RCSI SCHOOL OF PHYSIOTHERAPY

Patient Information Leaflet

Study title: A Randomised Controlled Trial of Multimodal Physiotherapy for Patients with Acute / Sub-acute Cervical Radiculopathy – the PACeR trial.

Principal investigator's name:	**Louise Keating**
Principal investigator's title:	**Chartered Physiotherapist / Lecturer in Physiotherapy, RCSI**
Telephone number of principal investigator:	**087-618 0348**
Consultant co-investigator's name:	**Prof. Ciaran Bolger**
Consultant co-investigator's title:	**Consultant Neurosurgeon, Beaumont Hospital**
Data Controller's Identity:	Louise Keating
Data Controller's Email:	lkeating@rcsi.ie
Data Protection Officer's Identity:	Dónall King, Legal Counsel, RCSI
Data Protection Officer's Email:	dataprotection@rcsi.ie

You are being invited to take part in a clinical research study to be carried out at RCSI in St. Stephen's Green, Beaumont Hospital and several private physiotherapy practices on the north and south side of Dublin, by researchers at RCSI.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part, it won't affect your future medical care. You can also change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

Cervical radiculopathy (entrapment of a spinal nerve root in the neck) is a very painful problem, characterised by neck and arm pain, pins and needles or numbness and sometimes muscle weakness.

This research is taking place to find out if the condition naturally improves with just medication and advice over the first 12 weeks and whether or not physiotherapy treatment can lead to extra improvement in symptoms, if provided early during these first 12 weeks.

A clinical trial is investigating if early physiotherapy treatment, during the first 12 weeks, is better at reducing pain and disability than medication alone. Two separate groups of patients are being recruited; one group will be advised to stay active and continue using medication already prescribed by your own doctor (GP) for 4 weeks, while a second group will be asked to attend a physiotherapist for twice weekly, thirty minute treatment sessions over 4 weeks. You can choose from the location that is most convenient for you if you are in this group i.e. northside patients can attend Collins Avenue Physiotherapy or Beaumont Hospital Physiotherapy Dept; and southside patients can attend Physiofusion (Ranelagh), Ballsbridge Physiotherapy Clinic (Ballsbridge) or Premier Physiotherapy (Ballinteer or Tallaght).

Who is organising and funding this study?

Louise Keating (principal investigator) is undertaking this research as part of a PhD degree, under the supervision of Prof. Ciaran Bolger, Consultant Neurosurgeon, Beaumont Hospital. Louise is a Specialist Chartered Physiotherapist and Lecturer in Physiotherapy at the Royal College of Surgeons in Ireland (RCSI).

This study is being funded by a research grant from EuroSpine, the Spine Society of Europe.

Unfortunately, there is no payment for volunteers to take part in the study but parking expenses or travel costs will be paid for to cover the assessments required on three separate dates during the study. You can choose the location for these assessments that is most convenient for you: Beaumont Hospital Physiotherapy Dept., RCSI School of Physiotherapy, 123 St. Stephen's Green or Premier Physiotherapy, Ballinteer.

Why am I being asked to take part?

You are being asked to take part because your GP suspects that you have a pinched nerve in your neck (cervical radiculopathy). We are looking for people who are 18 years or older, have had symptoms of neck or shoulder blade pain, as well as arm pain, tingling or numbness aggravated by neck posture or movement. Symptoms must be present for greater than 2 weeks but less than 3 months and no physical treatment for the problem has yet been tried (e.g. physiotherapy).

How will the study be carried out?

This study is recruiting between May 2015 and March 2019 and you may be asked to be involved in person or by telephone for up to 6 months.

The study is taking place at multiple locations: Beaumont Hospital Physiotherapy Department, RCSI School of Physiotherapy, Collins Avenue Physiotherapy Clinic, Physiofusion (Ranelagh), Ballsbridge Physiotherapy Clinic (Ballsbridge) and Premier Physiotherapy (Ballinteer or Tallaght) and 64 volunteers are needed.

Taking part in this study will take at least 3 hours of your time, and an additional 3-4 hours over 6-8 separate visits, if you are given the physiotherapy treatment.

What will happen to me if I agree to take part?

If you agree to take part, you will be asked to attend your most convenient location (Beaumont Hospital, RCSI or Premier Physiotherapy) on at least 3 separate occasions; at the beginning of the study, 4 weeks later and then another 8 weeks after that. These assessment visits will take no longer than an hour and will involve a series of non-invasive tests, including;

- a short physical examination of your neck and arm movement,
    - at your first visit only; reflexes in your knees, ankles and feet will also be tested.
- soreness to touch on your hands and shin (lower leg),
- filling out questionnaires about the pain and how it's affecting you.

Your parking costs or travel costs will be paid for each of these visits, if they arise.
At 6 months, you will be telephoned to answer questions about your symptoms and recovery.
All of these assessments will all be performed by the main researcher (principal investigator), who is a Specialist Chartered Physiotherapist and Lecturer in Physiotherapy in RCSI.
We will also ask for permission to contact your GP to inform them of your recruitment and provide them with details of your baseline screen; as well as to get the results of any scans (MRI) done of your neck, even if the scan has been done after the trial.

After your first assessment visit, you will be assigned to one of the 2 groups in the trial. A physiotherapist will telephone you to let you know which group you were put in:

A) **Advice group** – if this is the group you are assigned, you will receive brief weekly telephone calls from the same Beaumont Hospital musculoskeletal physiotherapist for 4 weeks, to discuss advice to better manage your condition, including taking medication that your GP prescribed and to monitor your progress.
B) **Physiotherapy group** – if this is the group you are assigned, you will be asked to make 6-8 additional 30 minute visits over 4 weeks, to the location most convenient for you: northside patients can attend Beaumont Hospital Physiotherapy Dept. or Collins Avenue Physiotherapy; and southside patients can attend Physiofusion (Ranelagh), Ballsbridge Physiotherapy Clinic (Ballsbridge) or Premier Physiotherapy (Ballinteer or Tallaght). You will be treated by a clinical specialist musculoskeletal physiotherapist. Treatment will include manual therapy (hands on treatment but not manipulation) to the spine, exercise for the neck and shoulder muscles, and taping to your shoulder to help reduce

the pinching of the nerve and as a result, reduce symptoms. If you know you are allergic to tape (e.g. sticking plasters), you will not be taped. You can also choose to refuse the tape, if you wish. The tape will run from your upper arm, over your shoulder and across to the back of your neck and should only be worn for a maximum of 48 hours. You will also be advised to continue taking medication that your GP prescribed. Appointments will be available Monday – Friday.

If you agree to take part, you won't have a choice about which group you are in. This will be done in a random way – that's the important feature of a clinical trial that helps us work out if treatment is really of benefit or not. You will also be asked not to have any other physical treatment outside of the trial for the first 3 months of the study. After that, if you were initially put in the Advice group and you are still having symptoms, you will be offered physiotherapy treatment at no cost, if the study has shown that it is beneficial.

What are the benefits?

Taking part in this study will benefit you in getting detailed advice from a specialist chartered physiotherapist about how to manage your condition.

We don't yet know if physiotherapy will be of benefit, but whichever group you are assigned to, you will be offered this free treatment at some point during the trial, if it does show a benefit.

Because of your participation in the trial, you will be monitored on a weekly basis, by phone or in person, depending on which of the 2 groups you are in. A benefit of being monitored is that if your condition significantly worsens over this time, your GP will be informed and you will be asked for permission for your case to be discussed with a neurosurgeon in Beaumont Hospital, which, in consultation with your GP, may lead to you being offered an outpatient neurosurgical appointment.

What are the risks?

No significant side effects have been reported for the physical treatment (manual therapy and exercise) planned. Treatment sessions will be aimed at reducing symptoms rather than increasing them but despite this, it is possible, due to the nature of the condition, that you might feel worse symptoms later that day or over the next 24 hours. You will be taught what to do by the senior physiotherapist who is treating you, if that happens. Taping of the skin can sometimes lead to allergic skin reactions. You will not be taped if you are known to be allergic. If you are not allergic, you will be given written instructions about how to spot a skin reaction and what to do if that occurs.

None of the assessments have the potential to cause harm. However, one of the questionnaires you fill out will help us identify if you are feeling anxious or depressed. If we find that, we will let you know and also let your GP know, so that they can help you deal with this problem.

Will it cost me anything to take part?

Parking costs or reasonable travel costs for each of the 3 assessment visits will be paid for.

If you are in the Physiotherapy treatment group, you will incur the cost of travel to and from your clinical site to receive your 6-8 visits over 4 weeks.

Is the study confidential?

Yes - all information that we find out about you during this study will remain confidential throughout the study and subsequently, when the study's findings are published. Only the researchers and treating physiotherapists will have access to this information.

Paper questionnaires that you fill out will be kept in a locked filing cabinet in the Physiotherapy Dept of Beaumont Hospital or RCSI School of Physiotherapy and all electronic information (e.g. questionnaire results) will be stored in an encrypted directory on RCSI's secure network without any identifying details, such as your name. All study paper work will have a unique identification number (UIN) on it, rather than your name and the code key linking your name and unique identification number, will be encrypted and kept on the computer servers in the Physiotherapy Department of Beaumont Hospital and RCSI School of Physiotherapy. The clinical sites will also store this information (to make contact with you) but only for the duration of the trial. Only the researcher and treating physiotherapists will receive the password for this encrypted Excel file.

Your GP will be informed of your recruitment to the trial and will receive summaries of your assessments. If you have had a scan (MRI) of your neck, the report will also be requested from your GP.

We would like you to know what we find out about your condition from your participation in this study, so we will offer you a summary of the study's results, by post, at the end of the study.

Data Protection

Personal Data that we Process

We will collect and process the following personal data in connection with this study:

- Personal details such as your name, date of birth, phone number and email address
- Sensitive personal data relating to your health including current symptoms and physical signs, diagnostic imaging reports, past medical history, medication usage and general well-being i.e. mood and quality of life.

Purposes of Processing and Legal Basis

Your personal data will be processed for the purposes of:

- Carrying out a research study to investigate the effectiveness of multimodal physiotherapy on recent onset cervical radiculopathy
- Providing summary assessment findings to treating and control physiotherapists who will be working with you

The legal basis for collecting and using personal data is your consent and falls under Article 6(1)(f) Legitimate Interests & Article 9(2)(j) Scientific Research purposes.

Who will my data be disclosed to?

- The research team
- Physiotherapists involved in delivering the treatment or control advice will receive a summary of your first assessment only
- Your GP will receive a brief summary of your assessment findings.

Will my data be transferred abroad?

No. Encrypted electronic data will be stored on RCSI's secure network at 123 St. Stephen's Green, Dublin. Your assessment and clinical data will be stored at the location of your assessments (RCSI or Beaumont Hospital) and at the clinical site where the treating or control physiotherapist is based.

How long will my data be retained?

We will retain your data for the duration of the research study and after publication, we will electronically store it in RCSI for a further 5 years. All electronic data will be deleted from the Physiotherapy Dept at Beaumont Hospital and private practice clinical sites at the end of the study and all hard copy data generated by treating and control group physiotherapists will be collected and stored in the School of Physiotherapy, RCSI.

Will my data be kept secure and confidential?

Study information will be stored electronically in an encrypted directory on RCSI's secure network without any identifying details, such as your name. An encrypted UIN code key will be stored separately on this network.

What rights do I have in relation to my data?

You have the following rights, in certain circumstances, in relation to your personal data:

- access to your personal data
- the right to request rectification and / or erasure of your personal data
- the right to restrict the use of your personal data
- the right to object to automated processing of your personal data
- the right to receive your personal data, which you provided to us, in a structured, commonly used and machine-readable format or to require us to transmit that data to another controller.

In order to exercise any of these rights or to withdraw your consent, please contact Louise Keating (lkeating@rcsi.ie).

Complaints

If you are not happy with the way we have used your information or addressed your rights, you have the right to make a complaint to the Irish Data Protection Commissioner by emailing info@dataprotection.ie.

Consent to Future Uses

When providing your consent to participate in this clinical trial, you may only wish to give consent to the use of your data in the current trial only. However, we will also ask for your permission to store and electronically process your data for the research team's possible future

research **related** to the current study, **without further consent being required** but only if the research is approved by a Research Ethics Committee. For example, our research team may seek to compare your data to that of other people with cervical radiculopathy or other types of pain. You will be asked to give explicit consent for such future use and are under no obligation to say yes.

Where can I get further information?

If you have any further questions about the study, now or at any time in the future, please contact:

Louise Keating SMISCP, MPhtySt (Manip)
Principal Investigator PACeR Trial,
Lecturer in Physiotherapy, Royal College of Surgeons in Ireland,
123 St. Stephen's Green,
Dublin 2.

Email: lkeating@rcsi.ie
Tel: 087 618 0348