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

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Background: More than two-thirds of pregnant women experience low back pain (LBP) that interferes with everyday activities, work and sleep. Most women receive very little in the way of treatment and are usually advised to self-manage. Acupuncture appears a safe, promising intervention used by some physiotherapists but there are no high quality trial data regarding its clinical or cost-effectiveness, in comparison to standard care. Evaluation of the clinical and cost-effectiveness of acupuncture in a future randomised controlled trial (RCT) is required, but before this can be done, a feasibility and pilot trial was needed.

Purpose: To assess the feasibility of a future large RCT testing the additional benefit of acupuncture to standard care for pregnancy-related LBP.

Methods: A single-centre pilot RCT. Participants were identified using six methods and randomised to one of three interventions delivered by physiotherapists. Standard Care (SC): A self-management booklet and onward referral for one-to-one physiotherapy (2 to 4 sessions) for those who needed it. SC plus true acupuncture: The self-management booklet and 6 to 8 treatments with a physiotherapist comprising true (penetrating) acupuncture, advice and exercise. SC plus non-penetrating acupuncture: The self-management booklet and 6 to 8 treatments with a physiotherapist comprising non-penetrating acupuncture, advice and exercise. Pilot RCT outcomes included recruitment rates, treatment fidelity, follow-up rate, patient-reported pain and function, quality of life and exploration of healthcare costs. Birth and neonatal outcomes were also assessed. Trial registration: Current controlled trials database ISRCTN49955124.

Results: We recruited 125 of 280 potentially eligible women (45%) in 6 months and randomised 41 to SC, and 42 to each of the SC plus acupuncture arms. Most participants were identified through questionnaires given to women at routine 20-week ultrasound scan appointments, community midwives informing women of the study and women self-referring following local awareness-raising. The consent meetings were audio recorded and indicate that women had no concerns about the use of acupuncture in pregnancy beyond the need for reassurance on positioning and safety. 10% of women (n=4) randomised to SC alone accessed one-to-one physiotherapy and they received an average of 2 treatments. The average number of treatments was 6 for SC plus true acupuncture and 6 for SC plus non-penetrating acupuncture. Treatments were in line with protocols. 8-week follow-up was 74%. Patient-reported outcomes (pain, function and quality of life) favoured the addition of acupuncture. Healthcare costs were higher for SC plus true acupuncture, due to the additional cost of the intervention. There was no evidence of serious adverse events on mothers, birth or 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 efforts to maximise follow-up are recommended for a main trial.

Implications: A full RCT is feasible and would provide important information for patients, clinicians and decision makers about the effectiveness of acupuncture for this client group.

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Publications to date

* Foster, N.E., Bishop. A., Bartlam, B., Ogollah, R., Barlas, P., Holden, M.A., et al. Evaluating acupuncture and standard care for pregnant women with back pain (EASE Back): a feasibility study and pilot randomised trial. *Health Technology Assessment* 2016 Vol. 20: No. 33 DOI http://dx.doi.org/10.3310/hta20330
* Bishop A, Ogollah RO, Bartlam B, Barlas P, Holden MA, Ismail KM, Jowett S, Lewis AM, Lloyd A, Kettle C, Kigozi J, Foster NE and the EASE Back study team. Evaluating acupuncture and Standard care for pregnant womEn with BACK pain: The EASE Back pilot randomised controlled trial (ISRCTN49955124). (*Submitted to BMC Pilot and Feasibility Studies*)
* Bartlam B, Waterfield J, Bishop A, Holden MA, Barlas P, Ismail KM, Kettle C, Foster NE. The role of qualitative research in clinical trial development: the EASE Back study. *Journal of Mixed Methods* Available online July 13, 2016 doi: 10.1177/1558689816656740.
* Bishop A, Holden MA, Ogollah RO, Foster NE (2015). Current management of pregnancy-related low back pain: A cross-sectional survey of UK physiotherapists. *Physiotherapy* 2016;102:78-85
* Waterfield J, Bartlam B, Bishop A, Holden MA, Barlas P, Foster NE. Physical therapists’ views and experiences of pregnancy-related low back pain and the role of acupuncture: a qualitative exploration. *Physical Therapy* Sep;95(9):1234-43. doi: 10.2522/ptj.201402982015 Apr 30.