

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

¹Research Institute of Primary Care and Health Sciences, Faculty of Health, Keele University, Keele, Staffordshire, UK

²Reproduction, Genes and Development Department, School of Clinical and Experimental Medicine, University of Birmingham, Birmingham, West Midlands, UK

³Health Economics Unit, School of Health and Population Sciences, University of Birmingham, Birmingham, West Midlands, UK

⁴Faculty of Health Sciences, Staffordshire University, Stoke-on-Trent, Staffordshire, UK

*Corresponding author

Declared competing interests of authors: Dr Panos Barlas received funding from training health professionals in acupuncture.

Published April 2016

DOI: 10.3310/hta20330

Scientific summary

The EASE Back feasibility study and pilot randomised trial

Health Technology Assessment 2016; Vol. 20: No. 33

DOI: 10.3310/hta20330

NIHR Journals Library www.journalslibrary.nihr.ac.uk

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

This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 20, No. 33. See the NIHR Journals Library website for further project information.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.027

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nhredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

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

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: <http://www.nets.nihr.ac.uk/programmes/hta>

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 10/69/05. The contractual start date was in June 2012. The draft report began editorial review in June 2014 and was accepted for publication in November 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health.

© Queen's Printer and Controller of HMSO 2016. This work was produced by Foster *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Health Technology Assessment Editor-in-Chief

Professor Hywel Williams Director, HTA Programme, UK and Foundation Professor and Co-Director of the Centre of Evidence-Based Dermatology, University of Nottingham, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May Chair of NIHR Journals Library Editorial Group (EME, HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Professor Aileen Clarke Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Health Sciences Research, Health and Wellbeing Research and Development Group, University of Winchester, UK

Professor John Norrie Health Services Research Unit, University of Aberdeen, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: nihredit@southampton.ac.uk