University Hospital of North Staffordshire NHS

NHS Trust

Keele University

EASE BACK Study

Evaluating Acupuncture and Standard care for pregnant womEn with BACK pain

www.keele.ac.uk/easeback

Participant Information Leaflet
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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.

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