

A series of five examples of public involvement in research developed by the NIHR Evaluation, Trials and Studies Coordinating Centre.

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

About the research

Lead researcher: National Institute for Health Research (NIHR) Professor Nadine Foster, Arthritis Research UK Primary Care Centre, Institute of Primary Care and Health Sciences, Keele University.

Funder: National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme.

Project aims: (a) To assess the current management of back pain in pregnant women and the effectiveness of the treatments on offer, and (b) to explore the feasibility of a large, multi-centre trial testing the benefits of acupuncture for back pain during pregnancy.

Type of research: Mixed methods: surveys, focus groups, interviews and a pilot randomised clinical trial.

Duration: Two years, May 2012 – May 2014.

Who we spoke to

We interviewed the project lead, NIHR Professor Nadine Foster. Her comments are written in blue text below.

About the involvement

How patients and carers were involved in the study

Prior to responding to a call for proposals, the research team held a workshop to consult pregnant women attending a local back pain clinic. Their views helped shape the study.

“We found that back pain was assumed to be a natural part of pregnancy – by the women themselves and their midwives. It was just expected to go away after baby was born. Very few women were getting referred to specialist services and there was limited data available nationally about standard treatment. So we realised we needed to include a Phase 1 in our study, to find out more from pregnant women about their experience of back pain and its impact on them, and about the treatment options available. We also wanted to ask how they viewed acupuncture as a potential treatment.” **Nadine**

Once the study was funded, the team recruited two women with experience of pregnancy-related back pain as patient representatives. One woman was recruited via the back pain clinic and the other was known to the acupuncturist on the research team. The patient representatives joined the Trial Steering Committee and were involved throughout the entire project.

Impact of the involvement

Early on, the patient representatives reviewed the information for trial participants and the data collection tools. Their feedback led to a change to one of the key outcome measures in the trial.

“That was probably the most significant change in our thinking in response to their involvement. We had planned to use a particular pain and disability scale that had previously been used in a Swedish trial, so that our data would be comparable. Our patient representatives told us we needed to find something better than that, saying ‘If you want to hear about my experience, I can’t tell you about it using that outcome measure’. They felt very strongly that the scale wasn’t fit for purpose... in the end, we changed it to another scale, specifically designed for pregnancy-related pain, which was much, much more relevant.”

Nadine

The patient representatives also provided helpful feedback on the publicity material used for recruitment. One of the women took part in an infomercial on local radio and featured in a newspaper article that told her personal story. These were used to advertise the trial to local women.

“We had not tried this before, using a professionally produced infomercial... One of the patient representatives effectively became the voice for women with pregnancy-related back pain. It was authentic and felt genuine... and the radio infomercial turned out to be very helpful for recruitment.” **Nadine**

The research team also developed a booklet on self-management of back pain for use in the trial. The patient representatives were very involved in reviewing early drafts. They made sure the language was suitable for the target audience and made simple suggestions to make it more relevant. For example, they suggested using photos of pregnant women to illustrate postures and self-help tips, rather than unrealistic drawings of stick men.

What helped the involvement to work well?

The patient representatives were well supported in their involvement role, not only by the research team, but also by others involved in the trial.

“We had a very good chair of the Trial Steering Committee, who was experienced in engaging patient representatives in those sorts of formal processes. That really helped. Making sure that everyone involved in the trial is supporting patient and public involvement (PPI) in the process is very helpful.”

Nadine

The research centre where Nadine works has also established a more formal system of support for all patients involved in research.

“We have two patient support workers, who have worked with us previously, and are now salaried and working part-time. They support patients involved across the whole range of our studies – about 60 in total. They meet with patient **representatives** before some of the formal meetings just to run through the kind of things they can expect – and they provide glossaries of research jargon and abbreviations. Essentially, they make the process smoother and easier, by providing a point of contact outside of the research team. And of course, since they are patients themselves, it really helps.” **Nadine**

Lessons learnt

“Be sure that the kinds of things you ask patient **representatives** to do can genuinely influence the research team’s decisions. You need to create a space and a dialogue to support genuine involvement – so that if they say they want a change, then that’s heard, listened to and acted on by the research team.”

It’s inevitable when patients are involved that they won’t be able to come to every meeting and you have to be prepared to work flexibly with them. Working with our two patient **representatives** was super. But we recognised that with young women, with small children at home as well as commitments at work, their time was very precious. So we did have to do a bit of liaising with them separately outside of formal meetings and did some things over the phone and by email.

The more innovative things that we did really engaged people. It was something they were interested in doing and ensured the patient **representatives** enjoyed working with the research team.” **Nadine**

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References:

Plain English summary of the study:
www.nets.nihr.ac.uk/projects/hta/106905

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