

**Non-specific Mechanisms in Orthodox and Complementary Alternative Medicine
(CAM) Management of Low Back Pain**

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Please read this information carefully before deciding to take part in this research. If you are happy to participate please complete and sign the consent form.

What is the purpose of the study?

We know that different types of treatment can help patients with low back pain. We also know that parts of treatment such as the physical environment or the therapeutic relationship between a patient and their practitioner can influence how successful a treatment is overall. These parts of treatment are known as “non-specific” factors. We do not know which non-specific factors most influence treatment success for patients with low back pain. We also do not know whether different non-specific factors are more important in different treatments. Our main aim is to find out which non-specific factors most influence treatment success for patients with low back pain. Our second aim is to compare non-specific factors across three different treatments - physiotherapy, osteopathy, and acupuncture. We hope our results will help improve treatments in the future, for example by showing which non-specific factors we should focus on improving.

Why have I been invited?

Because you are a physiotherapist, osteopath, or acupuncturist, and you have expressed interest in taking part in this study. We hope that around 195 practitioners and 1,500 patients will take part.

What will happen to me if I take part and what will I have to do?

If you decide to take part, we will ask you to give study information packs to eligible patients who consult you for low back pain. We would like you to recruit between 10 - 30 patients into the study. Full details about how to recruit patients into the study are appended to this information sheet.

We will also ask you to fill in questionnaires at 3 time-points.

1. The first questionnaire is included in this pack. It asks about your approach to treating low back pain and where you practice. If you decide to take part, please fill it in and send it back to us with your completed consent form in the prepaid envelope provided.
2. The second questionnaire is simply 1 question which you complete and post back to us in a prepaid envelope provided, each time you give a patient an information pack.
3. The third questionnaire is very short and will need to be filled in by you for each patient that you recruit into the study. It will ask about what treatment you provided for the patient. We will send you this questionnaire 3 months after each patient enrolls in our study. Again there is a prepaid envelope for you to post it back to us

What are the possible benefits and risks of taking part?

Taking part offers you the chance to reflect on your thoughts about treating low back pain; some people might find this helpful. Filling in the questionnaires and recruiting patients will take some time, but we do not foresee any other disadvantages or risks. We will provide some financial reimbursement for the time you spend identifying suitable patients for this study (known as ‘Support Costs’); this reimbursement will be worked out on a case-by-case basis, please contact the researcher (details below) for more details.

How does this study relate to my patients’ treatment?

This study will have no impact on your patients’ treatment, which should continue as normal.

What happens when the study stops?

The information that you and your patients provide in the questionnaires will be combined with the information that other participants provide. It will be used to examine, using statistical methods, which non-specific aspects of treatment influence treatment success for patients with low back pain. We will write to you to tell you about our results. We will publish the results in various forms, including at scientific conferences, in scientific journals, and in publications for the general public. You will not be identified in any publications.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you decide not to take part this will not affect your legal rights. If you decide to take part and then change your mind, you are free to withdraw from the study at any time without giving a reason. This would not affect your legal rights. If you withdraw we will use any questionnaires you have completed up to your withdrawal, unless you tell us not to.

Who is funding the study and who has reviewed it?

The charity Arthritis Research UK is funding the study. Before it was funded, the study was reviewed by independent academics. Before it started, the study was reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have any concerns about this study, please speak to the researchers who will do their best to answer your questions (contact the Chief Investigator, Felicity Bishop, on 023 8059 9020 or F.L.Bishop@southampton.ac.uk). If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure or the University of Southampton. Please contact the University of Southampton Research Governance Office, on rgoinfo@soton.ac.uk or 023 8059 5058.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Data will be collected and retained in accordance with the Data Protection Act 1998.

We will only use your personal details to contact you about this study. Your contact details will be stored in a locked cabinet at the University of Southampton and will also be kept securely on a password-protected electronic database that will only be accessed by the researchers working on this study. Authorised personnel who check that the study is being carried out correctly may also need to access this information. All will have a duty of confidentiality to you as a research participant.

When this study is completed, we will destroy all records of your personal contact details. We will securely archive your original consent form and the anonymous questionnaire data for 10 years, in line with University of Southampton policy.

Who can I contact for further information?

If you have any questions about this research please contact the researchers on 023 8059 1942 or mocam@soton.ac.uk or the chief investigator, Dr Felicity Bishop, on 023 8059 9020 or F.L.Bishop@southampton.ac.uk

If you are happy to take part in this study please now complete and sign the enclosed consent form and questionnaire and return them to us in the freepost envelope provided.