiotherapists using acupuncture for musculoskeletal pain, they articulated a reluctance to use acupuncture in pregnant women. They expressed a lack of confidence about the use of acupuncture in pregnancy, particularly relating to fears of inducing early labour and the threat of litigation.

Agreeing a standard care treatment package

We developed an intervention protocol with the following components: (1) a high-quality posted self-management booklet and (2) an onward pathway to one-to-one physiotherapy for those who both the pregnant women and their midwives felt needed it. One-to-one physiotherapy involved (1) a detailed patient assessment; (2) education and advice about pregnancy-related low back pain and PGP; (3) an individualised exercise programme; and (4) help with pain relief. Between two and four one-to-one sessions were agreed for those accessing physiotherapy in the SC alone arm over 6 weeks, with the episode of care left open until the end of the pregnancy.

Women's attitudes towards acupuncture and design of patient information material for a randomised controlled trial

Our sample included 17 women with current, or experience of, pregnancy-related low back pain. Few concerns were expressed about acupuncture; these focused on positioning, requirements for treatment and whether or not the needling would be painful. These concerns were addressed within the patient information material for the pilot RCT.

Phase 2: pilot randomised controlled trial

Of 388 women assessed for eligibility in 6 months, 280 were screened as eligible and 125 women (45% of those eligible) were recruited and randomised (41 to SC, 42 to SC plus true acupuncture and 42 to SC plus non-penetrating acupuncture). Baseline characteristics were similar among the three treatment arms; mean age was 28 (SD 5.3) years, 54 (44%) were married, 87 (70%) were in full/part-time employment and 53 (42%) were 24 or more weeks pregnant. More than half had back pain for more than 6 weeks and mean pain severity was 4.6 (SD 1.7) out of 10. About one-third had low back pain with anterior PGP and pain in other parts of the body.

Of the 108 women who did not participate, 67 did not attend the face-to-face eligibility screening visit, 50 declined to participate and 38 were unable to be contacted in order to conduct a full eligibility screen. The most frequent reasons for ineligibility were previous acupuncture (25%) and previously giving birth before 37 weeks (12%). Audio-recordings showed that women had few concerns, mostly related to the bodily sites of needling and length of time needed for treatment. Recruitment challenges were getting in contact with women by telephone and the time constraints of the target population (e.g. their work and childcare commitments).

In total, 10% of women randomised to SC alone accessed one-to-one physiotherapy. The average number of physiotherapy-led treatment sessions per arm was two for SC alone, six for SC plus true acupuncture and six for SC plus non-penetrating acupuncture and the content of treatment was in line with the specified protocols.

The 8-week follow-up rate was 74%: 80% in the SC group, 76% in the SC plus true acupuncture group and 66% in the SC plus non-penetrating acupuncture group. Those lost to follow-up were on average younger, were more likely to come from the most deprived neighbourhoods and had more severe disability and pain at baseline. Only 14% of participants had given birth by the time they returned the 8-week follow-up questionnaire.

Exploratory analyses of clinical outcomes showed reductions in pain and disability at 8-week follow-up. There was an indication of between-group differences in symptoms and activity (PGQ) and pain severity (NRS) between the SC plus true acupuncture arm and the SC alone group and between the SC plus non-penetrating acupuncture arm and the SC alone arm, but not between the two acupuncture arms. Half of the participants (45 out of 91) reported complete recovery or much improvement. This proportion was much lower in those randomised to SC alone (19%) than SC plus true acupuncture (66%) or SC plus non-penetrating acupuncture (67%). There was substantial reduction in pain intensity before going to bed and the proportion of women woken up every night or most nights at 8 weeks compared with baseline in both acupuncture arms but not in the SC alone arm.

No serious adverse events attributable to the trial interventions or trial processes were reported (there were four cases of brief hospitalisation for other reasons and all resumed EASE Back study treatment). The most common minor and expected adverse event was a slight bleed at the needle site (in 35 of 164 true acupuncture treatment sessions and 1 of 197 non-penetrating acupuncture treatment sessions). Overall, 10 women (five in the SC plus true acupuncture group and five in the SC plus non-penetrating acupuncture group) reported side effects from treatment in their follow-up questionnaire (mostly drowsiness/light-headedness).

Fourteen physiotherapists (13 female) participated in a 3-day training programme, completed three questionnaires (before and immediately after the training programme and at the end of the pilot RCT) and offered all three treatment arms in the pilot RCT. They were experienced [median (interquartile range) of 9 (5–18) years in clinical practice] and all had prior experience of treating pregnancy-related low back pain. Physiotherapists' self-confidence in the diagnosis and management of pregnancy-related low back pain increased after the EASE Back study training and remained high at the end of the pilot RCT.

We identified the PGQ at 8 weeks post randomisation as an appropriate outcome measure for a future main trial and observed favourable additional benefits with acupuncture over SC alone in the pilot RCT. We used these data to estimate the required sample size for a future multicentre trial.

In May 2014, we hosted a consensus conference with 35 participants (physiotherapists, service and research managers, midwives and nurses, members of the Trial Steering Committee and two Swedish researchers who had led previous RCTs in this field). The findings were presented and discussed. All felt that a future main trial was desirable and feasible and that an adaptive main trial design was favoured, alongside minor changes to recruitment (to ensure that all women attending a 20-week ultrasound scan were given a back pain screening questionnaire) and follow-up procedures (to add further follow-up reminders and consider financial incentives in the form of shopping vouchers to enhance follow-up rates).

Conclusion

A future large RCT testing the additional benefit of acupuncture to SC is desirable and feasible and would be welcomed by pregnant women and clinicians. A combination of recruitment methods including awareness raising through local media is needed, as are further efforts to increase follow-up rates. We propose a full RCT of an adaptive design (based on a pre-specified interim analysis) with three treatment arms and a primary outcome combining symptoms and impact on activities (the PGQ) at 8 weeks after randomisation, with longer-term follow-up at 3 and 6 postnatal months. The trial would need three maternity centres with linked community services, 15 months of recruitment and 600 participants.

Trial registration

This trial is registered as ISRCTN49955124.

Funding

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Chapter 1 Introduction

Pregnancy-related low back pain (with and without pelvic girdle pain)

Low back pain in pregnancy is defined as pain in the lower back, located above the lumbosacral junction, with or without radiation in the legs,¹ although this is a narrower definition than that used in the general population,² in which low back pain is usually defined as pain and discomfort localised below the costal margin and above the inferior gluteal folds, with or without leg pain. Pelvic girdle pain (PGP) is musculoskeletal pain located within the pelvic area between the posterior iliac crest and the gluteal folds, particularly in the vicinity of the sacroiliac joints, that develops in relation to pregnancy.^{3,4} The pain may radiate in the posterior thigh and can also occur in conjunction with or separately from pain in the pubic symphysis.

Low back pain and PGP during pregnancy are common and, although they can occur separately, many women experience both. Although prevalence estimates vary between studies owing to different definitions and diagnostic criteria, low back pain is reported to affect between 45% and 75% of women at some stage during their pregnancy,^{5,6} with a point prevalence of approximately 34%.⁶ Prevalence estimates for PGP range widely and include 20% overall,³ 35% to 50% in early pregnancy and 60% to 70% in late pregnancy.^{3,7,8} The pain increases with advancing pregnancy, is usually worse at night and interferes with sleep, daily activities and work.⁷ It is a common reason for sick leave, with reports suggesting that 20–23% of women take sick leave because of their pain.^{6,9} Studies have shown that pregnant women with back pain have lower quality of life than pregnant women without back pain.¹⁰ Hence, low back pain and PGP in pregnancy negatively affect activities of daily life and quality of life during pregnancy and are an important health problem. Some have reported an increasing number of affected women requesting induction of labour or elective caesarean section before the recommended 39th week of gestation in order to achieve symptomatic relief.¹¹ Although longitudinal data are limited, it has been estimated that in 1 in 10 women the pain becomes long-lasting and disability persists after childbirth.^{12,13} Pregnancy-related low back pain has been found to reduce soon after delivery but it improves in few women later than 6 months post partum.¹⁴ By 2 years after giving birth, the prevalence of back pain has been reported to fall to the same level found pre pregnancy (18%).

A range of biomedical, psychological and social factors may be important predictors of non-recovery from low back pain in pregnancy, but in general these have not been well studied. Cohort studies^{15,16} suggest that predictors of poor recovery from symptoms post partum include older age, work dissatisfaction and the presence of combined low back pain and PGP in comparison with pain in either location alone. There is some evidence that women with combined pubic symphysis pain and bilateral posterior PGP in pregnancy have a slower recovery than those women with fewer pain locations^{12,16} and that women with a high number of other bodily pain sites are more likely to have high pain intensity scores and postpartum non-recovery.¹⁷ Guidelines³ suggest risk factors for PGP include a previous history of low back pain and previous trauma to the pelvis. Studies of low back pain in general have shown the important role of psychosocial obstacles to recovery^{18,19} and there is some evidence that psychological factors such as a lack of belief in improvement,²⁰ exaggerated negative thoughts or catastrophising about the pain, fear avoidance beliefs²¹ and distress (anxiety and depression) are also important predictors of poor outcome in women with pregnancy-related back pain.⁸

Current clinical management

Women experiencing these problems most often report them to their midwives; for example, in an Australian study 71% reported their pain to their maternity carer,⁶ but it appears that few receive much in the way of treatment. Pierce *et al.*⁶ found that only 25% of women received any treatment. There are no high-quality UK data that describe current treatment for pregnancy-related low back pain or PGP. It is most often accepted as a 'normal' discomfort of pregnancy^{6,11} with some suggesting this may be related to health professionals' lack of knowledge about available treatments and fear of possible harmful effects of treatment on the developing fetus.¹¹ Women are encouraged to believe that their pain is temporary and self-limiting (which may not always be the case), a part of the normal aches and pains of pregnancy,¹¹ and those involved in their care tend to give women information on how to self-manage⁷ through postural changes, adaptations in lifting techniques, simple exercises to try at home, rest, heat and cold therapy, supportive belts and pillows, massage and relaxation. Some women, however, do proceed to use a range of treatments, such as physiotherapy-led exercise, manual therapy, acupuncture, massage, transcutaneous electrical nerve stimulation (TENS) and mobility aids as well as safe pharmacological options (mostly paracetamol) and, much less commonly, epidural injections.^{6,7,11} None of these treatment options has been well researched in women with pregnancy-related back pain.

Current NHS practice varies across services and geographical regions. Most women are not referred from their midwives or general practitioners (GPs) to other health professionals for treatment, but are advised to self-manage. The self-management advice tends to follow the guidance from national associations such as the National Childbirth Trust (www.nct.org.uk) or the Association of Chartered Physiotherapists in Women's Health (ACPWH; <http://pogp.csp.org.uk/>) and only the most severely affected women are referred to physiotherapists and receive individual assessment, advice or treatment. We estimate that approximately 10–20% of women are likely to be referred to see a NHS physiotherapist for help with severe back pain and/or PGP. In North Staffordshire, for example, 10% of women with back pain in pregnancy are referred by their midwife (and some cases by their GP), to women's health physiotherapists, who invite them to a group advice and education session, and are offered individual care following the group session only if needed. The referral is left open for the duration of the pregnancy so that the woman can access further physiotherapy support if needed. In other services, physiotherapists offer individual assessment and individualised advice and treatment.

Acupuncture

Acupuncture is based on needle stimulation of points on the surface of the body (acupuncture points) and originates from traditional Chinese medicine (TCM). It encompasses a variety of different procedures and techniques but most often is based on penetrating the skin at anatomical points on the body with thin, solid, metallic needles that are manipulated manually or by electrical stimulation. Since its introduction to the West several hundred years ago, many different styles of acupuncture have developed, including Japanese meridian therapy, French energetic acupuncture, Korean constitutional acupuncture and Lemington five-element acupuncture.²² Although similar to traditional acupuncture, these various styles have their own distinct characteristics. In the past several decades, new forms and styles of acupuncture have evolved, including ear (auricular), hand, foot and scalp acupuncture. As a result of advances in the understanding of the neurophysiology of pain and acupuncture, the boundary between acupuncture and conventional medicine is changing. For example, a simplified and more empirical Western approach to acupuncture of local dry needling at the site of pain or at points in the vicinity of pain, called trigger points, is popular among conventional health professionals (medical doctors and physiotherapists). Modern acupuncturists typically use a combination of both TCM meridian acupuncture points and non-meridial (or extrameridial) points. Once appropriate points are selected, the therapist inserts a needle into each point by gently tapping it into place and rotating it until the patient experiences a needle sensation or de-qi, usually described as a tingling, numbness or dull ache sensation. A typical session with acupuncture includes treatment with a varying number of needles (1–30) inserted and kept in place for 20–30 minutes, during which period the therapist may stimulate the needles by rotating or tapping them. Some therapists may also use electrical stimulation (in which an electrical stimulator is

connected to the acupuncture needles), injection acupuncture (herbal extracts are injected into acupuncture points), heat lamps or moxibustion. Although the neurophysiological mechanisms of acupuncture are well established in research for experimental pain, the exact mechanisms underlying the action of acupuncture in clinical practice are still unclear.²³ In terms of Western scientific principles, it is uncertain how acupuncture may help musculoskeletal pain such as back pain in pregnancy. Current theories suggest that acupuncture may produce its effects through the nervous system by stimulating the production of biochemicals such as endorphins and other neurotransmitters that influence pain sensation; that acupuncture works through the gate control theory of pain, in which the sensory input is inhibited in the central nervous system by another type of input (the needle); or that the presence of a foreign substance (the needle) within the tissue of the body stimulates vascular and immunomodulatory factors such as mediators of inflammation.²²

The use of acupuncture for musculoskeletal problems appears to be increasing and acupuncture has been recommended within recent UK national guidelines for the management of persistent non-specific low back pain.²⁴ One of the few randomised trials conducted within the UK²⁵ concluded that there was weak evidence of an effect of a short course of acupuncture on persistent non-specific low back pain (rather than back pain in pregnancy) at 12 months, but that at 24 months there was stronger evidence of a small benefit compared with usual GP care. The health economic analysis conducted alongside that trial²⁶ concluded that acupuncture confers a modest health benefit for minor extra cost to the NHS. The most recent Cochrane Review of acupuncture for low back pain²⁷ included 35 trials, but only three of these were of acute low back pain. Overall, no firm conclusions could be drawn but there was some evidence of short-term pain relief and functional improvement from acupuncture compared with no treatment or sham treatment. There was also some evidence that acupuncture, added to other conventional therapies, relieves pain and improves function better than conventional therapies alone.

A small number of trials have evaluated acupuncture for low back pain and PGP during pregnancy.²⁸⁻³³ To date, two rigorously conducted systematic reviews have been published.^{7,34} The first of these was a Cochrane Review of eight studies (1305 participants) testing the effects of adding various pregnancy-specific exercises, physiotherapy, acupuncture and pillows to standard pre-natal care.⁷ That review found positive results for the additional benefit of strengthening exercises, pelvic tilt exercises and exercise in water for women with low back pain. Both acupuncture and stabilising exercises relieved PGP more than usual pre-natal care, and acupuncture provided more relief from evening pain than exercise. One study found that acupuncture was more effective than physiotherapy for pain reduction,²⁸ although it was unclear if this was a result of the type of treatment delivery (acupuncture was individually delivered while the physiotherapy was delivered in groups). A further study showed that 60% of those who received acupuncture reported less intense pain, compared with 14% who had standard pre-natal care.³¹ The second systematic review³⁴ focused on randomised trials of needle acupuncture for back pain and PGP in pregnancy and included only three trials (448 women), all from Sweden.^{28,31,32} The conclusions were similar to the Cochrane Review by Pennick and Young.⁷ Overall, there was limited, though promising, evidence for the effectiveness of acupuncture. Both systematic reviews highlighted the need for further high-quality trials given the weaknesses in the available evidence. Most previous trials have a moderate to high risk of bias, with unclear randomisation and allocation concealment and lack of full intention-to-treat analyses, and only one trial reported work outcomes, despite these clearly being an important outcome for both pregnant women and society more generally. The one trial with low risk of bias³² focused on Swedish women with PGP at 12–31 weeks' gestation, and randomised them to standard treatment (information, advice about activities, a pelvic belt and a home exercise programme), standard treatment plus acupuncture (twice per week over 6 weeks using 10 local acupuncture points and seven extrasegmental points with the needles manipulated to evoke a de-qi sensation and left in situ for 30 minutes and stimulated every 10 minutes) or standard treatment plus stabilising exercise (individual stabilising exercises modified for pregnancy for a total of 6 hours over 6 weeks). Since the publication of the two systematic reviews in 2008, a small number of further studies were published. One small pilot study³⁵ found auricular acupuncture to be more effective than either sham acupuncture or a waiting list control. Another further high-quality trial by Elden *et al.*³³ from Sweden compared standard treatment plus acupuncture with standard treatment plus sham (non-penetrating) acupuncture for women with PGP. In that trial, 12 acupuncture treatments were provided over 8 weeks and results showed no differences between groups on pain or sick leave, questioning the

importance of needle penetration in the reported beneficial effects of acupuncture. The existing research clearly highlights the need for a high-quality randomised trial in the UK NHS setting, testing the clinical effectiveness and cost-effectiveness of the addition of acupuncture to standard care (SC) for pregnant women with low back pain (with or without PGP). It also highlights the importance of including a sham or non-penetrating acupuncture intervention.

Key methodological issues for the EASE Back study

Given the known limitations of previous trials of acupuncture, we followed published recommendations about methods and reporting trials of acupuncture,³⁶ non-pharmacological interventions³⁷ and sham interventions in trials of physical medicine and rehabilitation²³ for our pilot trial. This was informed by the results of our pre-pilot work in phase 1 of the Evaluating Acupuncture and Standard carE for pregnant women with Back pain (EASE Back; a national survey and interviews) study and includes the rationale for acupuncture type, the details of the needling, the intervention protocol, other components of the treatment, practitioner background and experience, full details of the treatments, similar protocols for the true and sham acupuncture treatments and data on participants' treatment preferences and expectations before they are randomised. There are several key methodological issues relevant to conducting trials of acupuncture (and, more broadly, non-pharmacological interventions for pain); these include sham treatment considerations, issues of blinding, safety, protocolising or standardising what is usually a highly individualised acupuncture treatment for the purposes of a trial and choosing the most appropriate package of SC for comparison. Each of these is discussed along with the implications for the EASE Back study.

Sham acupuncture

A key discussion in the existing research on acupuncture focuses on the challenge of adequate sham or placebo acupuncture treatments.²³ In fact, some believe that it is virtually impossible to construct a completely inert placebo that sufficiently mimics the insertion and manipulation of acupuncture needles; hence we use the term 'sham'. The use of sham intervention helps to ensure participant blinding and reduces the risk of potential bias that can interfere with the observed outcomes.²³ We believe that any future large trial should include a treatment group that receives sham acupuncture to enable us to better understand the possible basis of acupuncture effects. Previous trials have used different methods of sham and there is little agreement on the best sham, given that some methods appear to induce physiological effects (e.g. inserting needles at non-acupuncture points or superficial needling at acupuncture points).²³ A perfect sham for acupuncture would induce the needle or de-qi sensation,²³ but it is increasingly clear that inducing this needling sensation regardless of the stimulation point is associated with the physiological effects of acupuncture. A recent review³⁸ concluded that the effect of acupuncture seems to be unrelated to the type of sham acupuncture used as control and that non-penetrating acupuncture shams are thought to be least likely to have physiological effects. We believe that using non-penetrating needles on a small number of the same acupuncture points that would be used for true acupuncture alongside the inclusion of acupuncture-naïve participants are the best solutions to this challenge. Similar approaches have been used successfully in previous trials of acupuncture for musculoskeletal problems³⁹ and pregnant women with PGP.³³ Thus, we included three treatment arms in the pilot EASE Back trial: SC, SC plus true acupuncture and SC plus sham acupuncture using non-penetrating needles. The use of sham in trials of acupuncture remains a matter of debate, and some may consider it an ethical dilemma. However, by ensuring that all our pilot trial participants received a package of SC, and that the acupuncture treatment (either true or non-penetrating) was in addition to this SC, we are confident that all participants received appropriate treatment for their pain.

Blinding

A further methodological challenge is the need to ensure adequate blinding: ideally, patients, therapists, outcome assessors and data analysts should be adequately blinded. In a trial of SC and acupuncture, clearly, the therapist cannot be blinded to treatment, but it is possible to blind acupuncture-naïve patients to the type of acupuncture (true or non-penetrating), as well as those involved in collecting data and data analysis. Successful blinding has been achieved in a previous trial of acupuncture within the NHS³⁹ and we incorporated

this level of blinding into the EASE Back pilot trial. In particular, by gaining ethics approval to explain to potential participants that they would all receive SC and some would receive one of two forms of acupuncture, we were able to ensure that all participants expected to receive good treatment, thus maximising expectation and treatment credibility effects. We included measures of treatment preference and expectation in our pilot trial data set and captured information on treatment credibility at follow-up.

Safety/risks of acupuncture

Despite promising evidence for the effectiveness of acupuncture for relief of back pain and PGP in pregnant women, some clinicians express concerns about safety. One concern is that acupuncture might induce pre-term labour, but available data show this not to be the case. The normal risk of pre-term labour (before 37 weeks' gestation) is 7–10%. In one of the Swedish trials, Elden *et al.*⁴⁰ assessed the adverse effects of acupuncture on the pregnancy, mother, delivery and fetus/neonate. Acupuncture that may be considered strong was used and treatment was started in the second trimester of pregnancy. Adverse effects were recorded during treatment and throughout the pregnancy. The results showed that there were no serious adverse events (SAEs) after any of the treatments, in either babies or mothers. Minor adverse events were common in the acupuncture group, but women rated acupuncture favourably despite this. Therefore, acupuncture administered with a stimulation that may be considered strong led to minor adverse complaints from the mothers and had no observable severe adverse influences on the pregnancy, mother, delivery or fetus/neonate. In addition, acupuncture in early pregnancy (for nausea and vomiting) has been shown to be safe, with no adverse effects on perinatal outcome, congenital abnormalities, pregnancy complications and other infant outcomes.⁴¹ In the wider literature, most side effects associated with acupuncture are minor and transient, such as dizziness/light-headedness and slight bleeding after the needles are removed.⁴² Although there have been reports of fatal events following acupuncture (14 cases in a review of literature over the last 50 years),⁴³ these appear to have been related to cases of clear malpractice and negligence (e.g. as described by Halvorsen *et al.*⁴⁴). In the UK, acupuncture training for health professionals, including physiotherapists, is set at a high level, and in trained hands acupuncture is a safe intervention. In our pilot trial in phase 2 of the EASE Back study, the participant information leaflet and consent procedures made the known risks clear and explained the frequency of these risks where these data were available while reassuring pregnant women that even strong acupuncture stimulation has been shown to have no adverse effects on the pregnancy, mother, delivery or developing baby. In addition, the trial design ensured that all women received SC and that acupuncture was in addition to this SC. Therefore, we did not withhold SC from any woman in the EASE Back trial.

Standardising acupuncture treatment for a randomised controlled trial

Since the location and manipulation of the needles in acupuncture are thought to be important in achieving successful outcomes, the therapist usually individualises the treatment for each patient in clinical practice. For the purposes of a trial, however, some degree of standardisation is needed in order to be able to describe the treatment that participants were expected to receive (the intervention protocol) and then to be able to judge whether or not patients received the treatment as expected (protocol adherence). Previous trials of acupuncture have been criticised for lack of clarity about the acupuncture intervention provided as well as for being overly prescriptive with the selection of acupuncture points and needle manipulation to the point that those using acupuncture in clinical practice do not feel that the acupuncture provided in the trial reflects their practice. We believe the best solution to this challenge, for the purposes of a randomised controlled trial (RCT), is to agree a semiflexible acupuncture protocol, in which therapists assess the individual patient's pain type and location, they palpate for tender points and then they select points from a large number of points that have been agreed to be suitable for inclusion in the protocol (including acupuncture and tender points). This approach has been used successfully in previous trials^{33,39} ensuring that the acupuncture treatment is individualised, reflecting clinical practice, and that it can be amended over a course of treatment sessions but can also be clearly described in publications.

Copy of the Health Technology Assessment commissioning brief (Health Technology Assessment number 10/69/05)

Question: what is the clinical effectiveness and cost-effectiveness of acupuncture in pregnant women with back pain, in comparison to SC?

Technology: a 6-week acupuncture package, as may plausibly be delivered in the NHS.

Patient group: pregnant women with back pain (including women attending antenatal clinics and outpatients clinics because of back pain).

Control or comparator treatment: sham acupuncture.

Design: a feasibility study to assess the acceptability and design of a trial in the NHS. Methods are likely to include a survey of current practice and qualitative work with clinicians, patients and commissioners. Researchers should identify an appropriate acupuncture intervention and control. They should explore the merits of a sham acupuncture arm.

Important outcomes of main study: pain.

Other outcomes: adverse events, consumption of analgesics, obstetric outcomes, absence from work, functional status, health-related quality of life and cost-effectiveness.

Outcome of the feasibility study: outline plan for a randomised controlled study with evidence supporting its design and delivery.

Minimum duration of follow-up of main study: 6 months after delivery.

Appropriate standard care comparison

The choice of the comparison treatment in acupuncture trials is critically important. Previous trials that compare acupuncture with waiting list controls, ongoing stable medication or minimal care packages tend to show that acupuncture is superior, whereas those that compare acupuncture with more intensive or active interventions have tended to conclude that there are no differences between acupuncture and comparisons.³⁹ We wanted to include a SC comparison that accurately reflected what currently happens in the UK for pregnant women with low back pain. Thus, we followed the recommendations of Ee *et al.*³⁴ that some form of consensus about treatments for these women is essential to inform clinical trials. Although usual care differs in different services and geographical regions, our interview and survey results from the phase 1 pre-pilot work in the EASE Back study provide the most useful information on which to base a trial protocol for SC. These data ensured that the pilot trial protocol for SC reflected current care in the UK and thus is a fair comparison in the trial.

Rationale for the EASE Back study

A high-quality randomised trial in the NHS is needed to test the clinical effectiveness and cost-effectiveness of adding acupuncture to SC for pregnant women with low back pain (with and without PGP). Before such a large trial can be conducted, however, a feasibility and pilot study was commissioned by the National Institute of Health Research (NIHR) Health Technology Assessment (HTA) programme to inform the design, recruitment, interventions and outcomes. A feasibility study is a research study carried out prior to a main study in order to answer the question 'Can this study be done?', and it is used to estimate important parameters needed to design the main study.⁴⁵ In the EASE Back study we wanted to find out whether or not pregnant women with low back pain would be willing to try acupuncture as a treatment and whether or not they had concerns about acupuncture or being involved in a trial. We also wanted to find out the likely proportions of eligible women from all of the pregnancies overseen by a large maternity centre and whether or not clinicians (community

midwives and physiotherapists in particular) would be willing to recruit to, and treat, this patient population in a trial of acupuncture. We needed to test out all the processes of a future main trial and, therefore, the EASE Back study also involved a pilot RCT. A pilot study is a version of the main study run in miniature to test whether or not all the components of the main study can work together.⁴⁵ The EASE Back pilot RCT therefore tested the inclusion and exclusion criteria, the processes of identification of potentially eligible women, screening and recruitment, randomisation, training of participating research staff and physiotherapists, delivery of treatment, treatment fidelity and credibility of treatment. It allowed us to test whether or not pregnant women with back pain would be willing to be randomised, to test out the outcome measures that might be used in a future main trial, to explore the short-term effects of treatment on these outcomes, to determine short-term follow-up rate, to select a primary outcome measure for a future main trial and to estimate the sample size for a future main trial.

The EASE Back study was a mixed-methods feasibility and pilot study, designed in two phases over 24 months (June 2012 to May 2014), combining survey research (of current practice), qualitative research (focus groups and individual interviews) and a pilot randomised trial with pregnant women with back pain (with and without PGP) with short-term follow-up and audio-recordings of screening and consent meetings with a subsample of women. The results were shared at a dissemination event with stakeholders in May 2014 and consensus achieved about the feasibility and desirability of a main trial. *Figure 1* provides a summary of the EASE Back study design.

Overall aim of the EASE Back study

The overall aim of the EASE Back study was to assess the feasibility of a future RCT to test the addition of acupuncture to SC in women with pregnancy-related low back pain.

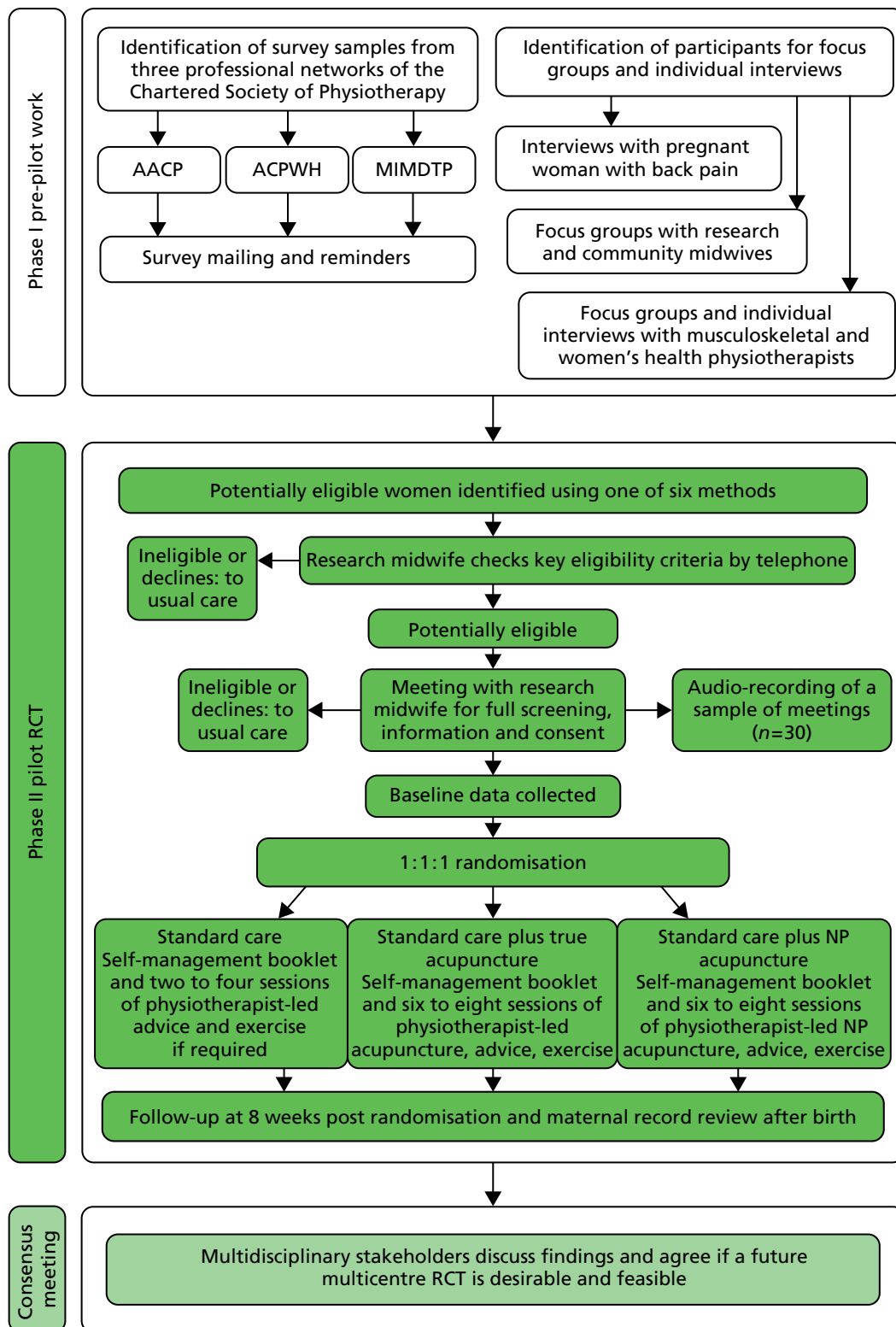


FIGURE 1 Summary of the EASE Back study design. ACCP, Acupuncture Association of Chartered Physiotherapists; MIMDTP, McKenzie Institute of Mechanical Diagnosis and Therapy Practitioners; NP, non-penetrating.

Chapter 2 Phase 1 pre-pilot work

Objectives of phase 1 pre-pilot work

The specific objectives of phase 1 were to:

- provide data on current UK SC and acupuncture treatment for low back pain in pregnant women
- explore the views of pregnant women with back pain about the acceptability of the proposed interventions, the content and delivery of participant information, the outcomes most important to them and the most appropriate timing of outcome measurement
- optimise trial information, recruitment and consent procedures by learning what works best from the perspectives of pregnant women with low back pain, midwives and physiotherapists
- investigate the views of NHS health professionals regarding (1) the acceptability and feasibility of referring women with back pain in pregnancy to physiotherapists for acupuncture, (2) the proposed trial design and interventions and (3) ways in which to maximise recruitment and retention to a trial.

In order to address the above objectives, we used mixed research methods of a descriptive survey and qualitative interviews. Findings from the survey informed the semistructured interview schedule, and findings from both methods were integrated at the analysis stage to give additional validation.⁴⁶ The pre-pilot work in phase 1 was reviewed and approved by National Research Ethics Service Committee North West – Greater Manchester North (ref. 12/NW/0227).

National survey of chartered physiotherapists

Methods

Design and setting

This was a national cross-sectional survey of national samples of physiotherapists working in the UK from June to July 2012. Consent of respondents was assumed if they completed and returned the questionnaire; therefore, written consent was not sought from each participant.

Survey sample and mailing

The inclusion criteria were physiotherapists who:

- were members of the Chartered Society of Physiotherapy
- had experience of treating women with pregnancy-related low back pain.

We randomly sampled from three professional networks of the Chartered Society of Physiotherapy. Although the optimal approach to generate representative survey findings is to use a simple random sample, there is no comprehensive sampling frame for all UK-based physiotherapists available at the current time. The professional networks selected were those with interests relevant to low back pain, acupuncture and pregnancy/women's health, with a total combined membership of around 7000 physiotherapists. This large sampling frame was required to access physiotherapists with a range of experience and clinical interests, to result in as generalisable a data set as possible about physiotherapy care for pregnancy-related back pain across the UK. The Chartered Society of Physiotherapy is the predominant professional trade union and educational body for physiotherapists in the UK and has 30 affiliated professional networks, usually with a specific clinical or occupational interest, which members have the option of joining. It was not possible to target only those physiotherapists working in the NHS. Random samples of members of the three professional networks (total $n = 1093$) were mailed by the administrators of each network and two reminder mailings were subsequently sent to non-responders.

The professional networks were chosen to include physiotherapists with a special interest in (1) women's health (ACPWH), (2) acupuncture (the Acupuncture Association of Chartered Physiotherapists) and (3) musculoskeletal pain conditions (McKenzie Institute of Mechanical Diagnosis and Therapy Practitioners). An initial filter question identified those respondents who had never treated a pregnant woman with low back pain in pregnancy, and only respondents with experience of treating this patient group were included in the analysis.

As the aim of this survey was primarily descriptive, a formal sample size calculation was not carried out. Previous surveys of physiotherapists in the UK indicated a likely response rate of 55–60%^{47–49} and so we expected approximately 600–650 overall responses from the mailing of 1093. This sample size is sufficient to estimate the proportions of the key survey variables within less than a 5% margin of error with 95% confidence.

Survey questionnaire

A previous national survey questionnaire of physiotherapy practice for non-specific low back pain (not related to pregnancy) was adapted for use in this study.⁴⁸ The questionnaire captured information about respondents' demographics and clinical practice including years in practice, practice setting, postgraduate training in musculoskeletal pain, women's health and acupuncture as well as experience of managing women with pregnancy-related back pain. The questionnaire investigated current clinical care using a patient vignette of a specific, typical case developed from a real patient example following recommendations from other studies^{50–52} and was pilot tested with 18 physiotherapists. The patient vignette is reproduced below, whereas the full questionnaire is provided in *Appendix 1*. Respondents were asked how they would manage this woman, including likely treatment approaches, advice offered and number of treatment sessions provided. Specific questions on their use of acupuncture were also included.

We additionally asked the physiotherapists whether or not they routinely used specific advice or self-management leaflets in the management of pregnancy-related low back pain and PGP and, if so, to enclose a copy of the leaflet in their response to the survey. This resulted in the research team receiving examples of 37 different advice and self-management leaflets currently used by physiotherapists. These were used to help develop the self-management booklet used in the pilot RCT in phase 2 of the EASE Back study (see *The development of a standard care protocol*).

The patient vignette of a typical patient

A 34-year-old woman was referred from her GP with symptoms of intermittent sharp pain at her lower thoracic and lumbar regions and reports that the symptoms began a few weeks ago. She is 24 weeks pregnant with her first child. She is in good general health and of normal weight for her height and has never had back pain before.

Her back pain presents as occasional sharp sensations at the lumbar/lower thoracic regions of her spine and seems to be unrelated to posture or activity. She also has some dull pain in the lower back region, which is more persistent but of lesser intensity than the sharp pain she occasionally experiences. Her symptoms are worse if she maintains a sitting posture for prolonged periods. She is reluctant to use any analgesic medication because of her pregnancy.

Upon examination there is no exacerbation with movement or any directional preference. She has normal range of movement and is moderately tender on the paraspinal muscles of her lower back. Straight-leg raise and slump tests are negative.

Statistical analysis

Analysis was primarily descriptive, using summary statistics to describe physiotherapists' characteristics and provide data on current practice, including SC and their use of acupuncture. As treatment has been shown to differ across practice settings,⁵³ treatment approaches used by respondents working in NHS and non-NHS settings were compared using Pearson's chi-squared tests. This survey was not designed to test for differences between members of different professional networks. However, as the survey sample was not a simple random sample of physiotherapists in the UK, some exploratory comparisons between the professional networks were undertaken to explore any inter-network differences. All analyses were performed using Stata version 13 (StataCorp LP, College Station, TX, USA).

Results

Response rate and characteristics of responders

Responses were received from 629 (58%) of those mailed. Of these, 499 had treated at least one woman with pregnancy-related low back pain and were included in the analysis. The demographic and practice characteristics of the respondents are presented in *Table 1*. The respondents were very experienced (mean of 22 years in

TABLE 1 Demographic and practice characteristics of physiotherapists. Values are frequencies and percentages unless specified as mean and SD

Characteristic (denominator) ^a	<i>n</i>	%
Years of experience (456)	21.5 (mean)	10.4 (SD)
Female (499)	459	92.0
Work setting (498)		
Exclusively NHS	201	40.4
Exclusively non-NHS	159	31.9
Combination of NHS and non-NHS	138	27.7
Frequency of treating pregnant women with back pain (499)		
Infrequent – at most one in last 6 months	173	34.7
Somewhat frequent – between two and five in last 6 months	148	29.7
Frequent – at least one per month	70	14.0
Very frequent – at least one per week	108	21.6
Referral source^b (499)		
Referral from GP	347	69.5
Referral from midwife	241	48.3
Self-referral	240	48.1
Referral from a physiotherapy colleague	147	29.5
Referral from obstetrician	137	27.5
Other	38	7.6
Training^b		
Specific postgraduate training in low back pain in general (491)	444	89.0
Specific postgraduate training in acupuncture (497)	370	74.5
Specific postgraduate training in women's health (492)	327	65.5
Specific postgraduate training in low back pain in pregnancy (496)	264	52.9
Use of acupuncture in management of musculoskeletal pain (496)	338	68.2

SD, standard deviation.

a Denominator varies according to number of valid responses because of varying missing data or not applicable cases.

b Respondents were able to indicate multiple responses.

practice) and most were female. Respondents worked in a variety of settings: NHS only, non-NHS only or a combination of practice settings. Referrals of women with pregnancy-related back pain were received by respondents from a variety of other health-care practitioners and self-referral to physiotherapy by women themselves was also commonly reported. Approximately one-third of respondents reported seeing a pregnant woman with back pain at least once a month.

Standard care management

Standard care was explored by asking respondents to indicate the management options they would use for the typical patient described in the vignette. Most respondents (88%, $n = 430$) reported that they would be responsible for the care of such a patient, but 12% ($n = 58$) reported it was not their role and that this type of patient would be specifically referred to a women's health specialist physiotherapist. A large majority of respondents (85%, $n = 364$) reported that they would manage this patient in one-to-one treatment sessions. The remainder reported that they would manage this patient as part of a group or class and that they would use one-to-one sessions for initial patient assessment only or only if required. This typical patient would be seen three or four times over a period of 3–6 weeks, although the episode would be left open for the duration of the pregnancy so that a woman could reconsult the physiotherapist if needed until after the birth of her baby. *Table 2* summarises the episode of SC by physiotherapists.

Many advice and treatment options were reported for the management of the typical patient described in the vignette, and combinations of advice and treatments were commonly reported. Advice on aspects of pregnancy, low back pain and activities of daily living was reported by the respondents and, although combinations of treatments were described in packages of care, most physiotherapists reported using exercise approaches to manage women with pregnancy-related low back pain (*Figures 2 and 3*).

TABLE 2 Episode of care details for the vignette patient

Characteristics of care (denominator) ^a	<i>n</i>	%
Number of times patient typically seen (425)		
Once	51	12
Twice	103	24.2
Three or four times	205	48.2
Five or more times	66	15.5
Time period over which patient would typically be treated (415)		
1–2 weeks	79	19
3–6 weeks	221	53.3
7–10 weeks	70	16.9
> 10 weeks	45	10.8
Typical episode of care (428)		
Finished after treatment, re-referral required for further treatment	27	6.3
Left open for duration of the pregnancy	258	60.3
Left open for a defined period after end of treatment	66	15.4
Other	77	18.0

^a Denominator varies according to number of valid responses because of varying missing data or not applicable cases.

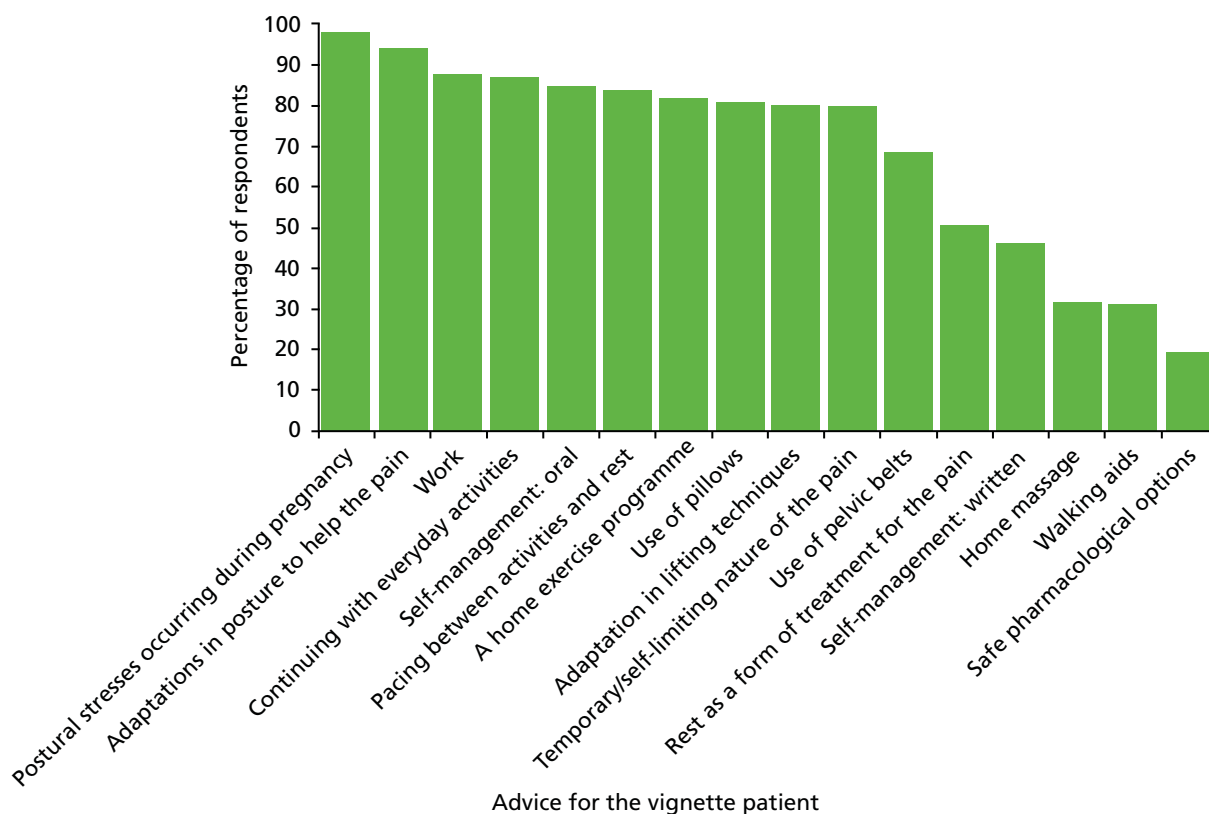


FIGURE 2 Survey findings: advice for the vignette patient.

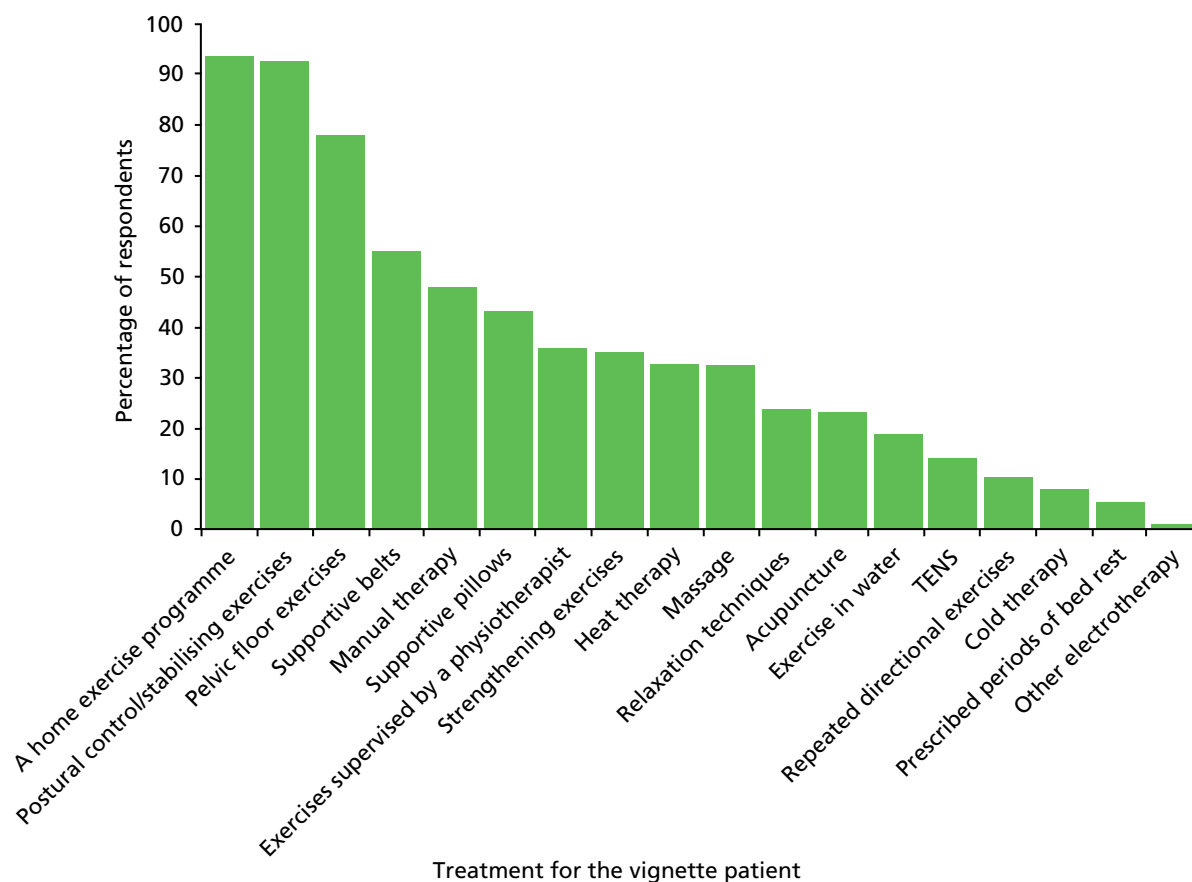


FIGURE 3 Survey findings: treatment for the vignette patient.

Acupuncture management

Regarding use of acupuncture, of the 469 individuals who responded to this item, 68% ($n = 338$) reported that they used it in the management of patients with musculoskeletal conditions, including low back pain not related to pregnancy, whereas 37% ($n = 126$ of 337 responses to this question) reported that they used it to treat women with pregnancy-related low back pain. However, when asked about the treatment they would provide to the specific patient described in the vignette (430 responses), 24% ($n = 101$) reported that acupuncture would be part of their treatment. Respondents had a mean of 11 [standard deviation (SD) 6.2] years' experience of using acupuncture in clinical practice. The majority of respondents (298 responses) used Western/medical acupuncture (71%, $n = 212$), 16% ($n = 48$) used TCM/traditional acupuncture and 11% ($n = 32$) used trigger point/myofascial acupuncture. Of 336 respondents completing details about acupuncture training, 37.5% had completed up to 80 hours of acupuncture training (the national minimum requirement for physiotherapists), 53% had completed more than 80 hours but less than 200 hours and 9.5% had completed a degree/diploma in acupuncture or equivalent.

If acupuncture was a treatment option selected by respondents for the vignette patient, further details about acupuncture management were requested in the questionnaire. The mean number of acupuncture points used in a treatment session was 7 (SD 2.6), with the needles being left in situ for a mean of 20 (SD 6.0) minutes, and 84% of respondents would elicit a de-qi needle sensation. The selection of acupuncture points varied considerably for the vignette patient, and the 10 most commonly reported local and distal acupuncture points are summarised in *Table 3*. Only two acupuncture points (BL25 and BL23) were reported by more than one-third of respondents. Of those using acupuncture in the treatment of pregnant women, 22 respondents (4%) reported they had observed some minor adverse effects during treatment. These included the patient feeling lightheaded/dizzy ($n = 8$) or fainting ($n = 5$), mild bruising at needle site ($n = 3$), worsening of symptoms ($n = 3$), vomiting ($n = 2$) and significant pain at a needle site ($n = 1$). One respondent reported that a patient she had treated with acupuncture miscarried the day after acupuncture treatment, but reported that the treatment was not thought to contribute to this.

Differences between respondents working in different practice settings (exclusively NHS or exclusively non-NHS) were few. However, those working exclusively in the NHS were more likely than those in non-NHS settings to report that they saw the patient only once or twice (52% compared with 17%). Conversely, physiotherapists reporting the most patient treatment visits (more than five) were more likely to be working in non-NHS settings (24%, compared with 7% in exclusively NHS settings). In addition, physiotherapists working in non-NHS settings more commonly than those working exclusively in NHS settings reported using treatment approaches that were classified as 'hands-on'. Overall, the proportion of respondents who would offer the patient any hands-on treatment approaches was significantly higher among those who worked exclusively in non-NHS settings than among those working exclusively in NHS settings (*Table 4*). For example, of the 33% (101 out of 304) of respondents who would offer massage, 71 (70%) worked exclusively in non-NHS settings, compared with 30 (30%) who worked exclusively in the NHS.

Differences between professional networks

Exercise was the most common treatment reported by respondents from all three professional networks. Data about the typical episode of care (number of treatment sessions, length of sessions, length of episode of care) were also similar across all networks. The one area in which reported practice differed between professional networks was in the use of acupuncture for the typical patient described in the vignette, with respondents from the acupuncture professional network (the Acupuncture Association of Chartered Physiotherapists) being more likely to report using acupuncture (43.9%) than those from either a general musculoskeletal (the McKenzie Institute of Mechanical Diagnosis and Therapy Practitioners; 9.0%) or a women's health professional network (ACPWH; 6.2%).

These survey findings, particularly those from NHS-based clinicians, were used to help develop the treatment content and intervention protocols for the pilot EASE Back trial in phase 2 of the EASE Back study (see *The development of a standard care protocol*).

TABLE 3 Most commonly reported acupuncture points for the vignette patient

Acupuncture points	<i>n</i>	%
Local acupuncture points (n = 93)		
BL25	33	35.5
BL23	31	33.3
GB30	24	25.8
BL26	22	23.7
BL24	18	19.4
BL28	13	14.0
BL27	12	12.9
HJJ	10	10.8
BL54	7	7.5
BL22	7	7.5
Distal acupuncture points (n = 81)		
GB34	25	30.9
LI4	20	24.7
BL60	16	19.8
LR3	16	19.8
BL62	14	17.3
ST36	13	16.0
BL40	11	13.6
GB41	7	8.6
BL57	6	7.4
SI3	5	6.2

BL, bladder; GB, gall bladder; HJJ, Huato Jia Ji; LI, large intestine; LR, liver; SI, small intestine; ST, stomach.

TABLE 4 Use of hands-on treatment approaches for pregnancy-related low back pain

Treatment offered (total responses, <i>n</i> = 304)	Overall, <i>n</i> (%)	NHS, <i>n</i> (%)	Non-NHS, <i>n</i> (%)	Significance ^a
Manual therapy	134 (44.1)	53 (32.9)	81 (56.6)	$p < 0.001$
Acupuncture	69 (22.7)	23 (14.3)	46 (32.2)	$p < 0.001$
Massage	101 (33.2)	30 (18.6)	71 (49.7)	$p < 0.001$

a p -value based on chi-squared test for the differences in treatment offered between the physiotherapists working exclusively in the NHS and non-NHS.

Qualitative focus groups and individual interviews

Methods

The qualitative research was guided by our initial research objectives but retained the flexibility to explore previously unforeseen avenues of enquiry.^{54,55} Methods consisted of focus groups or individual interviews (in person or by telephone) with pregnant women, midwives and physiotherapists. Given that both health-care professionals⁵⁶ and women⁵⁷ can be difficult to engage in research, the offer of choice over interview format was pragmatic rather than methodological and intended to meet the needs of participants in terms of convenience. All participants were given full information about the study ahead of deciding to participate, with the option of focus groups or individual face-to-face or telephone interviews. The health-care practitioners were invited to complete a brief questionnaire to describe their qualifications and experience (see *Appendix 2*). Semistructured interview guides were developed from the research objectives and from the findings of the national survey. They focused on exploring the acceptability of acupuncture, the sort of information that might be required to reach a decision around participation in a trial, the most important outcomes and the most appropriate timing of outcome measures for the pilot trial. In addition, participants were also invited to talk about the care and support they considered available for this population (see *Appendix 3* for copies of the topic guides). All interviews were audio-recorded with consent and the focus groups were facilitated by two members of the research team. Data collection was concurrent with all three sets of participants and ceased when data saturation was reached.

Interviews with pregnant women

For pregnant women, the original intention had been to hold a series of focus groups, offering individual interviews if these were more convenient. In the planned recruitment period for phase 1 of the study (June to September 2012) it was estimated that there might be as many as 600 pregnant women with low back pain under the care of the participating maternity hospital who could be invited to participate; however, owing to poor response to the invitation to participate in the interviews, we extended the recruitment phase by a further 2 months to November 2012. A convenience sampling strategy⁵⁸ was adopted and any pregnant woman with back pain could either self-refer or agree for the health-care practitioner caring for her to pass on her contact details to the research team. A flyer and poster were designed outlining the study and providing contact details of the research team. In total, 3000 flyers and 100 posters were distributed through a variety of means: general maternity information packs when the woman first booked in with her community midwife; local antenatal clinics; community midwives giving the flyers directly to pregnant women under their care; and the women's health physiotherapy service back class for pregnant women at the local hospital. In addition, an invitation to participate was also posted on internet sites [Mumsnet (www.mumsnet.com) and the Pelvic Pain Support Network (www.pelvicpain.org.uk)]. Contact was also made with the National Childbirth Trust (www.nct.org.uk) and the Pelvic Partnership (www.pelvicpartnership.org.uk), but administrative difficulties on the part of these organisations meant it was not possible for them to collaborate with the research team within the time frame of phase 1.

In total, 43 women gave consent to contact, which was attempted through telephone calls at differing times of the day, including in the evening, and a total of 18 women agreed to telephone interviews. On contact, if they were still willing to be interviewed, a convenient interview time was arranged. At that point, a letter confirming the interview arrangements, detailed information about the study and two copies of the consent form together with a stamped addressed envelope for the return of a signed copy of the consent form, were posted out. The information and consent form were discussed at the time of the interview and audio consent was also recorded then.

Interviews with midwives and physiotherapists

For the health professionals, a purposive sampling strategy was adopted to ensure a range of experience and perspectives.⁵⁹ Two teams of community midwives were approached, together with the group of research midwives working in the local maternity hospital who would be involved in recruiting women into the EASE Back pilot RCT. Physiotherapists from the local community musculoskeletal outpatient services and from the local hospital's women's health physiotherapy service were also invited to participate. In addition, a sample of those physiotherapists ($n = 30$) who consented to further contact on returned questionnaires from the national survey were also invited to take part. Owing to geographical spread and participant convenience, these individuals were also interviewed by telephone. The individual interviews took place after the focus groups with physiotherapists and, because of data saturation, were limited to three individuals. In total, 15 midwives and 21 physiotherapists took part, giving a total of 53 individuals interviewed in phase 1 (Table 5).

Analysis

An exploratory thematic analysis was adopted, within a constructivist grounded theory framework. Emergent findings were checked out in subsequent interviews across all three groups of participants in an iterative cycle.^{60,61} All interviews were digitally recorded, lasted between 20 and 60 minutes and were transcribed in full. To preserve participants' anonymity, all were given unique identification numbers. To maximise the benefits of the interdisciplinary research team, the interview coders brought differing disciplinary perspectives to bear on the qualitative data (BB, social science; PB, acupuncture; and JW, physiotherapy). To ensure intercoder reliability, each independently coded a random selection of interviews as part of agreeing the initial coding frame, which was then applied across the whole data set, checking for consistencies and confounding cases and for further refinements of the coding frame. The findings were then compared with those from the national survey to identify areas of corroboration and contradiction.

TABLE 5 Summary of participants in individual and focus group interviews ($n = 53$)

Participants	Individual interviews (telephone)	Focus group interviews (face to face)
Pregnant women	17 participants	0 focus groups
Midwives	0 participants	3 focus groups (2 with community midwives, 1 with research midwives), 15 participants in total (2 were maternity assistants)
Physiotherapists	3 participants	3 focus groups (2 with community physiotherapists, 1 with women's health physiotherapists), 18 participants in total (1 was a physiotherapy technician)

Results

Engagement in the interviews

Despite the many flyers, posters and efforts on the part of clinical staff to discuss the study with potentially eligible women, and extending the recruitment period by 2 months, only 43 women agreed to contact by (or contacted) the research team. Of these, two self-referred, two were referred by physiotherapists, three were referred by obstetricians and 20 were referred to the research team by community midwives. The remaining 16 were identified through members of the research team attending the back education class within the women's health physiotherapy service in the local hospital. We received no responses to the online invitations to participate that had been posted on Mumsnet or the Pelvic Pain Support Network. There were also challenges in making contact with the 43 women and in setting up focus groups. On average, it took five telephone calls spread over different times of day, including the evenings, to make initial contact. Two women declined to be interviewed during their first telephone contact (one no longer had low back pain and the husband of the other was ill) and 22 women were not contactable despite the five contact attempts. The difficulties in contacting these women were discussed at the focus groups with midwives and physiotherapists. They expressed little surprise, which they attributed to a patient population struggling to cope with everyday life and, moreover, discussions suggested that travelling to a focus group meeting would be an additional and unacceptable burden for pregnant women. The decision to offer individual telephone interviews instead of focus groups was made. Eighteen women agreed to interview, one was unavailable at the agreed time, and so a total of 17 women were interviewed over the 6-month period from June to November 2012, representing 39% of those who consented to further contact.

Characteristics of participants

Despite the initial difficulties in contacting women, the interview sample of 17 women was diverse and sufficient for data saturation. The average age was 26 years, with a range from 22 to 34 years; gestation ranged from 15 to 39 weeks, with a mean of 32 weeks; and for eight women it was their first pregnancy. In terms of ethnicity, eight described themselves as English, five were 'other British', three were 'other white' and one was 'African'. All were either married or living with a partner and employment included health professional and clerical worker.

Analysis of the midwives' profiles questionnaires indicated that the average length of practice was 18 years, with the majority ($n = 9$) qualified for over 12 years. The least experienced person had been qualified for 3 years, and there were also two maternity assistants included in the focus groups. None reported any specific postgraduate training around the area of back pain in pregnancy. Six midwives reported that they saw pregnant women with back pain either very frequently (at least one per week) or frequently (at least one per month). Just one midwife reported seeing such patients infrequently (at most one in the last 6 months).

As with the midwives, the physiotherapists were experienced practitioners. Their average length of practice was 12 years, nine had been qualified for 12 years or more (one for 36 years) and the least experienced person had been qualified for over 3 years. Fourteen individuals had a Bachelor of Science in Physiotherapy, of whom one also had a Master of Science in Musculoskeletal Healthcare, one a Master of Science in Acupuncture, one an Advanced Critical Care Practitioner (ACCP) foundation qualification in acupuncture and one Higher National Diploma in Sports Science. Another person had a Diploma in Physiotherapy, two individuals reported themselves simply as members of the Chartered Society of Physiotherapists (MCSP), and the final person was a physiotherapy technician with National Vocational Training Qualifications at Levels 1, 2 and 3. In terms of their contact with pregnant women, seven reported seeing such patients infrequently. All seven were community physiotherapists, and all apart from one reported that they had no specific postgraduate training in the topic of back pain in pregnancy. Unsurprisingly, the women's health physiotherapists leading the hospital-based back class for pregnant women reported seeing such patients frequently. They identified that their education around treating pregnant women came from either in-house training or short (1-day) courses (the exact nature of these was not specified).

Key themes

We identified three main themes from the qualitative data in phase 1: the high burden of back pain in pregnancy and outcomes most important to women; the paucity of treatment options; and acupuncture as an acceptable intervention for women and midwives but generating concerns for many physiotherapists. Each of these main themes is presented briefly below with example quotations from the transcripts.

Theme 1: high burden of back pain in pregnancy and outcomes most important to women

During the interviews with these women a picture of the burden of low back pain in pregnancy and its often wide-ranging impact on daily life emerged strongly, corroborating the views of the midwives and physiotherapists, and highlighting the importance of flexibility in appointment times and treatment locations for the pilot RCT. The interview data highlighted the severely disabling effects of back pain during pregnancy, which can affect all aspects of life, ranging from sleep through to being unable to carry out basic activities of daily living. Many of the women reported considerable support from partners and family. However, there were also reports of serious misunderstandings in the workplace, arising from managers and/or colleagues seeing back pain as a normal part of pregnancy and expecting women to 'just get on with it', with resulting lack of support. For some, even attending routine antenatal appointments was difficult to negotiate with their workplace and, consequently, anything that might incur further time away from work was seen as challenging. This is particularly significant because many women reported needing to work as long as possible up to their due date, because of their maternity leave entitlement and for financial reasons. It was clear others in severe pain were unable to work or participate in social activities, with consequences for their mental well-being and relationships, as the following quote illustrates:

W8: My mood at the moment is all over the place anyway [laughs], but it [the pain] affects you, because it does limit me, especially first thing in the morning when I've been in one position for a long period of time, it kind of freezes up. So in the morning when I get up, I kind of crawl out of bed rather than spring out of bed.

Individual interview: 56

The women interviewed did not expect to experience immediate pain relief with acupuncture but believed that it would take several treatments to make a difference. The severity of the pain and its impact on activities of daily life meant that they felt that it was unlikely the pain could be completely resolved but rather alleviation was seen as an acceptable outcome:

W10: I know nothing can sort of get rid of my pain completely but perhaps just alleviate, you know, something to alleviate it for a little bit and enable me to sort of get around and move around a little bit more [yeah] you know? I think that would be a pretty good outcome really.

Individual interview: 156

Theme 2: the paucity of treatment options

The responses to the survey indicated that SC varied widely for this patient group. This variation in care and lack of effective treatment options were also reflected in the narratives from women and professionals. It was clear that the emphasis is on self-management strategies, with only the most severely affected women being referred to physiotherapists for individualised advice about posture, movement and gentle exercise. Both midwives and physiotherapists tended to view these women as 'heart-sink' patients for whom they could offer very little in the way of effective interventions, as this illustrates:

P4: I think it's one of the few types of patients that we won't see more than once because you know that, physio-wise, there's very little to offer. So it's a case of give them what they need and leave them on hold for further appointments.

Community physiotherapists: group A, 48

Midwives and physiotherapists reported explaining the causes of back pain during pregnancy as a way of reassuring the women and, although they described offering advice, they felt that this amounted to 'fobbing off' their patients, expressing a lack of faith in the effectiveness of their suggestions. Moreover, the advice provided was clearly highly variable, indicating uncertainty among midwives and physiotherapists regarding the most appropriate forms of advice, and there clearly were no consistently used sources of advice in terms of either written leaflets or website resources. Examples of patient information leaflets (PILs) and websites recommended to women were collected from respondents to the national survey, and the 37 different leaflets returned underline the variation in current advice provided to these women. This reflects the uncertainty voiced by the professionals about what constitutes 'the right advice' for this group of patients. Most women were advised to try self-management techniques around posture, gentle exercise and pain relief medication. Women's health physiotherapists reported favouring a 'hands-off' approach, with advice on posture, preparation for labour and delivery and feeding positions after delivery. They identified an important part of their role as providing reassurance. The uncertainty about what constituted 'the right advice' for this group of patients was reflected in the accounts of the women, who conveyed a sense of being left to 'get on with it', as this severely affected individual reported:

W6: No, I refused to take that [co-codamol]. They did prescribe it in the end and I did take it home with me but I haven't took any because I just don't agree with that in pregnancy. And after that I was discharged because really there's nothing you can do. They referred me to the physio back class that I went to, and every time I've seen my midwife, she gave me a little tip of how to get in and out of cars, and things like that. But I don't really think it can be helped. I just think it's one of them things you've got to deal with.

Individual interview: 75

Theme 3: acupuncture as an acceptable intervention for women and midwives, but generating concerns for many physiotherapists

Although some women did express the need for information and reassurance over safety of acupuncture and whether or not the positioning for acupuncture would require them to lie in positions that could exacerbate their pain, in the main women expressed little concern expressed about its use in pregnancy.

W17: I think if people were telling me that it could help my back pain then I would pretty much do anything.

Individual interview: 149

W2: I don't know where they put the needles in pregnancy. If they were in my tummy I think I'd be a bit like, 'mmm, not quite sure about that'.

Individual interview: 98

Midwives were generally in favour of the idea that acupuncture could be offered to women with pregnancy-related back pain and that it could offer a useful additional treatment option. They felt that many women would be interested in knowing more about acupuncture for their back pain, particularly those women who are severely affected, and who, they felt, would be willing to try it within the context of a trial. The midwives felt that pregnant women with back pain under their care would have few concerns about acupuncture and these would be most likely linked to the location of and sensations from the needles, as this focus group excerpt indicates:

M1: [They'll] want to know where you're going to put the needles.

M2: That's the first thing I'd ask.

M3: Yeah, and they'd want to know if it hurts.

Community midwives: group B, 373

Physiotherapists were also generally in favour of testing the additional benefit of acupuncture for this patient group in a trial because of the difficulties in treating the pain through other treatment methods.

P4: I mean, it's [acupuncture] very interesting because drugs do not seem to work for these women. You know, talking about sort of real heavy painkillers . . . We had a lady admitted last week and was immediately put on morphine, it didn't touch her pain at all. And all that does then is make the baby sleepy, and the mum sleepy. So for some women it is very difficult pain to manage.

Women's health physiotherapist group

However, the physiotherapists raised concerns about safety of acupuncture in pregnancy, given their previous acupuncture training during which they recalled they had been advised that acupuncture was contraindicated in pregnancy.

P3: And again like the previous two people, I thought acupuncture was contraindicated, that was part of my training. And I wouldn't have done it to a pregnant lower back pain patient.

Community physiotherapists: group B, 57

Such concerns included the general safety of acupuncture in pregnancy and the specific acupuncture points and techniques to be used, and these concerns were rooted in their lack of confidence and/or experience in caring for pregnant women, as this excerpt indicates:

P2: With them being pregnant, you're just so aware that they're pregnant and you feel limited to what you can do because you don't want to . . .

P3: I think we're just scared to hurt them, aren't we?

Community physiotherapists: group A, 81

This fear was related to concerns over a perceived lack of adequate training, specifically in the application of acupuncture in pregnancy:

P6: I don't think I've got the training to do it. There might be other stuff out there, but I don't feel that I'm well enough equipped to deliver other things.

Interviewer: Is that the same for everybody?

P1: Yeah. I think because we don't see them often enough, we don't – there isn't the training out there. We don't know exactly . . .

Community physiotherapists: group A, 95

Such fears around possible harm to the mother and/or baby generated a culture of caution, underpinned by a fear of litigation. Although most physiotherapists shared these fears, the three who participated in individual interviews and who practised acupuncture with pregnant women held starkly contrasting views. They worked in NHS musculoskeletal outpatient departments in which acupuncture was available. One had been qualified for 11 years, one for 18 years and one for 28 years. They were confident about the safety and efficacy of acupuncture for this population and indeed considered it safer, in fact, than medication, as illustrated by this quotation:

SP1: I would use acupuncture as a first choice of treatment with pregnant ladies over medication because of the safety risks with medication. In fact, I find my pregnant patients respond better [to acupuncture] than perhaps my standard lower back pains.

Physiotherapists' survey

These interview findings were pivotal in developing the content of the training and support programme offered to physiotherapists participating in the EASE Back pilot trial in phase 2.

In addition, both the midwife and physiotherapist interviews highlighted a number of issues around recruitment, including the importance of detailed patient information and reassurance (about the acupuncture needling, any known side effects on the baby, information about positioning during treatment), flexibility around time and location of treatments and generally minimising the research burden on participants. The fact that the issues emerging through the interviews and focus groups were consistent with some of the survey responses acted as a further form of validation. The qualitative results specifically about physiotherapists' concerns in using acupuncture during pregnancy also help explain the practice patterns seen in the survey responses. The findings from the qualitative interviews were incorporated into the participant information leaflet, the recruitment methods, the selection of treatment sites, the treatment protocols and the outcomes for the EASE Back pilot trial in phase 2.

Implications for recruitment to the pilot randomised controlled trial

The challenges in recruiting pregnant women to participate in the phase 1 interviews made it clear that we needed to develop and test a range of approaches to identify and recruit eligible women for the pilot trial in phase 2. Originally the plan had been to raise awareness about the pilot trial by inserting a flyer within the booking information pack given when seen by their community midwives and for women with back pain in pregnancy to be given an information pack about the trial by their usual midwife. We tested these approaches in phase 1, and overall these approaches alone were not particularly successful in identifying suitable women who were willing to be involved in the interviews. Recruitment of this population to research in phase 1 was clearly challenging, and therefore we used the results of the interviews with pregnant women, midwives and physiotherapists as well as suggestions for additional recruitment methods from research midwives who had worked on other research studies with pregnant women in order to agree six methods with which to identify and recruit women to the pilot RCT in phase 2. While using six methods was complex for a pilot trial and we had not originally included these costs of some of these methods in the grant application, we were keen to test out the methods in order to identify a smaller set of methods that might work best for a future large trial. The details of the six methods are provided in the next chapter (see *Chapter 3, Recruitment methods and procedures*), but they included a brief questionnaire that screened for the presence of back pain and willingness to be contacted further among women attending their antenatal 20-week ultrasound scan appointment and a local awareness-raising campaign that included use of a study website, newspaper, radio and other local media in order to take the message about the study directly to local pregnant women who could then opt to self-refer to the research team for eligibility screening.

In addition, we had planned that research midwives would screen all women for eligibility in face-to-face information and consent meetings. Through discussions with the research midwives it was agreed that a much more efficient use of their time would be to conduct brief telephone screening first and invite only those who appeared potentially eligible to face-to-face meetings for full eligibility screening, informed consent and baseline data collection.

Specification of information and interventions for the pilot randomised controlled trial

The development of the participant information leaflet

In order for potential participants to be fully informed about what taking part in the pilot trial in phase 2 would involve, a detailed PIL was developed. The format and content of the PIL was both based on a best practice example provided within the good clinical practice and regulatory requirements for clinical trials and taken from the findings of the qualitative research in phase 1. Information was provided not only on the rationale of the study, why women were being invited to take part, what taking part would involve, issues around anonymity and confidentiality, payment and the funders of the study, but also on the acupuncture treatment. This specific information included the required positioning for treatment, the difference between acupuncture needles and other types of needles (e.g. those used to take blood), whether or not children were able to attend appointments, the ability to drive after treatment and the known risk of specific adverse events from acupuncture during pregnancy. The PIL was reviewed by patient representatives on the Trial Steering Committee (TSC) and amended following feedback. A copy of the PIL is in *Appendix 4*.

The development of a standard care protocol

Given the variation in SC for pregnancy-related back pain, we sought to use the results of the national survey and the qualitative interviews, along with available research evidence, to specify a SC intervention protocol for the pilot RCT. The protocol included a high-quality and comprehensive self-management booklet and, for those who needed it, an onward pathway to individualised assessment and treatment with an EASE Back study physiotherapist.

Self-management booklet

The national survey resulted in the research team receiving examples of 37 different advice and self-management leaflets currently used by physiotherapists across the UK. These were used to help develop the specific self-management booklet used in the pilot RCT. Other than the professionally produced leaflet *Pregnancy-Related Pelvic Girdle Pain*, published by the ACPWH, all others were examples of brief and inexpensive leaflets produced by individual NHS trusts or individual clinicians. It was clear that none was clearly fit for purpose for use in the EASE Back pilot RCT and, therefore, we developed the *EASE Back: Managing Your Back and Pelvic Girdle Pain in Pregnancy* booklet specifically for use in phase 2. The available leaflets were reviewed for common themes and good examples of both content and layout, taking into account the issues raised by pregnant women, midwives and physiotherapists during the phase 1 pre-pilot work. We sought to develop a booklet that would be seen as more comprehensive than those available to date, that was produced in colour, of high quality, with clear photographs of real pregnant women (rather than diagrams only, as was the case in most of the available examples), divided into sections and with clear page numbers and handy hints boxes throughout. We also wanted the booklet to be of a size that women could fit into their handbag so that they could, if they wished, carry it around with them and thus refer to it during the day (most of the available examples were photocopied A4 sheets of paper). Working with the women's health specialist physiotherapist at the participating hospital [University Hospital of North Staffordshire (UHNS)], who was also a member of the ACPWH, we developed sections for the booklet about the good prognosis of back pain in pregnancy, advice about appropriate self-management of back pain in pregnancy, including pacing between activities and rest, simple exercises to try at home, advice on adaptation in lifting techniques, tips about relieving postures for sitting, standing and sleeping, advice about work and continuing with everyday activities, the use of pelvic supports/belts and supportive pillows, and the use of simple and safe analgesics. We also included some self-management hints and tips, advice for labour and after the birth, a summary and useful websites.

The booklet was reviewed by patient representatives (women with experience of pregnancy-related back pain) on the TSC, physiotherapists and an antenatal and postnatal exercise specialist before we finalised the content, photographs and layout. A copy of the booklet is included in *Appendix 5*. In the pilot trial, the booklet was posted to all trial participants, who were advised to follow the advice and exercises in the booklet and that, if they felt they needed to see a physiotherapist, they should

discuss this with their community midwife (as in usual care) and then book an appointment with an EASE Back study physiotherapist.

One-to-one standard care physiotherapy

We protocolised the number and content of physiotherapy sessions for the pilot RCT using the data from the national survey and qualitative interviews. We knew that women who were severely affected would need help with pain and function, and that onward referral to physiotherapists for assessment, advice and treatment needed to be available within the SC protocol. Therefore, we provided information in the SC information pack on how to access EASE Back study physiotherapy care should both the woman and her midwife feel this was needed and we developed an EASE Back study SC protocol for those women, based on the results of our surveys and interviews from phase 1. This involved an individualised assessment of the problem, individualised advice particularly about posture and a home exercise programme (focusing mainly on stabilising trunk exercise and pelvic floor muscle exercise but which could include stretching, pelvic tilt exercises and gluteal muscle strengthening), with treatment options that included supportive Tubigrip™ (Mölnlycke Health Care Limited, Dunstable, UK), pelvic supports/belts, manual therapy including massage, supervised exercise therapy and use of walking aids for those that might need them. Hydrotherapy, group treatments and acupuncture were not permitted within the protocol for SC alone. If women enquired about or engaged in antenatal aqua classes this was fine, as long as the treatment from the physiotherapist did not involve exercise in water. The episode of care consisted of between two and four treatment sessions over 6 weeks, with the episode of care left open until the end of the pregnancy, in line with our survey findings.

The development of the acupuncture treatment protocol

The results from the national survey and the interviews with physiotherapists who used acupuncture in the management of pregnancy-related low back pain and PGP were used, alongside evidence from previous trials, to specify the content and delivery of the acupuncture treatments in the pilot RCT. We attended to the need for an individualised approach to acupuncture (in terms of selection of initial points to be needled and the flexibility to change the selection of points over the series of treatment sessions) while also needing to be able to describe the range of points that therapists could select from. Thus, following individual patient assessment including examination of tender points, physiotherapists could choose the most appropriate true acupuncture points for the individual patient from a long list of potential points. The agreed list of points was based on our survey findings and previous trials in similar patient populations. We ensured that formal service-level agreements with participating physiotherapy services stipulated between six and eight treatment sessions should be delivered within 6 weeks (based on the survey results and balancing the need to offer sufficient acupuncture sessions to be effective while also providing a treatment course that might be suitable for the NHS in future). Full details of both the true and non-penetrating acupuncture protocols are provided in *Chapter 3, Interventions*.

Development of training programmes for participating clinicians

Training programme for research midwives and nurses

The research midwives and nurses involved in the EASE Back pilot trial ($n = 8$) attended a half-day training programme prior to recruitment commencing, which included lectures, practical sessions, role play, group discussion, problem-solving and case studies. During the training programme, the research midwives and nurses were informed about (1) the rationale and design of the EASE Back study, including how the findings from phase 1 had informed the design of the pilot trial and (2) the planned procedures involved in identification of potentially eligible women, screening, gaining written informed consent, audio-recording a sample of the face-to-face screening and consent meeting, baseline data collection and the randomisation and completion of maternity record reviews after trial participants had given birth. Audit procedures were also finalised; these included clinic activities such as informed consent, guiding women in the performance of the two objective tests for PGP, the telephone calls to the randomisation service at the Clinical Trials Unit (CTU) as well as the collection of minimum data over the telephone at follow-up. A summary of the half-day training programme is provided in *Appendix 6*.

In order to consolidate learning, the initial half-day training programme was followed by a 2-hour refresher session that took place immediately prior to commencing recruitment in the pilot RCT. This included role play of a number of different scenarios from the point of initially identifying potentially eligible women, completing screening and eligibility checking over the telephone and completing the face-to-face screening and consent meeting. Example scenarios included women who were ineligible for various reasons, women who were eligible but who declined participation and women who were eligible and provided informed consent. Throughout all scenarios, study documentation was completed to enable the research midwives and nurses to become familiar with it before starting recruitment, and all research midwives and nurses were observed by a member of the study team to ensure that they were competent in completing all study eligibility screening and recruitment procedures as planned.

Training programme for physiotherapists

All the physiotherapists providing care in the pilot trial were trained in the use of acupuncture for pain conditions, in training programmes that met national standards. The EASE Back pilot trial training programme for participating physiotherapists took place over 3 full days and a copy of the programme content is available in *Appendix 7*. Day 1 summarised relevant literature, including the changes during pregnancy to women's bodies, the potential explanations for back pain during pregnancy, assessment of pregnant women with back pain (with or without PGP), and SC for pregnancy-related back pain, including key findings from phase 1. Day 2 focused on acupuncture for pregnancy-related back pain, available data on safety of acupuncture for this patient population and the details of the EASE Back study protocols for both the true and non-penetrating acupuncture treatments. Day 3 combined SC and acupuncture protocols together using patient case studies and included information about the practicalities of the trial, including use of EASE Back trial case report forms (CRFs); how to deliver the trial protocols, stressing the importance of patient blinding; and identification of any adverse events or SAEs. Training included lectures, group discussion and use of patient case examples, as well as practice of assessment and treatment skills. We trained 14 physiotherapists to deliver the treatments in the EASE Back pilot trial, supported by a training team including an expert acupuncturist, a women's health specialist physiotherapist and a consultant obstetrician. Ongoing support to deliver the treatments in the EASE Back trial was provided by an expert acupuncturist and a women's health specialist physiotherapist; this support took the form mostly of telephone and e-mail communications as well as some face-to-face visits during which the acupuncturist observed participating physiotherapists' treatment sessions with patients and provided feedback and support. Physiotherapists completed a brief questionnaire before and immediately after the training programme and at the end of the pilot RCT, in order to describe physiotherapists' characteristics and explore changes in their intended management of a patient with pregnancy-related low back pain and in their confidence to assess and treat this population. The results from these questionnaires are summarised in *Chapter 3, Physiotherapists' questionnaire results and feedback*.

Conclusions

In conclusion, the pre-pilot work in phase 1 provided high-quality data on current UK SC and acupuncture treatment for back pain in pregnancy. The survey and interviews results, particularly those from NHS-based clinicians, were used to help develop the intervention protocols for all the treatment arms in the pilot randomised trial in phase 2 of the EASE Back study. The interview findings from pregnant women, midwives and physiotherapists informed the content of the patient information materials, the recruitment methods and the clinician training programme for the pilot trial in phase 2, reported in *Chapter 3*.

Chapter 3 Phase 2 pilot randomised controlled trial

Objectives of phase 2 pilot randomised controlled trial

The specific objectives of phase 2 were to:

- test the trial procedures, training programme for health professionals, interventions and short-term outcomes with pregnant women with back pain, and provide data on recruitment and follow-up rates, treatment fidelity, outcome completion rates and an estimate of between-group difference on key outcomes
- bring the above findings together, with experts in SC, acupuncture and trial design, in a consensus conference to finalise the design, interventions, sample size, outcome measures and operational aspects of a main EASE Back trial.

Design and setting

We conducted a single-centre pilot three-arm parallel RCT with data collection before randomisation and at 8-week follow-up. The pilot trial included three treatment arms, randomising participants to receive SC, SC plus true acupuncture or SC plus non-penetrating acupuncture. North Staffordshire, including UHNS and associated antenatal clinics including community midwives, and physiotherapy clinics within the North Division of Staffordshire and Stoke-on-Trent Partnership Trust, was the site for the pilot trial.

Ethical approval and research governance

Research ethical approval was sought in December 2012 from West Midlands Staffordshire Research Ethics Committee (REC) and included the usual follow-up reminder procedures for clinical trials overseen by the musculoskeletal CTU at Keele University [a follow-up questionnaire, followed by a postcard reminder if no response, followed by a further full copy of the questionnaire if no response, followed by a minimum data questionnaire if no response, followed by a minimum data collection (MDC) over the telephone if no response]. The REC recommended using a maximum of two reminders, as they were concerned that the planned follow-up processes would be seen as burdensome and one member of the committee felt strongly that this was a vulnerable patient group, some of whom could be suffering with postnatal depression. Despite our formal appeal (25 January 2013, see *Appendix 8*) in which we provided evidence from the CTU from five previous trials about the importance of all of these follow-up reminders in achieving response rates in excess of 80% and our reassurance to the committee that the follow-up time point of 8 weeks had been chosen so that most women would not yet have given birth, the committee upheld their decision and we had to remove two reminders from our usual follow-up processes. The postcard reminder and minimum data questionnaire were removed and, therefore, the follow-up process in the EASE Back trial comprised an 8-week questionnaire and a further full copy of the questionnaire if no response was obtained in 2 weeks (at 10-week follow-up), followed by a telephone call for MDC if no response was obtained in 2 weeks (at 12-week follow-up). *Appendix 8* provides the evidence of the ethics committee appeal (which was conducted with the knowledge of the NIHR HTA programme contact person for the EASE Back study), the evidence from five of our previous trials about the importance of our usual follow-up processes in achieving high response rates and the response from the REC. Following ethics approval on 28 February 2013, we proceeded to apply for research and development approvals for all participating sites. Ethics and research and development approvals were all gained by 22 April 2013 for the pilot trial.

Given the known importance of patients' expectations in analgesic responses and in particular in acupuncture response, we obtained research ethics approval to explain in the participant information documentation that all trial participants would receive SC and that, in addition, they might or might not receive one of two forms of acupuncture, thus maximising non-specific effects. This approach has previously been successful in acupuncture trials using validated sham Streitberger needles (blunted, non-penetrating needles; Asia-med, Suhl, Germany),^{33,39} demonstrating both true and non-penetrating acupuncture to be safe and credible to patients.

Amendments

There were no substantial amendments submitted to ethics for the pilot RCT. The following minor amendments were made:

- 5 March 2013: this amendment related to the addition of a number of patient identification centre sites (Stoke-on-Trent Primary Care Trust, North Staffordshire Primary Care Trust, South Staffordshire Primary Care Trust) and a change of named study principal investigator (PI) for the UHNS.
- 9 April 2013: this amendment related to some minor changes to the wording of consent forms, PILs and information relating to the treatment sites.
- 4 June 2013: this amendment related to a minor clarification to the eligibility screening questionnaire.
- 31 July 2013: this amendment related to a minor clarification to the eligibility screening questionnaire and the covering letter for the 8-week follow-up questionnaire.

Participants

Participants were pregnant women with low back pain (with or without PGP) who contacted the research team in response to information about the trial or who were identified from primary care, referrals to the UHNS women's health physiotherapy service, community midwives and antenatal clinics within UHNS and the North Division of Staffordshire and Stoke-on-Trent Partnership Trust (SSOPT).

Inclusion criteria

Women were eligible to participate in the pilot trial if they were:

- women with pregnancy-related back pain [defined as self-reported pain in the lumbar area (between the 12th rib and the gluteal fold)] with or without PGP
- under the care of participating NHS sites and GP practices
- aged 18 years or over
- at 13 to 31 weeks' gestation (chosen in order to ensure that women could receive six to eight treatment sessions within 6 weeks, if they were randomised to SC plus acupuncture, and yet still have their 8-week follow-up questionnaire before they had given birth)
- naive to acupuncture treatment
- able to read and communicate in English (to provide full informed consent and to complete the baseline and outcome assessments)
- willing to participate.

Women who had low back pain episodes before this pregnancy were suitable for inclusion as long as the current episode of low back pain was either attributed to or made worse as a result of this pregnancy.

Exclusion criteria

Women were excluded from participation in the pilot trial if they:

- had ever had any form of acupuncture previously for any health problem
- were at high risk of miscarriage (previously had recurrent miscarriage, defined as three or more; abnormalities in the cervix deemed to increase risk of miscarriage; antiphospholipid syndrome; lupus anticoagulant)
- were at high risk of pre-term labour (previously giving birth before 37 weeks' gestation), multiple pregnancies, polyhydramnios (an excess of amniotic fluid in the amniotic sac, seen in about 1% of pregnancies), pre-term ruptured membranes (the rupture of membranes prior to the onset of labour in a woman who is at less than 37 weeks' gestation, seen in 2% of all pregnancies) or had a history to surgery to the uterine cervix (deemed to increase risk of pre-term labour)
- had diagnosed pre-eclampsia (a rapidly progressive condition characterised by high blood pressure and the presence of protein in the urine, affecting 5–8% of pregnancies)
- had a history of surgery to the spine or the pelvis
- had contraindications to any of the treatments (coagulation problems, haemophilia or bleeding disorders, were at increased risk of infection such as skin infections or loss of skin integrity from burns or ulcerations at the site of needling) or had a high needle phobia
- had pain in the anterior pelvic region only (anterior PGP or pubic symphysis pain only)
- had a current urinary tract infection.

Recruitment methods and procedures

Building on the findings from phase 1, we tested several ways to identify and recruit women to the EASE Back pilot RCT. Six methods were tested and participant flow through each is summarised in *Appendix 9* and explained below.

Method 1: research midwives identified women in antenatal clinics and determined eligibility

Research midwives identified potentially eligible women in usual antenatal clinics, discussed the trial directly with them and provided a PIL. If both the woman and the research midwife had the time to do so on the same day, a face-to-face appointment proceeded at which full eligibility was confirmed and written informed consent gained.

Method 2: brief screen for back pain at the 20-week ultrasound scan appointment

On arrival for their routine 20-week ultrasound scan, all pregnant women were to be given a study flyer and a screening questionnaire to complete either before or after they had their scan, and were asked to return the completed brief questionnaire to a dedicated box within the ultrasound scanning clinic. Questions included the presence of pregnancy-related back pain and a consent form for further contact. Questionnaires were collected on a weekly basis by research staff and screened by a research midwife. The research midwife telephoned potentially eligible women to determine their eligibility and their interest in the trial. If eligible, women were posted the PIL and a face-to-face appointment was booked to confirm full eligibility and to gain informed consent. If no contact could be made, the trial information leaflet and an EASE Back study card were posted to the woman, advising her to telephone the study administrator if she was interested in participating.

Method 3: women identified from the University Hospital of North Staffordshire women's health physiotherapy service referrals

Research midwives screened referrals from GPs, community midwives and antenatal clinic to the UHNS women's health physiotherapy service. A research midwife contacted all potentially eligible participants to determine their interest in the study and their eligibility. If eligible and interested, they were sent the PIL by post and a face-to-face appointment was booked to confirm full eligibility and to gain informed consent. If no contact could be made, the trial information leaflet and the EASE Back study card were posted to the woman, advising her to telephone the study administrator if she was interested in participating.

Method 4: research midwives identified women in antenatal clinics

Research midwives identified potentially eligible women in usual antenatal clinics. However, if either the woman or the research midwife did not have time to complete a face-to-face visit there and then, or if the woman wanted further time to think about participation, the research midwife provided the woman with an EASE Back study card, which directed the woman to telephone the study administrator.

Method 5: clinicians gave pregnant women with back pain an EASE Back study card

In the fifth method, we contacted participating GPs, obstetricians and community midwives to identify potentially eligible women and give them an EASE Back study card, which directed women to telephone the study administrator.

Method 6: self-referral from local awareness raising

Pregnant women with back pain who were made aware of the trial through our local media awareness raising could directly telephone the EASE Back study administrator (termed 'self-referring' women). We used several approaches to raise awareness about the pilot trial among local pregnant women and clinicians. Study flyers were included in the standard information booking packs that all pregnant women received at their first booking visit with a midwife, and were also to be given to women at their 20-week ultrasound scan appointment. The study flyers included details of how women could find more information (providing both a contact telephone number and a website address). We developed a study-specific website for the EASE Back trial and a YouTube (YouTube, LLC, San Bruno, CA, USA) video clip that was linked to the website; while we sought to include information about the trial on other internet sites including Facebook (Facebook, Inc., Menlo Park, CA, USA), Twitter (Twitter, Inc., San Francisco, CA, USA), Mumsnet and Pelvic Partnership, this was not possible in the end. In addition, study flyers and posters were distributed to, and displayed in, local GP practices, children's centres and the UHNS maternity centre and women's health department. We raised awareness of the trial through local radio (including one-off, free interviews about the trial on Radio Stoke and Six Towns Radio as well as professionally produced radio infomercials running frequently on 3 consecutive days on the local commercial radio station, Signal Radio), a free two-page spread in a local newspaper with wide readership (*The Sentinel*) and paid advertisements about the study on local buses. These awareness-raising methods were tested throughout the recruitment period and were phased in over time. The need for such advertising and payment for advertising had not been originally included in the grant application but the research team felt it was important to test out different methods in order to estimate their likely value for a future large trial.

Eligibility screening and informed consent

Women identified through method 1 were screened for eligibility by research midwives on the same day as their antenatal appointment. Those who appeared eligible were provided with a PIL. If time permitted, and the woman wished to do so, she completed the full eligibility checks, consent process and baseline data collection and was randomised on the same day. If time did not allow this, or if the woman wished to have more time to consider participation, then a further face-to-face research appointment was booked with a research midwife or research nurse or the woman was advised to telephone the study administrator if she was subsequently interested in participating (method 4).

In all other methods there was a brief initial eligibility check over the telephone (confirming intended clinical site of birth as UHNS, presence of back pain related to this pregnancy, age of 18 years or over, at gestational weeks 13 to 31 and naive to acupuncture treatment). If women met these initial eligibility criteria, a study letter and PIL were posted out to them and a research midwife or research nurse then contacted them by telephone to complete further eligibility checking. If the woman was eligible and interested in participating, a face-to-face appointment was booked for her with a research midwife or research nurse at a choice of either an EASE Back study research clinic at UHNS or the woman's own home for confirmation of final eligibility, consent, baseline assessments and randomisation.

If the woman was eligible and willing to participate, written consent to participate was obtained. Full baseline data collection took place, including completion of the baseline questionnaire and completion of two self-administered pain provocation tests (see *Baseline data collection*). Women had a choice in location and times of EASE Back study eligibility and consent appointments and in treatment location and times. Ineligible women and those who declined to participate were signposted back to normal care pathways. In order to explore generalisability, anonymised data were captured from women who were ineligible or declined participation.

Audio-recordings of eligibility and consent meetings

The purposes of these audio-recordings were to explore how the trial was explained and presented to women by those involved in obtaining informed consent, the potential usefulness and acceptability of the information provided and any concerns on the part of the women, in particular about acupuncture in pregnancy and/or the acceptability of randomisation to the different treatment groups. Previous research has pointed to frequent difficulties in recruitment to randomised trials.^{57,62} Such difficulties pose major threats to external validity, increase costs and reduce research staff productivity.⁶³⁻⁶⁵ Such research also highlights the importance of a clear understanding among potentially eligible participants of the concept of clinical equipoise, of threats to recruitment because of patient preferences^{66,67} and of tensions in the process of informed consent.⁶⁸ As part of testing the trial procedures in the light of these challenges, we examined in detail a sample of the face-to-face meetings that took place between the research midwife or research nurse and potentially eligible women.

Details on how to use the recorders, label the audio files to ensure anonymity, upload them to the secure research e-mail address and delete once confirmation of their safe arrival had been received were included in the training session for the research midwives and nurses. These recordings were transcribed in an anonymised format. Data collection stopped after 30 audio recordings, when data saturation was clear.⁶⁹ Analysis was carried out based on the constant comparative method⁶⁰ with transcripts read and text segments coded in order to identify themes which were then discussed within the research team.

Baseline data collection

The baseline data collection included a baseline questionnaire (see *Appendix 10*) and two objective self-administered tests of pain provocation. The baseline questionnaire included sociodemographic questions about age, education (highest qualification), marital status, social support (living alone), number of children and pregnancies, job title, work status, physical demands of work, time taken off work because of the back pain, performance at work and overall work satisfaction, as well as current body mass index (BMI) and pre-pregnancy BMI. The baseline questionnaire also included questions about symptoms including pain location using a body chart [in which responses were coded into low back pain only, low back pain with anterior PGP, low pain back with pain in other bodily regions (such as the thoracic spine, neck, shoulders and arms) or low back pain with anterior PGP and pain in other bodily regions], pain duration of this episode, pain severity using a pain index [mean score of three Numeric Rating Scales (NRSs) of least, usual and current pain⁷⁰], pain intensity before going to bed,³³ frequency of pain preventing being

able to fall asleep, frequency of pain waking the woman up at night, impact of pain on everyday activities [measured using both the Oswestry Disability Index (ODI)⁷¹ and the Pelvic Girdle Questionnaire (PGQ), a recently validated tool that captures self-reported symptoms and impact on activities specifically for pregnant and postpartum women^{72,73}], overall quality of life [measured by the European Quality of Life-5 Dimensions (EQ-5D)⁷⁴ and Short Form questionnaire-12 items (SF-12)⁷⁵], use of both over-the-counter and prescribed medications, treatments or appliances, treatment preferences and expectations for both SC and SC plus acupuncture. In order to further assess the proportion of participants in the trial with low back pain only or low back pain with PGP, the research midwife or research nurse instructed participants to conduct two self-administered tests for PGP. These were the self-test P4, which is a participant-generated thigh thrust, and the bridging test, where the woman performs a pelvic bridging manoeuvre with extension of one leg (see *Appendix 11*). Both tests are conducted in a supine position, can be performed by pregnant women and have been shown to have high sensitivity and specificity for posterior PGP compared with reference standard tests.⁷⁶ Compared with a reference standard, the sensitivity of the self-test P4 was 90% and for the bridging test 97%, with specificity being reported as 92% and 87% for the self-test P4 and bridging test respectively. Olsen *et al.*⁷⁶ report a positive pain drawing as the most sensitive (96%) and specific (85%) method of identifying anterior PGP (and we included a body chart in the baseline questionnaire on which women were asked to shade the areas of pain). The research midwives instructed the women to undertake the self-test P4 and the bridging test in a standardised way using a pre-prepared script. A positive test was a reproduction of their familiar pain in the sacroiliac region.

Randomisation and allocation concealment

Participants were randomised using the musculoskeletal CTU (registered CTU), a process of third-party remote randomisation. A random allocation sequence was used, based on computer-generated random numbers. The research midwife or research nurse telephoned the CTU administrator on the same day (whenever possible) or on the next working day following the face-to-face meeting at which written consent was taken and a research administrator conducted the concealed randomisation process and directly informed the participants about their treatment allocation, in writing, within 2–3 days of randomisation (in the next available post). This ensured that the person involved in randomisation was unaware of the baseline data of each trial participant. Given that back pain tends to worsen as pregnancy progresses, we stratified randomisation based on gestation weeks (dichotomised into two groups, less than or more than 24 weeks), in order to ensure that equal proportions of women at earlier and later gestation were randomised to each of the three treatment groups. The randomisation was also blocked (using randomly varying blocks of sizes 3 and 6) to ensure that the number of participants was equally distributed among the three treatment arms. All participants continued with their usual care from their midwife and other antenatal carers, and this was recorded in the follow-up questionnaire at 8 weeks. Participants were posted written confirmation of their treatment allocation along with the EASE Back study self-management booklet. Those randomised to SC alone also received information about how to access physiotherapy should both they and their community midwife feel they needed it. Those randomised to receive one of the acupuncture interventions also received, in the same postal package, information about the next steps for them to start their treatment. We developed written service-level agreements with participating physiotherapy services to facilitate the commencement of treatment within 2 weeks of randomisation to one of the acupuncture treatments and agreed the process of communication between trial participants and the physiotherapy service (through administrators in the existing physiotherapy hub who arrange all physiotherapy appointments in the participating trust).

Blinding

The women randomised to SC plus either true or non-penetrating acupuncture were blinded to whether they were receiving true or non-penetrating acupuncture. Physiotherapists providing the treatments were not involved in the baseline data collection or follow-up outcome assessment processes. The NIHR Clinical Research Network West Midlands research midwives and nurses dealing with the baseline and outcome data collection were blinded to the intervention assignments. Selection bias was avoided by the system of remote allocation to treatments described earlier. Data about outcomes were collected using self-completed questionnaires (and telephone follow-up for a minimum data set). These data were collected and entered by staff without knowledge of the allocation of the individual concerned. In addition, analyses of patient-reported outcomes at 8-weeks follow-up were conducted and verified by blinded statisticians.

Training and auditing processes

Research midwives in the Childbirth And REproductive health (CARE) for Comprehensive Local Research Network (CLRN) West Midlands North network and research nurses in the Clinical Research Network West Midlands were key to identifying potentially eligible women for the pilot trial, to providing full information to potentially eligible women, to determining eligibility for the trial and to gaining women's written consent and full baseline data. Following written consent, research midwives and research nurses were also responsible for telephoning the randomisation service. In addition, our EASE Back study administrator conducted brief initial eligibility screens during a telephone call initiated by interested women. Several training events led by the study team for these key staff ensured the processes for identification, explanation, screening and consent were feasible and clear (see *Chapter 2, Training programme for research midwives and nurses*, for full details of the research midwife and nurse training programme). This was facilitated by a named lead research midwife and a named lead research nurse, clear flow charts and a pro forma for completion during the eligibility screening and checking meetings (see *Appendix 12* for the full eligibility screening pro forma). The research team conducted audits of these eligibility screening and consent meetings.

The processes for identifying potentially eligible women, completing screening and eligibility checks, audio-recording face-to-face meetings, obtaining informed consent, collecting baseline data including guiding women to complete the two objective tests for PGP and contacting the CTU for randomisation were initially assessed as mock scenarios within the training session prior to commencing recruitment (see *Chapter 2, Training programme for research midwives and nurses*). During the recruitment period, any new members of the research nurse team who joined the study were also trained and assessed by the lead research nurse to ensure they were competent in these processes. The lead research nurse was audited by the trial co-ordinator. The lead research nurse then carried out audits on all other research midwives and nurses. The audit found that all research midwives and nurses were competent in the process of taking informed consent and guiding women to perform the objective tests, and that the pilot trial procedures were being adhered to.

The lead research nurse ran a training session on MDC telephone calls after the 8-week questionnaire with the research nurse team and listened to the telephone follow-up calls until she was happy that the nurses were competent in collecting follow-up data. This was checked again halfway through the MDC period by the lead research nurse, to ensure consistency across all the nurse team, and no problems were identified.

Physiotherapists' questionnaire results and feedback

Questionnaire results

Fourteen physiotherapists (13 female) who delivered the EASE Back pilot trial interventions completed three questionnaires (before and immediately after the training programme, and at the end of the EASE Back pilot RCT). Their demographic and practice characteristics are summarised in *Table 6*. All had prior experience (although mostly 'infrequently') of treating pregnancy-related back pain. The majority had previously received postgraduate training in back pain, but only one in women's health. Eleven currently used acupuncture in the management of musculoskeletal pain, including back pain, but none currently used acupuncture for back pain in pregnant women.

Physiotherapist questionnaires sought information about their self-confidence in managing pregnant women with back pain and their clinical management of a typical patient with this problem (in a patient case vignette), before and immediately after the training programme, and after delivering the EASE Back study interventions to participants. The results are summarised in *Table 7*. Self-confidence in diagnosis and management of back pain in pregnancy increased after the training and remained high at the end of the pilot RCT. In terms of SC, the large majority of respondents reported that they would manage the patient case in one-to-one treatment sessions, and the number of times the patient would typically be seen increased after the EASE Back study training, with many preferring to see the patient more than twice.

TABLE 6 Characteristics of participating physiotherapists

Characteristics (denominator ^a)	
Years of clinical experience, median (IQR)	8.5 (5.0–17.5)
Use acupuncture for musculoskeletal pain, <i>n</i> (%)	11 (78.6)
Work setting (13)	
Exclusively NHS, <i>n</i> (%)	6 (42.9)
Combination of NHS and non-NHS, <i>n</i> (%)	7 (50.0)
Frequency of treating pregnant women with back pain (13)	
Infrequent – at most one in last 6 months, <i>n</i> (%)	10 (71.4)
Somewhat frequent – between two and five in last 6 months, <i>n</i> (%)	2 (14.3)
Very frequent – at least one per week, <i>n</i> (%)	1 (7.7)
Circumstances under which pregnant women access physiotherapy ^b (13)	
Referred from their midwife, <i>n</i> (%)	1 (7.7)
Referred from their GP, <i>n</i> (%)	12 (92.3)
Referred from their obstetrician, <i>n</i> (%)	1 (7.7)
Self-referred to physiotherapy, <i>n</i> (%)	1 (7.7)
Postgraduate training (14)	
In women's health, <i>n</i> (%)	1 (7.14)
In back pain in general, <i>n</i> (%)	13 (92.9)
In back pain in pregnancy, <i>n</i> (%)	2 (14.3)
IQR, interquartile range.	
a Denominator varies, as some respondents did not answer all the questions.	
b Multiple responses possible.	

TABLE 7 Physiotherapists' confidence and reported management

Physiotherapists' questionnaire results	Before training (n = 14)	After training (n = 14)	At trial end (n = 12)
Self-confidence in diagnosis and management of back pain in pregnancy, ^a median (IQR)	8.0 (6.0–11.0)	16.0 (16.0–17.0)	16.0 (16.0–17.0)
Patient would normally be seen in individual, face-to-face sessions, n (%)	12 (85.7)	12 (85.7)	11 (91.7)
Patient would normally be seen as part of group, but could access one-to-one sessions, n (%)	1 (7.1)	1 (7.1)	1 (8.3)
Patient seen in up to two treatment sessions, n (%)	9 (64.3)	5 (35.7)	4 (33.3)
Patient seen in more than two treatment sessions, n (%)	5 (35.7)	8 (64.3)	8 (67.3)
Care episode would last 3–4 weeks, n (%)	10 (71.4)	4 (28.6)	6 (50.0)
Care episode would last > 4 weeks, n (%)	4 (28.6)	9 (71.4)	6 (50.0)
Typical length of session: up to 30 minutes, n (%)	11 (78.6)	8 (57.1)	10 (83.3)
Care would finish after treatment, re-referral required for further treatment, n (%)	3 (21.4)	0 (0)	1 (8.3)
Care would be left open for duration of the pregnancy, n (%)	7 (50.0)	9 (69.2)	6 (50.0)
Care would be left open for a defined period of time after end of treatment, n (%)	3 (21.3)	4 (30.8)	5 (41.7)

IQR, interquartile range.

^a Self-confidence measured using four items; responses from the four items were summed (after reverse coding the first item) to give a self-confidence score (0–20); the higher the score the higher the confidence.

The questionnaire sought information on physiotherapists' reported advice to, and management of, the patient case before and immediately after the training programme for the EASE Back study and at the end of the pilot RCT. *Figure 4* summarises the advice that therapists reported they would offer and *Figure 5* the clinical management approaches. We observed increases in the reported use of written advice on self-management, advice to continue with everyday activities, advice about safe pharmacological treatment options and advice about the use of home massage (see *Figure 4*), following the EASE Back study training programme. We also observed increases in the use of various management approaches after the training programme including exercises supervised by a physiotherapist, strengthening exercise, pelvic floor exercise and acupuncture (see *Figure 5*).

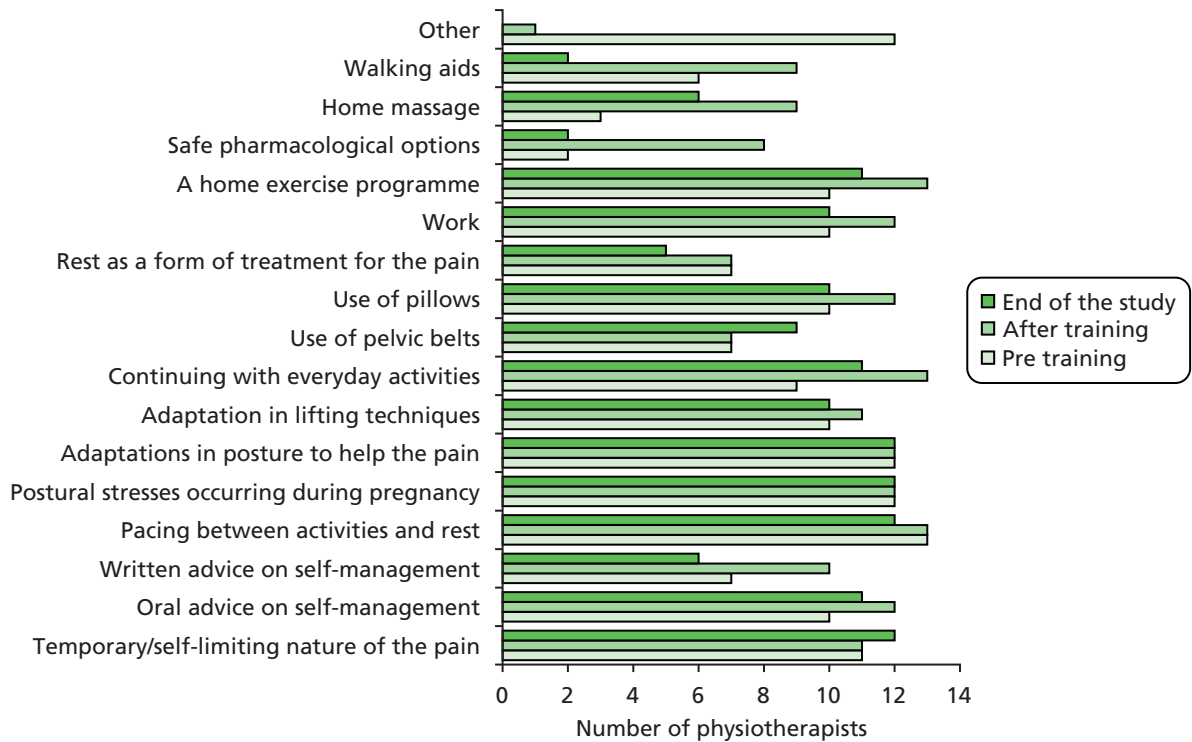


FIGURE 4 The EASE Back study physiotherapists' use of advice for the typical patient case.

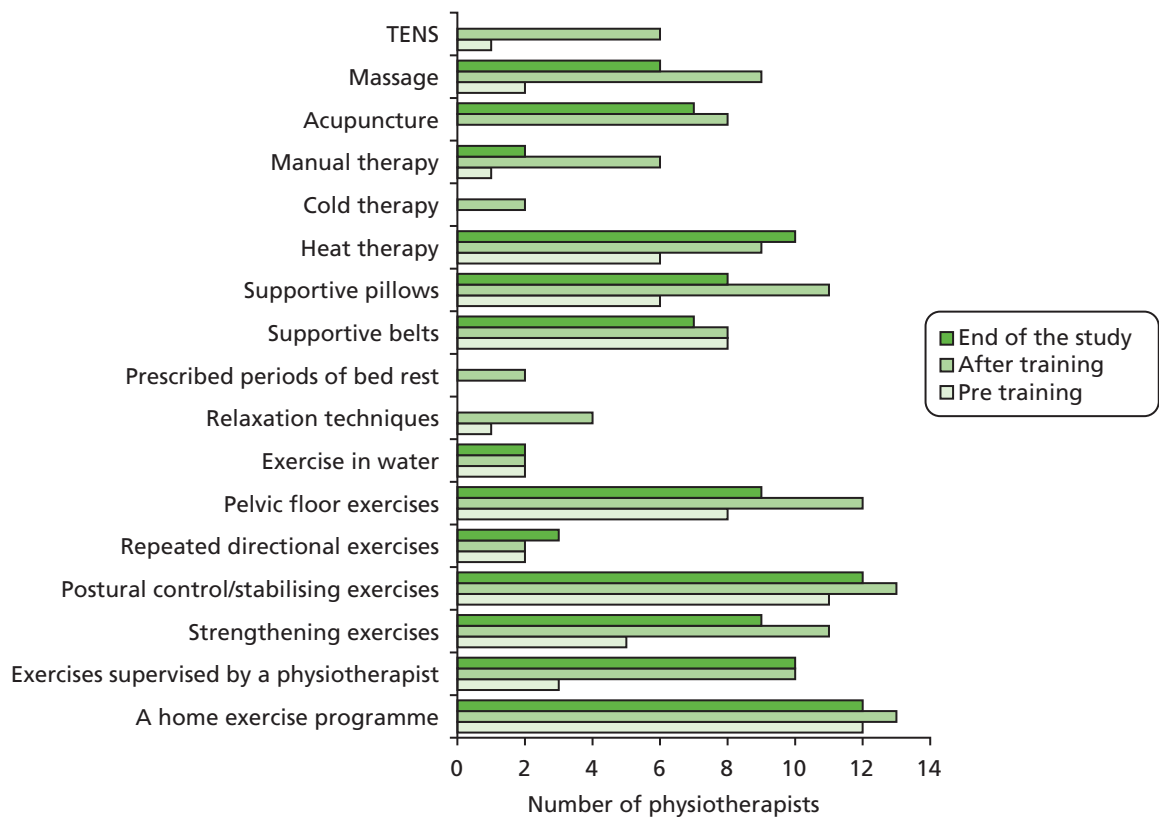


FIGURE 5 The EASE Back study physiotherapists' management of the typical patient case.

Physiotherapist feedback

Fourteen physiotherapists attended the EASE Back study training programme, 12 of whom provided treatment to the pilot trial participants. Each physiotherapist treated a median [interquartile range (IQR)] of five (two to nine) participants; six physiotherapists treated between two and four participants, three treated between five and eight participants and three treated between 10 and 19 participants. These differences were a result of women choosing some geographical treatment sites more frequently than others. Following the end of all treatment in the pilot trial, we invited the physiotherapists to a half-day feedback workshop (in April 2014) to gain their views of participation in the pilot trial, to explore what worked well and less well from their perspectives, in order to inform the future main RCT and any future training programme. Several key issues were highlighted including the following:

- Some women had not read the self-management study booklet prior to their first physiotherapy appointment, which meant that much of the first treatment session was taken up with the therapist needing to explain the self-management information before starting acupuncture,
- Uncontrolled epilepsy, allergy to metal and allergy to Tubigrip should be included in the list of exclusion criteria for a future main RCT.
- Women should receive a full explanation of what participation in the trial means in terms of commitment to attending treatment sessions.
- The course of physiotherapy treatment for each participant should be blocked out in physiotherapists' diaries well in advance.
- The training programme for physiotherapists' should include more content on management of pubic symphysis pain (anterior PGP).

Feedback from participating physiotherapists highlighted that the following worked particularly well in the pilot trial and should be continued for a future main RCT:

- the offer of evening treatment times to participants
- the block booking of participants' whole treatment course into physiotherapists' diaries
- ensuring flexibility in staff providing EASE Back study treatments to cover annual leave
- a minimum of two physiotherapists trained in the EASE Back study at each treatment site to provide peer support and sufficient capacity to treat participants
- the mentoring support and supervision from the acupuncture trainer
- new patient appointment slots that lasted 1 hour to ensure that there was sufficient time to provide advice, start the exercise programme and deliver acupuncture.

Interventions

The pilot trial included three treatment arms, randomising participants to receive SC, SC plus true acupuncture or SC plus non-penetrating acupuncture.

Standard care

Full details and justification for the SC protocol were provided in *Chapter 2, The development of a standard care protocol*. SC comprised a high-quality and comprehensive self-management booklet plus onward referral, if necessary, for face-to-face physiotherapy. This was felt to be the most appropriate SC package, as it mostly closely reflected current practice, according to which most pregnant women with back pain are not referred to other health professionals for treatment for their back pain but, rather, are advised to self-manage, with only those who are the most severely affected being referred to physiotherapists. This booklet (see *Appendix 5*) was posted to women in the SC group along with a letter explaining which group they had been randomised to. They were not instructed to avoid other treatments, but their use of other treatments was monitored through self-report questions in the 8-week follow-up questionnaire. We provided information in the SC information pack about how to access EASE Back study physiotherapy care should both the woman and her midwife feel that this was needed and we developed an EASE Back study SC protocol for

these women with participating physiotherapists, based on the results of phase 1 surveys and interviews (see *Chapter 2, The development of a standard care protocol*, for details). Physiotherapists assessing and managing these women completed EASE Back study CRFs (see *Appendix 13*) to describe the care provided.

Standard care plus true acupuncture

The same advice and education package was posted to women randomised to SC plus a course of true acupuncture, along with a letter explaining how to arrange the first physiotherapy appointment and that the first treatment should be within 2 weeks. Physiotherapists provided a course of SC plus true acupuncture informed by findings from the phase 1 surveys and interviews. In addition to SC, participants randomised to also receive true acupuncture were to receive treatment as follows: a patient assessment to ascertain the quality, location and intensity of the presenting back pain (with or without PGP) followed by acupuncture treatment, using acupuncture points from selected from the agreed list of points summarised in *Table 8*. The list of points was informed by the survey of current practice in phase 1, texts about acupuncture for back pain and PGP in pregnancy and previous RCTs. Point location and depth of insertion were as described in *Table 8*.

TABLE 8 Acupuncture points and depth of needling in the true acupuncture arm

Local points		
Point	Description	Depth of insertion/needle
BL23	1.5 cun lateral to the spinous process of L2	30–40 mm/50 mm
BL24	1.5 cun lateral to the spinous process of L3	30–40 mm/50 mm
BL25	1.5 cun lateral to the spinous process of L4	30–40 mm/50 mm
BL26	1.5 cun lateral to the spinous process of L5	30–40 mm/50 mm
BL27	1.5 cun lateral to the spinous process of S1	30–40 mm/50 mm
BL28	1.5 cun lateral to the spinous process of S2	20–30 mm/40 mm
BL54	3 cun lateral to the spinous process of S4	50–70 mm/75 mm
BL31	Over the first sacral foramen	20–30 mm/40 mm
BL32	Over the second sacral foramen	20–30 mm/40 mm
BL33	Over the third sacral foramen	20–30 mm/40 mm
GB30	Over the piriformis muscle, at junction of lateral third and medial two-thirds of line joining sacral hiatus and greater trochanter of the femur	50–70 mm/75 mm
HJJ L4	One finger-breadth lateral to the spinous process of L4	30–40 mm/50 mm
HJJ L5	One finger-breadth lateral to the spinous process of L5	30–40 mm/50 mm

All of the above points can be needled bilaterally. Tender points over the gluteus minimus and the pelvic rim can also be included.

Distal points		
GB34	One finger-breadth anterior and one inferior to the fibular head	25–30 mm/40 mm
ST36	3 cun below the joint line of the knee and a finger-breadth lateral to the tibial crest	25–30 mm/40 mm
LR3	Just distal to the junction of the bases of the first and second metatarsal bones	25–30 mm/40 mm
LI4	On the highest point of the first dorsal interosseous muscle of the hand	20–30 mm/30–40 mm
BL60	Midway between the lateral malleolus and the Achilles tendon	15–25 mm/30 mm
BL62	1 cun below the tip of the lateral malleolus	10–20 mm/30 mm

BL, bladder; GB, gall bladder; HJJ, Huato Jia Ji; LI, large intestine; LR, liver; ST, stomach.

One or two of the above points are to be included in the treatment. It is not necessary to needle bilaterally, unless the clinician judges it to be needed.

The patient was suitably positioned (side-lying wherever possible or prone) and the therapist chose a minimum of six and a maximum of 10 bilateral points in total, thus needling between 12 and 20 acupuncture points. The choice of these points was made using the principles of Western acupuncture and trigger point acupuncture. Acupuncture points were to be in the general location of the patient's pain (local points) with the addition of distal points. The therapists identified and needled the relevant points at the appropriate depth and rotated the needle to elicit the de-qi sensation. It was intended that all needles be inserted into muscle. Traditional acupuncture needles were used in sizes 50 mm × 30 mm, 40 mm × 30 mm, 70 mm × 30 mm and 30 mm × 30 mm. Therapists could change the points at each treatment session, should they feel this was appropriate, as long as all points used were those from the agreed list in *Table 8*. All needles were of the disposable, sterile, stainless steel variety. Acupuncture treatment was to last from 20 to 30 minutes, during which time the therapist was to stimulate the needles again, ensuring that the needling sensation (de-qi) was maintained. On completion of the treatment all needles were to be safely removed, any sensations felt by the participant during treatment and any adverse reactions were recorded on the CRF and the patient booked for the next appointment. Between six and eight treatment sessions were to be offered to participants over a period of 6 weeks, and efforts to engage women in treatment after failure to attend were agreed with participating physiotherapy services.

Standard care plus non-penetrating acupuncture

In order to control for time and attention with physiotherapists, we included a SC plus sham acupuncture arm using non-penetrating needles (the devices look exactly like real needles but the tip is blunted and the shaft of the needle is allowed to slide in the handle, giving an illusion of penetration). This trial arm consisted of the same advice and education booklet posted to women randomised to SC plus a course of non-penetrating acupuncture, along with a letter explaining how to arrange the first physiotherapy treatment session and that the first treatment should be within 2 weeks. The same NHS physiotherapists provided the non-penetrating acupuncture treatment, and the participants' letters explained that they had been randomised to receive SC plus one of two forms of acupuncture treatment. The non-penetrating Streitberger needle has been validated in several studies and used successfully in two previous trials of acupuncture.^{33,39} The device looks exactly like a real needle but has a blunted tip, and is tapped onto the skin, held in place by an O-ring, and gives the illusion of needle insertion. Women were treated in a side-lying or prone position, which permitted both comfortable positioning for the participant and adequate blinding to the non-penetrating acupuncture needles.

In addition to SC, participants randomised to also receive non-penetrating acupuncture received the treatment as follows: the patient was assessed to ascertain the quality, location and intensity of the presenting back pain (with or without PGP), the patient was suitably positioned and the therapist applied the non-penetrating needles bilaterally over the four points detailed in *Table 9*. After the non-penetrating needles were positioned, no further attempt to stimulate the needles was made. The treatment lasted for 20–30 minutes. On completion of the treatment all needles were safely removed, any sensations felt by participants during treatment and any adverse reactions were recorded on CRFs and the patient was booked for the next appointment. Between six and eight treatment sessions were offered by physiotherapists over a period of 6 weeks.

TABLE 9 Acupuncture points in the non-penetrating acupuncture arm

Local points		
Point	Description	Depth of insertion of the needles
BL26	1.5 cun lateral to the spinous process of L5	n/a
BL27	1.5 cun lateral to the spinous process of S1	n/a
BL54	3 cun lateral to the spinous process of S4	n/a
GB30	Over the piriformis muscle, at junction of lateral third and medial two-thirds of line joining the sacral hiatus and the greater trochanter of the femur	n/a

BL, bladder; GB, gall bladder; n/a, not applicable.

Fidelity of treatments

For each participant, physiotherapists recorded full details of the advice and treatments, number and mode of treatment sessions, any non-attendance, acupuncture points used, any sensations during acupuncture treatments and any adverse events on specifically designed CRFs (see *Appendix 13*). The CRFs also included one NRS to capture pain severity after treatment at each session. These CRFs were audited against the physiotherapists' clinical notes to ensure accuracy and to determine protocol adherence by participating physiotherapists before collation by the research team in order to fully describe the interventions delivered. Where protocol deviations were noted, these were discussed with the physiotherapists involved in order, whenever possible, to enhance adherence to the agreed intervention protocol. Protocol deviations were mostly related to challenges in getting women to attend for all of their arranged treatment sessions. Where participants did not attend for treatment, physiotherapists attempted to contact them to re-engage them in treatment whenever possible.

Outcome measures and follow-up

Process outcomes

Process outcomes from the pilot trial included recruitment rates (both overall and from each separate recruitment method), follow-up rates at 8 weeks (both overall and in each treatment arm), attendance at treatment sessions, treatment protocol adherence, completion rates on key outcome measures, and floor and ceiling effects of key outcome measures.

Clinical outcomes

Patient-reported outcomes were assessed at the 8-week follow-up (i.e. 8 weeks after randomisation). The decision about the most appropriate follow-up time point for the pilot trial was taken in order to maximise the chances of most participants having received their full course of treatment, but not yet having given birth. We expected that women recruited to the trial at 30 and 31 weeks' gestation would wait a maximum of 2 weeks for the start of their acupuncture treatment and would have a course of treatment over 6 weeks. Therefore, they should have completed their acupuncture treatment and received their follow-up questionnaire just before the birth of their baby. Studies of low back pain and PGP in pregnant women have previously followed up participants 1 week after the end of treatment³³ and at 12 weeks (3 months) post partum.^{15,17} We did not plan longer-term follow-ups in this pilot trial but, rather, we provide data on baseline and one follow-up time point only (at 8 weeks), in order to ensure that we delivered the feasibility and pilot study within a period of 24 months.

Outcomes at the 8-week follow-up were collected by postal questionnaire (see *Appendix 14*) and included the same measures of pain, everyday function and general health as at baseline, overall global rating of change since baseline, whether or not the woman was still pregnant (and, if yes, number of weeks' gestation), a series of questions about treatment credibility, satisfaction with the treatment package received, satisfaction with the results from treatment and side effects from treatment in the EASE Back study. In addition, we included an open question on the 8-week follow-up questionnaire about the participant's experience of treatment in the trial. We developed a minimum outcome data set from these wider set of outcomes which was collected over the telephone for those participants who did not respond to the postal reminder.

Cost outcomes

Data collection was undertaken to obtain patient-level cost and outcome data for all women participating in the trial in order to conduct a preliminary economic evaluation and inform the design of a cost-utility analysis alongside a future main trial. The SC plus non-penetrating acupuncture arm of the trial was not included in the economic analysis; therefore, data were analysed for only the SC and SC plus true acupuncture arms.

Resource use associated with SC and acupuncture treatment was based on primary data collected using information from the trial and self-completed questionnaires at 8 weeks. Cost data collection was undertaken on all women and from a broad perspective, taking into account health-care, patient and societal costs. NHS resource use data included GP consultations, visits to health-care professionals, outpatient appointments, investigations or treatments and inpatient stays related to their back pain during pregnancy. Information on costs borne by the patient with regard to over-the-counter medicines and devices was requested in the 8-week questionnaire. In order to assess broader societal economic consequences, productivity costs relating to both absenteeism (absence from work) and presenteeism (working with reduced productivity) were considered. Self-reported data on employment status, occupation and time off work and reduced productivity at work (presenteeism) owing to their back pain over the 8-week study period were collected. As it was assumed that some of the women attending the acupuncture treatment sessions might be in work or have other children, data were also collected regarding the travel costs, time off work and child care costs associated with attending a treatment sessions during the trial. As part of the pilot, the methods of collecting cost data from patient questionnaires and completeness of the data were assessed, in order to inform cost data collection in a future large trial.

Details of the number of treatment sessions attended by each participant were collected as part of the trial. The costs required to deliver the treatments included the acupuncture sessions, other aspects of SC, duration of each session and consumables needed.

For the purpose of costing staff time associated with the treatments, we estimated the average time of a treatment session with a physiotherapist during the study. Both the acupuncture intervention and SC involved, on average, a standard 60-minute initial consultation and follow-up consultations of 40 minutes per session.

In order to enable the calculation of quality-adjusted life-years (QALYs), all patients were asked to complete the five-level version of the EQ-5D questionnaire (i.e. EQ-5D-5L) at baseline and 8 weeks in order to assess quality of life.⁷⁷

Maternal/neonatal outcomes

We collected the following additional obstetric birth/neonatal outcomes from maternity records for all participants in order to inform a future main trial: gestation week at time of delivery, live births, length of labour (and second stage of labour), whether or not the woman needed to be induced, mode of delivery, whether or not the woman had an episiotomy or a perineal tear, estimated blood loss at birth, antenatal and postnatal haemoglobin count, pain relief during labour, baby's sex and weight, Apgar scores at 1 minute and 5 minutes after birth and whether or not the baby was admitted to the neonatal unit.

Adverse events

We collected adverse event data through CRFs completed after each physiotherapy treatment, through self-report of participants in the 8-week follow-up questionnaire and through maternity record reviews. Expected adverse events from the acupuncture interventions include drowsiness/light-headedness, nausea/vomiting, fainting, bruising at needle sites, feeling hot/burning, headaches and transient pain at needle sites. We defined SAEs as death, hospitalisation, significant disability or incapacity, any life-threatening circumstance (to the woman or developing child) or any other medically significant occurrence that were potentially attributable to any of the trial procedures or treatments. Potential SAEs were identified via treating physiotherapists.

Sample size

In line with pilot trial recommendations,⁴⁵ the EASE Back pilot trial did not have a primary outcome or the usual sort of power calculation that one would expect in a main RCT. The sample size was based on the number of births overseen by the participating maternity centre (UHNS) per year at the time of the funding application and estimates about the proportion of women likely to be eligible and consent to participate. The UNHS maternity service oversaw approximately 6100 births per year and we estimated that between 50% and 66% would self-report back pain at some point in their pregnancy and at least 30% would self-report back pain in gestational weeks 13–31. Thus, we estimated that approximately 1800 women would be potentially eligible over the course of 1 year, equivalent to approximately 600 over a recruitment period of 4–5 months. We estimated that we would need to raise awareness of the EASE Back pilot trial among these 600 pregnant women with back pain and that approximately one in four might agree to participate. To allow for some withdrawal and loss to follow-up, we anticipated needing to approach about 720 women in order to recruit 180 women and provide follow-up data on 150 women.

In reality, we recruited 125 women in 6 months. The research team and the TSC felt that 125 women provided an adequate number to estimate critical parameters in the pilot trial (e.g. recruitment rates, variation in key patient-reported outcome measures, treatment fidelity), using the rule of thumb of 30 patients or greater per group.⁷⁸

Analysis

To ensure transparency in analyses, a statistical analysis plan (SAP) was developed by the study statistician (RO), together with the PI (NF), trial co-ordinator (AL), senior CTU statistician (ML), health economists (SJ and JK) and other study team members. The SAP, including all the mock-up tables and figures, was presented to the TSC for review and discussion. All agreed amendments were implemented and the revised SAP was approved and signed off by the TSC.

The analysis of the pilot focused on (1) evaluation of the physiotherapy training programme through analysis of physiotherapy questionnaire data; (2) baseline description of the study population, including pain location and a summary of gestation weeks; (3) assessment of process measures including recruitment rate and methods of recruitment uptake and response to follow-up; (4) exploratory analysis of clinical outcomes; (5) descriptive summaries of treatment received (in relation to adherence with randomised intervention), satisfaction with care and evaluation of the adherence to treatment protocols through analysis of CRF data; (6) extent of missing data and data accuracy; (7) summary of birth and neonatal outcomes; (8) reports of adverse events in any of the treatment arms; and (9) summary of parameters to aid the choice of primary outcome measure and sample size calculation for a full RCT.

In the absence of standard practice regarding the type of economic evaluation to conduct alongside feasibility and pilot studies, a cost–consequence analysis was chosen. This allowed an exploration of the feasibility of conducting an economic evaluation as part of a future RCT testing acupuncture compared with SC in women with pregnancy-related back pain, rather than demonstrating cost-effectiveness at this stage. The SC plus non-penetrating acupuncture arm of the trial was not included in the economic analysis. The main purpose of including a non-penetrating acupuncture treatment was to explore the merits of this for a future main trial, in order to explore the importance of needle penetration in explaining acupuncture effects. The SC plus non-penetrating acupuncture intervention would not be commissioned in actual NHS practice. Therefore, health economic data were analysed for only the SC and SC plus true acupuncture arms. The cost–consequence analysis describes all the important results relating to costs and consequences of the treatments for the management of back pain in pregnant women in the SC and the SC plus true acupuncture arms of the pilot trial. The base case analysis for the evaluation adopted a NHS and Personal Social Services (PSS) perspective, with additional analysis considering a broader societal perspective taking into account patient-incurred costs and productivity losses. Costs are presented for each broad cost category

(health-care costs, patient-incurred costs, productivity costs) and in a disaggregated form within each of these cost categories. Unit costs were obtained from various sources including the *British National Formulary* (BNF),⁷⁹ NHS reference costs and Unit Costs of Health and Social Care^{80,81} and multiplied by resource use items from the trial. Unit costs are presented in *Table 10*. Discounting was not necessary as the follow-up period was 8 weeks. Owing to the lack of nationally representative unit cost estimates for private health-care visits, any private care was costed as the NHS equivalent. Patient-reported costs for over-the-counter treatments and patient-incurred time, travel and child care costs were used to estimate patient-related costs. Productivity losses were assessed using the human capital approach; self-reported days of work absence and reduced productivity at work due to back pain during the 8 weeks were multiplied by the average sex-specific wage estimates identified from annual earnings data and UK Standard Occupational Classification coding.^{82,83} Reduced productivity time loss was generated by translating the self-reported scores obtained using a 0–10 scale into work loss based on the actual number of days worked during this period. In addition, time off work and reduced time spent on unpaid activities in order to attend physiotherapy appointments was estimated using a similar approach. Responses to the EQ-5D questionnaire were converted to index scores using the interim crosswalk UK value set. The area-under-the-curve approach that links each patient's utility scores at different time points was applied to calculate QALYs for each study participant over the 8-week time period. Regression-based adjustment was used to account for baseline differences in EQ-5D score.

TABLE 10 Unit costs used in the economic analysis

Health-care resource	Unit cost (£)
Primary care^a	
GP consultation (11.7 minutes)	34
Practice nurse consultation (per hour)	44
Health visitor (per hour)	43
Nurse home visit (per hour)	60
Community physiotherapist (per hour)	30
Secondary care contacts^b	
Midwife: first attendance	96
Midwife: follow-up	54
Obstetrician: first attendance	165
Obstetrician: follow-up	112
Acupuncturist: first attendance	49
Acupuncturist: follow-up	44
Physiotherapist: first attendance	49
Physiotherapist: follow-up	44
Study treatment sessions	
First session: 60 minutes	30
Follow-up session: 40 minutes	23
Prescribed medication	Patient specific ^c
Medical investigations/interventions	Patient specific ^b
Day of sickness absence from work	One-fifth of average weekly earning wages
<p>a Unit Costs of Health and Social Care.⁸⁰ b NHS Reference Costs Schedule 2012/13.⁸¹ c BNF.⁷⁹</p>	

A complete case analysis was undertaken and all costs and outcomes were summarised using means, SDs and 95% confidence intervals (CIs). Cost and QALY data alongside RCTs are invariably skewed; therefore, bias-corrected accelerated bootstrapping with 1000 replications was used to generate 95% CIs around differences in mean costs and QALYs. All statistical analysis was performed using Stata version 13. The CHEERS (Consolidated Health Economic Evaluation Reporting Standards) statement and checklist were consulted for reporting the economic evaluation. Owing to a cost–consequence analysis being undertaken, some items of the checklist were not appropriate for this study.

Patient involvement

Prior to funding application, the study plans were discussed in detail with women attending the antenatal back pain class at the participating hospital (UHNS). The women felt that it was important to be able to offer a number of alternative treatments, as their perspective was that currently few options exist. They considered acupuncture a potentially attractive option but stressed that information had to be clear and particularly needed an explanation of safety issues. They felt that this information had to be given both verbally through health-care professionals, and in a written format which allowed women to reflect on it at home. In addition, two women who had attended the back class and were receiving one-to-one physiotherapy reviewed a draft of the PIL for the pilot RCT and commented on its content, style and readability.

We had two patient representatives on the TSC who:

- identified the limitations of the Disability Rating Index (included in the original funding application to be used as a second measure of back pain-related disability) for the pregnant population, which led to the inclusion instead of the PGQ, a newly developed outcome assessment tool specifically for those with back and PGP in pregnancy,⁷² reviewed and fed back on the PIL and the baseline and follow-up questionnaires in the pilot RCT
- fed back on the visibility of EASE Back study posters and banners when attending antenatal appointments
- reviewed and fed back on the draft self-management booklet *EASE Back: Managing Your Back and Pelvic Girdle Pain in Pregnancy*
- helped with the media advertising by appearing in a newspaper article in *The Sentinel* about the pilot trial and being the voice of a woman with pregnancy-related low back pain in the Signal Radio infomercials.

Results of the pilot randomised controlled trial

Participant flow

Of 388 women assessed for eligibility in 6 months, 280 were potentially eligible and 125 women (45%) were recruited into the EASE Back pilot trial and randomly allocated to one of the three treatment arms (*Figure 6*). One participant, in the SC plus non-penetrating acupuncture arm, was randomised in error (she fulfilled criteria for a high-risk pregnancy) and was subsequently withdrawn prior to treatment. Overall, the 8-week follow-up rate was 74% ($n = 91$).

Baseline comparability

Participants' baseline characteristics (*Table 11*) were largely similar among the three treatment arms. The mean (SD) age of the 124 participants was 28 (5.3) years; 54 (44%) were married, 87 (70%) were in full/part-time employment and 53 (42%) were ≥ 24 weeks pregnant at the time of inclusion. More than half (68 out of 124) had experienced back pain for more than 6 weeks and the mean (SD) pain severity score (mean score of three Pain NRSs on 0–10 scales) was 4.6 (SD 1.7). About one-third of participants (38 out of 144) had low back pain with anterior PGP and pain in other parts of the body. More than half of the participants (67 out of 124, 54%) had moderate back pain-related disability measured by the ODI.

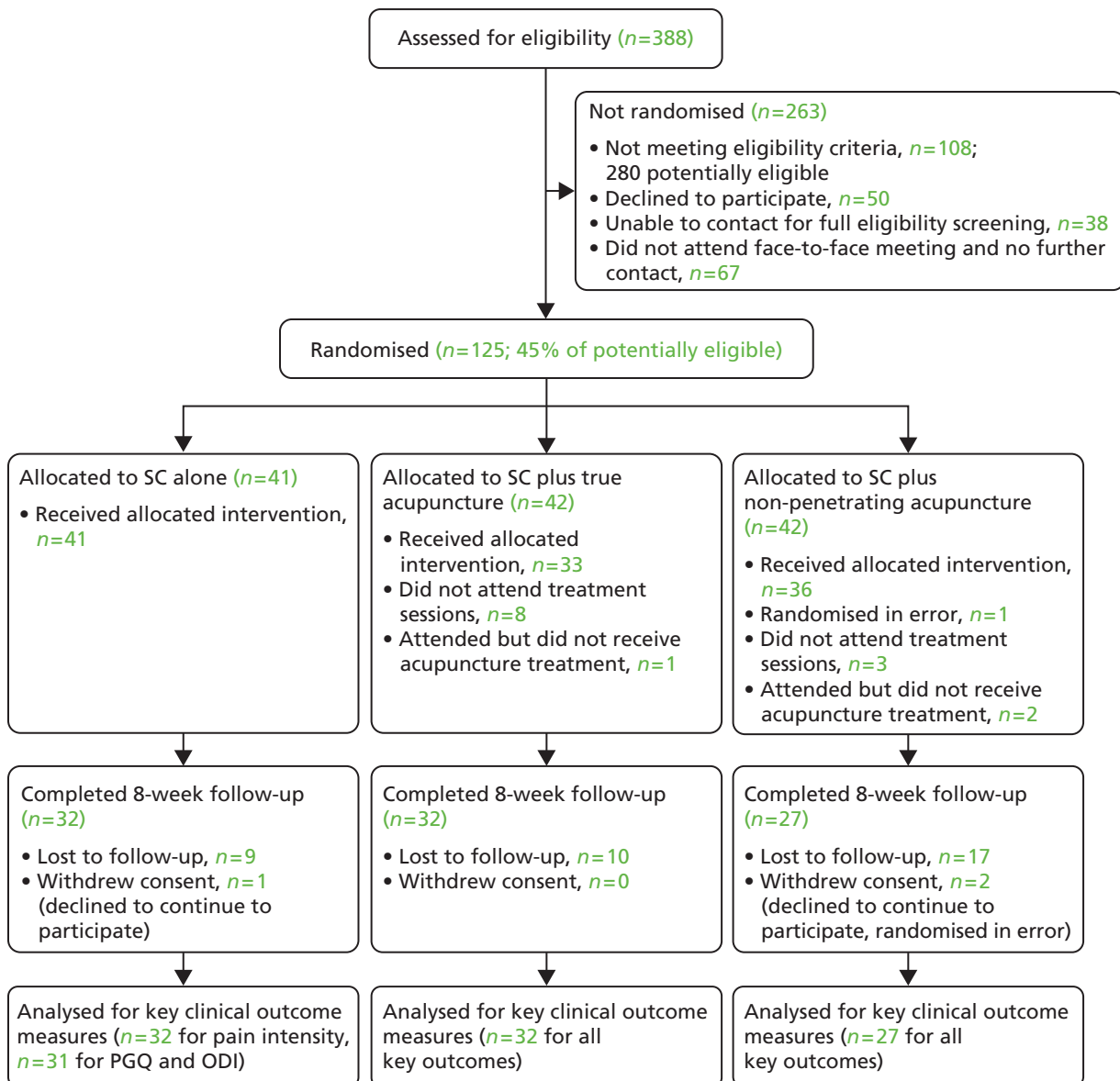


FIGURE 6 The CONSORT (Consolidated Standards of Reporting Trials) diagram for the EASE Back pilot trial.

TABLE 11 Baseline characteristics of pilot trial participants

Baseline characteristic	SC (n = 41)	SC + true acupuncture (n = 42)	SC + non-penetrating acupuncture (n = 41)
Age (years), mean (SD)	27.8 (5.4)	28.1 (5.1)	29.0 (5.3)
Highest qualification: degree/postgraduate, n (%)	13 (31.7)	14 (33.3)	18 (43.9)
Gestation weeks at inclusion: > 24, n (%)	17 (41.5)	18 (42.9)	18 (42.9)
Married, n (%)	16 (39.0)	19 (45.2)	19 (46.3)
No. of children, n (%)			
0	16 (39.0)	20 (47.6)	14 (34.2)
1	17 (41.5)	13 (31.0)	17 (41.5)
2 or more	8 (19.5)	9 (21.4)	10 (24.4)
Working, n (%)	28 (68.3)	27 (64.3)	32 (78.1)
Physical demands of current/most recent paid job: heavy/very heavy, n (%)	12 (29.3)	13 (32.5)	11 (26.8)
Taken time off during the current pregnancy because of back pain, ^a n (%)	8 (28.6)	9 (33.3)	15 (46.9)
Back pain interference with performance at work (0–10 NRS), ^{a,b} mean (SD)	5.0 (2.5)	4.9 (2.6)	5.0 (3.1)
Work satisfaction (0–10 NRS), ^{a,c} mean (SD)	6.6 (2.7)	5.4 (1.9)	6.6 (2.3)
Pain location (manikin), n (%)			
Low back pain only	7 (17.1)	9 (21.4)	7 (17.1)
Low back pain with anterior PGP	8 (19.5)	6 (14.3)	4 (9.8)
Low back pain with anterior PGP and pain elsewhere	10 (24.4)	14 (33.3)	12 (29.3)
Low back pain and pain elsewhere	16 (39.0)	13 (31.0)	18 (43.9)
Duration of pain episode: > 6 weeks, n (%)	23 (56.1)	20 (47.2)	25 (61.0)
Pain severity (mean score of three NRSs), mean (SD)	4.5 (1.6)	4.5 (1.5)	4.6 (1.8)
Pain intensity before going to bed, mean (SD)	6.8 (1.9)	6.8 (1.8)	7.0 (2.2)
Woken up most/every night by pain, n (%)	16 (39.0)	15 (35.7)	17 (41.5)
ODI score (0–100), ^d mean (SD)	34.8 (11.2)	32.9 (13.7)	35.7 (13.6)
ODI score (categorised), n (%)			
Minimal disability (0–20%)	5 (12.2)	8 (19.0)	4 (9.8)
Moderate disability (21–40%)	24 (58.5)	20 (47.6)	23 (56.1)
Severe disability (40–60%)	12 (29.3)	13 (31.0)	11 (26.8)
Crippled (61–80%)	0 (0.0)	1 (2.4)	3 (7.3)
PGQ score (0–100), ^e mean (SD)			
Total	56.9 (16.0)	48.7 (17.2)	54.2 (17.3)
Activity subscale	54.6 (17.0)	46.7 (18.1)	52.7 (18.1)
Symptom subscale	65.4 (17.1)	56.1 (17.2)	59.3 (19.9)

TABLE 11 Baseline characteristics of pilot trial participants (*continued*)

Baseline characteristic	SC (n = 41)	SC + true acupuncture (n = 42)	SC + non-penetrating acupuncture (n = 41)
Pre-pregnancy BMI, n (%)			
Normal/underweight	16 (40.0)	19 (47.5)	12 (31.6)
Overweight	8 (20.0)	11 (27.5)	17 (44.7)
Obese/morbidly obese	16 (40.0)	10 (25.0)	9 (23.7)
Taking prescribed medication, n (%)	7 (17.1)	5 (11.9)	5 (12.2)
Treatment preferences: yes, n (%)	10 (24.4)	8 (19.1)	10 (24.4)
SF-12 – Physical Component Scale score, mean (SD) ^e	36.4 (7.6)	38.2 (8.0)	37.0 (9.7)
SF-12 – Mental Component Scale score, mean (SD) ^f	46.6 (10.1)	44.7 (12.1)	48.1 (11.7)
Self-assessed P4 test: familiar pain produced or increased in lumbosacroiliac area, ^g n (%)	25 (75.8)	26 (81.3)	22 (66.7)
Bridging with extension of leg: familiar pain produced or increased in lumbosacroiliac area, ^g n (%)	25 (89.3)	24 (80)	23 (82.1)
Positive on both P4 test and bridging test, n (%)	17 (41.5)	21 (50.0)	16 (39.0)

a Applies only to those in a paid job.

b Higher mean score implies more interference.

c Higher mean score implies more satisfaction.

d The ODI has 10 sections with scores ranging from 0 to 5 in each section. Item scores are summed and transformed to yield a score of 0 to 100, where 100 is the worst possible score.

e The PGQ items are scored on a 4-point scale and item scores are summed and transformed to yield a score of 0 to 100, where a score of 100 is the worst possible score

f The SF-12 scales are based on a normalised general population average score of 50 with a SD of 10.

g Percentage applies to those who were able to perform the test.

Process outcomes (recruitment, retention, blinding)

Recruitment

Methods of raising local awareness of the trial

Multiple approaches of raising awareness about the EASE Back pilot trial among potentially eligible women in the local area were pilot tested. Women contacting the research office about the trial were asked how they had come to know about the study. Recruitment lasted for 6 months (27 weeks) from April to October 2013. Flyers and posters were used throughout the entire recruitment period, while the bus advertising campaign ran for 8 weeks (from week 19 to week 25 of the recruitment period). The internet website was available for the entire recruitment period with the addition of a YouTube video about the study from week 9. The radio and newspaper advertising campaign varied; some were one-off short radio advertisements and interviews with the trial PI (NF) and others were in the form of radio infomercials (running many times per day on a local commercial radio station, for 3 consecutive days, in week 25 of recruitment). We also published articles in a local newspaper on two occasions in weeks 7 and 12 of the recruitment period. These articles were linked to the newspaper's website, where interested women could obtain further information. There was also an advertisement in a local magazine in week 11 of the recruitment period. *Table 12* summarises these methods, the number of women identified through them and the number subsequently recruited into the pilot trial. Almost half of the women identified from the local awareness-raising campaign came to know about the study through flyers and posters, and the next most successful method was the advertisements on local radio or in local newspapers.

TABLE 12 Summary of methods of local awareness raising

Awareness-raising method	Identified, <i>n</i> (%) ^a	Recruited, <i>n</i> (%) ^b
Flyers or posters	25 (48.1)	12 (48.0)
Advertisements on local radio/newspapers	18 (34.6)	5 (27.8)
Internet website ^c	2 (3.9)	1 (50.0)
Advertisements on local buses	3 (5.8)	3 (100.0)
Word of mouth	4 (7.7)	3 (75.0)
Total	52	24

a Column percentage with the overall total as the denominator.

b Row percentage with the number identified as the denominator.

c Includes study-specific website and YouTube video posted on local media websites.

Success of six methods of identification and recruitment

The number and proportion of women identified and recruited through the six methods described in *Recruitment methods and procedures* are presented in *Table 13*. The brief screening questionnaire for back pain given to women as they attended their routine 20-week ultrasound scan appointment was the most successful method, followed by community midwives providing women with an EASE Back study card and women self-referring following the local awareness-raising efforts.

Recruitment figures over time

Recruitment is summarised in *Table 14*. The average weekly recruitment was five women per week (range 0–12). The lowest recruitment (no participants) was in the week of the height of the summer holiday period and highest recruitment (12 participants) was in the week following the radio infomercials on Signal Radio. Estimated (180 women over 5 months) compared with observed recruitment (125 women over 6 months) is presented in *Figure 7*.

Reasons for ineligibility

From 388 women we contacted, 280 were potentially eligible at initial screens and 108 ineligible. The reasons for ineligibility are presented in *Table 15*. The most common were previous acupuncture (26 out of 105, 25%), previous pre-term delivery (12%) and the woman being registered at a GP practice outside the included list of practices (11%). The number and proportion of eligible women who declined to participate are presented in *Table 13*.

Generalisability of the sample

Table 16 compares key baseline characteristics [age and index of multiple deprivations (from postcodes)] captured from the anonymised data on women who were ineligible or declined participation with the EASE Back trial participants. There was reasonable overall comparability in these key baseline characteristics.

Retention

The 8-week follow-up rate was 74%. *Table 17* presents the details of the follow-up responses (including number of responses after initial mailing, reminder mailing and MDC over the telephone) both overall and for each of the three treatment arms. There was a slight imbalance in the follow-up rates among the treatment arms, with the SC plus non-penetrating acupuncture arm having the lowest response rate at 8 weeks (66%). Only 14% of the women had given birth by the time they returned the 8-week follow-up questionnaire. Three participants withdrew from the trial: one in the SC arm (declined to continue to participate) and two in the SC plus non-penetrating acupuncture arm (one was subsequently ineligible as she had been consented in error; one declined to continue to participate).

TABLE 13 Summary of the success of the six methods of identification and recruitment

Women identified and recruited	Research midwives identify women through UHNS maternity clinic	Brief questionnaire at 20-week ultrasound scan	Screening of referrals to the women's health physiotherapy service at UHNS	Research midwives or obstetricians give women EASE Back study card	Community midwives or GP give women EASE Back study card	Self-refer due to local awareness raising	Total
Total number of women identified, <i>n</i> (%)	28 (7.2)	199 (51.3)	49 (12.6)	3 (0.8)	73 (18.8)	36 (9.3)	388
Ineligible at initial screen, <i>n</i>	4	21	17	0	13	9	64
Ineligible overall (initial screen + full screen), <i>n</i> (% of total)	9 (32.1)	42 (21.1)	20 (40.8)	1 (33.3)	21 (28.8)	15 (41.7)	108 (27.8)
Potentially eligible, <i>n</i>	19	157	29	2	52	21	280
Declined at initial screen, <i>n</i>	1	22	5	0	0	1	29
Declined overall, <i>n</i>	3	34	7	0	4	2	50
Unable to contact for full eligibility screening, <i>n</i>	0	24	10	0	4	0	38
Did not attend face to face for full screen with no further contact, <i>n</i>	4	51	4	0	5	3	67
Randomised <i>n</i> (% of potentially eligible)	12 (63.2)	48 (30.6)	8 (27.6)	2 (100.0)	39 (75.0)	16 (76.2)	125 (44.6)

TABLE 14 Summary of weekly recruitment

Week starting	Number recruited	Participant accrual
22 April	1	1
29 April	2	3
6 May	6	9
13 May	2	11
20 May	3	14
27 May	4	18
3 June	3	21
10 June	4	25
17 June	7	32
24 June	6	38
1 July	7	45
8 July	3	48
15 July	6	54
22 July	5	59
29 July	5	64
5 August	6	70
12 August	4	74
19 August	3	77
26 August	0	77
2 September	6	83
9 September	6	89
16 September	5	94
23 September	5	99
30 September	5	104
7 October	6	110
14 October	12	122
21 October	3	125

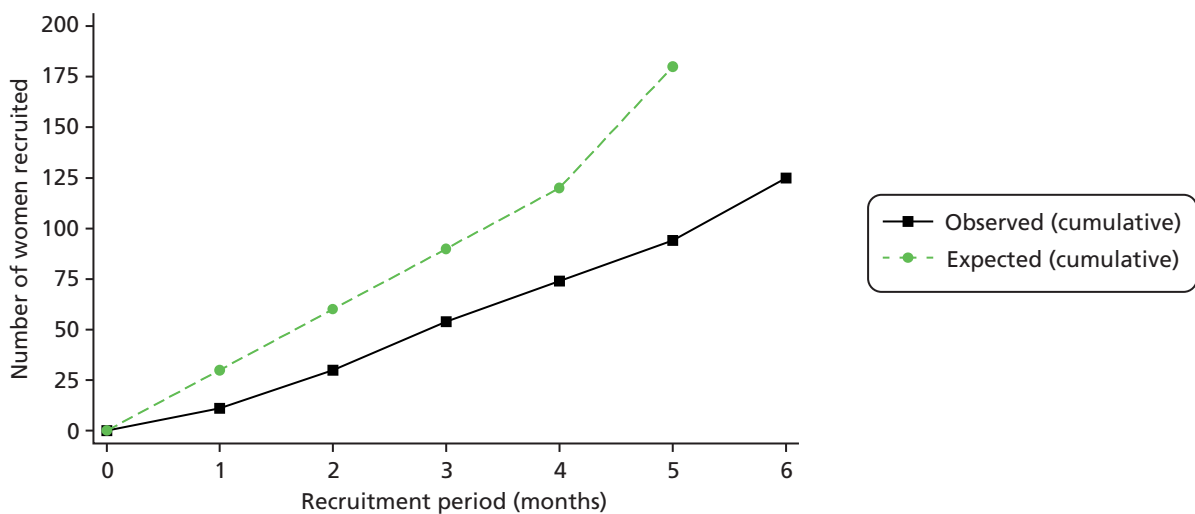


FIGURE 7 Expected vs. observed recruitment.

TABLE 15 Reasons for ineligibility

Reason	Frequency ^a	% of responses ^b	% of cases ^c
Previous acupuncture	26	20.2	24.8
Previously given birth before 37 weeks	13	10.1	12.4
GP practice not in eligible list for the trial	11	8.5	10.5
No current back pain	9	7.0	8.6
Recurrent previous miscarriage	9	7.0	8.6
Pregnancy classified as high risk	9	7.0	8.6
High risk of pre-term delivery	7	5.4	6.7
Previous surgery to uterine cervix	6	4.7	5.7
Not between 13 and 31 completed weeks of gestation	5	3.9	4.8
Unusually high fear or needles	5	3.9	4.8
Pregnant with more than one baby	4	3.1	3.8
Not planning to give birth at UHNS	4	3.1	3.8
Already under care of a physiotherapist	4	3.1	3.8
Back pain not caused/worsened by pregnancy	3	2.3	2.9
Previous surgery to spine or pelvis	3	2.3	2.9
Communication problems	3	2.3	2.9
Aged under 18 years	2	1.6	1.9
Has ruptured membranes	2	1.6	1.9
Not eligible pain location	1	0.8	1.0
Abnormalities with uterus	1	0.8	1.0
Antiphospholipid syndrome or lupus anticoagulant	1	0.8	1.0
Problem with blood clotting	1	0.8	1.0
Total	129	–	–

a Multiple responses possible as some women were ineligible for more than one reason.

b For '% of responses', the denominator is 129 (total number of all responses).

c For '% of cases', the denominator is 105 (total number of ineligible women).

TABLE 16 Baseline characteristics of trial participants and non-participants

Key characteristic	Consent (<i>n</i> = 125)	Potentially eligible but did not consent (<i>n</i> = 157)	Non-participants ^a (<i>n</i> = 263)
Age (years), mean (SD)	28.3 (5.3)	27.1 (6.5)	27.9 (6.2)
Deprivation tertile, <i>n</i> (%)			
Least deprived third	48 (40.3)	60 (39.5)	76 (29.6)
Medium	38 (31.9)	49 (32.2)	88 (34.2)
Most deprived third	33 (27.7)	43 (28.3)	93 (36.2)

a Includes all women who were assessed for eligibility but were not recruited into the trial because either they were not eligible or they were eligible but declined to participate.

TABLE 17 Response rates at 8-week follow-up

Mailing	Responded, <i>n</i> (%)			
	SC (<i>n</i> = 40) ^a	SC + TA (<i>n</i> = 42)	SC + NPA (<i>n</i> = 41)	Total (<i>n</i> = 123) ^a
Initial mailing	14 (35.0)	9 (21.4)	12 (29.3)	35 (28.5)
Reminder mailing	10 (11.5)	18 (54.5)	10 (34.5)	38 (20.5)
MDC ^b	8 (34.8)	5 (20.0)	5 (22.7)	18 (25.7)
Response rate	32/40 (80.0)	32/42 (76.2)	27/41 (65.9)	91/123 (74.0)
Number who had given birth by time of response	7 (21.9)	4 (12.5)	2 (7.4)	13 (14.3)

NPA, non-penetrating acupuncture; TA, true acupuncture.

a Two women had withdrawn from the trial by the time of their 8-week follow-up and so were not mailed the follow-up questionnaire.

b A number of women who were phoned for MDC then returned full questionnaires.

Blinding

During MDC via the telephone, three cases of unblinding out of the 70 MDC calls conducted were recorded between the participant and the research nurse collecting data. All three had been randomised to receive SC plus true acupuncture.

Results from audio-recordings of screening/consent meetings

The face-to-face meeting with a research midwife or nurse comprised a full eligibility screen and informed consent (followed by baseline data collection and randomisation), and we audio-recorded a sample of 30 of these meetings. The section *Audio-recordings of eligibility and consent meetings* previously described the methods. The average length of the recordings covering the discussion about the trial between the participant and midwife/nurse was 12 minutes. All audio files were transcribed and fully anonymised. Given the brevity of the recordings and early data saturation, it was not possible to apply the same analysis framework as in phase 1 (i.e. an iterative, constructionist grounded theory framework⁶⁰). Instead, a simplified constant comparative approach within and across cases was undertaken,⁸⁴ with relevant data for comparison identified as those that were pertinent to the research objectives.

The research midwives and nurses adhered well to the processes of information giving and eligibility screening; they could clearly be heard reading through the PIL and the eligibility criteria in line with the protocol, and from the earliest interviews it was clear that women had very few questions about the trial and those that were asked were consistent with those identified through the qualitative work in phase 1 (i.e. questions around positioning for treatment, whether or not the needles would be painful, the geographical location of treatment centres and the length of time needed for treatment). However, given the brevity of the recordings, it was decided to continue data collection (from the 10 originally foreseen) to 30 to ensure saturation had indeed been reached.

Treatment delivery and adherence

Case report forms were analysed to describe the interventions delivered (*Table 18*). In total, 4 of the 41 participants (10%) randomised to SC accessed face-to-face physiotherapy. Eight participants randomised to SC plus true acupuncture and four in the SC plus non-penetrating acupuncture arm failed to attend for any treatment and therefore received no acupuncture, and 21 (62%) and 29 (76%) received the number of treatment sessions specified in the protocol (between six and eight treatment sessions) for the arms respectively.

TABLE 18 Summary of treatments delivered

Treatment delivered	Treatment arm		
	SC (n = 41)	SC + TA (n = 42)	SC + NPA (n = 42)
Participants			
Number of participants who booked appointment to see a physiotherapist	4	37	41
Total number of participants who attended at least one treatment session with a physiotherapist	4	34	38
Total number of participants who received acupuncture treatment	0	33	36
Number of treatment sessions provided (per participant), median (IQR)	2 (1–4)	6 (3–7)	6 (6–7)
Number of treatment sessions per participant (categorised), n (% of number of participants seen)			
1–5	4 (100)	13 (38.2)	9 (23.7)
6–8	0 (0.0)	17 (50.0)	27 (71.1)
9–11	0 (0.0)	4 (11.8)	2 (5.3)
Number of treatments per participant in line with protocols, ^a n (% of number of participants)	2 (50.0)	17 (50.4)	27 (71.1)
Treatment sessions: total number planned	13	240	273
Total number of treatment sessions provided, n (% of total planned)	9 (69.2)	189 (78.8)	224 (82.1)
Total number of sessions that were not attended – DNAs/UTAs, n (% of total planned)	4 (30.8)	51 (21.3)	49 (17.9)
Total number of sessions attended where acupuncture was provided, n (% of attended)	0 (0.0)	163 (86.2)	197 (87.9)
Treatment content across all sessions, % (SD)			
Assessment/reassessment	100 (0)	91.8 (17.7)	80.6 (25.4)
Education and advice	100 (0)	81.4 (23.4)	73.2 (25.7)
Tubigrip provided with instruction	54.2 (41.7)	15.2 (25.5)	9.6 (11.6)
Pelvic support belt provided with instruction	50.0 (57.7)	4.5 (8.1)	5.4 (17.1)
Heat therapy used in clinic	0 (0.0)	5.4 (11.6)	3.9 (8.1)
Massage therapy used in clinic	0 (0.0)	5.4 (12.0)	3.9 (8.1)
Manual therapy used in clinic	0 (0.0)	0 (0.0)	2.1 (9.2)
Supervised exercises in clinic	6.3 (12.5)	24.1 (26.1)	18.1 (24.7)
Home exercises given/reviewed	83.3 (33.3)	39.7 (29.9)	35.2 (29.9)
Issued walking aids	31.3 (47.3)	1.9 (8.8)	2.4 (6.6)

continued

TABLE 18 Summary of treatments delivered (*continued*)

Treatment delivered	Treatment arm		
	SC (n = 41)	SC + TA (n = 42)	SC + NPA (n = 42)
Exercise approaches across all sessions, % (SD)			
Transversus abdominus muscle strengthening	43.8 (51.5)	23.4 (28.1)	19.7 (25.0)
Pelvic floor muscle strengthening	43.8 (51.5)	23.4 (28.1)	19.7 (25.0)
Pelvic tilt exercise	52.1 (44.3)	21.5 (16.9)	15.8 (17.5)
Gluteal muscle strengthening	27.1 (35.6)	27.6 (25.1)	20.9 (21.1)
Lower back/pelvic stretching	12.5 (25.0)	12.9 (18.2)	6.0 (11.0)
Advice/signposting to general physical activity opportunities	50 (57.7)	6.1 (17.9)	10.3 (20.9)
Other exercises ^b	12.5 (25.0)	13.7 (24.8)	12.9 (21.4)
Pain severity score after treatment (0–10), mean (SD)	6.0 (0.8)	1.9 (2.0)	2.3 (2.3)

DNA, did not attend; NPA, non-penetrating acupuncture; TA, true acupuncture; UTA, unable to attend.

a Two to four sessions for SC, six to eight for SC + acupuncture.

b Other exercises included advice on aquanatal classes, increase repetitions, correcting standing posture, gym ball, thoracic rotation, lumbar spine extension, obliques exercises and reviewing exercises in the EASE Back study booklet.

The number of treatments that participants received was lower than expected, mainly as a result of the challenges that prevented women attending for their allocated treatment. The did-not-attend rates ranged from 18% to 31%. While the average number of treatment sessions in both arms receiving acupuncture was six (in line with the specified protocols), 13 (38%) in the SC plus true acupuncture arm and nine (23.7%) in the SC plus non-penetrating acupuncture arm attended fewer than six sessions.

In terms of content of treatment, assessment/re-assessment and advice were provided at the majority of treatment sessions. The very small number of participants accessing face-to-face physiotherapy in the SC arm was expected but makes comparisons across the treatment arms difficult. The use of pelvic supports (belts or Tubigrip) and walking aids appears to have been more frequent in the SC arm. Exercise approaches were commonly used across all treatment arms, mostly a home exercise programme that focused on muscle strengthening of core trunk muscles and pelvic floor muscles as well as pelvic tilting exercises. Overall, the contents of treatment were delivered broadly in line with the specified protocols.

A pain severity NRS score recorded at the end of each treatment session indicated that, on average, those randomised to either of the acupuncture arms reported much lower pain after treatment than those in the SC only arm.

Table 19 shows the acupuncture points used in both the true acupuncture and non-penetrating acupuncture treatment arms. Both of the acupuncture protocols were delivered as intended. In the true acupuncture treatment arm, BL25, BL26, BL31 and BL54 (all points in the area of the lower back) were the most frequently used local points. Distal points were used much less commonly. In the non-penetrating acupuncture arm, the local points specified in the protocol were used in the large majority of sessions.

TABLE 19 Acupuncture points used

Acupuncture point	Treatment sessions				Participants ^a	
	SC + TA (N ^{a,b} = 163)		SC + NPA (N ^{a,b} = 197)		SC + TA (N = 33) ^c	SC + NPA (N = 36) ^c
	Left, n (%) ^c	Right, n (%)	Left, n (%)	Right, n (%)	n (%)	n (%)
Local points						
BL23	50 (30.7)	51 (31.3.0)	–	–	19 (57.6)	–
BL24	89 (45.4)	91 (55.8)	–	–	23 (69.7)	–
BL25	155 (95.1)	155 (95.1)	–	–	33 (100)	–
BL26	155 (95.1)	156 (95.7)	197 (100)	196 (99.5)	33 (100)	36 (100)
BL27	93 (42.9)	92 (56.4)	196 (99.5)	195 (99.0)	22 (66.7)	36 (100)
BL28	38 (23.3)	38 (23.3)	–	–	9 (27.3)	–
BL54	128 (78.5)	134 (82.2)	195 (99.0)	196 (99.5)	28 (84.9)	36 (100)
BL31	100 (61.4)	100 (61.4)	–	–	25 (75.7)	–
BL32	46 (28.2)	46 (28.2)	–	–	13 (39.4)	–
BL33	20 (12.3)	20 (12.3)	–	–	4 (12.1)	–
GB30	67 (41.1)	78 (47.9)	173 (87.2)	192 (97.7)	26 (78.8)	36 (100)
HJJ L4	35 (21.5)	35 (21.5)	–	–	11 (33.3)	–
HJJ L5	33 (20.3)	33 (20.3)	–	–	10 (30.3)	–
Distal points						
GB34	5 (3.1)	37 (22.7)	–	–	8 (24.2)	–
ST36	0 (0.0)	7 (4.3)	–	–	1 (3.0)	–
LR3	9 (5.5)	19 (11.7)	–	–	8 (24.2)	–
LI4	15 (9.2)	21 (12.9)	–	–	8 (24.2)	–
BL60	42 (25.8)	43 (26.9)	–	–	21 (63.6)	–
BL62	1 (0.6)	19 (11.7)	–	–	5 (15.2)	–

BL, bladder; GB, gall bladder; HJJ, Huato Jia Ji; LI, large intestine; LR, liver; ST, stomach.

a Points which were used when patients had treatments; points (left or right) per participant in any of the sessions;

b The denominator is the total number of treatment sessions attended where acupuncture treatment was provided;

c The denominator is the total number of participants who received acupuncture treatment; a dash (–) means not applicable for that treatment arm.

Needle or de-qi sensations

Participants were asked about needling (de-qi) sensations experienced at each treatment session. de-qi sensations such as an ache, a warmth, tingling and pressure were reported in the large majority (94%) of true acupuncture treatment sessions and also in 31% of the non-penetrating acupuncture treatment sessions (*Table 20*).

TABLE 20 Reported needling sensations

Needling sensation	Treatment arm	
	SC + TA (number of treatment sessions with acupuncture = 163)	SC + NPA (number of treatment sessions with acupuncture = 197)
Number of sessions in which de-qi sensations were reported, <i>n</i> (%)	153 (93.9)	61 (31.0)
Sensations described during acupuncture <i>n</i> (% of number of sessions in which de-qi sensation was achieved)		
Ache	66 (43.1)	14 (23.0)
Aching in the back	35 (22.9)	7 (11.5)
Warmth	29 (19.0)	13 (21.3)
Tingle	26 (17.0)	12 (19.7)
Sharpness	23 (15.0)	7 (11.5)
Tickle	11 (7.2)	0 (0.0)
Pressure	11 (7.2)	0 (0.0)
Numbness	4 (2.6)	9 (14.8)
Heaviness	4 (2.6)	3 (4.9)
Soreness	3 (2.0)	2 (2.8)
Sweaty palms	2 (1.3)	1 (1.6)
An 'awareness'	0 (0.0)	1 (1.6)
Twinge	0 (0.0)	0 (0.0)
Other ^a	35 (22.9)	10 (16.4)

a Other de-qi sensations included dullness, relaxed, tenderness, tightness, stinging, feeling strange and bruising pain.

Patient-reported outcomes

Exploratory analysis of key clinical outcomes

The descriptive statistics (mean and SD) of the key clinical outcomes (pain and disability outcomes) at baseline and the 8-week follow-up are presented in *Table 21*. *Table 22* shows the differences in the mean scores from baseline. Overall, there was a reduction in pain and disability scores from baseline to the 8-week follow-up. A greater reduction in score was observed in the two arms randomised to receive SC plus acupuncture than in the arm receiving SC alone.

Table 23 summarises the differences in mean scores among the treatment arms (with 95% CI) adjusted for baseline scores and other baseline covariates obtained from multiple linear regression. We do not place undue significance on these results since a formal sample size calculation was not carried out; rather we focus on CI estimation. As expected, the CIs are quite imprecise. Several comparisons have been made: SC alone versus SC plus true acupuncture; SC alone versus SC plus non-penetrating acupuncture; and SC plus true acupuncture versus SC plus non-penetrating acupuncture. These comparisons indicated some between-group differences in physical function (mean PGQ) and pain severity between SC alone and SC plus true acupuncture and between SC alone and SC plus non-penetrating acupuncture but not between SC plus true acupuncture and SC plus non-penetrating acupuncture.

TABLE 21 Descriptive analysis of key clinical outcomes

Key outcome	Baseline (n = 124)			8-week follow-up (n = 91)		
	SC	SC + TA	SC + NPA	SC	SC + TA	SC + NPA
ODI score (0–100), mean (SD)	34.8 (11.2)	32.9 (13.7)	35.7 (13.6)	32.2 (18.8)	21.3 (17.7)	26.2 (14.4)
PGQ score (0–100), mean (SD)						
Total	56.9 (16.0)	48.7 (17.2)	54.2 (17.3)	52.2 (28.4)	31.9 (21.8)	40.3 (21.8)
Activity subscale	54.6 (17.0)	46.7 (18.1)	52.7 (18.1)	51.5 (29.4)	31.3 (22.1)	40.0 (23.4)
Symptom subscale	65.4 (17.1)	56.1 (17.2)	59.3 (19.9)	54.4 (26.5)	33.8 (22.4)	40.2 (20.2)
Pain severity (mean score of three NRSs)	4.5 (1.6)	4.5 (1.5)	4.6 (1.8)	4.2 (2.2)	2.4 (2.2)	2.2 (1.5)

NPA, non-penetrating acupuncture; TA, true acupuncture.

TABLE 22 Differences in mean scores from baseline

Key outcome	SC (n = 32)	SC + TA (n = 32)	SC + NPA (n = 27)
ODI score, mean difference (95% CI)	1.9 (–5.1 to 8.8)	7.8 (1.6 to 14.0)	7.7 (2.9 to 12.5)
PGQ score, mean difference (95% CI)			
Total	5.1 (–5.1 to 15.2)	14.0 (6.9 to 21.2)	11.6 (5.2 to 18.0)
Activity subscale	4.1 (–6.4 to 14.6)	12.8 (5.4 to 20.3)	10.1 (3.5 to 16.8)
Symptom subscale	8.6 (–1.9 to 19.0)	18.8 (11.1 to 26.5)	17.8 (9.7 to 25.8)
Pain severity (mean score of three NRSs)	0.2 (–0.8 to 1.2)	1.8 (1.1 to 2.5)	2.1 (1.4 to 2.9)

NPA, non-penetrating acupuncture; TA, true acupuncture.

TABLE 23 Estimates of treatment effect

Outcome	Adjusted for baseline scores only		Adjusted for baseline scores and baseline covariates ^a	
	Marginal mean		Adjusted mean difference (95% CI)	
	Marginal mean	Adjusted mean difference (95% CI)	Marginal mean	Adjusted mean difference (95% CI)
SC vs. SC plus acupuncture arms				
ODI score (0–100)	–	31.2	–	–
SC (reference)	23.2	–8.0 (–16.1 to 0.1)	31.3	–
SC + TA	25.2	–5.9 (–14.2 to 2.4)	23.3	–8.0 (–16.2 to 0.2)
SC + NPA	–	–	25.0	–6.3 (–14.7 to 2.3)
PGQ total score (0–100)	–	48.3	–	–
SC (reference)	35.8	–12.6 (–23.8 to –1.3)	48.3	–
SC + TA	40.1	–8.2 (–19.6 to 3.1)	36.7	–11.6 (–22.9 to –0.4)
SC + NPA	–	–	39.0	–9.3 (–20.7 to 2.0)
PGQ activity subscale score	–	47.6	–	–
SC (reference)	35.3	–12.3 (–23.9 to –0.8)	47.7	–
SC + TA	39.9	–7.7 (–19.4 to 4.0)	36.2	–11.5 (–22.9 to –0.4)
SC + NPA	–	–	38.6	–9.1 (–20.9 to 2.6)
PGQ symptom subscale score	–	52.0	–	–
SC (reference)	36.2	–15.8 (–27.2 to –4.5)	52.4	–
SC + TA	40.1	–11.9 (–23.4 to –0.3)	36.0	–16.4 (–27.8 to –5.0)
SC + NPA	–	–	40.0	–12.4 (–24.1 to –0.7)
Pain severity (mean score of three NRSs)	–	–	4.2	–
SC (reference)	2.5	–1.8 (–2.7 to –0.8)	4.1	–
SC + TA	2.2	–2.0 (–3.0 to –1.0)	2.6	–1.6 (–2.5 to –0.6)
SC + NPA	–	–	2.2	–2.0 (–3.0 to –1.0)
TA vs. NPA arms				
ODI score (0–100)	–	23.2	–	–
SC + TA (reference)	25.2	2.1 (–6.3 to 10.5)	23.3	–
SC + NPA	–	–	25.0	1.8 (–6.8 to 10.3)
PGQ total score (0–100)	–	35.8	–	–
SC + TA (reference)	40.1	4.3 (–7.0 to 15.6)	36.7	–
SC + NPA	–	–	39.0	2.6 (–8.9 to 14.2)
PGQ activity subscale score	35.3	–	–	–
SC + TA (reference)	39.9	4.6 (–7.1 to 16.3)	36.2	–
SC + NPA	–	–	38.6	2.3 (–9.4 to 14.1)

TABLE 23 Estimates of treatment effect (*continued*)

Outcome	Adjusted for baseline scores only		Adjusted for baseline scores and baseline covariates ^a	
	Marginal mean		Adjusted mean difference (95% CI)	
	Marginal mean	Adjusted mean difference (95% CI)	Marginal mean	Adjusted mean difference (95% CI)
PGQ symptom subscale score	–	36.2	–	–
SC + TA (reference)	40.1	3.9 (–7.5 to 15.5)	36.0	–
SC + NPA	–	–	40.0	4.0 (–7.6 to 15.6)
Pain severity (mean score of three NRSs)	–	–	2.4	–
SC + TA (reference)	2.2	–0.2 (–1.3 to 0.78)	2.6	–
SC + NPA	2.2	–0.2 (–1.3 to 0.78)	2.2	–0.4 (–1.4 to 0.6)

NPA, non-penetrating acupuncture; TA, true acupuncture.

Estimates of other health outcomes

Table 24 summarises participants' global assessment of change at follow-up compared with baseline. About half (45 out of 91) reported complete recovery or much improvement. However, this proportion was much lower in the SC arm (6 out of 32, 19%) the SC plus true acupuncture (21 out of 32, 66%) or SC plus non-penetrating acupuncture (18 out of 27, 67%) arm.

Table 25 summarises other participants' outcomes at the 8-week follow-up. Overall, the majority (78 out of 91, 86%) of women were still pregnant by response to follow-up, with most more than 33 weeks pregnant, and this was fairly balanced across the treatment arms. There was substantial reduction in pain intensity before going to bed and in the proportion of women woken up every/most nights at 8 weeks compared with baseline in those randomised to SC plus acupuncture but not in the SC alone arm. Overall, quality of life did not improve substantially at 8 weeks but there was marked improvement in physical health (measured using the physical component scale of the SF-12) in the SC plus non-penetrating acupuncture arm (–5.7, 95% CI –10.7 to –0.7).

TABLE 24 Participants' global assessment of overall change from baseline (*n* = 91)

Change since baseline	Overall		SC		SC + TA		SC + NPA	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Completely recovered	6	6.6	1	3.1	4	12.5	1	3.7
Much improved	39	42.9	5	15.6	17	53.1	17	63.0
Somewhat improved	17	18.7	8	25.0	5	15.6	4	14.8
Same	7	7.7	2	6.3	1	3.1	4	14.8
Somewhat worse	11	12.1	8	25.0	2	6.3	1	3.7
Much worse now	11	12.1	8	25.0	3	9.4	0	0.0
Total	91	–	32	–	32	–	27	–
Completely recovered or much improved	45	49.5	6	18.8	21	65.6	18	66.7

NPA, non-penetrating acupuncture; TA, true acupuncture.

TABLE 25 Results of other health outcomes

Key characteristics	SC (n = 32)	SC + TA (n = 32)	SC + NPA (n = 27)
Taken at both baseline and follow-up, n	24	27	22
Pain intensity before going to bed, mean (SD)	6.5 (2.8)	3.7 (2.8)	3.5 (2.3)
Woken up most/every night by back pain, n (%)	9 (37.5)	4 (14.8)	1 (4.6)
SF-12 – Physical Component Scale, mean score(SD) ^a	36.5 (10.6)	41.4 (11.5)	43.3 (9.5)
SF-12 – Mental Component Scale, mean score (SD) ^a	49.1 (8.1)	48.4 (13.8)	50.2 (12.3)
Change from baseline (baseline to 8-week score)			
Pain intensity before going to bed, mean (95% CI)	0.04 (–1.5 to 1.6)	2.7 (1.4 to 4.0)	3.2 (1.8 to 4.5)
Woken up most/every night by back pain, percentage difference (95% CI)	1.5% (–22.9% to 25.9%)	20.9% (1.2% to 40.6%)	36.9% (19.5% to 54.3%)
SF-12 – Physical Component Scale, mean score difference (95% CI) ^a	–0.3 (–5.5 to 4.9)	–2.8 (–6.2 to 0.6)	–5.7 (–10.7 to –0.7)
SF-12 – Mental Component Scale, mean score difference (95% CI) ^a	0.03 (–4.1 to 4.1)	–0.2 (–4.2 to 3.9)	1.2 (–5.3 to 7.7)

a SF-12 scales are based on a 'normalised' general population average of score of 50 with a SD of 10.

Health-care use, treatment credibility and satisfaction with care

Table 26 presents use of other health-care services and self-reported satisfaction with care for the 73 participants who completed the full 8-week follow-up questionnaire. Overall, fewer than half of the participants (31 out of 73) had used any over-the-counter medicines, treatments or appliances (e.g. TENS machine, maternity belt), and this number was slightly lower (8 out of 22) among women in the SC plus non-penetrating acupuncture arm. Use of prescribed medicines, treatments or appliances and any other NHS or private health care (e.g. inpatient stays, physiotherapy) was generally low, and was lowest in the SC plus non-penetrating acupuncture treatment arm (see Table 26). No participants had attended either the NHS or private health-care services for investigation or treatments (e.g. radiography, surgery, injection) for back pain within the 8-week follow-up period.

In terms of treatment credibility, 60% (43 out of 71) of participants were very or quite confident that the information or treatment they received helped their back problem. In total, 69% (49 out of 71) reported they would be very or quite confident in recommending the information/treatment to a friend who suffered from a similar problem; however, the proportions rating treatment credibility as high were much lower in the SC alone arm (7 out of 24, 29%). Levels of satisfaction with the treatment package received and the results from treatment were high overall (65%) but lower in the SC arm (17%) than in the SC plus true acupuncture (85%) and SC plus non-penetrating acupuncture (96%) arms.

TABLE 26 Health-care use, treatment credibility and satisfaction with care

	Treatment arm		
	SC (n = 24)	SC + TA (n = 27)	SC + NPA (n = 22)
Health-care use, n (%)			
Over-the-counter medicines, treatments or appliances for back pain (n = 73)	12 (50.0)	11 (40.7)	8 (36.4)
Prescription of medicines or appliances for back pain (n = 72)	6 (26.1)	5 (18.5)	1 (4.6)
Attended any other NHS or private health care because of back problem (n = 73)	7 (29.2)	7 (25.9)	2 (9.1)
Attended NHS or private health care for investigation or treatments for back pain (n = 72)	0 (0.0)	0 (0.0)	0 (0.0)
Treatment credibility, n (%)			
Confidence with the information/treatment received: very/quite confident (n = 71)	3 (13.0)	22 (81.5)	18 (85.7)
Confidence in recommending the information/treatment: very/quite confident (n = 71)	7 (29.2)	22 (88.0)	20 (90.9)
How logical the information/treatment seemed: very/quite logical (n = 71)	13 (54.2)	21 (84.0)	20 (90.9)
Success of information/treatment in alleviating other complaints: very/quite successful (n = 71)	3 (12.5)	19 (76.0)	16 (72.3)
Satisfaction with care, n (%)			
Satisfaction with the treatment package received: very/quite satisfied (n = 72)	4 (16.7)	22 (84.6)	21 (95.5)
Satisfaction with results from treatment: very/quite satisfied (n = 72)	4 (16.7)	22 (84.6)	21 (95.5)
NPA, non-penetrating acupuncture; TA, true acupuncture.			

Responses to open question on follow-up questionnaire

In total, 14 women allocated to SC alone, 18 allocated to SC plus true acupuncture and 12 allocated to SC plus non-penetrating acupuncture provided responses to the open question on the follow-up questionnaire about their overall experience. A summary of the responses with examples is given.

Of those in SC alone, eight women expressed negative views of the value of the SC package they received in the trial, while others took the opportunity to explain the impact of back pain on their pregnancy and labour. Examples of comments include:

I don't feel I benefited at all from the standard care plan and the booklet showed me nothing that I wasn't already aware of. I do feel the acupuncture would have been better.

The EASE Back study did not help with my back pain at all, and I ended up finishing work sooner than I wanted to.

and

The back pain experienced during labour was unbearable and worse than my contractions, so resulted in me having an epidural for my back pain.

From those receiving SC plus true acupuncture, the comments were overwhelmingly positive (13 of the 18 comments suggested positive experiences). Examples include:

I feel that I have received excellent treatment during this study. I do believe that the acupuncture has really aided my back pain and am certainly in a lot less discomfort at this stage in my pregnancy. The acupuncture has allowed me to carry on with daily activities (especially those at night time) with less pain. I would recommend this treatment to others and would consider it again to treat any other conditions.

I have really benefited from taking part in this study. The treatment and advice given by the physiotherapist have dramatically improved my pain during my pregnancy and I will continue to use some of the techniques afterwards. I really hope this study continues and that more women are offered such treatment. Thank you!

The care received has been excellent despite my initial doubts, it eased my pain an awful lot.

Two comments suggested that participants wanted more acupuncture treatment than they were offered in the study; for example:

I think the course length can be extended to 12 weeks as the more acupuncture done, the pain reduces a lot.

In addition, several participants shared the reasons why they struggled to attend for treatment:

I was unable to attend physiotherapy appointments due to lack of childcare. I proceeded to continue to exercise caution in my daily movements.

I won't be able to get to any hospitals for acupuncture because of money problems, but the only thing I have for my back pain is paracetamol and my water bottle. Sometimes it works, sometimes it doesn't, it depends how bad my back pain is.

Finally, the comments made by women allocated to SC plus non-penetrating acupuncture were a little more varied. One felt that the acupuncture had not been helpful:

I didn't feel that the acupuncture helped at all, but the booklet contained some useful information. Thank you.

Several others particularly emphasised the benefits of the exercise component of treatment, for example:

I found the exercises I was given to do at home helped a lot, when I felt pain starting I would do the exercises and I could keep it under control. I feel the acupuncture also helped but you would need to keep up the exercises.

I have been very pleased with the impact of doing the exercises from the booklet. It was particularly useful having the physio show me exactly how to do the ones I wasn't sure about. Thank you!

In addition, several women clearly felt they had benefited from the treatment, including:

Fantastic care. I loved the acupuncture and felt more relaxed and comfortable at these sessions than I had in a while. I would often nod off to sleep I felt so relaxed. Although I am now wearing a support belt and walking with elbow crutches I am much more confident dealing with my back pain

The physio was very supportive and provided very good advice and support. The acupuncture was a first time experience and I am very surprised (positively) at the good results. Would recommend this treatment to all pregnant women! Thank you!

Missing data and data accuracy

Missing data levels on key disability outcomes

The Oswestry Disability Index

Missing data on the ODI at baseline were very minimal. Of the 1240 individual ODI items (10 items each for 124 participants), there were only 35 items with missing data (2.8%). The two most frequently missing items were activities reported as 'not applicable' by participants with pregnancy-related low back pain (with and without PGP): 'lifting' (7.3% missing) and 'sex life' (8.9% missing). More than 80% (103 out of 124) of participants completed all the questionnaire items. Missing ODI data at the 8-week follow-up were similarly very low but slightly higher than at baseline. Of the 910 individual ODI items (10 items each for 91 participants), there were 71 items with missing data (7.8%), 62 of which were on questions about lifting and sex life. About half of the participants (43 out of 91) completed all the ODI follow-up questionnaire items.

The Pelvic Girdle Questionnaire

Missing data for the PGQ were very low but slightly higher than for the ODI. Out of 3100 PGQ items at baseline (25 items for each for 124 participants), there were only 191 items with missing data (6.2%). Again missing data on individual items were very minimal except for a few questions frequently reported as not applicable (e.g. running, sporting activities). Forty-six per cent (57 out of 124) completed all the items of the PGQ at baseline. At the 8-week follow-up, the overall rate of missing data was 8.7% [197 out of 2275 items (25 items for each of the 91 participants)]. Forty-one per cent (37 out of 91) completed all the items of the PGQ at 8-week follow-up.

Data accuracy

A random check of 10% of the data entered into the trial database was carried out to verify the data entry accuracy before data cleaning and analysis. Overall, the data entry accuracy was very high, with more than 99.5% accuracy across all the questionnaires.

Health economic evaluation

Baseline and 8-week economic data were available for 73 participants (24 in the SC arm, 27 in the SC plus true acupuncture arm and 22 in the SC plus non-penetrating acupuncture arm); this represented 59% of the sample. The health economic analysis focused on the 51 participants receiving SC versus SC plus true acupuncture that informed the base case analysis. Details of NHS and broader health-care resource use are reported in *Table 27*. Primary care NHS resource use was similar between the two trial arms (SC vs. SC plus true acupuncture). Participants in the SC plus true acupuncture arm reported more visits to NHS physiotherapists and NHS acupuncturists, although this could be a problem with double-reporting. Despite the question asking for health-care use outside of the EASE Back study, it is possible that participants misunderstood this question.

TABLE 27 Mean health-care resource use

Resource use category	SC (n = 24)	SC + TA (n = 27)
Study back pain visits, mean (SD)	0.29 (0.9)	6.03 (2.76)
GP visits, mean (SD)	0.38 (0.9)	0.52 (1.2)
NHS midwife visits, mean (SD)	0.08 (0.4)	0.22 (0.6)
Private midwife visits, mean (SD)	0.00 (–)	0.04 (0.2)
'NHS acupuncture' visits, mean (SD)	0.00 (–)	0.22 (1.2)
NHS physiotherapist visits, mean (SD)	0.04 (0.2)	0.37 (1.5)
NHS 'other' health care professional visits, mean (SD)	0.25 (1.2)	0.11 (0.6)
'Over-the-counter' ^a treatments, n (%)	12 (50)	11 (41)
Prescribed medication, ^a n (%)	6 (25)	5 (19)
Visited NHS or private practice, ^a n (%)	7 (29)	7 (26)

TA, true acupuncture.

Values are mean (SD) number of consultations unless stated otherwise.

a The number (percentage) of participants reporting usage within over-the-counter treatments and prescribed medication categories are given.

Table 28 shows the EQ-5D scores at baseline and at 8 weeks, and the total QALYs in the two arms. At 8 weeks, we observed a lower EQ-5D score in participants in the SC arm and a higher score for the SC plus true acupuncture arm. The mean difference in QALYs was 0.010 (95% CI –0.001 to 0.024). Receiving the acupuncture intervention was, therefore, associated with incremental QALYs over the 8 weeks.

Table 29 shows the disaggregated mean (SD) costs for each treatment arm. The cost of treatment was reported as part of the total cost of each trial arm. The principal aim of the cost–consequence analysis was to look at all the costs of the two interventions (SC alone vs. SC plus true acupuncture) and compare these with the corresponding outcomes in terms of QALYs gained.

TABLE 28 European Quality of Life-5 Dimensions scores by treatment arm (mean and SD)

Complete case analysis	SC	SC + TA
Baseline	(n = 41)	(n = 42)
Mean (SD)	0.649 (0.12)	0.651 (0.16)
8 weeks	(n = 24)	(n = 27)
Mean (SD)	0.570 (0.23)	0.698 (0.22)
Total QALYs, mean (SD)	0.096 (0.02)	0.106 (0.02)
Mean difference (95% CI)	0.010 (–0.001 to 0.024)	
Adjusted ^a	0.096	0.106
Mean difference (95% CI)	0.009 (0.000 to 0.019)	

TA, true acupuncture.

a Incremental QALY estimates following multiple regression-based adjustment for baseline scores on the EQ-5D.

TABLE 29 Mean per participant costs by treatment arm over 8 weeks

Complete case analysis	Mean (£) (SD)	
	SC (n = 24)	SC + TA (n = 27)
Intervention cost	11.52 (43.2)	149.43 (71.14)
GP	12.75 (29.8)	17.62 (39.3)
NHS midwife	6.25 (30.6)	16.66 (48.03)
Private midwife	0.00 (–)	3.55 (18.4)
‘NHS acupuncture’	0.00 (–)	9.96 (51.76)
NHS physiotherapist	2.04 (10.0)	16.85 (69.2)
‘Other’ professionals in NHS	5.83 (28.6)	3.74 (19.43)
Prescriptions	1.76 (8.6)	0.54 (2.8)
‘Over-the-counter’ treatments	8.67 (14.3)	7.38 (21.7)
Back pain-related work absence ^a	98.36 (330.3)	258.86 (517.8)
Back pain-related reduced productivity	806.55 (769.58)	783.45 (762.7)
NHS/PSS cost	40.15 (90.78)	214.82 (191.92)
Adjusted mean difference ^b (95% CI)	174.67 (102.35 to 271.20)	
Incorporation of back pain-related health-care resource use (n = 42)		
Health-care cost ^c	48.82 (94.18)	225.77 (205.65)
Adjusted mean difference ^b (95% CI)	176.94 (100.73 to 265.50)	
Incorporation of back pain-related wider societal resource use (n = 42)		
Societal cost ^d	953.74 (921.14)	1268.08 (1207.24)
Adjusted mean difference ^b (95% CI)	314.34 (–256.84 to 887.86)	

TA, true acupuncture.
a Includes both work absence due to back pain and work absence to attend treatment sessions.
b Difference = intervention–control group. Reported CIs were generated using conventional parametric methods.
c Includes costs to the NHS, private health-care costs and over-the-counter medication costs.
d Includes health-care costs and productivity-related costs.
Values are mean (SD) number of consultations/investigations unless stated otherwise.

The results show that, although the SC plus true acupuncture intervention has a higher total NHS cost and health-care than SC alone, it is the intervention that also achieves higher QALY gains. From a NHS/PSS perspective, the difference in costs between SC plus true acupuncture and SC alone was £174.67 (95% CI £102.35 to £271.20). The differences in cost can be attributed to the additional acupuncture sessions and the relatively small reported increase in utilisation of acupuncture, midwifery and physiotherapy in a few participants in that treatment arm. On the basis of the NHS and health-care perspective, there is no intervention that is dominant (i.e. has lower costs and better outcomes). Acupuncture provided alongside SC, however, appears more effective in treating pregnant women with low back pain, but this increased effectiveness comes at an increased cost.

Work-related outcomes and out-of-pocket costs

Information on time off work and out-of-pocket costs related to treatment is reported in *Table 30*. Only two (9.5%) participants in the SC alone arm reported taking time off as a result of their back pain, compared with nine (33.3%) women in the SC plus true acupuncture group. The percentage of participants taking time off work as a result of back pain and to attend physiotherapy sessions was slightly higher in the SC plus true acupuncture arm for those in full-time employment and slightly lower for those in part-time employment than SC alone. The associated productivity-related costs showed higher costs

TABLE 30 Work outcomes for participants in paid and unpaid employment

Work outcome	SC	SC + TA
Employed at baseline	28 of 41	27 of 42
Employed at 8 weeks	21 of 24	23 of 27
Working full-time in paid job, <i>n</i> (%)	3 (12.5)	9 (33.3)
Working part-time in paid job, <i>n</i> (%)	7 (29.2)	2 (7.4)
Employed, but currently off sick as a result of back pain, <i>n</i> (%)	1 (4.2)	2 (7.4)
Employed, but currently on maternity leave, <i>n</i> (%)	10 (41.7)	10 (37.0)
Reported taking time off work as a result of back pain, <i>n</i> (%)	2 (9.5)	9 (33.3)
Mean (SD) number of days lost from work	1.4 (4.5)	3.4 (6.9)
Mean (SD) cost (£) of days lost from work	111.48 (352.1)	284.08 (554.8)
Mean (SD) number of days of reduced productivity at work	15.6 (10.1)	11.1 (9.0)
Mean (SD) cost (£) reduced productivity at work	921.77 (754.7)	919.70 (745.9)
Reported taking time off work to attend appointments, <i>n</i> (%)	1 (4.2)	14 (51.9)
Mean (SD) cost (£) of work absence to attend physiotherapy appointments	0.81 (3.98)	16.87 (24.34)
Reported reduced time in unpaid activities, <i>n</i> (%)	0 (-)	6 (22.2)
Reported paying someone to look after children, <i>n</i> (%)	0 (-)	1 (3.7)
Mean (SD) cost (£) of looking after children	0 (-)	5 (-)
Mode of transport to sessions, <i>n</i> (%)		
Car/van	2 (8.3)	18 (66.7)
Taxi/train/bus	0 (-)	2 (7.4)
Foot	0 (-)	1 (3.7)
Mean (SD) cost (£) of parking	1 (1.4)	1.6 (1.1)
Mean (SD) cost (£) of bus/taxi/train fare	0 (-)	5.5 (0.7)

TA, true acupuncture.

Work estimates based on sample of participants in paid employment at 8 weeks (39 out of 73).

among patients in the acupuncture treatment arm attending physiotherapy sessions (£0.81 vs. £16.87). Reduced productivity during paid work was reported by six (22%) women in the SC plus true acupuncture arm. Overall, slightly higher productivity costs were observed in the SC plus true acupuncture intervention arm than in the SC alone arm.

Taking a broader societal perspective, the cost of time lost from work during the trial follow-up period of 8 weeks, reduced productivity at work and time taken off work to attend physiotherapy sessions is also reported. From these perspectives, the SC alone treatment arm was the least costly, although it was also associated with higher presenteeism costs.

Maternity record review results

Obstetric birth/neonatal outcomes

Table 31 summarises the birth outcomes obtained from the maternity records of trial participants, overall and by treatment arm. All women who participated in the pilot trial had live births, at a mean gestation week of 40 (SD 1.5 week). Labour duration was similar across all three treatment arms, as were the need to be induced, the mode of delivery, the proportion of women who had either an episiotomy or a perineal

TABLE 31 Birth outcomes by treatment arms

Birth outcomes	Overall (n = 122)	Treatment arm		
		SC (n = 40)	SC + TA (n = 42)	SC + NPA (n = 40)
Gestation week at delivery, mean (SD)	39.7 (1.5)	39.5 (1.6)	39.6 (1.6)	40.1 (1.3)
Live birth, n (%)	122 (100)	40 (100)	42 (100)	40 (100)
Labour duration ^a (hours), mean (SD)	4.1 (4.5)	3.2 (2.8)	3.8 (3.7)	5.2 (6.1)
Second-stage labour duration ^a (minutes), mean (SD)	45 (57.4)	41.0 (57.0)	49.6 (54.1)	44.3 (62.9)
Needed to be induced, ^a n (%)	40 (35.7)	14 (36.8)	14 (35.9)	12 (34.3)
Mode of delivery, n (%)				
Spontaneous vaginal delivery	80 (66.1)	26 (65.0)	30 (73.2)	24 (60.0)
Instrumental delivery	14 (11.6)	4 (10.0)	4 (9.8)	6 (15.0)
Elective caesarean section	18 (14.4)	9 (22.5)	4 (9.8)	5 (12.5)
Emergency caesarean section	9 (7.4)	1 (2.5)	3 (7.3)	5 (12.5)
Had an episiotomy ^b	17 (18.1)	5 (16.7)	6 (17.7)	6 (20.0)
Perineal tear, n (%)				
No tear	56 (47.9)	17 (46.0)	20 (47.6)	19 (50.0)
First-degree tear	9 (7.7)	1 (2.7)	4 (9.5)	4 (10.5)
Second-degree tear	35 (29.9)	13 (35.1)	10 (23.8)	12 (31.6)
Third-degree tear	7 (6.0)	2 (5.4)	3 (7.1)	2 (5.3)
Information not available	10 (8.6)	4 (10.8)	5 (11.9)	1 (2.6)
Estimated blood loss at birth (ml), median (IQR)	300 (200–450)	300 (250–400)	300 (200–400)	350 (300–500)
Blood loss of 500 ml or more, n (%)	28 (24.1)	8 (20.5)	7 (18.0)	13 (34.2)
Last antenatal haemoglobin count (g/l), n (%)				
< 115	33 (27.3)	9 (23.1)	14 (33.3)	10 (25.0)
115–165 (normal range)	87 (719.9)	30 (76.9)	27 (64.3)	30 (75.0)
> 165	1 (0.8)	0 (0.0)	1 (2.4)	0 (0.0)
Woman's postnatal haemoglobin count (g/l),^c n (%)				
< 115	19 (70.4)	7 (77.8)	7 (77.8)	5 (55.6)
115–165	8 (29.6)	2 (22.2)	2 (22.2)	4 (44.4)

continued

TABLE 31 Birth outcomes by treatment arms (*continued*)

Birth outcomes	Overall (n = 122)	Treatment arm		
		SC (n = 40)	SC + TA (n = 42)	SC + NPA (n = 40)
Pain relief used during labour,^d n (%)				
TENS machine	5 (4.1)	3 (7.5)	1 (2.4)	1 (2.5)
Water birth	2 (1.6)	0 (0.0)	1 (2.4)	1 (2.5)
Entonox® (gas and air)	81 (66.4)	27 (67.5)	27 (64.3)	27 (67.5)
Pethidine	40 (32.8)	14 (35.0)	17 (40.5)	9 (22.5)
Morphine	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Epidural	26 (21.3)	5 (12.5)	12 (28.6)	9 (22.5)
Spinal	19 (15.6)	9 (22.5)	5 (11.9)	5 (12.5)
General anaesthetic	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Patient-controlled analgesia	1 (0.8)	0 (0.0)	1 (2.4)	0 (0.0)
Information not available	9 (7.4)	1 (2.5)	3 (7.1)	5 (12.5)

NPA, non-penetrating acupuncture; TA, true acupuncture.

a Excludes elective caesarean section.

b Applies only to spontaneous vaginal/instrumental delivery.

c Data available for 27 women only (nine in each arm).

d Possible multiple responses.

tear and the mean estimated blood loss at birth. The majority of women (66.4%) used Entonox® (BOC Ltd, Manchester, UK; gas and air) as pain relief during labour, 32% used pethidine and 21% had an epidural. Pattern of pain relief used during labour was the same across all three treatment arms.

Neonatal outcomes were also very similar across all three treatment arms (*Table 32*). Approximately 50% of all babies were male and the majority had a birthweight of 3000–4000 g. In total, only three babies (2.5%) were admitted to the neonatal unit and 95% or more of all babies had an Apgar score of 7–10 at 5 minutes after birth.

Adverse events

No SAEs attributable to the trial interventions or trial processes were reported. There were four SAEs reported by treating physiotherapists to the trial team (one in SC, two in SC plus true acupuncture and one in SC plus non-penetrating acupuncture), all examples of brief periods of hospitalisation or admission to the maternity assessment unit at UHNS, for reasons other than those related to the trial or treatments. All women were discharged after monitoring and all resumed treatment.

Self-reported side effects

Ten women (five in SC plus true acupuncture and five in SC plus non-penetrating acupuncture) reported some side effects from treatment in response to this question on the 8-week questionnaire, summarised in *Table 33*.

Minor adverse reactions following treatment

Minor adverse reactions reported by physiotherapists on CRFs are summarised in *Table 34*. All were expected minor adverse effects. The most common was slight bleeding at the needle sites in 35 (21%) treatment sessions in the SC plus true acupuncture arms and in one (0.5%) treatment session in the SC plus non-penetrating acupuncture arm.

TABLE 32 Neonatal outcomes by treatment arms

Neonatal outcomes	Overall (n = 122)	Treatment arm		
		SC (n = 40)	SC + TA (n = 42)	SC + NPA (n = 40)
Baby's sex (female), n (%)	62 (51.2)	19 (48.7)	23 (54.8)	20 (50.0)
Birthweight of baby (g), n (%)				
< 2500	1 (0.8)	0 (0.0)	1 (2.4)	0 (0.0)
2500–3000	21 (17.2)	8 (20.0)	9 (21.4)	4 (10.0)
3000–3500	41 (33.6)	12 (30.0)	16 (38.1)	13 (32.5)
3500–4000	48 (39.3)	17 (42.5)	13 (31.0)	18 (45.0)
> 4000	11 (9.0)	3 (7.5)	3 (7.1)	5 (12.5)
Apgar score^a at 1 minute after birth, n (%)				
0–3	1 (0.8)	1 (2.5)	0 (0.0)	0 (0.0)
4–6	6 (4.9)	2 (5.0)	3 (7.1)	1 (2.5)
7–10	115 (94.3)	37 (92.5)	39 (92.9)	39 (97.5)
Apgar score at 5 minutes after birth, n (%)				
4–6	1 (0.8)	1 (2.5)	0 (0.0)	0 (0.0)
7–10	121 (99.2)	39 (95.5)	42 (100)	40 (100)
Baby admitted to the neonatal unit, ^b n (%)	3 (2.5)	2 (5.0)	0 (0.0)	1 (2.5)

NPA, non-penetrating acupuncture; TA, true acupuncture.

a Apgar score has five components – appearance (skin colouration), pulse (heart rate), grimace response (reflex irritability), activity (muscle tone) and respiration (heart rate) – each given a score of 0–2, with a total score of 0–10, 10 being the perfect score.

b Reasons for admissions included low Apgar score (no muscle tone) at 30 minutes, respiratory distress syndrome and suspected sepsis, and breathing difficulty.

TABLE 33 Self-reported side effects in 8-week questionnaire

Side effect	Number	
	SC + TA	SC + NPA
Nausea	1	1
Vomiting	1	0
Drowsiness/light-headedness	4	4
Fainting	1	0
Headaches	1	0
Pain or soreness	2	3

TABLE 34 Treatment adverse events reported on physiotherapy CRFs

Adverse events	Treatment arm		
	SC (total number of treatment sessions = 9)	SC + TA (number of sessions of acupuncture = 164)	SC + NPA (number of sessions of acupuncture = 197)
Standard care, n (%)			
Pain while exercising	0 (0.0)	5 (3.0)	1 (0.5)
Muscle soreness	0 (0.0)	1 (0.6)	0 (0.0)
Discomfort as a result of exercise	0 (0.0)	0 (0.0)	1 (0.5)
Acupuncture, n (%)			
Slight bleed at needle site	–	35 (21.3)	1 (0.5)
Pain on needle insertion	–	6 (3.7)	0 (0.0)
Slight bruising	–	6 (3.7)	0 (0.0)
Slight soreness	–	2 (1.2)	1 (0.5)
Muscle spasm	–	2 (1.2)	0 (0.0)
Numbness	–	1 (0.6)	0 (0.0)
Feeling slight sharpness	–	1 (0.6)	0 (0.0)
Feeling uncomfortable	–	1 (0.6)	0 (0.0)
Slight drowsiness	–	0 (0.0)	4 (2.0)

NPA, non-penetrating acupuncture; TA, true acupuncture.

Primary outcome measure and sample size for a full randomised controlled trial

Choice of primary outcome for future main trial

We included two outcomes measures capturing data on physical function (the ODI and the PGQ) and one measure of pain severity in the pilot trial, in order to help inform the decision about a primary outcome measure for a future main trial. Several factors were taken into consideration in examining the performance of these measures. These included the number of missing data at the item and scale levels; any evidence of floor or ceiling effects; the precision of the outcome measures based on the 95% CI; and their responsiveness to change.

The number of missing data was minimal for both these measures (reported in *Missing data and data accuracy*). No floor or ceiling effects were shown in the total score of either the ODI (minimum score = 10%, scored by $n = 1$; maximum score = 66%, scored by $n = 1$) or the PGQ (minimum score = 13.6, scored by $n = 1$; maximum score = 85.3, scored by $n = 1$). The standard errors for the estimated treatment effect were large in both the ODI and the PGQ measures, leading to wider CIs (which could partly be a result of the small sample size). However, the PGQ total score had a slightly larger margin of error than the ODI.

A number of statistical indices were used to assess the relative responsiveness of the key outcome measures. These included standardised effect size (SES), the mean change score divided by the SD of the measure at baseline; standardised response mean (SRM), the mean change score divided by the SD of the change scores; responsiveness statistic (RS), based on the mean change score divided by the SD of change of stable patients;

and the paired *t*-test statistic, overall and in improved patients. The global assessment of improvement used as the anchor was the participant's self-reported global rating of change in her back pain problem at the 8-week follow-up measured using a 6-point ordinal scale dichotomised into 'improved' (combining options 'completely recovered', 'much improved', 'somewhat improved') and 'not improved' (combining options 'same', 'somewhat worse', 'much worse'). A SES/SRM/RS greater than 0.8 can be considered large, moderate values range from 0.5 to 0.8, and values below 0.5 are small.⁸⁵ A higher value of the above indices indicates greater sensitivity to clinical change. For a better comparison of the scores we present standardised pain intensity scores of 0–100 by multiplying each score by 10. All the three outcome measures showed moderate or large SES, SRM and RS; the PGQ symptoms scale particularly outperformed the other outcomes on most of these indices (*Table 35*).

Responsiveness was also quantified through a receiver operating characteristic (ROC) curve analysis by plotting the true positive (sensitivity) versus the false positive (1 - specificity) for multiple cut-off points of the outcome measures against the patient's global assessment of change. Patients were grouped into improved ('completely recovered'/'much improved'/'somewhat improved') or no change and worse ('same'/'somewhat worse'/'much worse'). The best discrimination occurs with a curve that reaches most to the upper left; a sharp initial rise (high true-positive rate and low false-positive rate), then flattens while the false-positive rate is still small. For each outcome measure (*Figure 8*) the curve was to the left above the diagonal, showing some discriminative ability, and the areas under the curve were all above 0.85 showing good discrimination.

Based on all of the above parameters, we feel that the PGQ (total score measuring both symptoms and impact of everyday activities) is the best choice of primary outcome measure for a future main RCT.

TABLE 35 Tests of responsiveness for the pain and disability outcome measures

Key outcomes	n	Responsiveness measures			Paired <i>t</i> -test statistic (overall)	Paired <i>t</i> -test statistic (improved)
		SES	SRM	RS		
ODI score (0–100), mean (SD)	90	0.494	0.345	0.370	3.274	8.099
PGQ score (0–100), mean (SD)						
Total	90	0.598	0.461	0.474	4.378	8.893
Activity subscale	90	0.498	0.395	0.393	3.748	7.933
Symptom subscale	90	0.829	0.625	0.712	5.930	9.794
Pain severity (mean score of three NRSs) ^a	91	0.814	0.549	0.656	5.236	13.088

a 0–10 scale transformed to 0–100.

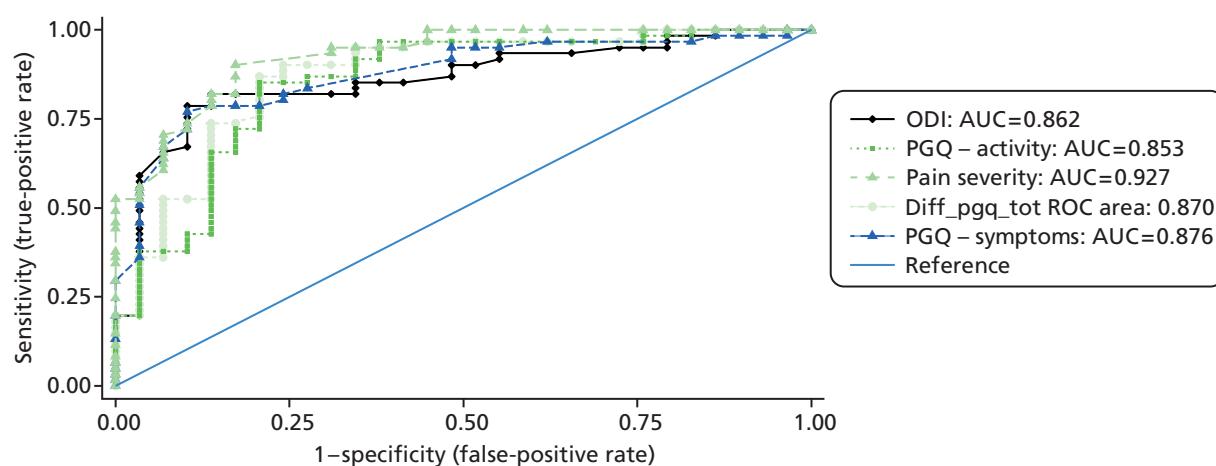


FIGURE 8 The ROC curves of key outcomes against self-rated change. AUC, area under the curve.

Sample size estimate for a future main EASE Back trial

A future main trial is likely to be best powered to detect small to moderate differences between SC and SC plus true acupuncture (testing effectiveness) but given the results of this pilot trial we feel it will also be helpful for a future main trial to compare a package of SC plus true acupuncture with SC plus non-penetrating acupuncture (specifically testing the added efficacy of needle penetration and manipulation).

The sample size calculation is therefore based on a three-arm, parallel-group RCT with the PGQ total score as the primary outcome measure and follow-up at 8 weeks as the primary time point. As there are no previous studies reporting a minimum clinically important difference (MCID) for the PGQ in this population, our parameters for the sample size calculation are based on the pilot data. The point estimate for the comparison of true acupuncture with SC was 12.6 (95% CI 1.3 to 23.8) and for true acupuncture with sham acupuncture was 4.3 (95% CI -7.0 to 15.6) with a SD of 17.0 for the PGQ total score at baseline. The best cut-off point that maximises sensitivity and specificity from the ROC curve analysis was found to be approximately a 4-point difference in the total score. At this difference in score, the sensitivity was 0.87 and specificity was 0.79. Since the estimated optimum cut-off sits within the CIs for both the two point estimates, this provides sufficient justification that the MCID would be achievable for testing for superiority in treatment effect in a main trial. We have, therefore, chosen a mean difference of 4 points in the PGQ total score as the minimum important difference for this population of women, and a SD of 18 (one-sided 80% upper limit of the baseline SD) – translating to a small effect size of 0.22. We have adopted a conservative approach of using an 80% upper one-sided confidence limit of the SD rather than the estimate itself, in line with the conservative approach recommended by Browne⁷⁸ when using pilot data.

Given that the primary analysis will use analysis of covariance to compare the mean score between the two groups 8 weeks after randomisation adjusting for baseline scores, a sample size of 160 participants in each arm will be required to detect a 4-point difference in the mean scores between SC plus true acupuncture and SC plus non-penetrating acupuncture and between SC and SC plus true acupuncture with a power of 80% at a 5% two-sided significance level, assuming an autocorrelation of 0.5. The pilot data showed a correlation of 0.52 between the baseline and 8-week PGQ total scores; thus, an autocorrelation of 0.5 seems reasonable. Therefore, a total of 480 participants will be required. It is expected that no more than 20% of the participants will be lost to follow-up (as we have identified ways to increase the response rate to at least 80% from 74% from pilot data); thus, a future main trial would need to recruit 600 participants in total (200 per arm). Our pilot data have shown that it is possible to recruit an average of five women per week from one maternity centre using six recruitment methods. Therefore, for a main trial we estimate that three maternity centres will need to recruit participants for approximately 12–15 months using the three most successful recruitment methods.

The above suggestions for a primary outcome measure and estimated sample size for a future main EASE Back trial were presented to stakeholders at the EASE Back study dissemination event in May 2014 for discussion (see *Chapter 4*).

Conclusions

In conclusion, phase 2 of the EASE Back study was a pilot RCT in which participants were recruited over 6 months, randomised to one of three treatment arms (SC alone, SC plus true acupuncture and SC plus non-penetrating acupuncture), and followed up at 8 weeks following randomisation. Through this pilot RCT, we tested six recruitment methods, and randomised 45% of potentially eligible women. Our linked audio-recordings highlighted that women expressed no new concerns about acupuncture treatment that had not been identified in phase 1 interviews. Treatments were delivered in line with intervention protocols, although some women did not attend for treatment. The follow-up rate was 74% at 8 weeks, lower than the usual follow-up rates observed in our previous trials. We believe this resulted from the REC decision to reduce the number of follow-up reminders from our usual procedure. While all analyses of patient-reported clinical outcomes (pain, function, quality of life), health economic outcomes and safety outcomes can be considered only exploratory in this pilot RCT, the results overall tended to favour the addition of acupuncture to SC for pregnancy-related back pain. We used the results from the pilot trial to determine which outcome should be the primary outcome for a future main RCT and to estimate the sample size required for such a trial. All of the findings from the pilot RCT were presented and discussed at an end of study dissemination event in May 2014, summarised in *Chapter 4*.

Chapter 4 End of study dissemination event

At the end of the pilot trial (May 2014), we hosted a dissemination event to share the key findings of the EASE Back study with a range of stakeholders.

Participants and programme

We shared the results with a wide range of key stakeholders including national experts in the care of pregnant women, international experts from Sweden (Elden and Stener-Victorin) who had conducted the previous high-quality RCTs testing acupuncture for pregnancy-related PGP, representatives from the community and research midwives, physiotherapists, physiotherapy managers and research managers that we had worked with in the study, as well as trial methodologists. Women who had participated in the pilot trial were also invited but were unable to attend because of time and family commitments. In total, 35 people attended the event.

The programme for the day is provided in *Appendix 15* and included an overview of the EASE Back study aims and objectives, summaries of the methods and findings of both phase 1 (the pre-pilot work) and phase 2 (the pilot RCT) and a short presentation on the potential aims, design and plans for a future main EASE Back trial. They listened to examples of the radio advertising used to raise local awareness about the pilot trial and reviewed the self-management booklet used in the pilot trial. The key focus of the day was to consider the key findings of the pilot RCT (the process outcomes, and the exploratory safety, clinical and cost outcomes) and their implications, in order to agree whether or not the findings provided sufficient evidence that a future main RCT might be desirable and feasible.

Discussion points

After hearing a summary of all of the results of the EASE Back study, participants worked in three separate multidisciplinary groups to discuss six key questions. The questions and a summary of the feedback from participants are provided:

Is a main trial desirable and feasible? If so, which trial design is best?

All felt that a future main trial was desirable but would benefit from modifications. The rationales for deciding a main trial would be desirable included the need to reduce the negative impact of back pain in pregnancy, the need to improve the quality of life during pregnancy of this group of women, the need for a better evidence base to underpin NHS practice, and the need to test additional treatment options for this population given that referral rates to NHS women's health specialists were perceived to be rising.

The group felt that a future main trial was also feasible, and that the pilot RCT had provided the evidence needed to inform a larger and multicentre RCT. This group of women were considered to be a challenging group to recruit to RCTs and to commit to a course of treatment. Some modifications were suggested in order to ensure high rates of recruitment, follow-up and treatment attendance in a future main trial (these are described in the following section).

Several options for the design of a future main trial were discussed. These included a two-arm parallel RCT, randomising participants to either SC or a combination of SC and true acupuncture, powered to detect superiority of the addition of acupuncture to SC. Some participants felt that the SC treatment should be further standardised for a future main trial, so that either all women receive the self-management booklet only or all women receive the booklet and at least one session with a physiotherapist who would go through the booklet advice and demonstrate helpful exercises and self-management tips. A second option discussed was a three-arm parallel RCT randomising participants to the same three treatment arms as the pilot RCT, powered to also detect

superiority of the SC plus true acupuncture arm in comparison with the SC plus non-penetrating acupuncture arm. Some concerns were raised by acupuncture experts among the stakeholders about the non-penetrating needles still being 'active' treatment (and not a true inert or sham treatment). This led to recommendations about using fewer needles and placing them outside the pain area in the sham acupuncture arm of a future main trial. We also discussed the merits of a three-arm parallel RCT with unequal randomisation (1 : 2 : 2 to SC, SC plus true acupuncture and SC plus non-penetrating acupuncture, respectively) and an adaptive trial design that starts with these three arms but is informed by an interim analysis to continue as either a three-arm trial or a two-arm trial (should the interim analysis shown futility in attempting to continue as a three-arm trial that could demonstrate superiority of SC plus true acupuncture over SC plus non-penetrating acupuncture). Some stakeholders felt that the question of most relevance to the NHS would be the one answered by a simple two-arm RCT (thus dropping the idea of a sham acupuncture comparison group altogether) while several others recommended a four-arm design adding in a treatment arm where women all receive one-to-one SC treatment offered by physiotherapists but not acupuncture of any sort. However, the preferred design was the adaptive trial design starting with three arms, as it appeared to offer benefits in terms of greater efficiency for a future large trial; if an interim analysis revealed futility (i.e. even if recruitment to all three arms continued, there would be no differences in patient outcome between the true and non-penetrating acupuncture arms) then recruitment, treatment and follow-up efforts could be directed to two trial arms (SC alone and SC plus true acupuncture). Using the PGQ as the primary outcome measure and an 8-week time point as the primary time point (with longer-term follow-ups at 3 and 6 months) would mean needing to recruit 600 women to a full EASE Back trial. We estimate that this would require three maternity centres with linked community midwifery and physiotherapy services, recruiting for a maximum of 15 months.

How could recruitment be maximised in a future main trial?

Although overall the recruitment rate in the EASE Back pilot trial was high (we recruited 45% of those women who were eligible), it was clear that we did not reach all the pregnant women likely to have back pain in the locality during the 6 months of recruitment (we had contact with 366 women out of the 720 we estimated might be suitable for screening for the pilot trial). The six recruitment methods tested in the pilot RCT had varied success, but the three most successful methods were a brief questionnaire screening for back pain given to women as they attend their routine 20-week ultrasound scan appointment, community midwives giving women under their care the EASE Back study card and self-referral of women in response to local awareness raising, particularly the regular radio infomercials. Overall, the stakeholders at the dissemination event felt that all three of these successful methods should be used in a future main trial but that efforts were needed to ensure, as far as possible, that all women attending their 20-week ultrasound scan appointment were given a screening questionnaire and were also given an EASE Back study flyer to take home with them (in case they currently did not have back pain but developed it later in the pregnancy). Research midwives suggested the use of small voucher incentives for staff within the ultrasound scan clinics to reward those getting most questionnaires completed and returned (based on examples of similar incentives used in other trials with pregnant women). They recommended that there was regular and extensive use of radio advertising to raise awareness of local women about a full trial (and it was ensured that the costs of these were included in any main trial application). Other recommendations included a model in which research midwives dedicate more sessions per week to supporting recruitment in a full trial and a slight change to several exclusion criteria for the trial (to exclude only women with previous acupuncture treatment in the last 2 years, to exclude women who had previously delivered a baby prior to 37 weeks and to include women with anterior pelvic pain only and include acupuncture points in that area such as KI11 and SP12).

How could follow-up rates be improved in a future main trial?

The overall follow-up rate in the pilot trial was 74%, and this is lower than previous RCTs led by our team at Keele. We believe that the decision of the REC which reviewed the pilot RCT to allow us to use only two reminders contributed to this low follow-up rate and that a future full RCT using the usual processes of reminders for RCT follow-up in the CTU at Keele would result in approximately 10% higher retention at the 8-week follow-up (see *Appendix 8* for evidence from our previous trials). A future main trial would also collect longer-term follow-up data (at 3 and 6 postnatal months) and, therefore, additional efforts were felt to be needed to ensure high longer-term follow-up rates. Therefore, in addition to making a

stronger case (with evidence from the pilot RCT) for the need for the usual follow-up reminder process to any future REC reviewing the main RCT, stakeholders at the end of study event also recommended offering women the option of online questionnaire completion prompted through emails and/or reminders by Short Message Service text messaging. Many of those attending also felt that the use of low-value shopping voucher incentives (such as £10 for each returned questionnaire or a total of £20 after return of the last questionnaire) should also be considered, based on the recent systematic review evidence that monetary incentives and offers of monetary incentives increase postal and electronic questionnaire response in randomised trials.⁸⁶ Stakeholders felt it important to provide trial participants with the option of declining the vouchers. Home visits to collect outcome data were discussed but felt by the group not to be feasible in a large future trial.

How could participant attendance at treatment be maximised?

Interventions in the EASE Back pilot trial were delivered in line with protocols, in terms of the content of treatment. However, the challenge we observed was in women attending for the full course of treatment (between six and eight treatment sessions in those participants allocated to receive acupuncture). Recommendations from the dissemination event included ensuring that the consent process very clearly describes the commitment needed on the part of included women to engage in the full course of treatment as well as making sure treatment appointments are as flexible as possible (to include evening appointments and to consider the possibility of weekend appointments for those women struggling to attend for treatment owing to work commitments). Additional suggestions included working with a greater number of physiotherapists to deliver EASE Back study interventions (thus offering great flexibility of treatment slots) and using Short Message Service text reminders to participants the day before their appointment to prompt them to attend for treatment.

How should physiotherapists be supported?

All felt that any future main trial should include a similar training and mentoring programme for participating physiotherapists, and that building in plans for peer support and pair-working (with at least two EASE Back-trained physiotherapists per treatment site) would be beneficial. The group of stakeholders recommended regular refresher workshops throughout the recruitment and treatment period of a future main trial, to offer the opportunity to discuss problems, patient case examples and obtain support from those leading the training. They wanted easy telephone contact to community midwives to address questions they might have about normal (and abnormal) features of pregnancy. They suggested that the group of 14 physiotherapists trained in EASE Back study interventions could proceed to support the wider group of therapists who might deliver treatment in a future multicentre trial. Some also suggested using community midwives to offer treatment in a future main trial, where those midwives might already be trained in using acupuncture for pain problems.

Should qualitative research be included in a future main trial?

There was mixed opinion about the value of linked qualitative research within a future main EASE Back trial. Those that felt it would be valuable recommended seeking REC approval to conduct qualitative interviews with those women who are eligible for a main trial but who decline to take part, in order to better understand the reasons for decline, and to interview a sample of women receiving treatment in order to fully understand their experiences of treatment, perceived treatment benefits, challenges faced in committing to a course of treatment and the impact particularly on work, time off work and the start of maternity leave. Such in-depth qualitative data could also help to explain the reasons for the results of a future main trial. A further purpose to qualitative research in the future main trial would be to explore the role of the therapeutic relationship between the women and the physiotherapists. This appeared to be important in the open responses women gave on their 8-week questionnaires.

Key conclusions and recommendations

In summary, a multidisciplinary group attending the end of study dissemination event at which the aims, design, methods and results of the EASE Back feasibility and pilot trial were presented reached the conclusion that a future main RCT testing the additional benefit of acupuncture to SC for women with pregnancy-related back pain (with and without PGP) is desirable and feasible. Recommendations included an adaptive trial design for the main trial with a pre-planned interim futility analysis in order to decide whether to continue with a three-arm full RCT or to stop recruiting to the SC plus non-penetrating acupuncture arm. Other recommendations included ways to maximise recruitment, follow-up rates, attendance at treatment sessions, support of participating physiotherapists and the potential role of linked qualitative research in a future main EASE Back trial.

Chapter 5 Discussion and conclusions

We have shown that that a RCT testing the addition of acupuncture to SC for pregnancy-related back pain is feasible.

Over 24 months, the EASE Back feasibility and pilot trial included (1) a pre-pilot phase comprising a national survey of physiotherapists and qualitative focus group and individual interviews with pregnant women, midwives and physiotherapists; (2) development of SC, true acupuncture and non-penetrating acupuncture treatment protocols; (3) development and delivery of a brief training programme to support physiotherapists to deliver treatment; (4) development of six methods with which to identify and recruit potentially eligible pregnant women; (5) a pilot RCT to assess recruitment rate, treatment fidelity and follow-up rate; (6) several patient-reported outcome measures of pain and function in order to select the most suitable one for use in a future main trial; and (7) a consensus conference with multiple stakeholders to reach agreement on the merits of, and procedures for, a future main trial.

The feasibility and pilot trial specifically:

- Provided data on current UK SC and acupuncture treatment for low back pain in pregnant women. We described current practice for pregnant women with low back pain and used these data in the development of treatment protocols for SC, SC plus true acupuncture and SC plus non-penetrating acupuncture. Features of the treatment protocols including the number of treatment sessions, the types of advice and exercises, the acupuncture points and the overall course of treatment are, therefore, in line with what the NHS currently provides or would be reasonably expected to provide.
- Explored the views of pregnant women with back pain about the acceptability of the proposed interventions, the content and delivery of participant information, the outcomes most important to them and the most appropriate timing of outcome measurement. We found that pregnant women and midwives welcome the idea of a trial as they want more treatment options for this clinical problem. Other than minor questions about positioning for treatment, the location of the needles and the time needed to attend for treatment, women expressed very few concerns. The participant information for the pilot trial ensured that these details were explained, including the information about the known risks of minor side effects of acupuncture such as feeling drowsy or light-headed. Women wanted help with the pain but particularly the impact of the pain on their everyday activities, including work. We tested several outcome measures of pain and function in the pilot trial, including a recently developed instrument specifically for this patient population (the PGQ). In order to ensure that most women would not yet have given birth at the time of their follow-up data collection, we selected a follow-up time point of 8 weeks after randomisation. Only 14% of participants had given birth by the time of their follow-up.
- Optimised trial information, recruitment and consent procedures by learning what works best from the perspectives of pregnant women with low back pain, midwives and physiotherapists. The results of the pre-pilot work highlighted that this patient group are young, busy working women trying to continue to look after other small children and stay in work despite their pain, and these challenges mean they find it difficult to get to NHS appointments and to engage with research. We therefore developed six methods of identifying potentially eligible women for the pilot trial, as we needed to find out which might work best. The methods included a brief screen for back pain when women attend their routine 20-week ultrasound scan appointment, the development of small EASE Back study business cards that midwives could simply give women they look after and a local media awareness-raising campaign to get the message about the pilot trial directly to local women (using YouTube, a website, radio, newspaper and local bus advertisements). We used brief telephone screens to assess initial eligibility before asking women to attend for a full eligibility and information meeting with a research midwife or nurse. We audio-recorded 30 of these meetings and again found that women expressed few concerns other than positioning for treatment and the time commitment required for treatment.

- Investigated the views of NHS health professionals regarding (1) the acceptability and feasibility of referring women with back pain in pregnancy to physiotherapists for acupuncture, (2) the proposed trial design and interventions and (3) ways in which to maximise recruitment and retention to a trial. The pre-pilot work highlighted that both midwives and physiotherapists felt that there are currently very few effective treatment options for pregnant women with low back pain and that acupuncture has merit and should be researched. Midwives welcomed the trial, felt acupuncture would be very acceptable to women and were keen to ensure that the women they looked after could access care in the trial. Physiotherapists were keen to participate in the trial but had concerns about the safety of acupuncture in pregnancy, mostly related to their original acupuncture training, through which at least some had been told that pregnancy was a contraindication for acupuncture. These concerns informed the development of a training programme for the 14 physiotherapists that took part, led by the research team, including an experienced acupuncturist, a women's health physiotherapist and a consultant obstetrician. Physiotherapists' confidence in the diagnosis and management of pregnancy-related back pain increased after the training and remained high to the end of the trial. The findings of the interviews with physiotherapists and midwives highlighted the need to offer women choice about geographical treatment sites, flexibility in the timing of treatment sessions (including evening appointments) and the provision of cover for annual leave periods for participating physiotherapists. Within the constraints of a pilot trial we offered some choice to women in line with these suggestions (of up to four treatment sites, one of which could offer evening appointments) and trained more physiotherapists than needed in order to specifically provide reasonable cover for annual leave and part-time working patterns of physiotherapists.
- Tested the trial procedures, training programme for health professionals, the interventions and short-term outcomes with pregnant women with back pain, providing data on recruitment and follow-up rates, treatment fidelity, outcome completion rates and an estimate of between-group difference on key outcomes. We recruited 125 women over 6 months (45% of those who were eligible) and randomised them to one of the three treatment arms. Three of the six methods of identifying and recruiting women were more successful. We designed protocols, eligibility criteria, patient information material and CRFs and found that they performed well in the pilot RCT. We trained 14 physiotherapists to deliver the EASE Back study interventions and provided mentoring support during the pilot trial. They delivered the treatments in line with specified protocols, although some women did not attend for their allocated treatments despite efforts to contact them and re-engage them in treatment. Our usual follow-up processes for RCTs were reduced based on the decision of the REC reviewing the pilot trial (despite our appeal and evidence from five previous trials). The follow-up rate at 8 weeks was 74%, lower than we had hoped, but in our view unsurprising given the decision of the REC about using fewer reminders than we have previously used in RCTs. Outcome completion rates on key measures were high, with few missing data. Exploratory analysis of patient-reported clinical outcomes highlighted benefits from acupuncture over SC alone for pain and function and potential benefits of true acupuncture over non-penetrating acupuncture for function. The pilot data allowed us to estimate between-group differences on outcomes of symptoms and impact on activities using the PGQ; we determined the MCID for this measure and concluded that this would be a suitable primary outcome measure for a future main trial. In the pilot trial, the baseline SD for the PGQ total score was 17 (one-sided 80% upper confidence limit = 18) and we determined that the MCID is 4 points; therefore, a future RCT using this measure should be able to demonstrate a SES as low as 0.22. We also tested out ways to collect health economic data and conducted an exploratory health economic analysis. Overall, the preliminary results suggest that adding acupuncture to SC shows potential for providing a cost-effective alternative to SC alone. The results of both the clinical outcomes and health economic analyses presented in this report are exploratory and can inform a future main trial.

- Brought the above findings together, with experts in SC, acupuncture and trial design, in a consensus conference to finalise the design, interventions, sample size, outcome measures and operational aspects of a main EASE Back trial. We presented all the results at an end of study dissemination event and consensus meeting, and discussed the feasibility and desirability of a future main trial. We estimate that 160 women per arm (480 in total) with pregnancy-related low back pain (with and without PGP) would be required for a full trial to have 80% power, at 5% significance, to detect an effect difference equal to or more than the MCID at the 8-week follow-up between treatment arms. Assuming a 80% follow-up rate (using our CTU standard follow-up processes and adding options for follow-up data collection and the offer of small shopping voucher incentives for response), we estimate a total sample size of 600 women need to be recruited. Being conservative, we estimate this could be achieved from three centres (three maternity centres and linked community services) over 15 months' recruitment. A full trial would benefit from longer-term follow-up (most likely at 3 and 6 months postpartum) and an adaptive trial design using a pre-specified interim analysis to decide whether the trial should continue with all three treatment arms.

In conclusion, based on the learning from this feasibility and pilot RCT, a future main RCT testing the additional benefit of acupuncture over SC is feasible. The design and structure of the main RCT was developed and tested in this pilot RCT. Recruitment and follow-up were challenging, largely because this patient population comprises young, busy women often with other small children at home and demanding jobs to continue with, despite pain. We have shown that three recruitment methods are successful and these could be made more successful if the changes recommended at the consensus conference are implemented. We also believe that our usual RCT follow-up processes need to be followed in a future trial and we need to work with the REC reviewing the main trial, to help them see the need for all of the reminders. We believe there is a good window of opportunity to proceed to a large, multicentre RCT and have had requests from several sites in the UK interested in working with us on a future large trial.

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Contributions of authors

Professor Nadine E Foster, NIHR Professor of Musculoskeletal Health in Primary Care, led the research as chief investigator. She designed the study, wrote the proposal, supervised the research, facilitated several focus groups and wrote the final report.

Dr Annette Bishop, NIHR Research Fellow, helped plan the study and funding proposal, developed the national physiotherapy survey, facilitated a focus group, contributed to the analyses of the survey and interviews in phase 1 and supported aspects of the training programmes for participating clinicians.

Dr Bernadette Bartlam, Lecturer in Health Services Research, led the qualitative research in phases 1 and 2, conducted and analysed interviews with women, midwives and physiotherapists and contributed to the development of the PIL.

Dr Reuben Ogollah, Research Associate in Biostatistics, performed the quantitative analyses.

Dr Panos Barlas, Lecturer in Physiotherapy and Acupuncture, led the development of the acupuncture treatment protocols, delivered the training in acupuncture, mentored the participating physiotherapists, contributed to the analysis of the qualitative data and was part of the team that considered the adverse effects of treatments.

Dr Melanie Holden, Arthritis Research UK Allied Health Professional Training Fellow, was the study co-ordinator for phase 1, helped develop the survey and interview procedures, developed the participant information, led the development of the research ethics application for the pilot RCT and contributed to the training programmes for participating clinicians.

Professor Khaled Ismail, Professor of Obstetrics and Gynaecology, helped design the study, contributed to the recruitment methods and the training programme for physiotherapists, and was part of the team discussing reported adverse effects.

Dr Sue Jowett, Senior Lecturer in Health Economics, developed the economic data collection and analysis plan and supervised Jesse Kigozi, who conducted the health economic analysis.

Professor Christine Kettle, Professor of Midwifery, helped to design the study and contributed to the recruitment methods and oversight of the delivery of study.

Jesse Kigozi, Research Fellow in Health Economics, conducted health economics analysis.

Dr Martyn Lewis, Reader in Biostatistics and Health Economics, helped to design the study and supervised Dr Reuben Ogollah in developing and delivering the analysis plan.

Alison Lloyd, trial co-ordinator for the pilot RCT, was responsible for the day-to-day running of the trial and supporting the research nurses and midwives working on the trial.

Dr Jackie Waterfield, Senior Lecturer in Physiotherapy, helped to analyse the qualitative data and developed the questionnaire that physiotherapists completed before and after their training programme.

Julie Young, Senior Research Nurse, was the lead research nurse for the study and led the development and delivery of the auditing procedures for recruitment, eligibility screening, consent and MDC.

All authors contributed to the final report and approved the final version.

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Appendix 1 Survey questionnaire to physiotherapists



Physiotherapist Questionnaire



- When completing this questionnaire, please try to be as honest as you can throughout. There are no 'correct' or 'incorrect' answers.
- We are interested in your clinical opinion about the management of **back pain during pregnancy**.
- Most questions can be answered by putting a cross in the box like this
- If you have any questions about this questionnaire or the study in general, you can telephone **Melanie Holden** on **01782 734863** during office hours.
- Please return this questionnaire in the pre-paid envelope provided. **You do not need a stamp.**

Thank you for your help with this research study

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

For this study we are seeking the views of physiotherapists who treat **pregnancy-related back pain**.

Have you **ever** treated a pregnant woman with back pain?

Yes

No

* If no, please do not fill in any further questions and return the questionnaire to us in the envelope provided. Your response is valuable to us even if you do not treat pregnant women with back pain. Thank you.

* If yes, please continue with the questions below.

Section One – about you

1.1 Please state the year in which you qualified as a physiotherapist.....

1.2 Are you

Female

Male

1.3 Do you work..... (Please cross one box)

.....Exclusively in the National Health Service (NHS)

.....Exclusively in non-NHS settings (e.g. private practice / hospital, education/research, military, sports club)

.....In a combination of NHS and non-NHS settings

1.4 What is your current agenda for change banding? (Please cross one box only)

.....Band 5

.....Band 6

.....Band 7

.....Band 8a

.....Band 8b or above

.....Not applicable

1.5 How frequently do you see pregnant women with back pain? (Please cross one box only)

.....Infrequently; at most 1 in the last 6 months

.....Somewhat frequently; between 2 to 5 in the last 6 months

.....Frequently; at least 1 per month

.....Very frequently; at least 1 per week

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

1.6 Under what circumstances do you typically see pregnant women with back pain?
(Please cross all boxes that apply)

-They are referred from their midwife to me
-They are referred from their GP to me
-They are referred from the obstetrician to me
-They are referred from other physiotherapy colleagues to me
-They self refer, directly to me
-Other, please specify.....

1.7 Do you have a clinical speciality/special interest?

- Yes No

If yes, please state the **main one**.....

1.8 Are you a member of any Clinical Interest Groups / Professional Networks?

- Yes No

If yes, please state which ones

.....
.....
.....
.....
.....

1.9 Have you received any **specific postgraduate training** in the field of **women’s health**?

- Yes No

If yes, which of the following describes your training in the field of women’s health?
(Please cross all boxes that apply)

-Day or weekend courses with no formal assessment
-Courses or modules with formal assessments (exams, marked assignments etc.)
-MSc or equivalent
-Other, please specify.....

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

Please provide any further details below

1.10 Have you received any **specific postgraduate training** in the management of **back pain**, in general?

Yes

No

If yes, which of the following describes your training in the field of back pain?
(Please cross all boxes that apply)

.....Day or weekend courses with no formal assessment

.....Courses or modules with formal assessments (exam, marked assignments etc.)

.....MSc or equivalent

.....Other, please specify.....

Please provide any further details below

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

1.11 Have you received any **specific postgraduate training** in the management of **back pain in pregnancy**?

Yes

No

If yes, which of the following describes your training in the field of back pain?
(Please cross all boxes that apply)

.....Day or weekend courses with no formal assessment

.....Courses or modules with formal assessments (exam, marked assignments etc.)

.....MSc or equivalent

.....Other, please specify.....

Please provide any further details below

1.12 Have you received any **specific postgraduate training** in the field of **acupuncture**?

Yes

No

If yes, please specify

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

1.13 Do you use acupuncture in the management of musculoskeletal problems, including back pain in general?

Yes

No

If yes, please continue to complete the remaining questions in this section.

If no, please go straight to Section 2 on page 8.

1.14 Do you use acupuncture in the management of pregnant women with back pain?

Yes

No

If no, please briefly state the main reason why

.....

.....

.....

.....

1.15 Please cross the one box that best describes the predominant style of acupuncture that you use.

.....TCM / Traditional acupuncture

.....Western / Medical acupuncture

.....Auricular acupuncture

.....Trigger point / Myofascial acupuncture

.....Other, please specify.....

1.16 Which of the following best describes your acupuncture training? (Please cross one box only)

.....Up to and including 80 hours of training

.....More than 80 hours, but less than 200 hours of training

.....Degree / Diploma or equivalent training

1.17 For how many years have you been using acupuncture in your practice?
(Please provide one number)

years

Section Two – Clinical scenario of a pregnant woman with back pain

Presented below is a clinical scenario of a **pregnant woman with back pain**. All questions that follow relate to the care you would give this particular patient. Please think about the patient's **first** consultation with you.

A 34 year old woman has been referred to you with symptoms of intermittent sharp pain in her lumbar region and reports that the symptoms began a few weeks ago. She is 24 weeks pregnant with her first child. She is in good general health, of normal weight for her height and has never had back pain before.

Her back pain presents as occasional sharp sensations in the lumbar region of her spine. She also has some dull pain in the lower back region which is more persistent but of lesser intensity than the sharp pain she occasionally experiences. Her symptoms are worse if she maintains a sitting or standing posture for prolonged periods. This is making it difficult at work as she has an office based job. She is reluctant to use any analgesic medication due to her pregnancy.

Upon examination there is no exacerbation with movement, nor any directional preferences. She has normal range of movement and is moderately tender on the paraspinal muscles of her lower back. The SLR and Slump tests are negative.

2.1 Would it be part of your role to treat this patient? (Please cross one box only)

Yes

No

If yes, please **miss question 2.2** and go straight to **question 2.3** below.

If no, please complete **question 2.2** below and then go to section 3 on page 13

2.2 What would typically happen for this patient next? (Please cross one box only)

.....Onward referral to a women's health physiotherapist

.....Onward referral to another physiotherapist

.....Onward referral to a pain specialist

.....Onward referral to a midwife

.....Onward referral to a GP

.....Onward referral to an obstetrician

.....Other, please specify.....

2.3 Which one of the following best describes the pattern of care you would offer this patient? (Please cross one box only)

.....The patient would normally be seen in individual, face to face appointments

.....The patient would normally be seen as part of a group

.....The patient would normally be seen individually for an initial assessment and then offered care as part of a group

.....The patient would initially be seen as part of a group but would be able to access individual, one to one appointments if needed

.....Other (please specify).....

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

2.4 What advice would you offer this patient?
 (Please cross all boxes that reflect the advice that you would typically offer this patient)

-Advice about the temporary / self-limiting nature of the pain
-Oral advice on self-management
-Written advice on self-management
If written advice on self management is ticked, it would be very helpful to see a copy by enclosing it with your completed questionnaire, or alternatively by providing a website address.

-Advice about pacing between activities and rest
-Advice about postural stresses occurring during pregnancy
-Advice about adaptations in posture to help the pain
-Advice about adaptation in lifting techniques
-Advice about continuing with everyday activities
-Advice about the use of pelvic belts
-Advice about the use of pillows
-Advice about rest as a form of treatment for the pain
-Advice about work
-Advice about a home exercise programme
If advice about a home exercise programme is ticked, it would be very helpful to see a copy by enclosing it with your completed questionnaire, or alternatively by providing a website address.

-Advice about safe pharmacological options
-Advice about home massage
-Advice about walking aids
-Other, please specify.....

2.5 From the list of advice in question 2.4, please rank up to 3 types of advice that you **would use most often** with pregnant women with low back pain.

- 1.
- 2.
- 3.

2.6 What treatment would you offer this patient?(Please cross all boxes that reflect the treatment you would typically offer this patient)

-Exercises to try at home / a home exercise programme
-Exercises supervised by a physiotherapist
-Strengthening exercises
-Postural control exercises / stabilising exercises
-Repeated directional exercises
-Pelvic floor exercises
-Exercise in water
-Relaxation techniques
-Prescribed periods of bed rest
-Supportive belts
-Supportive pillows
-Heat therapy
-Cold therapy
-Manual therapy
-Acupuncture
-Massage
-TENS
-Other electrotherapy, please specify.....
-Other, please specify.....

2.7 From the list of treatments in question 2.6, please rank up to 3 types of treatment that you **would use most often** with pregnant women with low back pain.

1.
2.
3.

2.8 How many times would you typically see this patient including both assessment and treatment?
(Please cross one box only)

- | | |
|-------------------------------------------|--------------------------------------------------|
| <input type="checkbox"/>Once | <input type="checkbox"/>7 - 8 times |
| <input type="checkbox"/>Twice | <input type="checkbox"/>9 - 10 times |
| <input type="checkbox"/>3 - 4 times | <input type="checkbox"/>More than 10 times |
| <input type="checkbox"/>5 - 6 times | |

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

2.9 Over how long (in weeks) would you typically see this patient? (Please cross one box only)

- | | |
|-------------------------------------------|--------------------------------------------------|
| <input type="checkbox"/>1 - 2 weeks | <input type="checkbox"/>7 - 8 weeks |
| <input type="checkbox"/>3 - 4 weeks | <input type="checkbox"/>9 - 10 weeks |
| <input type="checkbox"/>5 - 6 weeks | <input type="checkbox"/>More than 10 weeks |

2.10 What would be the typical length (in minutes) of your physiotherapy sessions for this patient? (Please state one number)

Minutes

2.11 What would be your typical 'episode' of care for this patient? (Please cross one box only)

-It would usually stop following treatment and a re-referral would be required for further treatment
-It would usually be left 'open' for the duration of the pregnancy
-It would be left 'open' for a defined period after the end of the treatment (e.g. 4 weeks)
-Other, please specify.....

If acupuncture **is** a treatment that you would offer this patient, please continue to complete the remaining questions below.

If acupuncture **is not** a treatment that you would offer this patient, please go straight to **section 3** on **page 13**.

2.12 Please state which acupuncture points you would use 'normally' for the vignette patient.

Local acupuncture points – Please state which points

Distal acupuncture points – Please state which points

2.13 On average, how many points would you need in a treatment session? (Please state number)

points

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

2.14 Which of the following would best describe the depth of needling you would use?
(Please cross one box only)

-Shallow / Intra-dermal
Intramuscular
Other, please specify.....

2.15 Would you usually aim to achieve a needling sensation / De Qi? (Please cross one box only)

- Yes No

2.16 What type of needle manipulation would you normally use? (Please cross one box only)

-None
Rotation
Lift and Thrust
Other, please specify.....

2.17 How long would you leave the needles in situ (in total) in minutes?

Please state the closest full number Minutes

2.18 Would you also use any of the following? (Please indicate by crossing Yes or No)

- Electrical stimulation of needles / electro- acupuncture..... Yes No
Moxibustion..... Yes No
Cupping..... Yes No

2.19 In your practice, have you ever observed any adverse effects of acupuncture treatment with pregnant women? (Please cross one box only)

- Yes No

If yes, providing some detail about this would be really helpful for our research

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

Section Three – Open Questions. We are interested in your experiences of treating women who have back pain during pregnancy. Please use the following boxes to tell us any additional things which you think might be relevant.

- 3.1 Do you have any further comments about any aspect of treatment for back pain in pregnancy?
(Please cross one box only)

Yes

No

If yes, please use this space for those comments

- 3.2 Do you have any concerns about the use of acupuncture for back pain in pregnancy?
(Please cross one box only)

Yes

No

If yes, please note your concerns here

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

3.3 Would any aspect of your management change if the patient described in the vignette ALSO had pubic symphysis pain/dysfunction? (Please cross one box only)

Yes

No

If yes, please provide details

**This is the end of the EASE BACK questionnaire, but please complete this consent form before returning everything in the pre-paid envelope provided.
Thank you.**

Study number:
(office use only)

EASE BACK Questionnaire_v1.0_05/03/12_REC ref: 12/NW/0227

Consent Form

We would like to keep you informed about the results of this study and in addition we may want to contact you again. Giving us permission to contact you again does not mean you have to take part further.

Would you be willing to be contacted again? *(Please cross one of the boxes below).*

• **YES**, I am happy to be contacted again

Contact telephone number.....

Please print your name, address (at which you are happy to be contacted) and e-mail address:

Title:.....

Forename(s):.....

Surname:.....

Address:.....

.....

.....

.....

Postcode:

e-mail address:.....

Your Signature:

Today's Date:


.....

• **NO**, I do not want to be contacted again


Please note: If you do not want to be contacted again, we **do not** require your contact details or signature

Please return the questionnaire in the **pre-paid** envelope provided.
If you have any questions about this questionnaire or the study in general, you can telephone **Melanie Holden** on **01782 734863** during office hours.

Appendix 2 Focus group participant brief questionnaire



Arthritis
Research UK
Providing answers today and tomorrow



Keele
University

PRIMARY CARE SCIENCES
ARTHRITIS RESEARCH UK PRIMARY CARE CENTRE

Appendix 19: Interview study (practitioner) personal profile

EASE BACK : Health care practitioner profile – interview study

Study number (to be completed by researcher):

Thank you for taking part in this research. Please complete this short questionnaire which will allow us to outline brief details of those who took part in the study. Please note that all information will be anonymised and it will not be possible to identify you personally.

1. Please give your qualifications and state the year(s) in which you qualified:

Qualification	Year

2. Are you Female Male

3. Do you work..... (Please tick one box only)

.....Exclusively in the National Health Service (NHS)

.....Exclusively in non-NHS settings
(e.g. private practice / hospital, education/research)

.....In a combination of NHS and non-NHS settings

4. What is your current agenda for change banding? (Please tick one box only)

.....Band 5 Band 6

.....Band 7 Band 8a

.....Band 8b or above Not applicable

Interview study (practitioner) personal profile_v1.0_05_03_12_REC ref: 12/NW/0227

5. How frequently do you see pregnant women with back pain?
(Please tick one box only)

-Infrequently; at most 1 in the last 6 months
Somewhat frequently; between 2 to 5 in the last 6 months
Frequently; at least 1 per month
Very frequently; at least 1 per week

6. Do you have a clinical speciality/special interest?

Yes

No

If yes, please state the **main one**.....

7. Have you received any **specific postgraduate training around the area of back pain in pregnancy?**

Yes

No

Please provide any further details:

Study ID Number

Interview study (practitioner) personal profile_v1.0_05_03_12_REC ref: 12/NW/0227

Appendix 12: Interview study (women with back pain) personal profile

EASE BACK: Participant Profile

Study number (to be completed by researcher).....

Thank you for taking part in this research. Please complete this short questionnaire which will allow us to summarise the characteristics of the women who took part in the study. Please note that all information will be anonymised and it will not be possible to identify you personally.

1. Are you currently experiencing pregnancy related back pain? *(Please tick one box only)*

Yes

No

2. Does your pregnancy related back pain limit your activities in any way?
(Please tick one box only)

Yes

No

→ Please go to Question 4

3. If yes to question 2, in what way(s)?

.....

4. Have you previously experienced back pain which is not related to pregnancy?
(Please tick one box only)

Yes

No

→ Please go to Question 7

5. If yes to question 4, did this limit your activities in any way? *(Please tick one box only)*

Yes

No

→ Please go to Question 7

Interview study (women with back pain) personal profile_v1.0_05_03_12_REC ref: 12/NW/0227

6. If yes to question 5, in what way(s)?

.....

7. In very general terms, how would you rate your quality of life? Is it
 (Please tick **one** box only)

.....Very good
Good
Neither good nor poor
Poor
Very poor

8. Have you any children? (Please tick **one** box only)

Yes

No

↳ Please go to question 11

9. If yes to question 8, how many children do you have?

10. What is your current employment status? (Please tick **one** box only)

<input type="checkbox"/>Employed	<input type="checkbox"/>Unemployed/seeking work
<input type="checkbox"/>Not working due to pregnancy related back pain	<input type="checkbox"/>Not working due to other health problems
<input type="checkbox"/>Housewife	<input type="checkbox"/>Other.....

11. If working, what is your job title?
 (for example – factory worker, administer, shop assistant, solicitor)

.....

12. If you are not working, what was your last job title?

.....

Interview study (women with back pain) personal profile_v1.0_05_03_12_REC ref: 12/NW/0227

13. What is your date of birth? / /

(for example, if you were born on the 5th June 1936, this would be entered as 05/06/36)

14. What is your current marital status? (*Please tick **one** box only*)

- | | | | |
|--------------------------|-----------|--------------------------|------------|
| <input type="checkbox"/> | Married | <input type="checkbox"/> | Widowed |
| <input type="checkbox"/> | Separated | <input type="checkbox"/> | Cohabiting |
| <input type="checkbox"/> | Divorced | <input type="checkbox"/> | Single |

15. To which of these groups do you consider that you belong? (*Please tick **one** box only*):

- English
- Other British
- Irish
- Other White
- Indian
- Mixed (White and Black Caribbean)
- Mixed (White and Black African)
- Mixed (White and Asian)
- Other mixed
- Pakistani
- Bangladeshi
- Chinese
- Other Asian
- Caribbean
- African
- Other Black
- Arab
- Other

Thank you for completing this short questionnaire.

Study ID Number

Interview study (women with back pain) personal profile_v1.0_05_03_12_REC ref: 12/NW/0227

Appendix 3 Topic guides for interviews and focus groups

EASE Back study interview topic guide: acupuncturist

1. Introduction.

- i. Explain usual arrangements for completion of brief profile, consent, recording, anonymity, focus group rules, etc.
- ii. NB: signing of consent form to be at termination of discussion as check that consent still in place.

2. Experience of back pain among patients.

- i. Just to check: what are your qualifications and when did you qualify?
- ii. Tell me a little about your experience of back pain among your pregnant patients . . .
- iii. Probe for symptoms, effects on daily life, work, sleep, partner/family relationships, physical activities, mood, etc.
- iv. Have you received any specific postgraduate training around the area of back pain in pregnancy?

3. Views on complementary therapies generally.

- i. What are your views on complementary therapies generally other than acupuncture?
- ii. Have you any experience of using them?
- iii. If so, which and in what ways?
- iv. NHS or private?
- v. Reasons for use?
- vi. Outcomes?

4. Managing symptoms.

- i. Do you feel you can offer any help with managing symptoms other than acupuncture?
- ii. What would be the usual type of approach you would take with these patients?
- iii. Probe – how effective, anything else that might be done, does it depend on the severity of the back pain or other symptoms?
- iv. Are there any 'standard' self-management resources that you use?

5. Managing patients using acupuncture.

- i. Do you provide acupuncture within a private or a NHS setting? Say more . . .
- ii. Are there particular aspects of a patient's symptoms that influence your approach?
- iii. Is acupuncture your first line approach?
- iv. If yes, are there circumstances in which it might not be?
- v. If no, what is? Say more . . .
- vi. Are there particular points that you would not use? Say more . . .
- vii. Any particular needles?
- viii. Any variation on depth?
- ix. Is there any particular aspect of managing these patients you find difficult? Say more . . .
- x. Any adverse effects?
- xi. What do you feel are patients' expectations about what you have to offer them?
- xii. What kinds of explanations about the problem do you use with these women?

- xiii. Do you have any procedures for informed consent?
 - xiv. Is there any particular information, and in what format, that you give patients?
6. Views on acupuncture in pregnancy – depending on above responses.
- i. What sorts of expectations do you think patients have around acupuncture?
 - ii. When do you consider acupuncture most helpful in the course of the pregnancy?
 - iii. What sorts of outcomes are be important to you? To women? Prompts RE: employment, childcare, etc.
 - iv. When would it be most appropriate to assess those outcomes, e.g. directly after a course of treatment, a month or so after the end of treatment but before the birth, after the birth?
7. Views on taking part in the trial.
- Women:
- i. How would you think women might feel about taking part? Reasons and any specific concerns they anticipate women having . . .
 - ii. Any particular groups of women that might/not be willing?
 - iii. What might support/encourage women to take part?
 - iv. What might discourage/inhibit/prevent them?
8. Professionals:
- i. How would you think professionals might feel about inviting women to take part? Reasons. . .
 - ii. Any particular groups of women that they might/not be willing to invite?
 - iii. What might support/encourage them in inviting women to take part?
 - iv. What might discourage/inhibit/prevent them?
9. Close of interview.
- i. Any other final remarks/additional views.
 - ii. Signing of consent form as a check that consent is still in place.
 - iii. Reimbursement of travel expenses (where appropriate).

EASE Back study interview topic guide: midwives and physiotherapists

1. Introduction.
- i. Explain usual arrangements for completion of brief profile, consent, recording, anonymity, focus group rules, etc.
 - ii. NB: signing of consent form to be at termination of discussion as check that consent still in place.
2. Experience of back pain among patients.
- i. Tell me a little about your experience of back pain among your pregnant patients . . .
 - ii. Probe for symptoms, effects on daily life, work, sleep, partner/family relationships, physical activities, mood, etc.

3. Managing symptoms.
 - i. Do you feel you can offer any help with managing symptoms?
 - ii. What would be the usual type of approach you would take with these patients?
 - iii. Probe – how effective, anything else that might be done, does it depend on the severity of the back pain or other symptoms?
 - iv. Are there any 'standard' self-management resources that you use?
4. Managing patients.
 - i. Is there any particular aspect of managing these patients you find difficult? Say more . . .
 - ii. What do you feel are patients' expectations about what you have to offer them?
 - iii. What kinds of explanations about the problem do you use with these women?
 - iv. How do you usually manage these patients?
5. Views on complementary therapies generally and acupuncture specifically.
 - i. What are your views on complementary therapies generally?
 - ii. Have you any experience of using them?
 - iii. If so, which and in what ways?
 - iv. NHS or private?
 - v. Reasons for use?
 - vi. Outcomes?
 - vii. Repeat for acupuncture specifically.
6. Views on acupuncture in pregnancy – depending on above responses.
 - i. Have used in pregnancy?
 - ii. Reasons for doing so?
 - iii. If not used, probe for reasons, including specifically any concerns about adverse effects.
 - iv. What sorts of expectations do you think patients have around acupuncture?
 - v. If acupuncture was to be provided, when would be most helpful in the course of the pregnancy?
 - vi. What sort of outcomes would be important to you?
 - vii. When would it be most appropriate to assess those outcomes, e.g. directly after a course of treatment, a month or so after the end of treatment but before the birth, after the birth?
7. Views on taking part in the trial.

Explain the trial.

Women:

 - i. How would you think women might feel about taking part? Reasons and any specific concerns they anticipate women having . . .
 - ii. Any particular groups of women that might/not be willing?
 - iii. What might support/encourage women to take part?
 - iv. What might discourage/inhibit/prevent them?
8. Professionals:
 - i. How would you think professionals might feel about inviting women to take part? Reasons . . .
 - ii. Any particular groups of women that they might/not be willing to invite?
 - iii. What might support/encourage them in inviting women to take part?
 - iv. What might discourage/inhibit/prevent them?

9. Midwives:
 - i. Which women with back pain do you refer on to physiotherapists? Probe for details.
 - ii. Explain the plan for audio-recording in pilot trial of consent meeting and explore their views of these plans.
10. Close of interview.
 - i. Any other final remarks/additional views.
 - ii. Signing of consent form as a check that consent is still in place.
 - iii. Reimbursement of travel expenses (where appropriate).

EASE Back study interview topic guide: women

1. Introduction.
 - i. Explain usual arrangements for completion of brief profile, consent, recording, anonymity, focus group rules, etc.
 - ii. NB: signing of consent form to be at termination of discussion as check that consent still in place.
2. Experience of back pain in pregnancy.
 - i. Tell me a little about your experience of back pain in your pregnancy . . .
 - ii. Probe for symptoms, effects on daily life, work, sleep, partner/family relationships, physical activities, mood, etc.
3. Help received with managing symptoms.
 - i. Do you feel you have received any help with managing symptoms?
 - ii. If yes, probe who from, what sorts of help, how effective, anything else that might be done?
 - iii. If no, has help been sought?
 - iv. If yes, from whom, what sort of responses received?
 - v. If no, reasons for not seeking help.
 - vi. Anything else that you have done to help with the pain, including self-help strategies and accessing information, and if so, from where? How effective?
4. Expectations after pregnancy.
 - i. How do you expect the situation to be after the baby is born?
 - ii. Reasons?
5. Views on complementary therapies generally and acupuncture specifically.
 - i. Have you any experience of complementary therapies?
 - ii. If so, which types? (Probes as follows.)
 - iii. NHS or private?
 - iv. Reasons for use?
 - v. Financial cost?
 - vi. Outcomes?
 - vii. Repeat for acupuncture as appropriate.

6. Views on acupuncture in pregnancy – depending on above responses.
 - i. Willingness to consider acupuncture for back pain in pregnancy – initial ideas about this and any specific concerns.
 - ii. Have you used acupuncture in pregnancy?
 - iii. If used, probe for reasons.
 - iv. How did you decide which acupuncturist to use?
 - v. NHS or private?
 - vi. Practitioner background?
 - vii. Outcomes?
 - viii. If not used, probe for reasons.
 - ix. If acupuncture was to be provided, when would be most helpful in the course of the pregnancy?
 - x. What sort of outcomes would be important to you?
 - xi. When would it be most important to you to assess those outcomes, e.g. directly after a course of treatment, a month or so after the end of treatment but before the birth, after the birth?
7. Views on taking part in research.

Explain about the trial.

 - i. How would you feel about taking part? Reasons . . .
 - ii. How do you think women generally might feel? Reasons . . .
 - iii. Any particular concerns about being invited to take part in this type of trial?
 - iv. What might support/encourage women to take part? Specifically what information would they want before deciding to take part?
 - v. What might discourage/inhibit/prevent them?
8. Closing the interview.
 - i. Any other final remarks/additional views.
 - ii. Signing of consent form as a check that consent is still in place.
 - iii. Reimbursement of travel expenses (where appropriate).

Appendix 4 Participant information leaflet

University Hospital of North Staffordshire 
NHS Trust



EASE BACK Study

Evaluating Acupuncture and Standard care for pregnant women with BACK pain

www.keele.ac.uk/easeback

Participant Information Leaflet

REC ref: 13/WM/0021

Version 2.2. Date: 02/04/13

You are being asked to take part in a research study. The study will test ways of managing back pain during pregnancy. It is being carried out by the University Hospital of North Staffordshire (UHNS), local community midwives, and physiotherapy services working with a research team at Keele University. This leaflet explains why the research is being done and what it will involve. Please take time to read the information carefully, before you decide whether or not to take part, and discuss it with others if you wish.

Why is the research being carried out?

We are trying to find out how best to help women with back pain during pregnancy.

Back pain during pregnancy is common and can affect daily activities, work and sleep. Usual care for pregnant women with back pain typically involves advice about things that they can do to help ease their pain, for example, changes in posture and simple exercises to do at home. Acupuncture may also be a treatment that could help. It is already recommended in UK guidelines for treating back pain in the general population. Some midwives and physiotherapists also use it to treat pregnant women with back pain. However, we do not know if it is better than usual care. In order to understand whether acupuncture can really help pregnant women with back pain, we want to offer some women 'usual care' and other women 'usual care plus acupuncture' in what is called a 'randomised trial'. This is what the EASE BACK study is all about.

Why have I been invited to take part?

You have been invited to take part because you are pregnant and experiencing back pain. We are asking 180 pregnant women in total to take part in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. Your involvement is purely **voluntary**. Whether or not you decide to take part in this study, your midwife or

obstetrician will still give you the best care they can. If you do decide to take part, you will still be free to **withdraw** from the study at any time, without giving a reason and withdrawing will **not** affect your current or future health care in any way.

What are the treatment packages?

The treatment packages on offer are usual care, or usual care in combination with one of two types of acupuncture, which are described in more detail below. This means that all women in the EASE BACK study will receive usual care, and some will also receive acupuncture.

- **Usual care**

Across the UK usual care for pregnant women with back pain involves advice, education and guidance about things that women can do to help themselves, as well as postural changes and exercises to try at home. A detailed booklet containing this guidance will be posted to all women that take part in the study, explaining how to reduce and prevent your back pain. In addition, as would be the case normally, those with the most severe problems may also be referred to physiotherapy for additional treatment.

- **Usual care and one of two different forms of acupuncture**

In addition to usual care, some participants in the EASE BACK study will also receive one of two different forms of acupuncture. This will help us see whether the type of acupuncture makes a difference to your pain. Acupuncture will be delivered by fully trained physiotherapists, and you have a **choice of four locations** at where to receive your treatment: the University Hospital of North Staffordshire, Bradwell Hospital (Chesterton), Cobridge Community Health Centre and Bentilee Health Centre.

Acupuncture originated from the Far East nearly 4000 years ago, and involves the stimulation of certain parts of your body, using very fine needles at particular points. The needles do not bear any resemblance to those used for taking blood or giving injections. You may experience a mild discomfort when they are inserted but, in general, acupuncture is considered painless. Your physiotherapist will explain the procedure fully.

If you are allocated to receive usual care plus acupuncture you will receive between 6 to 8 treatments over approximately 6 weeks. Each treatment session will last 30 to 40 minutes. To receive acupuncture the physiotherapist will work out the most comfortable position with you, but this is likely to involve lying on your side, or being propped up on your back. Your physiotherapist will make sure you are comfortable before starting treatment. As you need to keep still and be as relaxed as possible when the acupuncture needles are in place it would be better if you **do not** bring young children into the treatment room with you. If you have to bring your children along, it would be helpful if you could also bring along a family member or friend to help look after them in the waiting area.

What will happen to me if I decide to take part?

First, a Research Midwife or Nurse will contact you over the **telephone** to talk to you about the study, and to answer any questions that you may have after reading this information leaflet. She will ask you about your general health, your pregnancy and your back pain to see if you are eligible to take part. The phone call should take approximately **15 minutes**.

Second, if you are eligible and are interested in taking part, you will be invited to a face to face meeting at the University Hospital of North Staffordshire. If you cannot

make it to the hospital, the Research Midwife or Nurse can visit you in your own home. The visit should take approximately **45 minutes**.

Because we are interested in knowing the sorts of questions that you might ask, and the sorts of concerns you might have, we would like to audio-record some of these meetings. If your meeting is going to be recorded you will be asked to agree to this before it starts. As with all parts of the research, you do not have to agree and if you decide you do not want the meeting recorded, you can still take part in the rest of the research. If you are happy for it to be recorded, you will be asked to sign a consent form.

At the face to face meeting the Research Midwife or Nurse will answer any questions you may have and will explain the study to you in detail. They will also be able to tell you more about each of the centres where treatment is offered, for example information about car parking and the availability of child friendly facilities. Please do not hesitate to ask about anything that is not clear. It is very important you fully understand what taking part in the study means. If you agree to take part you will be asked to sign a second consent form. Once you have agreed to take part, you will be asked to complete a questionnaire about you, your circumstances, your back pain and how it is affecting you. The Research Midwife or Nurse will also ask you to do two simple tasks so they can understand your back pain in more detail.

It is important to realise that the Research Midwife or Nurse **will not know** which treatment package you will get. The study treatment given to you will be chosen at random, which is done using a computer so it is purely by chance. This means that you will have an equal chance of getting any one of the treatment packages. If you are still happy to take part in the study after your visit, you will receive a letter in the post telling you which treatment package you are going to receive.

What else do I have to do?

Eight weeks after the meeting with the Research Midwife or Nurse, you will be sent another questionnaire by post. We would like you to complete the questionnaire and post it back to us (we pay the postage). The questionnaire should take approximately **20 minutes** to complete. A researcher may contact you by phone if we do not receive your completed questionnaire to find out how you are doing. We will also look at your maternity records after you have had your baby to collect information on your birth. **If you want to take part in the study but do not want us to look at your maternity records you are still able to do so – just let us know.**

Who will see the information collected from me?

All information that is collected about you will be kept strictly confidential. Research data will be sent from the Research Midwives and Research Nurses at the University Hospital of North Staffordshire to the research team at Keele University. This will include your name and address in order that research staff can stay in touch with you over the course of the study and send you the follow up questionnaire. These details will be sent securely and kept in locked filing cabinets or in password protected computer databases accessible only to essential research staff within the EASE BACK study team. All other information about you will have your name and address removed so that you cannot be recognised from it. If you agree, your GP will

be notified that you are taking part in this study. Again, just let us know if you do not want them informed.

What are the possible benefits of taking part?

We hope the treatment packages will help you, however this cannot be guaranteed. If you feel that your treatment has not worked, you are free to go back to your midwife or obstetrician to see what else they can offer you. The information that we get from this study may help us to treat pregnant women with back pain in the future.

What might be the risks?

Serious risks are extremely unlikely and the Research Midwife or Nurse will check that there is no reason why you should not receive any of the treatment packages before you are able to take part. In a previous study of acupuncture in pregnancy, there were no serious side effects for women, their babies or the birth. Minor side effects were common but women felt that acupuncture helped their back problems despite this. Overall, about 5% of women are expected to experience minor side effects with acupuncture. The most frequent side effects are:

- Momentary discomfort where the needles are inserted (happens in about 1 in 5 women)
- Drowsiness after treatment (happens in about 1 in 10 women)
- Nausea with feeling faint (happens in about 3 in 100 women)
- Headache (happens in about 2 in 100 women)

Other possible minor side effects include mild bruising where the needles are inserted and temporary worsening of your symptoms. There are no specific risks with usual care, other than the temporary soreness that can follow starting a new exercise programme.

What if something goes wrong?

If you are harmed whilst taking part in this research as a result of negligence on the part of a member of the study team, then you may have grounds for legal action against the NHS organisation which is hosting this research and to seek compensation via the NHS indemnity scheme, but you may have to pay for any legal costs. There are no arrangements to cover non-negligent harm. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism will be available to you.

Will you pay me any expenses?

We will provide you with £10 to cover any travel and car parking costs that you may have to pay for attending the research visit with the Research Midwife or Nurse.

What will happen to the results of the research study?

As well as helping with the development of a future larger trial in the NHS, the findings from this study will be published in medical journals and presented at conferences for healthcare professionals. You will not be identified in any reports or publications resulting from the study. The results will be made available for you to see on the study website once the study has been completed.

Who is organising and funding the research?

The research team is led by Professor Nadine Foster from the Primary Care Centre at Keele University and includes physiotherapists, midwives and obstetricians. The study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme, the UK's largest funder for NHS-based trials.

Who has reviewed the study?

To protect your interests, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given favourable opinion by the National Research Ethics Service Committee West Midlands - Staffordshire. The study has also been reviewed by scientific experts on behalf of the National Institute of Health Research (NIHR), who assessed it before awarding funding.

Who can I talk to if I have any questions?

You will have the chance to talk to the Research Midwife or Nurse both on the telephone and during your face to face meeting. However, if in the meantime you have any questions, or would like further information about this study, please contact the study co-ordinator Mel Holden on **01782 733921** during office hours.

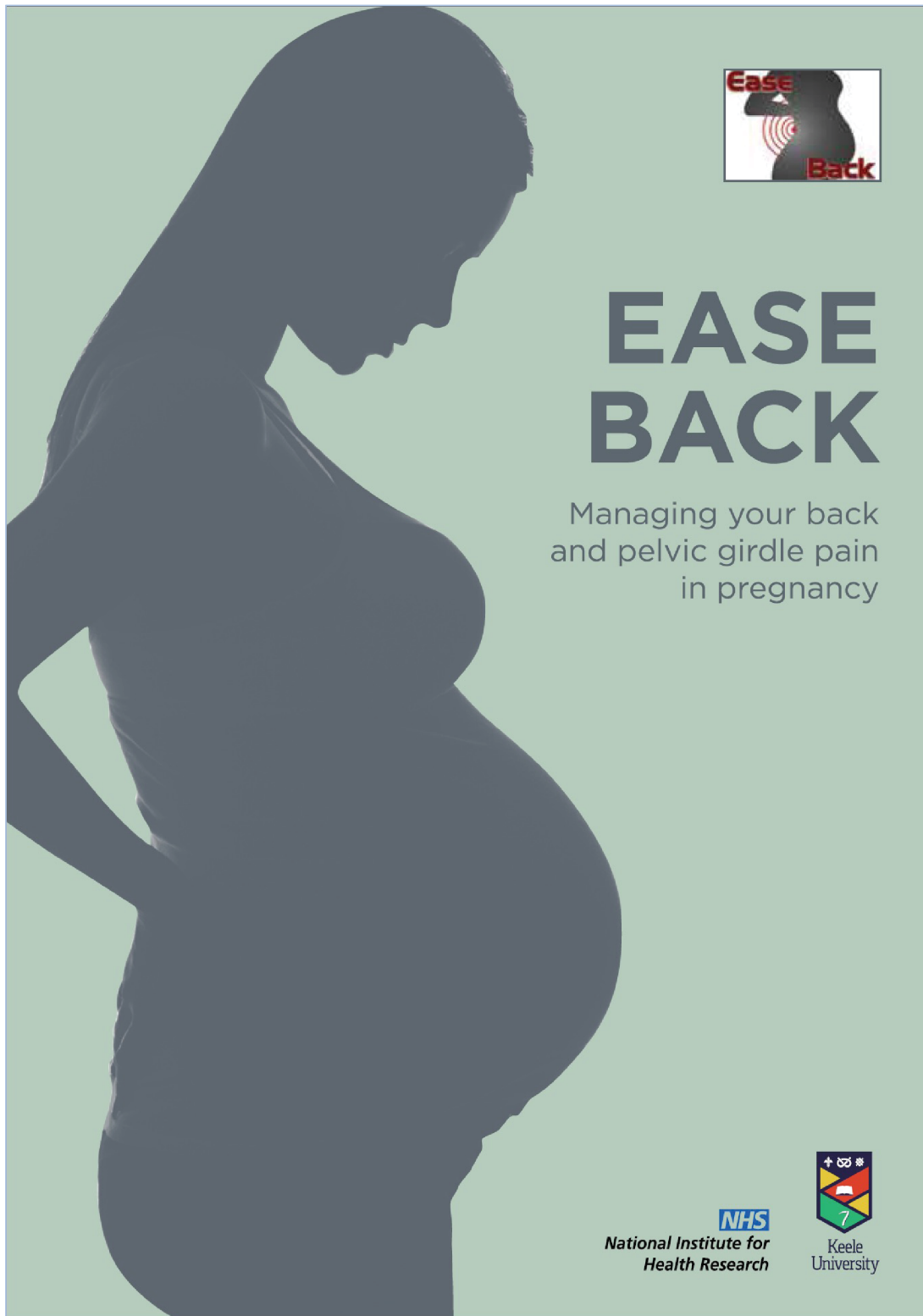
What if I need to speak to someone outside of the study team, about this study?

If you have any questions or concerns about taking part in this research you can also contact the Patient Advice and Liaison Service (PALS). The phone number for the PALS office at the University Hospital of North Staffordshire is 01782 676450. The phone number for the PALS office for the Staffordshire and Stoke-on-Trent Partnership NHS Trust is Free Phone 0800 783 2865.

Thank you for taking the time to read this information leaflet.

This project was funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (project number 10/69/05) and will be published in full in Health Technology Assessment*.

Appendix 5 Self-management booklet



EASE BACK

Managing your back and pelvic
girdle pain in pregnancy

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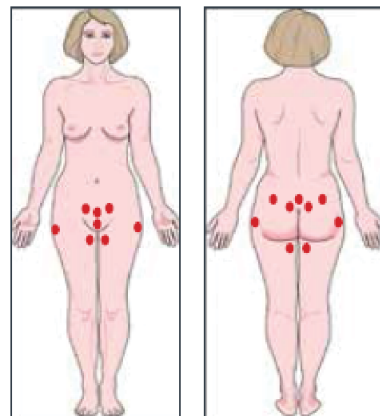
Introduction

During pregnancy there are many changes to your body. Some of these may cause you to experience pain or discomfort in your lower back, pelvis and legs. This booklet is designed to provide information and to advise you about ways to help manage your symptoms, to reduce the pain, prevent it from getting worse, maintain your day to day activities, and reduce the possibility of your pain continuing after your pregnancy.

Back pain and pelvic girdle pain in pregnancy

What is back and pelvic girdle pain?

This is pain in or around your back and pelvic region. You may experience pain in some or all of the areas shown in the diagram. It may be in your lower back, buttock(s), the outside of your hips, or in your groin or pubic area. You may have pain in one or both legs. Pain may be mild, moderate or severe.



Symptoms

You may experience:

- Back, pelvic or leg pain during normal activities of daily living
- Clicking or grinding in the back or pelvic area
- Pain or difficulty moving your legs apart, for example getting into a car or bath
- Difficulty and pain on walking
- Difficulty and pain standing on one leg, for example to climb stairs, or to get dressed
- Difficulty and pain turning over in bed
- Disturbed sleep
- Difficult and painful sexual intercourse

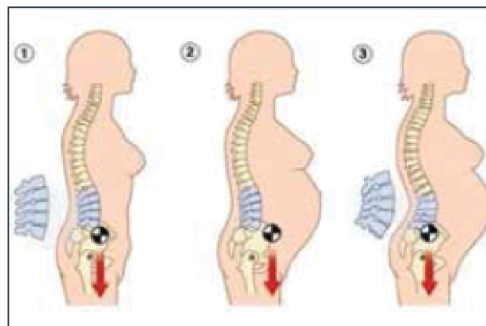
Why do I have this pain?

During pregnancy, hormones (relaxin and progesterone) are released which affect your soft tissues (muscles and ligaments). They work to soften the muscles and ligaments around your back and pelvis in order to prepare your body for pregnancy and labour. These hormones allow your ligaments to stretch more than normal and can cause the joints in your back and pelvis to move more than they would normally. The muscles and ligaments can become overstretched and weak, which then leads to pain.

Changes occur in the muscles of your stomach, pelvic floor and pelvis which can lead to your back and pelvis not being supported properly. Your tummy muscles soften and lengthen as your baby grows. This can make them less effective in supporting your back and pelvis. There could be an imbalance in your muscles, with some working too hard and becoming tight and painful, and others becoming weak.

As your pregnancy progresses both your posture and balance change which can affect how your muscles and joints move. This may cause pain during your everyday activities. Sometimes there may be uneven movement in your back and pelvic joints. This could have been present before your pregnancy and is exaggerated now because of the changes to your body. This could also happen in pregnancy as a result of you having poor posture, poor ways of moving, or doing repetitive movements.

Your body adjusts to the weight gain during pregnancy by changing your posture and the way you stand. This can result in increased strain through your back and pelvis, as shown below. Sometimes the position of the baby can alter your posture which could cause pain. In addition, the hormones released make you feel more tired, which puts extra strain on your body.



1. **NEUTRAL** spine, with body weight through pelvis
2. As baby bump grows, body weight is pulled forward
3. The lower curve of the spine can become exaggerated to accommodate the weight of the bump, putting increased strain on the back

How common is it?

Back pain is very common in pregnancy, and is experienced by up to 2 out of every 3 women. The pain usually starts around the 18th week of pregnancy although it can start earlier, and is often worse at night. It can mean that you have some restriction in your movement. Your ability to sit, stand, or walk for long periods of time may also be affected. This is a normal part of pregnancy. However, it is not normal to have pain which stops you doing your daily activities. The pain is rarely due to a serious problem that requires further tests or investigations. However, severe back pain that is accompanied by vaginal bleeding or discharge could indicate an underlying problem that needs prompt attention. If this applies to you, you should contact your midwife or GP right away.

What should I expect over the course of the rest of my pregnancy?

You may find that your back pain and pelvic pain remains the same, improves or worsens as your pregnancy progresses. You may get emotional because of the pain. Do not suffer in silence. Let your family, friends, midwife, and doctor know about it, as it is better to seek help and advice than not. We hope you will find the information in this booklet helps you to manage and reduce your pain.

The majority of women with back or pelvic girdle pain can have a vaginal delivery. Many women worry that their back or pelvic pain will increase during labour but this is not usually the case. There are alternate birthing positions which will help to reduce the stress on your back and pelvis; these are discussed later, on page 24.

Your back pain or pelvic pain should reduce or go completely after delivery. The vast majority of women find that their pain disappears by 3 to 6 months after the birth of their baby.

What will help my back and pelvic pain?

Many women can manage their pain through pregnancy with the right information about good self-management, particularly postural changes and simple exercises. These are explained in the following sections and include:

- Posture during pregnancy
- Physical activity during pregnancy
- Exercises
- Advice about the workplace
- Handy self-management hints and tips
- Advice for labour and after the birth

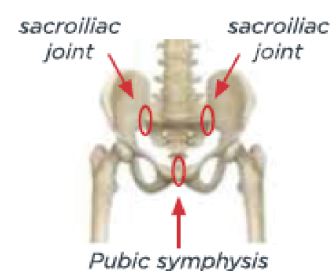
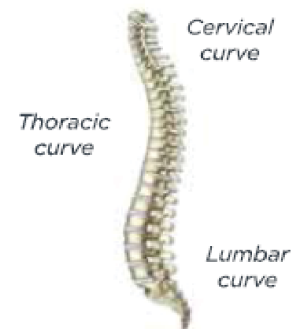
Posture during pregnancy

Maintaining good posture throughout your pregnancy is very important.

Structure of the back and pelvis

The spine is a double S shape. When it is in this position it puts the least stress on the structures in the spine – the nerves, discs, muscles, and ligaments. This ideal position is called the **NEUTRAL** position. Any alteration in posture from the **NEUTRAL** position will cause stress on the back and pelvis, which in turn can lead to pain.

The pelvis is made up of two large bones which form a basin-shape. The bones are joined by cartilage and ligaments at the back where they connect with the spine (the sacroiliac joints), and at the front (pubic symphysis). During late pregnancy hormones soften and relax these ligaments. This gives the pelvic bones the ability to stretch and open more easily for the birth of the baby.



Maintaining correct posture

Think about your posture – how you sit, stand and move – throughout your pregnancy, and use the following information to help reduce your pain.

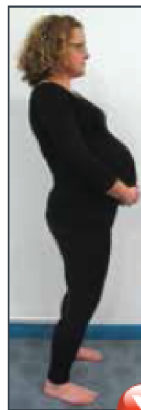
How should I stand?

- Stand with equal weight on both legs
- Keep your knees soft, not locked back
- Keep your head upright over your body, and keep your shoulders back and down
- Think tall and maintain a **NEUTRAL** spine

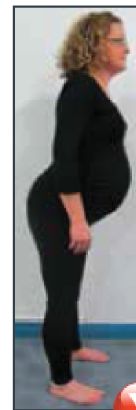
How should I NOT stand?



- Don't put most of your weight through one hip



- Don't swing your hips forward and lean your body backwards to try to 'balance' your bump



- Don't let your tummy bump tip you forward - it could over exaggerate the curve in your lower back

- Avoid standing on one leg to get dressed: sit down to put on underwear, trousers and shoes
- Try to change your position frequently: alternate between standing, sitting and walking

*The **NEUTRAL** position or S shaped curve of your spine is lost when you adopt poor postures. This can cause excess pressure on your back and pelvis, stretch your ligaments too much, and does not encourage your abdominal and bottom muscles to work.*

How should I walk?

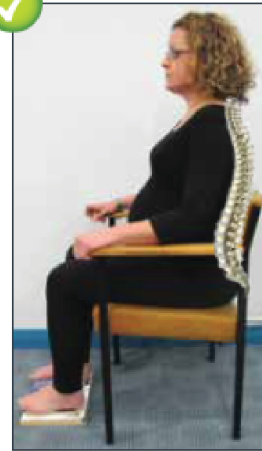
If you have pain during walking, take smaller strides. Try to walk evenly, spending an equal length of time on each leg. Take even size strides controlling any waddling. You may find you waddle more when you get tired. It may help if you slow down your walking pace. Try to avoid walking for long periods of time - pace yourself.

How should I go up and down the stairs?

Do stairs one at a time. If you have more pain on one side, then go up the stairs leading with your less painful side, and come down leading with your more painful side. Use the handrail if there is one. Try to avoid using the stairs frequently throughout the day. Try to bring everything that you need for the day downstairs at the same time to save you unnecessary stair climbing whilst you are in pain.

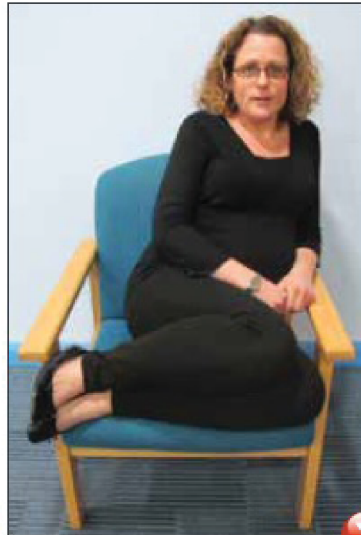
How should I sit?

- Sit on a firm chair preferably with 2 arms – avoid soft squidgy sofas which will make you adopt a poor posture
- Your bottom should be right at the back of the chair
- If you do sit on a deep sofa, put a few pillows behind you so your knee crease is 2 fingers' width out from the front edge of the sofa
- Ensure that your feet are firmly on the ground
- Your knees should be level with your hips – not higher or lower. You may need to put something under your feet, for example a box file, old biscuit tin, catalogue, or book
- Sit with equal weight on both buttocks
- Support your lumbar curve using a folded towel. Lumbar supports are available to buy, but unlike a towel, cannot be adapted for individual use
- It is usually best not to use a cushion to support your back, as they are often too big
- Maintain the spine **NEUTRAL** position (S shaped curve)
- Do not sit in one position for too long. Every 20-30 minutes check that you are still in that good position, or get up and move around
- Having a chair with arm supports makes it easier to stand up and sit down. If you do not have a suitable chair, try a garden chair (the green/white plastic stackable ones) with a slim cushion on the seat so there is no dip in the seat of the chair
- If you have any upper back, neck or shoulder pain, sit with pillows under your arms as shown in the picture



How should I NOT sit?

- Avoid leaning to one side. If you sit with your legs curled up, or lean on one arm at the side, the **NEUTRAL** position of your spine is lost, causing stress on your back and pelvis. This in turn will cause pain



- Avoid slouching. If you need to put your feet up, then lie down. If you sit with your feet up, you become slumped and lose the **NEUTRAL** position of your spine. This increases the pressure on your back and pelvis and can cause pain



Sitting in a poor posture puts a lot of stress on your back and pelvis. Sitting poorly during pregnancy adds even more stress to your back and pelvis.

How should I stand up from a chair?

- Maintain a **NEUTRAL** spine position throughout
- Follow the stages in the photographs below, one at a time
- Tighten your tummy, pelvic floor and buttock muscles
- Move your bottom to the front of the chair, using the arms of the chair to push yourself forward. Keep your spine in a **NEUTRAL** position with an S shaped curve. Imagine that the base of your spine, your tailbone, is pointing up and back. Do not tuck your bottom under
- Once at the front of the chair, check your tummy, bottom and pelvic floor muscles are tight
- Bend at the hip slightly, keeping the **NEUTRAL** spine position and stand up
- Push evenly through both arms and use the strong muscles in your legs: don't twist as you stand up
- In standing, keep your knees over your toes. Don't let your knees knock together
- Reverse this procedure to sit down



How should I lie?

If you get pain on your outer hip from lying on your side, it may help to place an extra duvet or sleeping bag on the bed to make it softer.



How should I sleep?

You need to sleep on a firm bed. Your mattress should support your weight and not sag, but there should also be some cushioning to the bony points of your shoulder and side of your hip.

Place pillows between your legs so your top leg is fully supported and parallel to the lower leg. Place a small cushion or folded towel under your bump to stop it pulling you forward and twisting your spine. You should avoid lying on your back for long periods of time whilst pregnant. It is not good for your back and pelvis due to stress on the ligaments from extra abdominal weight, and it can also cause you to become breathless or dizzy.

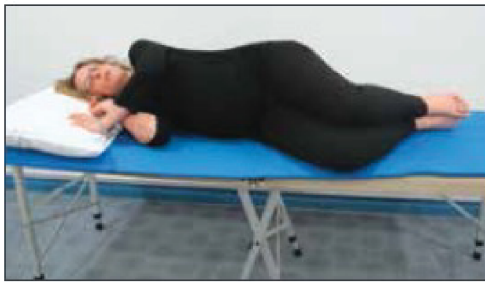
To turn over in bed, tighten your tummy muscles, buttocks and pelvic floor, and bend both knees up. Then turn your body and legs together in several stages. Avoid twisting your spine. You may benefit from using a silky nightshirt and silky bedding to help you to turn over more easily.

- Remember to keep your spine in a **NEUTRAL** position

Take care how you move and position yourself during the day as this will help to reduce your symptoms at night.

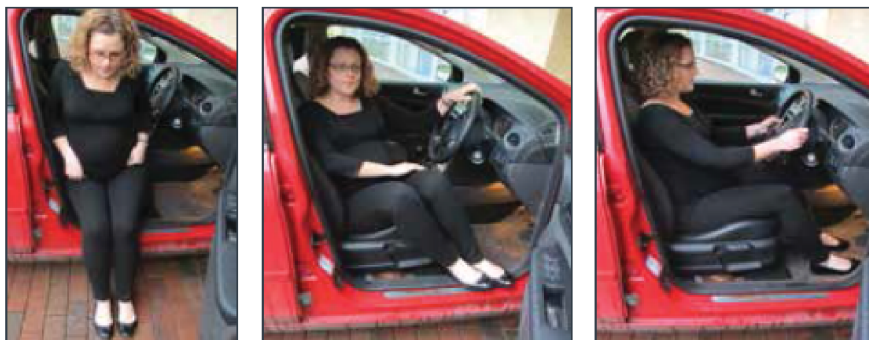
How should I get out of bed?

- Tighten your tummy muscles, pelvic floor and buttocks
- Bend both knees up
- Roll onto one side - move your shoulders, hips and knees at the same time, so you are not twisted. Keep your spine in a **NEUTRAL** position
- Tighten your tummy and pelvic floor muscles, and squeeze your buttocks together
- Keep your legs together
- Move your legs forward, and as they swing off the bed push through your hands and arms so you come into sitting without twisting your pelvis or back
- To get into bed, reverse this process
- You may find one side of the bed easier to get in and out of. If this is not the side you normally sleep on, consider swapping sides



How should I get into a car?

- Place 2 plastic bags on the car seat and move the seat right back to give you enough room
- Stand with your back to the open car door
- Tighten your tummy muscles, pelvic floor and buttocks maintaining a **NEUTRAL** spine
- Sit down with your bottom first into the car
- Swivel your bottom on the plastic bags and keeping your legs together; lift them round into the car. If this is painful, slowly walk your feet round in small steps into the car, limiting the distance that you open your legs
- Position yourself with your bottom right back in the car seat and your feet on the floor of the car foot-well
- Use a folded towel to keep the **NEUTRAL** spine position
- Remember to adopt the **NEUTRAL** spine sitting posture whether you are the driver or the passenger
- Remember to remove the plastic bags before driving
- You may be able to use the mother and children parking bays at supermarkets and large stores, which will give you extra room to get in and out of the car



How should I get in and out of the bath?

- If you have a shower cubicle use this rather than the bath
- If possible, have someone available to help you
- If using the bath, sit on the side of the bath and swing your legs over, keeping them together

- Lower yourself down into the bath using your arms
- To get out of the bath, roll onto your knees and push up with both arms
- Sit on the side of the bath and swing your legs over and out
- Boards which fit across the bath enabling you to sit and use the shower are available to purchase (for around £30 from large high street chemists). Speak to your midwife if you need further information
- Only have a bath when someone else is in the house in case you have any problems getting out

How should I lift?

If possible, try to avoid lifting. Ask for help. However, if you have to lift:

- Keep your back in a **NEUTRAL** position and bend your knees to kneel down
- Do not stoop to pick up an object
- Bring the load close to your body and tighten your tummy muscles, pelvic floor muscles and buttocks
- Use your thigh muscles to stand up





How should I lift children?

Rather than lifting, encourage your child to climb onto your knee whilst you are sitting in a chair. When bathing your child, kneel or squat next to the bath before lowering them in or taking them out. When putting your child into, or taking them out of the car stand close to the car, and bend your knees, keeping your back straight. Encourage older children to climb in themselves.

How should I carry objects?

There are many items we carry as part of our everyday activities. It is important to try and avoid carrying heavy items, and carrying for prolonged periods of time. The example given here is for carrying a handbag, an item that most women carry on a daily basis.

- Try to avoid heavy shoulder bags, as these make your posture uneven
- Keep the minimum possible in your bag and consider using a smaller sized bag 
- It is best to have a rucksack on your back (using both arm straps, not just one), or a bag that goes across your body 



If you have a toddler, try to avoid carrying them on one hip. Encourage your toddler to do as much as they can themselves, so you don't need to lift or carry them.

What type of footwear should I wear?

The effect of hormones in pregnancy and the additional weight can make your feet roll inwards, which can affect your back and pelvis. You will find it more comfortable to wear shoes which support your feet properly and are flat or low heeled. Avoid high heels, flimsy flip-flops, mules or slip-on shoes, and 'UGG-style' boots, as they do not give your feet the support they need whilst you are pregnant.

Physical activity during pregnancy

Shopping:

- Try to avoid carrying heavy loads
- Ensure that bags are carried evenly in both arms – carrying more on one side will cause your back and pelvis to twist
- When loading the boot of the car put the heaviest bags nearest to you to save you stretching
- Ask for help with shopping, or consider shopping online and getting shopping delivered
- Take regular breaks

Housework:

- Don't expect to be able to clean the whole house in one go like you may have managed before your pregnancy
- Sit down whenever possible – for example, at the kitchen table to prepare food
- Raise the height of your washing up bowl by placing a large saucepan upside down in the sink, and then place the bowl on top
- Consider kneeling rather than bending over for activities such as cleaning windows, emptying the washing machine and dish washer
- Ensure your ironing board is at waist level to avoid prolonged stooping, or sit down in a supported chair to do the ironing
- Try to avoid vacuuming as it puts pressure on your back and pelvis

Learn to pace yourself with your housework – do a little at a time and take frequent breaks

Which positions should I use for sexual intercourse?

Try positions which allow you to keep your legs closer together, such as lying on your side or kneeling on all fours. You might choose to be intimate at times of the day when you are not already tired. If you cannot find a comfortable position, you may wish to consider other ways to be intimate until your pain eases.

Exercise:

Regular physical activity can help keep your back muscles strong and can help to relieve pain. Certain activities are ideal for pregnant women, for example, walking and swimming. However it is best to avoid cycling. Exercising in water is great as the water supports your body weight. Your local pool may have antenatal water classes – remember if you have back or pelvic pain, avoid breast stroke legs, where your legs move wide apart.

Yoga and pilates can help you stretch and tone your muscles. Make sure your teacher is properly qualified and knows that you are pregnant. Work at your own pace. There may be antenatal yoga, pilates, or other antenatal exercise classes available locally. Contact your local leisure centre for more information.

Pregnancy is NOT the time to start a completely new exercise regime. If you were quite sporty and active before your pregnancy there is no need to give it up, although contact sports are best avoided. Check with your midwife if you have any concerns about exercising.

Exercises to relieve and prevent pain

Why is exercise important?

The exercises below are important as they will help maintain muscle strength, which in turn will help you preserve good posture. Try to do each exercise 10 times then rest. Repeat this 2 or 3 times. If any of the exercises aggravate your pain, reduce or stop doing them.

Muscles can become stretched and weakened during pregnancy, so it is important to exercise

Exercises to help strengthen your stability muscles

You have muscles that act like a 'corset' to support your back and pelvis. This exercise will help to strengthen them.

- Get onto all fours
- Breathe in, and as you breathe out, gently draw your tummy-button upwards towards your spine
- Do not arch your back
- Hold for 10 seconds (3 to 4 breaths), then release
- Repeat 2 to 3 times
- During this exercise, your back should not move; you should feel a tightening in your lower abdomen



Pelvic tilt:

- Stand against a wall with your back straight but relaxed, and legs hip width apart
- Put equal weight on both legs, with knees gently bent



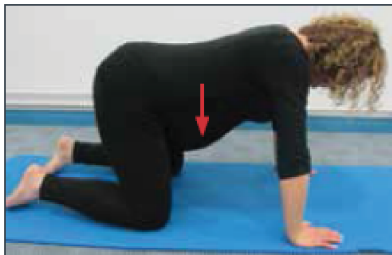
- Gently tilt your pelvis forwards



- Gently tilt your pelvis backwards so your back is flat against the wall and hold

- Do this 10 times then rest. Repeat 2 to 3 times

This exercise can also be done in sitting, on all fours, and in side lying. Choose the position that is most comfortable for you.

**Exercises for your pelvic floor muscles**

Your pelvic floor muscles act like a hammock to support your pelvis and the weight of your baby. These muscles also help to control your bladder and bowels. During pregnancy these muscles become weakened. The following exercises will help to strengthen your pelvic floor muscles.

- Tighten the muscles around your back passage, your vagina and front passage
- Lift up inside - imagine you are trying to stop passing wind and urine at the same time, and hold

- Do not hold your breath, squeeze your legs together, tighten your buttocks or hold your tummy in when you do these pelvic floor exercises

It is important to do two types of pelvic floor exercises: slow and fast.

- Slowly tighten your pelvic floor muscles, as above. Hold for 10 seconds, and then relax. Rest for 10 seconds. Repeat 10 times. If you cannot hold for 10 seconds, hold for as long as you can, making a note of how many seconds you can hold for. Then gradually build up to 10 seconds as you practice.
- Tighten your pelvic floor muscles quickly. Let go quickly and then re-tighten quickly. Repeat 10 times.

Repeat 2 to 3 sets of these exercises.

Exercises to strengthen your bottom, pelvis and hips

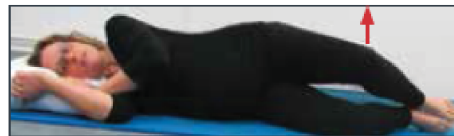
1. Static squeeze

- Stand with your legs straight and your arms by your sides
- Tighten your buttocks and hold for a count of 10, remembering to breath throughout
- This exercise can also be done in sitting or lying. Choose the position that is most comfortable for you
- Practice 2 to 3 sets of these exercises throughout the day



2. 'Clams' exercise

- Lie on one side, with your hips and knees bent
- Imagine you are lying against a wall, with your back and heels touching the wall

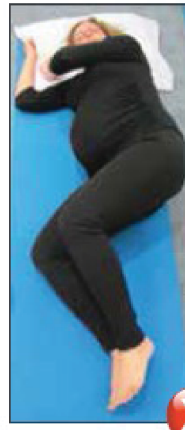


- Keeping your feet together, slowly lift the top knee, turning the hip out. Go only as far as is comfortable
- Do not roll forwards or backwards on your hip

- Hold, then return to the start position, controlling your leg as you lower it slowly
- Repeat 10 times. Rest, then repeat 2 to 3 times
- Turn over and repeat 10 times on the other side



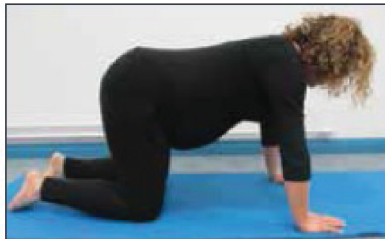
Maintain the **NEUTRAL** position throughout this exercise



Do not roll forwards or backwards on your hip, when lifting your knee

Exercise to gently stretch your lower back

- Start on all fours, with a slight gap between your knees, with your back in the **NEUTRAL** position
- Keeping your back flat, and your arms in front of you, slowly move backwards until your bottom is resting on your heels
- Keeping your bottom on your heels, lean into the stretch, and gently stretch your arms out in front of you, lowering your head and body towards the floor

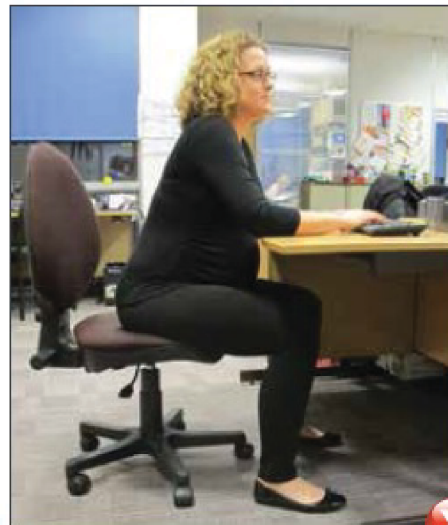
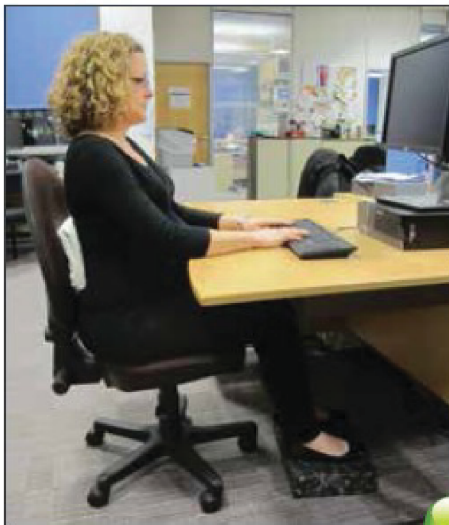


- The size of your bump may prevent you from getting your head and body near to the floor, but just stretch as far as is comfortable for you
- Hold for 20 seconds then return to the starting position. Repeat 2 to 3 times. Do this stretch several times a day

Advice about the workplace

- If your job involves a lot of sitting make sure you have an appropriate chair and you sit in a good posture as described in the section on posture (page 9)
- Check your posture regularly to ensure you are sitting correctly
- Stand up and move around regularly
- You may find a chair with arms is more supportive than one without
- Your feet should be flat on the floor or on a footrest (or you could use a box file or large book)
- Tuck your chair under your desk as far as possible
- The computer screen should be at eye level
- Ensure your mouse, telephone and any documents are within easy reach, so you do not have to twist or bend to reach them

If your job involves a lot of standing, walking or stair climbing talk to your employer to see if you can reduce the length of time you spend on your feet and have regular breaks.



Check with your employer - you may be able to have an occupational health work assessment done for your back pain whilst pregnant.

Handy self-management hints and tips

Drink plenty of water and eat a healthy diet: Try to avoid becoming constipated. The lower back muscles are easily strained when extra effort is needed. Ensure you eat plenty of fibre rich foods (fruit, vegetables and wholegrain), and try to drink 2 litres (3½ pints) of water a day.

Keep your feet moving: If you have swollen ankles or legs do not sit with feet up as it will make you slouch and aggravate your back or pelvic pain. Lie on your side instead. Keep your feet moving: bend your ankles forward and backward to try and help reduce the swelling. Support stockings may help. Ask your partner to massage your feet and legs regularly.

Try regular relaxation: It is hard work being pregnant, listen to your body and rest when you need to. Regular relaxation can help to reduce your pain. There are many different ways to relax. Some techniques concentrate on breathing, whilst others relax your whole body, relieving muscle tension caused by the stresses of everyday life during pregnancy. Yoga and pilates can help you to relax. There may be classes available locally. Contact your local leisure centre for more information.

Try heat and cold: If you have tight muscles or muscle spasms applying gentle heat or cold can help reduce the pain and discomfort. This can be done several times a day.

Before you apply heat or cold you should ensure you have normal sensation over the area and can tell if something hot or cold is touching the area.

You can use a hot water bottle or a wheat bag over your lower back, hips or buttocks. Applying heat will cause the area it comes into contact with to become red. This is normal, but ensure that the heat applied is not too hot. Do not lie or sit against a heat pack, or put it directly on your bump. Leave it in place for a maximum of 20 minutes.

Cold can be applied by using a wheat bag put in the freezer, or a bag of frozen peas wrapped up in a wet cloth. Do not apply cold directly to skin. Leave in place for a maximum of 20 minutes. Do not place directly on your bump.

Try massage: Ask your partner or a friend to massage the muscles which are tight or sore, ensuring that they do not press too hard. You could also use heat prior to this massage. You can use baby oil, almond oil or moisturising cream to massage with. Do not use aromatherapy oils.

Try medication for pain relief: If you feel you need to take painkillers, paracetamol is usually safe to take. However, before taking any medicine when you're pregnant, you should get advice from your midwife or GP. Paracetamol is the preferred choice to treat mild or moderate pain, and is used routinely during all stages of pregnancy for pain relief. There is no clear evidence that it has any harmful effects on the unborn baby. However, as with any medicine taken during pregnancy, use paracetamol at the lowest effective dose for the shortest possible time. If the recommended dose of paracetamol doesn't ease your symptoms speak to your midwife or GP.

Try equipment to help: Some women with back and pelvic pain find walking aids useful. This should be discussed with your midwife. Supportive underwear, pelvic supports and maternity belts are available and some women find them helpful. These are available on the internet and from larger high-street chemists and maternity shops. Cost typically ranges from £12 to £40. (Also see section on 'Useful websites' page 29).

Advice for labour and after the birth

If you have severe back or pelvic pain you can ask to be examined in a side lying or kneeling position during labour. The position you adopt in labour and to give birth is important. Try to think about which positions are comfortable for you beforehand. If possible, try to avoid delivering on your back with your legs wide apart or bent up in stirrups. There are other positions which will reduce the stress on your back and pelvis. Some examples are shown below.



1. High Kneeling



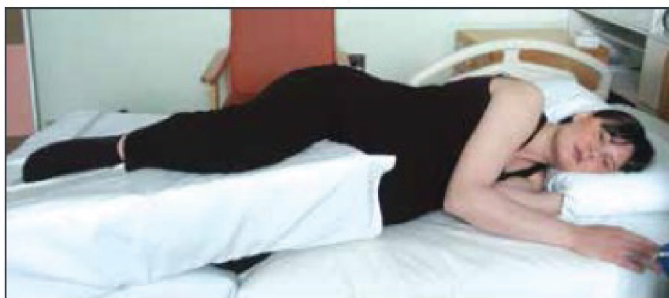
2. Ball Kneeling



3. Leg neutral



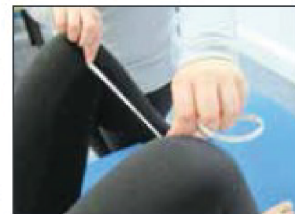
4. Standing forward leaning



5. Side lying with wedge

The positions you can use may vary depending on whether you give birth at the midwife birth centre or the consultant delivery suite. Ensure you regularly change position during labour. Make sure whoever is delivering the baby is aware of your history of back and pelvic pain. Your birth partner can support you in communicating this.

If you have pubic pain and it hurts to open your legs, it is worthwhile you measuring your 'pain free gap'. Whilst sitting or lying on your back with your knees bent, measure how far you can separate your legs without pain. You could use a piece of string or ribbon to do this then attach it to your maternity notes so you can give it to the midwife when you give birth. If you have an epidural ensure the midwife knows what your 'pain free gap' is, so she can try to avoid moving your legs beyond this.



If you need to have stitches after delivery, ensure the midwife knows you have had back and pelvic pain so they can move both your legs together.

Having back and pelvic pain is not a reason to have a caesarean section. Most women are able to have a vaginal delivery.

After the baby is born, most women find that their back and pelvic pain improves quickly. However you may continue to experience some pain while your body takes time to recover from the birth. Caring for a new baby can put strain on your back and pelvis, so it is important to continue following all the advice given for 3 to 6 months after the birth. If you continue to have symptoms after you have delivered, seek advice from your GP or midwife.

Feeding your baby:

- Whether you are breast or bottle feeding your baby, you will spend a lot of time in a sitting position
- Try to sit in a comfortable, but firm chair
- Make sure your back is well supported to maintain the **NEUTRAL** position
- Wedge a small towel in your lower back to keep your spine in the **NEUTRAL** position
- Use pillows to support your arms and your baby
- There are leaflets available from your midwife which explain good positioning in more detail

Changing nappies:

- Ensure you have everything you need to hand and close to you
- A small baby may be changed on your knee whilst you are sitting
- Avoid stooping - use a changing station, a cot top changer, or kneel at the side of the bed or sofa

Bathing your baby:

- Stand to bathe your baby. Use a changing station with integral baby bath, or use a washing up bowl in the sink
- If you are using the bath, kneel down at the side of it rather than bending over
- Ask for help from others, if this is available



Lifting and carrying:

- Try to avoid lifting and carrying where possible
- Carry your baby (and other objects) in front of you and close to your body – a baby sling may be helpful
- Try to avoid carrying your baby in the car seat – ideally put the seat on the pram if possible
- If you do need to carry the car seat, carry it in front of you with equal weight in both arms, not on your hip or using only one arm
- Ask for help from others, if this is available

Pram:

- If you have not already bought your pram think about getting one with an adjustable handle particularly if you and your partner are different heights
- If your pram has a shopping trolley underneath it, always bend down from the knees to load and unload it - do not bend from your back
- Do not stoop to put your baby in the pram – bend your knees and keep your back in a good position

Cot:

- Cots with drop down sides and an adjustable mattress height are best
- Avoid stooping over the side of the cot. Lower the side of the cot to lift or lower your baby

Handy summary

- **Ensure good posture at all times: sitting, standing, lying, moving. Keep your spine in a NEUTRAL position**
- **Find a chair that will support your good posture and use it instead of a low, soft sofa**
- **Avoid heavy lifting, bending or twisting your spine**
- **Exercise your pelvic floor and the muscles in your tummy, hips and bottom regularly**
- **Using techniques such as massage or a heat pack can be helpful**
- **Ask for help**

We hope that you have found the information in this booklet helpful, as you manage your back and pelvic pain. Note that posture and exercise can take several weeks to help, but keep following the advice given in this booklet.

If after trying the advice in this booklet you continue to experience a lot of pain which stops you from doing your usual activities, or you have any other concerns, please talk to your midwife about accessing further help.

Useful websites

National Childbirth Trust (NCT)

www.nct.org.uk

The National Childbirth Trust has evolved to support parents and parents-to-be through a nationwide network of local branches.

Pelvic partnership

www.pelvicpartnership.org.uk

The pelvic partnership offers support and information about pelvic girdle pain.

The Association of Chartered Physiotherapists in Women's Health (ACPWH)

www.acpwh.csp.org.uk

The ACPWH is a UK based professional network of the Chartered Society of Physiotherapy. The 'Publications and booklets' page has information relating to pelvic girdle pain for mothers-to-be and new mothers, as well as information on relaxation and pelvic floor exercises.

Homestart

www.home-start.org.uk

Home-Start is a national family support charity that helps parents to build better lives for their children.

The Guild of Pregnancy and Post-Natal Exercise Instructors

www.postnatalexercise.co.uk

This website provides lots of information about exercise in pregnancy and lists instructors who are trained by the Guild of Pregnancy and Postnatal Exercise.

Acknowledgements


We would like to thank the many physiotherapists who responded to the EASE BACK survey in 2012, providing different examples of information and advice leaflets they give to pregnant women with back and pelvic pain. This information has been invaluable in shaping the content of this self-management booklet.

We would also like to thank the women with experience of pregnancy related back pain, physiotherapists, and the exercise specialist who provided feedback on the draft version of this booklet. We would like to express particular thanks to Kris Wilkinson, Emily Mounsey, Heather Minors and Helen Myers for their assistance in producing this booklet.



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The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.



EASE BACK

Managing your back and pelvic girdle pain in pregnancy

Appendix 6 Training programme for research midwives and nurses



EASE BACK Trial Research midwife/ nurse training programme

Version 4
6th February 2013

This is a half day training programme for all Research Midwives and Nurses participating in the EASE BACK trial, plus a two hour refresher session immediately prior to commencing recruitment.

Enclosed is some pre-reading that if possible we would like you to read ahead of the training. These are as follows:

- Summary of the pilot trial, including recruitment targets
- Study flow diagram
- Participant information leaflet
- Inclusion / exclusion criteria
- Eligibility screening questionnaire

Please come in comfortable, practical clothing as there is a practical session.

Key to Session Leads:

NF – Nadine Foster
MH – Melanie Holden
AB – Annette Bishop
BB – Bernadette Bartlam
JY – Julie Young

Learning outcomes:

- To familiarise participants about the key results from EASE BACK phase 1 national survey and qualitative interviews, and in particular, how these findings have informed the plans for the EASE BACK pilot trial.
- To update participants about the rationale, design and purposes of the EASE BACK pilot trial.
- To familiarise participants about the planned processes for the EASE BACK pilot trial, including the identification of potentially eligible women, screening and eligibility checking, face to face research meetings, obtaining informed consent and randomisation.
- To increase participants' confidence in the objective testing of pelvic girdle pain.
- To familiarise participants with the planned processes for audio-recording a sample of the face to face research meetings and the practical use of audio-recording equipment.
- To review the paperwork supporting the above processes and agree auditing procedures.

The EASE BACK trial
Friday 15th February OR Friday 1st March 2013

Time	Content	Format	Lead
12.00-12.30	Registration and lunch (provided)		
12.30-12.35	Welcome and introductions Aims of the training	Lecture	NF
12.35-1.15	Rationale for the EASE BACK study including pilot RCT design and results of phase 1 studies	Lecture	NF, AB, BB
1.15-4.10 (with break, refreshments provided)	EASE BACK pilot RCT study flow and study procedures 1. Identification of women 2. Eligibility screening 3. Face to face research meeting <ul style="list-style-type: none"> - Checklist - Audio recordings of face to face research meetings - Informed consent - Baseline measures including objective tests of pelvic girdle pain - The randomisation process - Reimbursement of travel expenses 4. Medical record review	Lecture and practical	MH, JY, AB, BB
4.10-4.30	Agreement of audit procedures	Lecture	JY, MH
4.30-4.45	Update on timescales, final questions and close	Lecture	NF

Appendix 7 Training programme for physiotherapists



EASE BACK Trial Intervention training programme

**Draft 3
21st November 2012**

This is a three day training programme for all physiotherapists participating in the EASE BACK trial, and we will plan an additional half day refresher session.

All physiotherapists are being trained to deliver all three interventions:

- Intervention 1: Usual care (a postal self-management pack plus onward referral for one to one physiotherapy for women with the most severe problems)
- Intervention 2: Usual care plus a course of true acupuncture
- Intervention 3: Usual care plus a course of sham acupuncture

Please note:

There are pre-reading and pre-training tasks for each day – please see enclosed

Please come in comfortable, practical clothing as there are practical sessions on each day; you might like to bring shorts and T-shirts.

Key to Session Leads:

- NF – Nadine Foster
- PB – Panos Barlas
- HM – Heather Minors
- MH – Melanie Holden
- KI – Khaled Ismail
- AB – Annette Bishop
- BB – Bernadette Bartlam

Day 1: The EASE BACK trial and Usual care**Learning outcomes:**

- To update participants' knowledge about the prevalence and impact of pregnancy related back pain
- To explain the current uncertainty surrounding treatments for pregnancy related back pain, including acupuncture
- To describe the HTA funded EASE BACK trial and its rationale
- To update participants' knowledge about key changes in pregnancy and the explanations for back pain and pelvic pain in pregnancy
- To increase participants' confidence in the assessment of back pain with or without pelvic pain in pregnancy
- To update participants on the results of a recent national survey and interviews describing current practice and the use of acupuncture for this patient population
- To agree the protocol for the usual care arm of the EASE BACK trial
- To agree the delivery of the usual care treatment package

Pre-training task for Day 1:

- Have you treated any women with back pain in pregnancy? If so, reflect on what you did with them and make a note of this, to help with discussion on the day.
- Identify and list any concerns you have about assessing or treating women with pregnancy-related back pain
- Re-cap on any of your previous learning about postural assessment and types of posture

Pre-reading for Day 1:

- Pennick and Young 2008: Interventions for preventing and treating pelvic and back pain in pregnancy (review). Cochrane Collaboration Issue 4
- Perkins J et al 1998. Identification and management of pregnancy-related low back pain. *Journal of Nurse-Midwifery* 43(5): 331-340
- Katonis P et al 2011. Pregnancy-related low back pain. *Hippokratia* 2011;15: 205-210

Day 1: The EASE BACK trial and Usual Care
Monday 3rd December
Practical Room 1

Time	Content	Format	Lead
08.45-09.15	Registration – Practical Room 3		
9.15-9.30	Welcome and Introductions Aims of Day 1	Lecture	NF
9.30-10.30	Rationale for the EASE BACK study - prevalence, impact and risk factors of back pain in pregnancy - distinction between back pain and pelvic girdle pain - treatments and uncertainty about treatments - the pilot trial design, aims and outcomes - eligibility criteria in the trial - rationale for the sham acupuncture treatment - discussion	Lecture Discussion	NF
10.30-10.45	Coffee (provided) – Practical Room 3		
10.45-11.45	The body in pregnancy - Key changes to the body in pregnancy - Physical and hormonal changes explaining pain - Why women get back pain during pregnancy Discussion of pre-training task	Lecture Discussion	HM
11.45-12.45	Assessment of back pain during pregnancy	Lecture and Practical session with pregnant woman	HM
12.45-1.15	Lunch (provided) – Practical Room 3		
1.15-2.00	Results of EASE BACK phase 1 studies - The national survey of current practice - The interviews with professionals and women - Discussion		AB and BB
2.00-2.30	The EASE BACK usual care treatment package - Self-Management Pack - Onward referral to physiotherapy in EASE BACK trial		NF and HM
2.30-2.45	Coffee (provided) – Practical Room 3		
2.45-3.45	EASE BACK usual care: practical session - Reinforcement of messages in self-management pack - Additional physiotherapy support - Exercise programme, neutral posture, supportive belts and tubigrip - Patients expectations	Lecture and Practical session	HM
3.45-4.30	Working with trial 'protocols' Case report form Protocol for EASE BACK usual care package		MH, NF and HM

Day 2: Acupuncture interventions**Learning outcomes:**

- To introduce the role of acupuncture in pregnancy in general
- To describe the role of acupuncture for back pain in general
- To address the issues of risk and safety of acupuncture in pregnancy
- To increase participants' confidence in the use of both true and sham needling acupuncture for pregnancy related back pain

Pre-training task for Day 2:

- Identify and list any concerns you have about treating women with pregnancy-related back pain with acupuncture

Pre-reading suggestions for Day 2:

- Elden H, Ladfors L, Olsen MF, Ostgaard HC, Hagberg H. Effects of acupuncture and stabilising exercises as adjunct to standard treatment in pregnant women with pelvic girdle pain: randomised single blind controlled trial. *BMJ*. 2005 Apr 2;330(7494):761.
- Elden H, Ostgaard HC, Fagevik-Olsen M, Ladfors L, Hagberg H. Treatments of pelvic girdle pain in pregnant women: adverse effects of standard treatment, acupuncture and stabilising exercises on the pregnancy, mother, delivery and the fetus/neonate. *BMC Complement Altern Med*. 2008 Jun 26;8:34.
- Tables of acupuncture points for EASE BACK trial

Day 2: Acupuncture
Wednesday 12th December
Practical Room 1

Time	Content	Format	Lead
08.45-09.15	Registration – Practical Room 3		
9.15-9.20	Aims of Day 2		NF
9.20-10.30	The role of acupuncture in pregnancy in general The role of acupuncture for back pain in general Achieving needling sensation 'De Qi' The safety of acupuncture in pregnancy Discussion about safety of acupuncture	Lecture Lecture Discussion	PB
10.30-11.00	Coffee (provided) – Practical Room 3		
11.00-12.45	EASE BACK Protocols for Acupuncture - Identification and needling of the points - Including positioning - Practice	Lecture and Practical session with pregnant woman	PB
12.45-1.30	Lunch (provided) – Practical Room 3		
1.30-3.00	EASE BACK Protocol for Sham Acupuncture - Identification and needling of points - Sham acupuncture needling practice - Practice	Practical session with pregnant woman	<u>PB</u> /NF
3.00-3.15	Coffee (provided) – Practical Room 3		
3.15-4.00	Protocol for EASE BACK acupuncture arms - True acupuncture - semi-flexible protocol - Sham acupuncture – standardised protocol - Case report forms	Lecture	<u>PB</u> /NF/ MH

Day 3: Bringing it all together (combining usual care and acupuncture)**Learning outcomes:**

- To agree EASE BACK treatment for 3 real case examples of pregnant women with back pain, with and without pelvic girdle pain
- To increase participants' confidence in combining usual care and acupuncture for pregnancy related back pain
- To describe the EASE BACK trial processes of how women will be identified and recruited and consented in the trial, and how treatment will then be organised
- To provide the opportunities for questions and answers about pregnancy and back pain treatment from an expert acupuncturist, a womens health specialist and a consultant obstetrician

Day 3: Bringing it all together
Friday 14th December
Practical Room 1

Time	Content	Format	Lead
08.45 – 9.15	Registration - Practical Room 3		
9.15-9.20	Aims of Day 3		NF
9.20-10.45	Case examples And agreeing EASE BACK treatment, for those randomised to usual care and to usual care plus acupuncture <ul style="list-style-type: none"> - Back pain in pregnancy - Back pain and posterior pelvic girdle pain - Back pain and symphysis pubis pain 	Small group work <ul style="list-style-type: none"> - Working in pairs to discuss treatment plan 	HM, PB
10.45-11.00	Coffee break – Practical Room 3		
11.00-12.00	<ul style="list-style-type: none"> - Presentations from each small group on treatment of case examples 	Small group feedback and discussion <ul style="list-style-type: none"> - With pregnant model 	HM, PB, KI
12.00-12.30	Questions and answers session with obstetrician		KI
12.30-1.15	Lunch (provided) – Practical Room 3		
1.15-2.30	Trial issues <ul style="list-style-type: none"> - Review of plans for EASE BACK pilot trial - From consent to treatment, treatment sites - Treatment protocols - DNAs, UTAs - Case report forms and audit - Mentorship arrangements (with PB and HM) - Blinding and the sham acupuncture - Adverse events and reporting 	Lecture and discussions	MH with NF, PB and HM
2.30-3.00	Training feedback Completion of personal proforma Plans for refresher session(s) – dates to be arranged	Lecture and discussions	MH with all tutors

Appendix 8 Correspondence with Research Ethics Committee

Professor Nadine Foster
Chief Investigator
Arthritis Research UK Primary Care Centre
Primary Care Sciences,
Keele University,
Staffordshire, ST5 5BG

F.A.O Dr Kathryn Kinmond
West Midlands – Staffordshire REC
Barlow House 3rd Floor
4 Minshull Street
Manchester, M1 3DZ

25th January 2013

Dear Chair,

Ethics application:- **The EASE BACK study: Pilot Randomised Controlled Trial**

REC Reference Number:- **13/WM/0021**

Please find below our responses to your requests for further information following ethical review of the above study at the meeting held on the 9th January 2013. Based on the feedback we received from ethics, we have also included a revised participant information leaflet, pilot trial consent form, advertisement materials, study protocol and study flow chart for your review. In addition we have also included a letter that we would like to send to women participating in the pilot trial and randomised to receive usual care plus acupuncture if the physiotherapy service is unable to contact them over the telephone to arrange an initial appointment.

Summary of included documentation for review

- Participant information leaflet for pilot RCT, v2.0, 24/1/13
- Pilot trial consent form, v2.0, 24/1/13
- Advertisement materials (EASE BACK study card, flyers/ posters, v2.0, 24/1/13)
- Study protocol, v2.0, 24/1/13
- Study flow chart, v2.0, 24/1/13
- Letter if physiotherapy service unable to contact woman, v1.0, 24/1/13

Responses to your requests for information are as follows:

1. Follow-up reminders

The Committee have asked for a maximum of two reminders to participants to return the follow-up questionnaire. At the meeting we clarified with the Committee that the procedure for reminders that was included in the original protocol was in line with the Keele University Clinical Trial Unit's Standard Operating Procedures, developed through experience with multiple previous randomised trials. We also stressed the importance of high follow-up rates in randomised trials, in order to ensure a robust and trustworthy analysis. We have gathered examples of the reminder processes that we have recently used within trials approved under the NRES system and their response rates (where available), and would like to share them with you as follows:

SWAP trial (REC ref: 12/WM/0020), n=360 (recruitment currently ongoing), approval granted for 4 reminders following initial questionnaire

- Questionnaire
- Reminder postcard at 2 weeks if no response
- Reminder questionnaire at 4 weeks if no response
- Postal brief questionnaire at 6 weeks if no response
- Minimal data collection via telephone at 8 weeks if no response

PhysioDirect trial (REC ref: 08/H0102/95), n=2250 randomised patients, total response rate at 6 weeks following 3 reminders after initial questionnaire = 89%

- Response to questionnaire (without reminders): 40%
- Response after first reminder + questionnaire: a further 22%
- Response after second reminder + questionnaire: a further 9%
- Response to minimum data collection via telephone: a further 18%

SMOOTH trial (REC ref: 07/H1008/235), n=257 randomised patients, total response rate at 3 months following 3 reminders after initial questionnaire = 88%

- Response to questionnaire (without reminders): 49%
- Response after reminder postcard at 2 weeks: a further 22%
- Response after second questionnaire (at 4 weeks): a further 15%
- Response to minimum data collection (at 6 weeks): a further 2%

STarTBack trial (REC ref: 07/Q2604/5), n=851 randomised patients, total response rate at 4 months following 3 reminders after initial questionnaire = 81%

- Response to questionnaire (without reminders): 32%
- Response after reminder postcard at 2 weeks: a further 25%
- Response after second questionnaire (at 4 weeks): a further 16%
- Response to minimum data collection (at 6 weeks): a further 8%

APEX trial (REC ref: 02/07/114), n=352 randomised patients, total response rate at 6 weeks following 3 reminders after initial questionnaire = 95%

- Response to questionnaire (without reminders): 52%
- Response after first reminder + questionnaire at 2 weeks: a further 31%
- Response after second reminder + questionnaire (at 4 weeks): a further 7%
- Response to minimum data collection (at 6 weeks): a further 5%

From the above, it is clear that the reminder process is critically important to achieving high response rates in randomised trials, and we would ideally prefer to continue to follow our usual processes, in order to achieve more than 80% response at the follow-up time point in the EASE BACK pilot trial. Women will have provided their consent to this study as part of a face-to-face informed consent process, where the reminder process can be explained, and the need to provide follow-up data can be made clear, so women will be aware of the importance of providing follow-up information. Given evidence from the above examples, combined with the feedback from the ethics committee, we propose that removing one planned reminder from the EASE BACK trial process (the minimum data questionnaire) will deliver the level of follow-up rates needed for the study in a way that has proven to be acceptable to participants in previous recent trials approved under the NRES system, and takes into account the concerns to achieve an acceptable level of burden to participants in this trial. Our revised plan would therefore be to carry out the following:

EASE BACK pilot trial, n=180 randomised patients, aiming for a total response rate at 8 weeks of 80% or more

- The 8 week questionnaire
- A reminder postcard at 2 weeks if no response

- A second questionnaire at 4 weeks if no response
- Minimum brief data collection via telephone at 6 weeks if no response

In order to reflect this change we have modified the study protocol and study flow chart, and enclose the updated versions of these documents for your review.

2. Health economics should be added to the secondary research objectives

Within the study protocol the study objectives are listed in section 3.2, on page 15:

- Test the trial procedures, training programme for health care professionals, interventions and outcomes with 180 women with pregnancy-related back pain.
- Provide data on likely recruitment and follow-up rates for the main trial plus completion rates on key outcomes and an estimate of likely effect size difference between the intervention (usual care plus acupuncture) and control (usual care) arms.

The health economic outcomes are encompassed in each of the above objectives, along with all the other outcome measures being used in the study. Specific detail about the health economic data that is being collected is provided in full within section 3.11.4 (page 26) of the protocol.

3. Specific consent for the collection of socio-economic data should be included in the consent form.

This has now been included in the consent form, and more information about this has also been included within the participant information leaflet (revised versions included for your review).

4. Appendix 2 should be removed from study documentation.

This has been removed.

5. The wording “we may be able to help” on the study advertisement is coercive and should be removed.

The wording has been changed and the revised versions included for your review.

6. Collecting women’s full date of birth means women are more identifiable. Is the full date of birth needed?

To allow us to check for duplicates within the study (i.e. to ensure that we do not contact the same woman more than once) we do need every women’s full date of birth. However, we do have clear policies and procedures in place for use of personal data, and how to ensure the confidentiality of such data, which are outlined in our responses to questions A36 and A38 of the REC form.

7. Change the wording on the participant information leaflet under ‘what if something goes wrong’.

The wording has been changed and the revised version is included for your review.

Should you require any further information, please do not hesitate to contact me, on telephone number 01782 734705, or Melanie Holden, the EASE BACK study co-ordinator on telephone number 01782 734720. I look forward to hearing from you in due course.

Yours sincerely,

Professor Nadine Foster
Chief Investigator
Tel: 01782 734705
Email: n.foster@keele.ac.uk



Health Research Authority

National Research Ethics Service

NRES Committee West Midlands - Staffordshire

HRA NRES Centre Manchester
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7835

20 February 2013

Professor Nadine Foster
Professor of Musculoskeletal Health in Primary Care
Keele University
Arthritis Research UK Primary Care Centre
Keele, Staffordshire
ST5 5BG

Dear Professor Foster,

Study Title: Evaluating acupuncture and standard care for pregnant women with back pain (EASE BACK). Pilot randomised controlled trial.
REC reference number: 13/WM/0021

Thank you for your email of 04 February 2013, responding to the Committee's request for further information on the above research.

The further information has been considered at the Full-Committee meeting of the REC on 13 February 2013.

Following is the committee's discussion and decision:

The Committee discussed your request to send participants three reminders instead of two, taking into account that most of the women would not have given birth yet at that point. The Committee agreed that two reminders are already above and beyond what is normally acceptable. Stress levels are generally higher in pregnant women and it is irrelevant whether they are post-natal or pre-natal. The Committee understands the procedure but the decision remains the same and it is final. Therefore, confirmation is required that only two reminders will be sent to participants and any relevant study documents should be amended accordingly.

Any further revised document submitted should be given a revised version number and date.

The 60 day clock for issue of a final ethical opinion on this application will re-start when the Committee has received a response on the outstanding points.

13/WM/0021	Please quote this number on all correspondence
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Yours sincerely



Signed on behalf of:
Mr Victor Scofield
Committee Alternate Vice-Chair

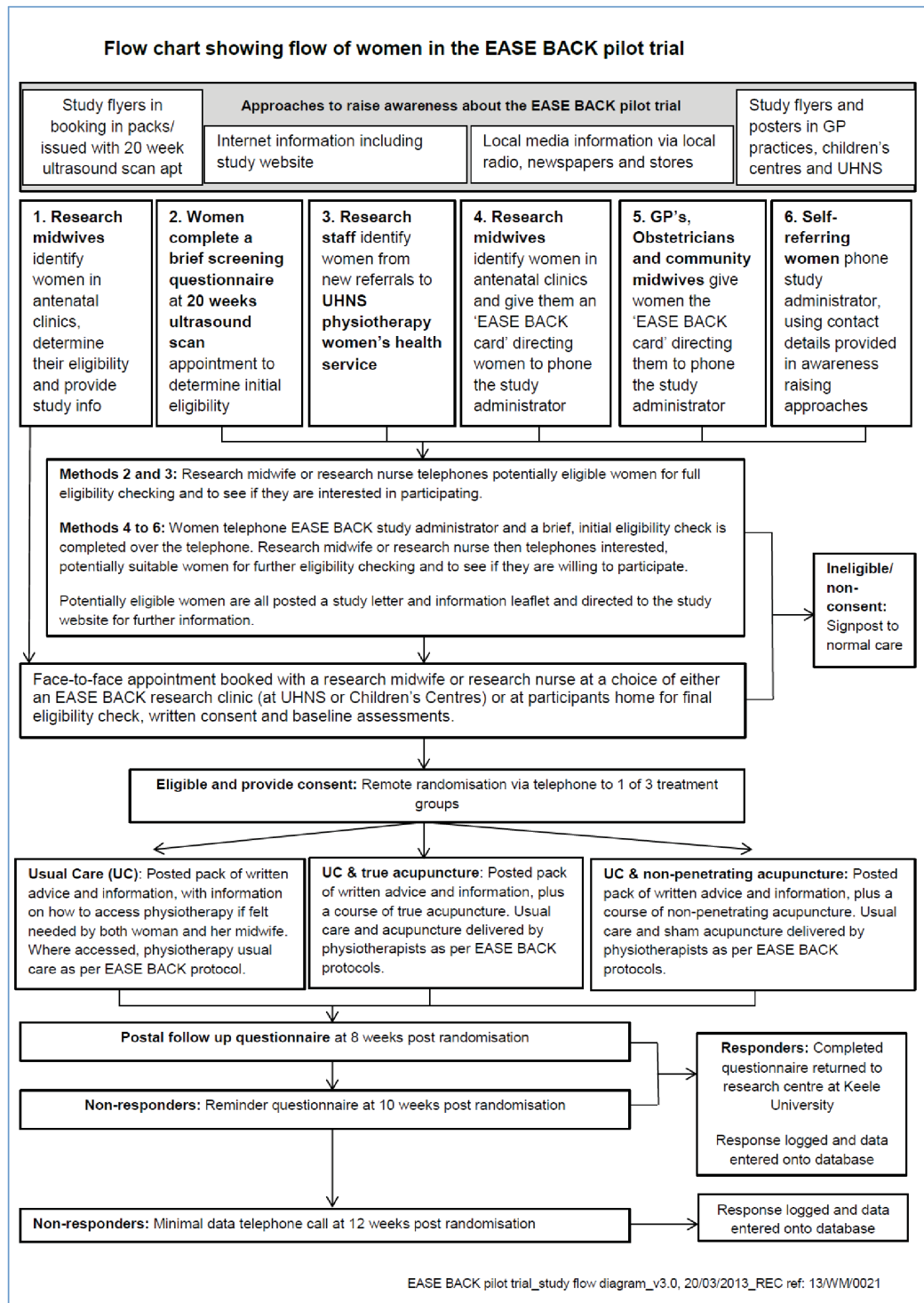
Email: nrescommittee.westmidlands-staffordshire@nhs.net

Copy to: *Ms Jackie Gray*




Ms Pamela Devall, Staffordshire Cluster of PCTs

A Research Ethics Committee established by the Health Research Authority

Appendix 9 Participant recruitment methods and flow



Appendix 10 Baseline questionnaire



Baseline Questionnaire

- When completing this questionnaire, please try to be as accurate and honest as you can throughout.
- There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think most people will answer.
- If you have any questions, you will be able to discuss these with the Research Midwife/ Nurse during your visit.
- Please hand your completed questionnaire back to the Research Midwife/ Nurse.

Thank you very much for your help with this research study

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

INSTRUCTIONS FOR THIS QUESTIONNAIRE

It is important to answer **all** the questions, even if you feel that they do not apply to you. Some questions may look like others, but they tell us different things, so all are important to answer. Some of the questions are arranged in sections according to the period of time that they ask about.

Many of the questions are about your pain. Some questions are about work, and others are about you and your general health. Please take the time to read and answer each question carefully.

Most of the questions can be answered by putting a **cross** in a box next to or under your answer. For example, if you wish to answer 'Not at all', **cross** the box like this:

Not at all	Slightly	Moderately	Very much	Extremely
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Here is an example of how to answer a question if you **don't** have any pain:

No pain											Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Now please continue and fill in this questionnaire

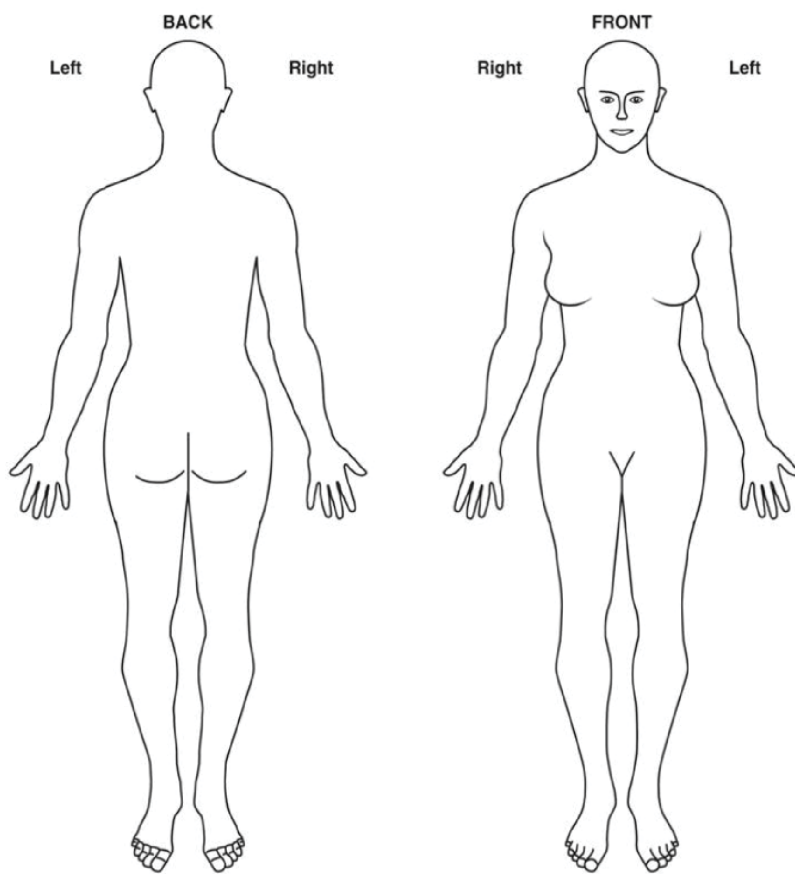
EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Section A – Your back problem

The following question is about **recent pain** you may have had in **any part of your body**; it does not only refer to your back problem.

1. Please *shade in the diagram* below any pain that has lasted for **one day or longer** in the **last 4 weeks**. By pain we also mean ache, discomfort or stiffness. Please **do not** include pain due to feverish illness such as flu.

If you have **not had any body pain** that has lasted for one day or longer in the last **4 weeks**, please put a cross in this box.....



EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Some people with pain in their muscles or joints tell us that they have **distinct bouts or episodes** of pain, with periods in between when they have no pain. For the first question we would like you to think about your **most recent bout or episode** of **back pain**.

You **do not** need to be exact, please cross the **one** box nearest to your answer.

2. Have you had this current bout / episode of **back pain** for...

Less than 2 weeks	2 to 6 weeks	6 to 12 weeks	3 to 6 months	7 to 12 months	More than 12 months
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. In the **last 2 weeks**, on **average**, how intense was your **usual** back pain rated on a 0–10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

(Please cross **one** box only)

No pain											Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. In the **last 2 weeks**, how intense was your **least** painful back pain rated on a 0–10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

(Please cross **one** box only)

No pain											Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. In the **last 2 weeks**, on **average**, how intense was your back pain **just before going to bed at night**, rated on a 0–10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

(Please cross **one** box only)

No pain											Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

6. During the **last 2 weeks**, how often has your back pain prevented you from falling asleep?
(Please cross **one** box only)

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. During the **last 2 weeks**, how often has your back pain woken you up at night?
(Please cross **one** box only)

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. How would you rate your **pain** on a 0-10 scale **at the present time**, that is, **right now**, where 0 is 'no pain' and 10 is 'pain as bad as could be'?
(Please cross **one** box only)

No pain										Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. The following questions have been designed to give us information as to how your **back pain** is affecting your ability to manage in everyday life. Please answer by crossing **one box in each section** for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply, but please just put a cross in the **one box** that indicates the statement which **most closely describes your problem**.

Section 1: Pain Intensity

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Please continue to answer the questions by putting a cross in the **one box** that indicates the statement which most clearly describes your problem.

Section 2: Personal Care (e.g. washing, dressing)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but can manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting

- Not applicable
- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives me extra pain
- Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed (e.g. on a table)
- Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- I can only lift very light weights
- I cannot lift or carry anything

Section 4: Walking

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1 mile
- Pain prevents me from walking more than ½ mile
- Pain prevents me from walking more than 100 yards
- I can only walk using a stick or crutches
- I am in bed most of the time

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Please continue to answer the questions by putting a cross in the **one box** that indicates the statement which most clearly describes your problem.

Section 5: Sitting

- I can sit in any chair as long as I like
- I can only sit in my favorite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

Section 6: Standing

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 30 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

Section 7: Sleeping

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Please continue to answer the questions by putting a cross in the **one box** that indicates the statement which most clearly describes your problem.

Section 8: Sex Life

- Not applicable
- My sex life is normal and causes no extra pain
- My sex life is normal but causes some extra pain
- My sex life is nearly normal but is very painful
- My sex life is severely restricted by pain
- My sex life is nearly absent because of pain
- Pain prevents any sex life at all

Section 9: Social Life

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

Section 10: Travelling

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

For the following questions, please tell us to **what extent you find it problematic** to carry out the activities listed below **because of your back pain**.

For each activity, please **cross one box** that best describes how you are today.

How **problematic** it is for you, because of your back pain to:

	Not at all problematic	To a small extent	To some extent	To a large extent	Not applicable
10. Dress yourself.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Stand for less than 10 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Stand for more than 60 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Bend down.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Sit for less than 10 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Sit for more than 60 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Walk for less than 10 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Walk for more than 60 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Climb stairs.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Do housework.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Carry light objects.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Carry heavy objects.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Get up/ sit down.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Push a shopping trolley.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Run.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Carry out sporting activities.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Lie down.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Roll over in bed.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Have a normal sex life.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Push something with one foot.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Please answer the following questions by putting a cross in **one** box.

30. How much back pain do you experience:

	None	Some	Moderate	Considerable
a. In the morning.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. In the evening.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

31. To what extent because of your back pain:

	Not at all	To a small extent	To some extent	To a large extent
a. Has your leg/ legs given way?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Do you do things more slowly?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Is your sleep interrupted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B - Your general health

In the following section we are asking for your views about your general health.

For the following questions, please **cross one box on each line** that best describes your answer. Remember to think about your **general health at present**.

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

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

2. The following questions are about **activities** you might do **during a typical day**. Does your **health now limit you** in these activities? If so, **how much**?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Moderate activities , such as moving a table, pushing a vacuum, bowling or playing golf.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Climbing several flights of stairs.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. During the **last week**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your **physical health**?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Accomplished less than you would like.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Were limited in the kind of work or other activities.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Accomplished less than you would like.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Did work or activities less carefully than usual.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Remember to think about your **general health at present**.

The following questions relate to your general health in **the last week**.

5. During the **last week** how much did **pain** interfere with your normal work (including work both outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

These questions are about how you feel and how things have been with you during the **last week**. For each question, please give the one answer that comes closest to the way you have been **feeling**.

6. How much time during the last week:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Have you felt downhearted and depressed?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. During the **last week**, how much of the time has your physical health or emotional problems interfered with your **social activities** (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

The following questions relate to your general health in **today**. Under each heading, please put a cross in the one box that best describes your health **today**.

8. MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

9. SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

10. USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Under the following heading please remember to put a cross in the one box that best describes your health **today**.

11. PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

12. ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

Please continue and answer all of the questions on page 15.

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Section C - About you

1. What is your **date of birth**?

				1	9		
--	--	--	--	---	---	--	--

2. What is your highest qualification? (Please cross one box)

-O-level, CSE, GCSE or equivalent
-A-level, BTEC, HNC or equivalent
-Degree or postgraduate qualification
-Other work related or vocational qualification e.g. City & Guilds, NVQs, technical apprenticeships, teaching or nursing qualifications
- Please specify.....
-Other qualification
- Please specify.....
-No qualifications

3. What is your current marital status? (*please put a cross in one box only*)

- | | | | |
|----------------|--------------------------|-----------------|--------------------------|
| Married..... | <input type="checkbox"/> | Widowed..... | <input type="checkbox"/> |
| Separated..... | <input type="checkbox"/> | Cohabiting..... | <input type="checkbox"/> |
| Divorced..... | <input type="checkbox"/> | Single..... | <input type="checkbox"/> |

4. Do you live alone?

- | | | | |
|----------|--------------------------|---------|--------------------------|
| Yes..... | <input type="checkbox"/> | No..... | <input type="checkbox"/> |
|----------|--------------------------|---------|--------------------------|

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

5. How many children do you have? children

6. Including this pregnancy, how many times have you been pregnant ?

Times

7. What is your height?

feet inches **OR** cms

8. What is your current weight?

stones lbs **OR** kgs

9. What was your weight immediately before this pregnancy?

stones lbs **OR** kgs

10. What is your current or most recent paid job title?

.....

11. How would you rate the physical demands of your current or most recent paid job?
(Please cross **one** box)

- Light
- Moderate
- Heavy
- Very heavy
- Not applicable

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12. Which of the following best describes your **current** situation (we realise that you may currently be on maternity leave)? (*Please cross **one** box*)

- Working full-time in a paid job.....
- Working part-time in a paid job.....
- Employed but currently off sick due to back pain.....
- Employed but currently off sick due to other health reason ...
- Employed but currently on maternity leave.....

*Please continue with **question 13***

- Housewife/ stay at home mum.....
- Unemployed due to back pain.....
- Unemployed for other health reason.....
- Unemployed for other reason.....
- Student.....
- Other (*please specify*).....
-

*Please continue with **section D, on page 19***

13. Have you **taken time off work since the start of your pregnancy** because of your back pain? (*Please put a cross in **one** box only*)

Yes.....

No.....

If **yes**, please write the **total number** of days, weeks or months you were off work due to your back pain **since the start of your pregnancy**.

Days

Weeks

Months

*Please only enter a number in **one** of these boxes*

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

14. On average, to what extent has your back pain affected your **performance at work** since your pain started? *(Please put a cross in **one** box only)*

	Not at all										The pain is so bad that I am unable to do my job
	0	1	2	3	4	5	6	7	8	9	10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15. If you take into consideration your work routines, management, salary, promotion possibilities and co-workers, how satisfied are you with your work? *(Please put a cross in **one** box only)*

	Not at all satisfied										Completely satisfied
	0	1	2	3	4	5	6	7	8	9	10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please continue and answer all of the questions on page 19.

Section D - Treatment and care

1. So far since this pregnancy started, have you personally bought any **over-the-counter medicines** (items that you buy from the chemist / supermarket), **treatments** or **appliances** to help your **back pain**?

These can include painkillers, creams, sprays, heat pads, massage oils, TENS machine, belts or corsets etc, as well as any herbal or complementary remedies. *(Please cross **one** box)*

Yes..... *Please complete the table below to give us some details.*

No..... *Please turn to **question 2** on the next page.*

*Please give details of all the medicines or treatments you have used for your back pain **since the beginning of this pregnancy...***

Medicine / treatment / appliance	Cost (£)
<i>For example - support belt/ brace</i>	<i>£9.50</i>

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref.13/WM/0021

2. Since the beginning of this pregnancy, have you been **prescribed any medicines, treatments or appliances** (e.g. painkillers, TENS, heat pads) for your **back pain**?
 (Please cross **one** box)

Yes..... Please complete the table below to give us some details.

No..... Please continue to answer **question 3** below.

Please give details of all treatments or medications you have been prescribed for your back pain....

Medicine/ appliance prescribed	Tablets per day	Dosage per tablet	Length of supply
<i>Example</i>	3	200mg	1 month

Before this study begins, we want to know about **your preferences** for the **different treatments** you **may** receive as part of this study.

3. Do you have a **preference** for the **type of treatment** you receive?

Yes.....

No.....

4. If you had a free choice, **which treatment would you choose** for your back pain?

(Please **put a cross in one box only**)

Usual care.....	<input type="checkbox"/>
Usual care plus acupuncture.....	<input type="checkbox"/>
No preference.....	<input type="checkbox"/>
Other (please give details).....	<input type="checkbox"/>

.....

The following questions are about your **expectations** about the different treatments being offered in the study.

5. On a scale where 0 is **no change at all** and 10 is **completely better**, please **put a cross** through the number which best describes how much you would **expect** your back problem to **improve** with each of the following treatments:

a) Usual care

No change at all										Completely better	
0	1	2	3	4	5	6	7	8	9	10	

b) Usual care plus acupuncture

No change at all										Completely better	
0	1	2	3	4	5	6	7	8	9	10	

End of Questionnaire

Please check that you have answered all the questions in the EASE BACK questionnaire. Now please hand this questionnaire to the research midwife or research nurse.

Thank you very much for your help.

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

The remainder of this questionnaire is for office use only and will be completed by the research midwife or research nurse.

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

1. Self-assessed P4 test



Is the woman's familiar pain produced or increased in the lumbar or sacro-iliac area?

Yes.....

No.....

Unable to perform test.....

2. Bridging with extension of the leg



Is the woman's familiar pain produced or increased in the lumbar or sacro-iliac area?

Yes.....

No.....

Unable to perform test.....

EASE BACK pilot trial_baseline questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

Appendix 11 Self-tests for pelvic girdle pain

Self-assessed P4 test



Bridging with extension of the leg



Appendix 12 Eligibility screening proforma

EASE BACK

Eligibility Screening Questionnaire

To be completed by the EASE BACK Study Administrator,
Research Midwife or Research Nurse

**NOTE: PLEASE REMEMBER TO WRITE THIS WOMAN'S STUDY
ID NUMBER ON ALL RELEVANT STUDY DOCUMENTATION**

Study ID

EASE BACK pilot trial_eligibility screening questionnaire_v4.0_26/7/13_Rec ref: 13/WM/0021

	Yes	No
1. Are you aged 18 years or over?	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you pregnant?	<input type="checkbox"/>	<input type="checkbox"/>
3. What is your expected date of delivery? _____ / _____ /201__		
4. (Is this between 13 and 31 completed weeks pregnant?).....	<input type="checkbox"/>	<input type="checkbox"/>
5. Are you carrying more than 1 baby (e.g. twins, triplets)?	<input type="checkbox"/>	<input type="checkbox"/>
6. Have you got pain in the area of your back (with or without pain lower down around your buttocks)?.....	<input type="checkbox"/>	<input type="checkbox"/>
7. Have you EVER had acupuncture before?.....	<input type="checkbox"/>	<input type="checkbox"/>
8. Are you planning to give birth under the care of the University Hospital of North Staffordshire?.....	<input type="checkbox"/>	<input type="checkbox"/>
9. Which GP surgery are you registered with?		
10. (Is this practice on the eligible list?).....	<input type="checkbox"/>	<input type="checkbox"/>
11. What is the name of your GP?		
12. How did you learn about the study/ how has the woman been identified? (please tick)		
<input type="checkbox"/> ...Obstetrician or midwife at the University Hospitals of North Staffordshire		
<input type="checkbox"/> ...Community midwife		
<input type="checkbox"/> ...GP		
<input type="checkbox"/> ...Screening questionnaire at 20 week ultrasound scan		
<input type="checkbox"/> ...Screening Women's Health Physiotherapy referral		
<input type="checkbox"/> ...Flyers or posters		
<input type="checkbox"/> ...Local radio/ newspaper or magazine		
<input type="checkbox"/> ...Internet		
<input type="checkbox"/> ...Not known		
<input type="checkbox"/> ...Other (please specify).....		

	Yes	No
Is this woman eligible for further screening? (all un-shaded boxes must be ticked).....	<input type="checkbox"/>	<input type="checkbox"/>
If yes, is this woman interested in learning more about the EASE BACK study?.....	<input type="checkbox"/>	<input type="checkbox"/>
Date:.....		
Name of Administrator/ Research Midwife or Nurse:		

Part B: To be completed by the research midwife/ research nurse only:

Please ask:

EASE BACK pilot trial_eligibility screening questionnaire_v4.0_26/7/13_Rec ref: 13/WMM/0021

13. Where exactly is your pain?

.....

.....

	Yes	No
(Is this eligible? (N.B. pain in the anterior pelvic region ONLY or symphysis pubis pain ONLY is not eligible)).....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
14. Do you feel that your back pain has been caused by, or made worse because of your pregnancy?.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
15. Do you have an unusually high fear of needles?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16. Do you currently have a diagnosed urine infection?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
17. Have you had three or more consecutive miscarriages?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
18. Do you have any abnormalities with your uterus?.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>

If yes provide details:

.....

.....

19. Do you have known anti-phospholipid syndrome or lupus anticoagulant?...

If yes provide details:

.....

.....

20. Is this pregnancy classified as high risk, based on questions 17-19, or for any other reason?.....

If yes provide details:

.....

.....

21. Have you previously given birth before 37 weeks?

If yes provide details:

.....

.....

22. Have you got ruptured membranes?

23. Have you got polyhydramnios (excess of amniotic fluid)?.....

24. Have you had any previous surgery to your uterine cervix?.....

If yes provide details:

.....

.....

25. Is there a high risk of pre-term labour based on questions 21-24, or for any other reason?

If yes provide details:

.....

.....

	Yes	No
26. Have you been diagnosed with pre-eclampsia?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

27. Have you had any previous surgery to your spine or pelvis?
If yes provide details:

28. Do you have any problems with blood clotting?.....
If yes provide details:

29. Do you have any skin infections over your back, pelvis, legs or hands?.....
If yes provide details:

30. Do you have any burns over your back, pelvis, legs or hands?.....
If yes provide details:

	Yes	No
Is this woman fully eligible to take part in the EASE BACK study? (all un-shaded boxes must be ticked).....	<input type="checkbox"/>	<input type="checkbox"/>
If yes, is this woman interested in taking part in the EASE BACK study?.....	<input type="checkbox"/>	<input type="checkbox"/>
Where is the woman prepared to attend for physiotherapy (please tick <u>all</u> that apply):		
<input type="checkbox"/> ...University Hospital of North Staffordshire		
<input type="checkbox"/> ...Community sites	→ Which sites would the woman be prefer to attend:	
	<input type="checkbox"/> ...Cobridge Community Health Centre	
	<input type="checkbox"/> ...Bentilee Health Centre	
	<input type="checkbox"/> ...Bradwell Hospital (Chesterton)	
Date:		
Name of Administrator/ Research Midwife or Nurse:		

EASE BACK pilot trial_eligibility screening questionnaire_v4.0_26/7/13_Rec ref: 13/WM/0021

Research Midwife/ Nurse Contact Record

FACE TO FACE RESEARCH MEETING

1. Appointment date and time:

2. Name of Research Midwife/ Nurse:

3. Did the face to face meeting take place?

...Yes

...No (if no please provide details in question 9)

4. Appointment location (please tick one box):

...EASE BACK Research Clinic

...Within normal working hours at UHNS antenatal clinic

...Home visit

5. Woman asked if meeting can be audio-recorded?

...Yes

...No

6. Consent provided for audio-recording?

...Yes

...No

7. Informed consent to take part in the pilot trial provided?

...Yes

...No

If yes, date of telephone randomisation:

8. Baseline questionnaire completed?

...Yes

...No

9. If the face to face meeting did not take place please state the reason why:

...Woman did not attend with no further contact

...Woman subsequently declined

...Woman became ineligible


...Other (please specify).....

Study ID

Notes:

EASE BACK pilot trial_eligibility screening questionnaire_v4.0_26/7/13_Rec ref: 13/WM/0021

Appendix 13 Physiotherapy case report forms

S	EASE BACK Usual Care Plus S Acupuncture: Case Report Form			
<p>This form is to be used for each patient who is allocated to usual care plus S acupuncture. Please also complete the <u>reverse of the form</u> to tell us about the acupuncture treatment you delivered. You will need two forms completed for each EASE BACK patient (ie. to record the 6 to 8 treatment visits).</p>				
Patient name:		Date of birth:	Study number:	Your diagnosis:
Physiotherapy centre:		Treating physiotherapist:		
Date of visit (e.g. 13/11/12)				
Initials of treating physiotherapist:				
Patient UTA'd or DNA' visit (please state)				
Modalities used (please tick):				
Assessment/ reassessment				
Education and advice given				
Tubigrip provided with instruction				
Pelvic support belts provided with instruction				
Heat therapy used in clinic				
Massage used in clinic				
Manual therapy used in clinic				
Issued walking aids				
Supervised exercises in department				
Home exercises given/ reviewed				
Exercises selected were (please tick):				
Transversus abdominus				
Pelvic floor				
Pelvic tilt				
Gluteal strengthening				
Lower back/ pelvic stretch				
Physical activity advice/ signposting				
Other exercises (please provide brief description):				
Other treatments used (please state, e.g. ice pack)				
Usual care adverse reactions/ events (please state, e.g. injury whilst exercising):				
General comments:				
<p>Please state the date this patient was discharged:/...../.....</p>				
<p>Many thanks for your help with the EASE BACK Study. Any trial treatment queries - please phone study team: 01782 733921</p>				

Details of acupuncture treatment provided (8 needles i.e. 4 points bilaterally)

Date of visit (e.g. 13/11/12)									
Local points: (please tick)	Left	Right	Left	Right	Left	Right	Left	Right	
BL26									
BL27									
BL54									
GB30									
Sensations:									
De Qi sensation achieved? (y/n)									
Patient's sensations described (e.g. 'aching', 'tingling'):									
Note any minor adverse reactions to acupuncture (e.g. feeling faint, bleeding at the needle site):									
General comments about acupuncture treatment:									
Pain Rating Scale following treatment (0=no pain, 10=pain as bad as could be):									

Many thanks for your help with the **EASE BACK** Study. Any trial treatment queries - please phone study team: 01782 733921



EASE BACK Usual Care Plus T Acupuncture: Case Report Form



This form is to be used for each patient allocated to usual care plus T acupuncture. Please also complete the reverse of the form to tell us about the acupuncture treatment you delivered. You will need two forms completed for each EASE BACK patient (ie. to record the 6 to 8 treatment visits).

Patient name:	Date of birth:	Study number:	Your diagnosis:	
Physiotherapy centre:	Treating physiotherapist:			
Date of visit (e.g. 13/11/12)				
Initials of treating physiotherapist:				
Patient UTA'd or DNA' visit (please state)				
Modalities used (please tick):				
Assessment/ reassessment				
Education and advice given				
Tubigrip provided with instruction				
Pelvic support belts provided with instruction				
Heat therapy used in clinic				
Massage used in clinic				
Manual therapy used in clinic				
Issued walking aids				
Supervised exercises in department				
Home exercises given/ reviewed				
Exercises selected were (please tick):				
Transversus abdominus				
Pelvic floor				
Pelvic tilt				
Gluteal strengthening				
Lower back/ pelvic stretch				
Physical activity advice/ signposting				
Other exercises (please provide brief description):				
Other treatments used (please state, e.g. ice pack)				
Usual care adverse reactions/events (please state, e.g. injury whilst exercising, muscle soreness):				
General comments:				

Please state the date this patient was discharged:/...../.....

Many thanks for your help with the EASE BACK Study.
Any trial treatment queries - please phone study team: 01782 733921

Details of acupuncture treatment provided
(Between 12 and 20 needles needed in total)

Date of visit (e.g. 13/11/12)								
Local points (required depth of insertion/ needle listed): (please tick)	Left	Right	Left	Right	Left	Right	Left	Right
30-40mm/ 50mm BL23								
30-40mm/ 50mm BL24								
30-40mm/ 50mm BL25								
30-40mm/ 50mm BL26								
30-40mm/ 50mm BL27								
20-30mm/40mm BL28								
50-70mm/75mm BL54								
20-30mm/40mm BL31								
20-30mm/40mm BL32								
20-30mm/40mm BL33								
50-70mm/75mm GB30								
30-40mm/ 50mm HJJ L4								
30-40mm/ 50mm HJJ L5								
Distal points (required depth of insertion/ needle listed): (please tick)								
25-30mm/40mm GB34								
25-30mm/40mm ST36								
25-30mm/40mm LR3								
20-30mm/40mm-30mm LI4								
15-25mm/30mm BL60								
10-20mm/30mm BL62								
Sensations:								
De Qi sensation achieved? (y/n)								
Patient's sensations described (e.g. 'aching', 'tingling'):								
Note any minor adverse reactions to acupuncture (e.g. feeling faint, bleeding at the needle site):								
General comments about acupuncture treatment:								
Pain Rating Scale following treatment (0=no pain, 10=pain as bad as could be):								

Many thanks for your help with the **EASE BACK Study**.
Any trial treatment queries - please phone study team: 01782 733921

EASE BACK Usual Care: Case Report Form



This form is to be used for each patient who is allocated to receive usual care alone.

Patient name:	Date of birth:	Study number:	Your diagnosis:	
Physiotherapy centre:	Treating physiotherapist:			
Date of visit (e.g. 13/11/12)				
Initials of treating physiotherapist:				
Patient UTA'd or DNA' visit (please state)				
Modalities used (please tick):				
Assessment/ reassessment				
Education and advice given				
Tubigrip provided with instruction				
Pelvic support belt provided with instruction				
Heat therapy used in clinic				
Massage used in clinic				
Manual therapy used in clinic				
Issued walking aids				
Supervised exercises in department				
Home exercises given/ reviewed				
Exercises selected were (please tick):				
Transversus abdominus				
Pelvic floor				
Pelvic tilt				
Gluteal strengthening				
Lower back/ pelvic stretch				
Physical activity advice/ signposting				
Other exercises (please provide brief description):				
Other treatments used (please state, e.g. ice pack)				
Adverse events (please state, e.g. injury whilst exercising, muscle soreness):				
General comments:				
Pain Rating Scale following treatment (0=no pain, 10=pain as bad as could be):				

Please state the date this patient was discharged:/...../.....

Many thanks for your help with the EASE BACK Study. Any trial treatment queries - please phone study team: 01782 733921



The EASE BACK Usual Care Protocol


- Face to face assessment
- Reinforcement of the advice and education in the self-management booklet
- An individualised and progressed home exercise programme including:
 - Stabilisation exercises
 - Pelvic floor exercises
 - Gluteal strengthening
 - Pelvic tilt exercises
 - Simple stretches
- Other treatment options include:
 - Supervised exercise therapy
 - Postural correction
 - Pelvic supports/belts and pillows
 - Heat therapy
 - Massage
 - Manual therapy (soft tissue techniques, Maitland mobilisation techniques for pain relief)
 - Provision of walking aids
- Delivered in two to four treatment sessions over 6 weeks
- Episode of care to be left 'open' for the duration of the pregnancy

NOTE: Acupuncture, group sessions and hydrotherapy are NOT permitted as part of the EASE BACK usual care protocol.

Many thanks for your help with the EASE BACK Study. Any trial treatment queries - please phone study team: 01782 733921

Appendix 14 Follow-up questionnaire

 National Institute for Health Research	 Keele University
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Follow-up Questionnaire

- Thank you for filling in our questionnaire. Your help is much appreciated.
- There are no 'correct' or 'incorrect' answers. Answer according to your own feelings, rather than how you think most people will answer.
- When you've finished, just return the questionnaire in the envelope provided. **You do not need a stamp.**
- If you have any questions, please contact Mel Holden, the EASE BACK study co-ordinator on **01782 733921** during office hours.

Thank you very much for your help with this research study

EASE BACK pilot trial_follow up questionnaire_v1.1_8_5_13_REC ref:13/WM/0021

INSTRUCTIONS FOR THIS QUESTIONNAIRE

It is important to answer **all** the questions, even if you feel that they do not apply to you. Some questions may look like others, but they tell us different things, so all are important to answer. Some of the questions are arranged in sections according to the period of time that they ask about.

Many of the questions are about your pain. Some questions are about work, and others are about you and your general health. Please take the time to read and answer each question carefully.

Most of the questions can be answered by putting a **cross** in a box next to or under your answer. For example, if you wish to answer 'Not at all', **cross** the box like this:

Not at all	Slightly	Moderately	Very much	Extremely
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Here is an example of how to answer a question if you **don't** have any pain:

No pain											Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Now please continue and fill in this questionnaire

Section A - Your back problem

1. In the **last 2 weeks**, on **average**, how intense was your **usual** back pain rated on a 0–10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

(Please cross **one** box only)

No pain											Pain as bad as could be
	0	1	2	3	4	5	6	7	8	9	10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. In the **last 2 weeks**, how intense was your **least** painful back pain rated on a 0–10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

(Please cross **one** box only)

No pain											Pain as bad as could be
	0	1	2	3	4	5	6	7	8	9	10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. In the **last 2 weeks**, on **average**, how intense was your back pain **just before going to bed at night**, rated on a 0–10 scale, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

(Please cross **one** box only)

No pain											Pain as bad as could be
	0	1	2	3	4	5	6	7	8	9	10
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. During the **last 2 weeks**, how often has your back pain **prevented you from falling asleep**?

(Please cross **one** box only)

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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5. During the **last 2 weeks**, how often has your back pain **woken you up** at night?
(Please cross **one** box only)

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. How would you rate your **pain** on a 0-10 scale **at the present time**, that is, right now, where 0 is 'no pain' and 10 is 'pain as bad as could be'?
(Please cross **one** box only)

No pain											Pain as bad as could be
0	1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Compared with when you completed your first EASE BACK study questionnaire, approximately 8 weeks ago, how would you say your back pain problem is now?
(Please cross **one** box only)

Completely recovered	Much improved	Somewhat improved	Same	Somewhat worse	Much worse
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. The following questions on pages 5, 6 and 7 have been designed to give us information as to how your **back pain** is affecting your ability to manage in everyday life. Please answer by crossing **one box in each section** for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply, but please just put a cross in the **one box** that indicates the statement which **most closely describes your problem**.

Section 1: Pain Intensity

- I have no pain at the moment
- The pain is very mild at the moment
- The pain is moderate at the moment
- The pain is fairly severe at the moment
- The pain is very severe at the moment
- The pain is the worst imaginable at the moment

Section 2: Personal Care (e.g. washing, dressing)

- I can look after myself normally without causing extra pain
- I can look after myself normally but it causes extra pain
- It is painful to look after myself and I am slow and careful
- I need some help but can manage most of my personal care
- I need help every day in most aspects of self-care
- I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting

- Not applicable
- I can lift heavy weights without extra pain
- I can lift heavy weights but it gives me extra pain
- Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed (e.g. on a table)
- Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- I can only lift very light weights
- I cannot lift or carry anything

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Section 4: Walking

- Pain does not prevent me walking any distance
- Pain prevents me from walking more than 1 mile
- Pain prevents me from walking more than ½ mile
- Pain prevents me from walking more than 100 yards
- I can only walk using a stick or crutches
- I am in bed most of the time

Section 5: Sitting

- I can sit in any chair as long as I like
- I can only sit in my favorite chair as long as I like
- Pain prevents me sitting more than one hour
- Pain prevents me from sitting more than 30 minutes
- Pain prevents me from sitting more than 10 minutes
- Pain prevents me from sitting at all

Section 6: Standing

- I can stand as long as I want without extra pain
- I can stand as long as I want but it gives me extra pain
- Pain prevents me from standing for more than 1 hour
- Pain prevents me from standing for more than 30 minutes
- Pain prevents me from standing for more than 10 minutes
- Pain prevents me from standing at all

Section 7: Sleeping

- My sleep is never disturbed by pain
- My sleep is occasionally disturbed by pain
- Because of pain I have less than 6 hours sleep
- Because of pain I have less than 4 hours sleep
- Because of pain I have less than 2 hours sleep
- Pain prevents me from sleeping at all

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Please continue to answer the questions by putting a cross in the **one box** that indicates the statement which most clearly describes your problem.

Section 8: Sex Life

- Not applicable
- My sex life is normal and causes no extra pain
- My sex life is normal but causes some extra pain
- My sex life is nearly normal but is very painful
- My sex life is severely restricted by pain
- My sex life is nearly absent because of pain
- Pain prevents any sex life at all

Section 9: Social Life

- My social life is normal and gives me no extra pain
- My social life is normal but increases the degree of pain
- Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
- Pain has restricted my social life and I do not go out as often
- Pain has restricted my social life to my home
- I have no social life because of pain

Section 10: Travelling

- I can travel anywhere without pain
- I can travel anywhere but it gives me extra pain
- Pain is bad but I manage journeys over two hours
- Pain restricts me to journeys of less than one hour
- Pain restricts me to short necessary journeys under 30 minutes
- Pain prevents me from travelling except to receive treatment

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For the following questions, please tell us to **what extent you find it problematic** to carry out the activities listed below **because of your back pain**.

For each activity, please cross one box that best describes how you are today.

How problematic it is for you, because of your back pain to:

	Not at all problematic	To a small extent	To some extent	To a large extent	Not applicable
9. Dress yourself.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Stand for less than 10 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Stand for more than 60 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Bend down.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Sit for less than 10 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Sit for more than 60 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Walk for less than 10 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Walk for more than 60 minutes.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Climb stairs.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Do housework.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Carry light objects.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Carry heavy objects.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Get up/ sit down.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Push a shopping trolley.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Run.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Carry out sporting activities.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Lie down.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Roll over in bed.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Have a normal sex life.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. Push something with one foot.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Please answer the following questions by putting a cross in **one** box.

29. How much back pain do you experience:

	None	Some	Moderate	Considerable
a. In the morning.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. In the evening.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

30. To what extent because of your back pain:

	Not at all	To a small extent	To some extent	To a large extent
a. Has your leg/ legs given way?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Do you do things more slowly?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Is your sleep interrupted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section B - Your general health

In the following section we are asking for your views about your general health.

For the following questions, please **cross one box on each line** that best describes your answer. Remember to think about your **general health at present**.

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

Excellent	Very good	Good	Fair	Poor
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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2. The following questions are about **activities** you might do **during a typical day**. Does your **health now limit you** in these activities? If so, **how much**?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Moderate activities , such as moving a table, pushing a vacuum, bowling or playing golf.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Climbing several flights of stairs.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. During the **last week**, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your **physical health**?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Accomplished less than you would like.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Were limited in the kind of work or other activities.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Accomplished less than you would like.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Did work or activities less carefully than usual.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Remember to think about your **general health at present**.

5. During the **last week** how much did **pain** interfere with your normal work (including work both outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

These questions are about how you feel and how things have been with you during the **last week**. For each question, please give the one answer that comes closest to the way you have been **feeling**.

6. How much time during the last week:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Have you felt downhearted and depressed?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. During the **last week**, how much of the time has your physical health or emotional problems interfered with your **social activities** (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Under each heading, please put a cross in the one box that best describes your health today.

8. MOBILITY

- I have no problems in walking about
- I have slight problems in walking about
- I have moderate problems in walking about
- I have severe problems in walking about
- I am unable to walk about

9. SELF-CARE

- I have no problems washing or dressing myself
- I have slight problems washing or dressing myself
- I have moderate problems washing or dressing myself
- I have severe problems washing or dressing myself
- I am unable to wash or dress myself

10. USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities
- I have slight problems doing my usual activities
- I have moderate problems doing my usual activities
- I have severe problems doing my usual activities
- I am unable to do my usual activities

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11. PAIN / DISCOMFORT

- I have no pain or discomfort
- I have slight pain or discomfort
- I have moderate pain or discomfort
- I have severe pain or discomfort
- I have extreme pain or discomfort

12. ANXIETY / DEPRESSION

- I am not anxious or depressed
- I am slightly anxious or depressed
- I am moderately anxious or depressed
- I am severely anxious or depressed
- I am extremely anxious or depressed

Section C - About you1. What is your **date of birth**?

2. Are you still pregnant?

Yes..... No.....

If yes, how many weeks pregnant are you?

 Weeks days

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5. On average, to what extent has your back pain affected your **performance at work** since the last EASE BACK study questionnaire (approximately 8 weeks ago)? (*Please put a cross in one box only*)

Not at all										The pain is so bad that I am unable to do my job
0	1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Did you receive treatment from a physiotherapist as part of the EASE BACK study?

Yes → *Please continue to answer all the questions in this section*

No → *Please go to section D, on page 18*

The following questions are important because they will help us to understand the cost to you when attending your physiotherapy appointments as part of the EASE BACK study.

7. Did you have to take any time off work to attend any of the physiotherapy appointments?

Yes → *Please continue and answer question 8*

No → *Please go to question 11 on the next page (page 16)*

8. How much time did you have to take off work to attend any **one** of these physiotherapy appointments?

..hoursminutes

9. Were you paid during this time off? (*Please put a cross in one box only*)

Yes.....

No.....

I'm self-employed.....

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10. What was the main way your absence from work was dealt with while you attended any one of the physiotherapy appointments? *(please cross **all** that apply)*

Work was done by colleagues in addition to their own work.....

Someone was employed temporarily to cover.....

I had to catch up by doing extra hours when I returned to work.....

The work was not done or it was put off until a further date.....

Other, please specify.....

.....

11. Did you have to reduce your time spent on unpaid activities (e.g. voluntary work, leisure pursuits, family and domestic responsibilities) to attend any one of the physiotherapy appointments?

Yes → *Please answer questions (a) and (b) below*

No → *Please go to question 12 on the next page (page 17)*

a) Approximately how much time was affected?hoursminutes

b) What types of activities were affected *(please cross **all** that apply)*

Looking after children

Looking after other relatives

Leisure activities

Housework

Studying.....

Other, please specify.....

.....

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12. If looking after children or other relatives was affected, did you pay someone to look after them in your absence?

Yes..... → If yes, how much did it cost? £.....:.....p.

No.....

Not applicable.....

13. Did someone accompany you to any **one** of your physiotherapy appointments?

Yes.....

No.....

14. When you attended any **one** of your physiotherapy appointments, what form of transport did you use? (*please cross **one** box only*)

Car/ van..... → Please go to question 15

Motorbike/ scooter..... → Please go to question 15

Taxi/ train/ bus..... → Please go to question 16

On foot..... → Please go to **section D**, on page 18

15. If you travelled by car, van or motorbike/scooter:

a) Approximately how many miles was the return journey? Miles

b) Did you have to pay to park?

Yes..... → c) It cost: £.....:.....p.

No.....

16. If you travelled by train, bus or taxi, how much was the return fare? £.....:.....p.

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Section D - Treatment and care

This section is about **ALL** the health care you have received for your **back pain or related symptoms**.

1. During the **last 8 weeks** (since your last EASE BACK study questionnaire), have you personally bought any **over-the-counter medicines** (items that you buy from the chemist / supermarket), **treatments** or **appliances** to help your **back pain**?

These can include painkillers, creams, sprays, heat pads, massage oils, TENS machine, belts or corsets etc, as well as any herbal or complementary remedies. *(Please cross **one** box)*

Yes..... *Please complete the table below to give us some details*

No..... *Please turn to **question 2** on the next page (page 19)*

Please give details of all the medicines or treatments you have used for your back pain in the **last 8 weeks** (since your last EASE BACK study questionnaire)...

Medicine / treatment / appliance	Cost (£)
<i>For example - support belt/ brace</i>	<i>£9.50</i>

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2. During the last 8 weeks (since your last EASE BACK study questionnaire), have you been prescribed any medicines, treatments or appliances (e.g. painkillers, TENS, heat pads) for your back pain?

(Please cross one box)

Yes..... Please complete the table below to give us some details

No..... Please continue to answer **question 3** on the next page (page 20)

Please give details of all treatments or medications you have been prescribed for your back pain in the last 8 weeks (since your last EASE BACK study questionnaire)

Medicine/ appliance prescribed	Tablets per day	Dosage per tablet	Length of supply
<i>Example</i>	3	200mg	1 month

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3. In the last **8 weeks** (since you last EASE BACK study questionnaire), apart from any EASE BACK treatment visits, have you attended for NHS or private health care **because of your back problem**? This may include inpatient stays, visits to accident and emergency, other physiotherapy treatments, treatments received at your family doctor's surgery, or extra visits to your midwife.

Yes..... Please provide details in the table below

No..... Please continue with question 4 on page 21

Please write in the table below the number of times you have seen each type of health professional (**for your back pain**) in the **last 8 weeks** (since your last EASE BACK study questionnaire). Any treatments or investigations or investigations you may have received as a result of these consultations (e.g. x-rays, surgeries, injections) are covered later in the questionnaire and should not be reported here.

Health care professional	Number of visits in NHS	Number of visits in private practice
<i>For example – Doctor (GP)</i>	3	0
Doctor (GP)		
Midwife		
Physiotherapist		
Health visitor		
Acupuncturist		
Obstetrician		
Practice/ District nurse		
Occupational therapist		
Rheumatologist		
Other (please specify)		
Other (please specify)		

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4. In the **last 8 weeks** (since you last EASE BACK study questionnaire) have you attended an NHS or private health care centre for any investigations or treatments (e.g. x-ray, surgery, injection) for your back pain? Please do not include any initial appointments reported in the previous question.

Yes..... *Please provide details in the table below*

No..... *Please continue with question 5 below*

In the table below, please give details of each investigation or treatment you have received in the **last 8 weeks** (since you last EASE BACK study questionnaire) ...

Treatment or investigation	Reason for attendance	Number of days at or in hospital
<i>e.g. injection</i>	<i>Increase in back pain</i>	<i>1</i>

The following section asks about the information/ treatment you received within the EASE BACK study.

5. How **confident** do you feel that the information/ treatment you received helped your back pain problem? (*Please cross one box only*)

Very confident	Quite confident	No opinion	Not very confident	Not confident at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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6. How **confident** would you be in **recommending this information/ treatment to a friend** who suffered from a similar problem?
(Please cross **one** box only)

Very confident	Quite confident	No opinion	Not very confident	Not confident at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. How **logical** did the **information/ treatment** seem to you?
(Please cross **one** box only)

Not at all logical	Not very logical	No opinion	Quite logical	Very logical
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8. How **successful** do you think the **information/ treatment you received** would be in **alleviating other complaints**?
(Please cross **one** box only)

Not at all successful	Not very successful	No opinion	Quite successful	Very successful
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Do you believe that you have had any side effects as a direct cause of treatment package that you have received in the EASE BACK study?
(Please cross **one** box only)

Yes..... Please continue with question 10 on the next page (page 23)

No..... Please continue with question 11 on the next page (page 23)

10. We would like to know more about any side effects of the EASE BACK treatment packages. Please **put a cross in any box that applies to you**:

Nausea	<input type="checkbox"/>
Vomiting.....	<input type="checkbox"/>
Drowsiness/ light headedness.....	<input type="checkbox"/>
Fainting	<input type="checkbox"/>
Bruising.....	<input type="checkbox"/>
Feeling hot/ burning.....	<input type="checkbox"/>
Headaches.....	<input type="checkbox"/>
Pain/ soreness.....	<input type="checkbox"/>
Other (please specify).....	<input type="checkbox"/>

.....

11. How **satisfied** are you with the **treatment package you received** in the EASE BACK study concerning your back pain problem? (*Please cross **one** box*)

Very dissatisfied	Quite dissatisfied	No opinion	Quite satisfied	Very satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. How **satisfied** are you with the **results from the treatment** you received in the EASE BACK study for your back problem? (*Please cross **one** box*)

Very dissatisfied	Quite dissatisfied	No opinion	Quite satisfied	Very satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Comments

If you have any other comments about your back problem or the care you have received in the EASE BACK study, please write them in the space below.

**Thank you for taking the time to fill in this questionnaire,
your answers will be very useful to us.**

We assure you that any information will be held in strictest confidence.

Now please return this questionnaire in the prepaid envelope provided. You do not need a stamp. If you have any questions about this questionnaire or the study in general please contact Mel Holden, the study co-ordinator, on **01782 733921** during office hours.

Thank you very much for your help.

Study ID (Office Use Only)

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Appendix 15 Evaluating Acupuncture and Standard care for pregnant women with Back pain study dissemination event



EASE BACK Study Dissemination event (Evaluating Acupuncture and Standard care for pregnant women with BACK pain)

Monday 19th May 2014

Arthritis Research UK Primary Care Centre, Keele University, Keele, Staffordshire.

Room 0.78

10:00am – 16:30pm

Registration and welcome from 9:30am

10:00 Welcome and overview of EASE BACK study aims & objectives

Prof Nadine Foster

10:15 Current clinical care for pregnancy-related back pain: survey results

Dr Annette Bishop

10:35 Perspectives of pregnant women, midwives and physiotherapists: interview results

Dr Bernadette Bartlam, Dr Jackie Waterfield

10:55 EASE BACK pilot trial design and methods

Prof Nadine Foster

11:20 Coffee

11:35 EASE BACK interventions

Prof Nadine Foster

Dr Panos Barlas

11.50 EASE BACK study results: feasibility and acceptability of study procedures (eligibility criteria, consent, recruitment, follow-up) and interventions delivered

Alison Lloyd, Dr Bernadette Bartlam, Dr Annette Bishop

12.10 EASE BACK study results: safety, clinical and cost data

Prof Nadine Foster, Dr Reuben Ogollah, Dr Jessie Kigozi

12:30 Lunch

13:00 Main trial – feasible and desirable?

Prof Nadine Foster

13.30 Discussion groups: planning a main trial

Facilitators: Dr Annette Bishop

Dr Bernadette Bartlam

Prof Nadine Foster

15:15 Feedback on workshop discussions

16:00 Conclusions and next steps

Prof Nadine Foster

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

**EME
HS&DR
HTA
PGfAR
PHR**

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