

University of Brighton
School of Health Professions

Participant Information Sheet Study 1

**Reliability of measurements of vibration and pressure pain in people with leg pain
thought to be referred from the spine**

2 Invitation paragraph

You are being invited to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this information.

3 What is the purpose of the study?

The study aims to look at if two commonly used measures of sensation and pain are reliable between sessions in people who suffer with leg pain thought to be coming from their spine.

4 Why have I been chosen?

You have been chosen for the study as you have had low back pain and/or leg pain for 3 months or longer and are not currently receiving any treatment for this condition. You will need to meet the requirements for eligibility into the study as described below.

The following conditions **do not** apply to you

- Previous spinal surgery
- Current or previous medical diagnoses that may affect your participation in the study (e.g. Rheumatoid Arthritis, diabetes, thyroid disease, HIV/AIDS, stroke, cancer, osteoporosis)
- Currently Pregnant
- Hip, knee or ankle disorders within the last year
- New unexplained bladder and bowel problems, and/or pins and needles in your genital region)
- Currently receiving treatment for the LBP/leg pain
- On regular high levels of pain medication (over the counter pain medication is fine, but you will be asked to stop taking this for 24 hours prior to the study)

5 **Do I have to take part?**

Your participation is entirely voluntary. If you are unsure about taking part then feel free to decline. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form and send it back to the researcher (by email cr19@bton.ac.uk or in the stamped addressed envelope sent to you). If you *do not* want to participate, you are still asked to send back the form, and sign in the section indicated on the form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way.

6 **What will happen to me if I take part?**

The researcher will first contact you by phone and ask you some questions to ensure that you are able to take part in the study (these will include questions about your back pain and any relevant medical history). If you are eligible to take part in the study you will be given a convenient time for you to attend the Human movement laboratory at the

University of Brighton, Darley Rd, Eastbourne. You will have 2 specific tests performed twice in this session with a break of 30 minutes between them. The 2 specific tests will each take approximately ½ an hour. All appropriate travel costs will be met by the researcher and will be discussed prior to participation in the study.

You will be asked a number of questions by the researcher who is an experienced Physiotherapist with 19 years experience about your back and /or leg problem. You will then be asked to change into a pair of shorts and bra top (for ladies) before a number of tests will be applied:

- Your height and weight will be measured.
- You will be asked to move your back and leg and let the researcher know if you have any of your pain during these movements. You will be asked to lie on your stomach and the researcher will press on your spine with her hand and you will again be asked if this brings on your pain. The strength in your legs will be tested and your reflexes will be checked (you may have had this done by the doctor before- where the tendon in your knee and ankle is tapped to see if your leg jumps). The researcher will then apply some cotton wool lightly to your leg (or tissue paper if you do not tolerate cotton wool), and you will be asked if you can feel it.
- You will be asked to lie on your stomach whilst a small probe is applied to your pain free leg which will vibrate. You will be asked to let the researcher know when you feel the probe vibrating and then when it stops. Once you and the researcher are happy with this test it will be repeated on your painful leg.
- Another probe will be applied to your pain free leg which will gradually increase the feeling of pressure and you will be asked to push a button when this pressure sensation changes to discomfort (this will stop any further pressure from being applied). Once you are familiar with this, then the same procedure will occur on your painful leg and also on your arm. The order in which the vibration test and the pressure test are applied will vary from subject to subject.

You will have a break of 30 minutes and then the vibration tests and pressure tests will be repeated.

7 What do I have to do?

Please do not drink caffeine, alcohol or take any pain medication for 24 hours prior to the study. You will need to remain in the laboratory between the test procedures where refreshments will be provided. However no caffeine will be given as it may affect the results of the study. Please could you bring a pair of shorts with you (if you do not have shorts, these will be provided by the researcher).

8 What are the possible disadvantages and risks of taking part?

There are no reported risks attached to the use of the two pieces of equipment.

9 What are the possible benefits of taking part?

There are no benefits to you directly from participating in the study, however the information from this study will be used in a larger study analysing the effects of a specific Physiotherapy treatment for patients with referred leg pain.

10 What if something goes wrong?

You can contact the researcher or supervisor if any problems arise as a result of this study (contact details are given below), or if you would prefer to get in touch with someone independent of the study you should contact:

*Professor Valerie Hall
Head of the Centre for Nursing and Midwifery Research
University of Brighton
Mayfield House, Falmer,
Brighton BN1 9PH
Tel 01273 644015
Email v.hall@brighton.ac.uk*

11 Will my taking part in this study be kept confidential?

All your personal details will be kept separately from the actual data collected. These details will be stored on a computer that has a password only known to the researcher. The only other people that have access to these details are the dissertation supervisors.

12 What will happen to the results of the research study?

The results of the study will form part of a PhD thesis. In addition the researcher hopes to publish the results of this study in a journal and present the findings at a national or international conference. In this case, no participants will be mentioned by name, hence your confidentiality will be upheld at all times.

13 Who has reviewed the study?

The study has been reviewed by the two academic supervisors and the University of Brighton faculty of research and governance committee.

14 Contacts for Further Information

Researcher

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Thank you for reading this information.

University of Brighton
School of Health Professions

Participant Information Sheet study 2

Do people with different types of leg pain thought to be coming from their spine have different outcomes when treated with the same sort of Physiotherapy treatment. A pilot study.

2 Invitation paragraph

You are being invited to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this information.

3 What is the purpose of the study?

The study aims to look at how different groups of people who suffer with leg pain thought to be coming from their spine respond to a particular treatment commonly given by Physiotherapists. This study is a preliminary study to assess the feasibility of the main project.

4 Why have I been chosen?

You have been chosen for the study as you have low back pain and/or leg pain for 3 months or longer and are not currently receiving any treatment for this condition. You will need to meet the requirements for eligibility into the study as described below.

The following conditions **do not** apply to you

- Previous spinal surgery
- Current or previous medical diagnoses that may affect your participation in the study (e.g. Rheumatoid Arthritis, diabetes, thyroid disease, HIV/AIDS, stroke, cancer, osteoporosis)
- Currently Pregnant
- Hip, knee or ankle disorders within the last year
- New unexplained bladder and bowel problems, and/or pins and needles in your genital region)
- Currently receiving treatment for the LBP/leg pain
- On regular high levels of pain medication (over the counter pain medication is fine, but you will be asked to stop taking this for 24 hours prior to the study)

5 **Do I have to take part?**

Your participation is entirely voluntary. If you are unsure about taking part then feel free to decline. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form and send it back to the researcher (by email cr19@bton.ac.uk or in the stamped addressed envelope sent to you). If you *do not* want to participate, you are still asked to send back the form, and sign in the section indicated on the form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect you in any way.

6 **What will happen to me if I take part?**

The researcher will first contact you by phone and ask you some questions to ensure that you are able to take part in the study (these will include questions about your back pain and any relevant medical history). If you are eligible to take part in the study you will be given a convenient time for you to attend the Human movement laboratory at the

University of Brighton, Darley Rd, Eastbourne. The session will last approximately 1 ½ hours. All appropriate travel costs will be met by the researcher and will be discussed prior to participation in the study.

Part 1 Initial assessment

You will be asked a number of questions by the researcher (who is an experienced Physiotherapist with 19 years experience) about your back and /or leg problem. A number of questionnaires will be used to assess how your pain affects certain aspects of your life.

You will then be asked to change into a pair of shorts and bra top (for ladies) before a number of tests will be applied. You will firstly be asked to move your back and leg and let the researcher know if any of your pain occurs. You will be asked to lie on your stomach and the researcher will press on your spine with her hand and you will again be asked if this brings on your pain. The strength in your legs will be tested and your reflexes will be checked (you may have had this done by the doctor before- where the tendon in your knee and ankle is tapped to see if your leg jumps). The researcher will then apply some cotton wool lightly to your leg (or tissue paper if you do not tolerate cotton wool), and you will be asked if you can feel it.

For some subjects, a piece of equipment which applies pressure to different aspects of your body will be placed on various points. You will be asked to let the researcher know what happens to the sensation of pressure as it increases up to a predetermined level

Part 2 Other measures and treatment

If you are able to participate in this part of the study (depending on the outcome of the initial assessment) you will have your height and weight measured. You will then be asked to lie on a plinth on your stomach if this is comfortable for you and a small probe will be applied to your pain free leg first which will vibrate. You will be asked to let the researcher know when you feel the vibration and then when it disappears again. Once you and the researcher are happy with this test it will be repeated on your affected leg.

Once the vibration test is complete another probe will be applied to your normal leg (similar to the pressure probe in the first part of the study if this was applied to you) which will gradually increase the feeling of pressure and you will be asked to push a button when this pressure sensation changes to discomfort (this will stop any further pressure from being applied). Once you are familiar with this, then the same procedure

will occur on your affected leg and also on your arm. The order of the vibration test and the pressure test will vary from subject to subject.

You will then be asked to lie on your side on and an ultrasound probe (small plastic device) will be applied to the back of your thigh, a layer of gel will be applied between the probe and your skin to improve the contact between you and the probe (this may feel cold). Two plastic splints will be applied to your feet to keep your feet and ankles still during the procedure. With your knee straight your leg will be moved forwards a little and then stopped. This will be repeated a few times until either you feel a worsening of any of your symptoms (if you have some symptoms all of the time) or start to feel any symptoms (if you do not have them all of the time) or until your leg does not move any more (you may let the researcher know that it doesn't want to go any further, or the researcher may feel that the leg has reached its maximum movement). During these movements the ultrasound machine will build up pictures of your nerve moving

You will then be asked to lie on your back with one splint remaining on your foot, and your leg will be lifted from the plinth with your knee straight until you feel a worsening or onset of your symptoms or the leg has reached its limit of movement as described above. Your knee will then be bent and straightened a few times (a straight leg raise (SLR) mobilisation technique) before all of the measures taken previously are repeated.

7 What do I have to do?

Please do not drink caffeine or alcohol or take any pain medication for 24 hours prior to the study. Please could you bring a pair of shorts with you (if you do not have shorts, these will be provided by the researcher).

8 What are the possible disadvantages and risks of taking part?

The SLR test is a commonly used test that physiotherapists use on a regular basis, and in some individuals may bring on your symptoms. You will be asked to inform the researcher if this occurs during the test procedure and if this happens, no additional movements will be added. The risks of increasing your symptoms after the study has completed will be minimised by asking you specific questions about your pain and doing certain tests to assess your eligibility into the study. If the researcher has concerns that your condition could be aggravated by the procedure you will be withdrawn from the study.

9 What are the possible benefits of taking part?

It is possible that the mobilisation technique applied to your leg may help to alleviate some of your symptoms, however this is not the aim of the study and any positive effects should be considered “a bonus”, and as such should not be expected. This form of treatment is only one of a number of possible treatments that could be given to you, and may not be the most beneficial; therefore you may not notice any improvement in your symptoms. The results of this study will be used in a large study assessing the effects of SLR treatment on patients suffering from referred leg pain.

10 What if something goes wrong?

You can contact the researcher or supervisor if any problems arise as a result of this study (contact details are given below), or if you would prefer to get in touch with someone independent of the study you should contact:

*Professor Valerie Hall
Head of the Centre for Nursing and Midwifery Research
University of Brighton
Mayfield House, Falmer,
Brighton BN1 9PH
Tel 01273 644015
Email v.hall@brighton.ac.uk*

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14 Contacts for Further Information

Researcher

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