Implementation of a novel clinical PAthway of CarE for common musculoskeletal disorders in primary care (PACE study)

PARTICIPANT INFORMATION STATEMENT

(1) What is this study about?

You are invited to take part in a research study about PAthways of CarE (PACE) that aims to help people recover from musculoskeletal conditions (low back pain, neck pain and whiplash and knee osteoarthritis). Musculoskeletal conditions are a major concern in the community and have a significant effect on health outcomes and health care costs. Over the last several years, our research team has been working hard to understand recovery from musculoskeletal conditions to help develop more effective treatments. The PACE musculoskeletal study will implement an innovative approach that guides health professionals in managing patients based on their prognosis. This research will investigate the effect on patient health outcomes and health care cost of the PACE study.

We do not know if this approach will be any better than the current care process. We are asking you to help us find out the answers to this question.

You have been invited to participate in this study because you have indicated that you have either low back pain, neck pain or whiplash or knee osteoarthritis. Also, you have recently consulted, or plan to consult, a primary health care professional about this condition. This Participant Information Statement tells you about the study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don’t understand or want to know more about. Participation in this research study is voluntary. So it’s up to you whether you wish to take part or not.

By giving your consent to take part in this study you are telling us that you:

✓ Understand what you have read
✓ Agree to take part in the research study as outlined below
✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.
Who is running the study?

The study is being carried out by the following researchers:

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This study is funded by the National Health and Medical Research Council. Data is being collected in NSW, Qld, Victoria and WA, with the sites leads listed in the table above.
What will the study involve for me?

This study is a randomised controlled trial. This means you will be randomly assigned to one of two groups: a) usual care by your health professional or b) the PACE program. The group you are in will be determined by random allocation (as if by the toss of a coin) and you have equal chance of being in either group.

Should you agree to participate, you will first be asked to complete questionnaires. The questionnaires will include questions about your pain, any treatment received to date, compensation status, employment status and weekly income along with questions related to time lost from paid employment and unpaid duties (e.g. home duties). You will also be asked to complete questionnaires relating to how pain is affecting your daily activities and how pain is affecting you personally.

If you are allocated to usual care, you will receive the treatment normally provided to people with musculoskeletal pain.

If you are allocated to the PACE program, your care will be based on your responses to one of the questionnaires and will range from 1-3 sessions with your usual health care professional or you may be referred to a health care professional with specialist expertise in managing musculoskeletal conditions (i.e. a musculoskeletal specialist). The specialist will then undertake a more detailed assessment of physical and psychological health. The specialist will liaise with your primary health care professional and make decisions with you on ongoing care. This may involve care provided entirely by your own primary health care professional with advice from the specialist, or the specialist may need to manage you for a few sessions. On some occasions you may need to be referred to another health professional for additional treatment. This could be a medical or surgical specialist doctor or psychologist for example. You will receive up to a maximum of six (6) treatment sessions. A website has been created specifically for this study [www.mypainhub.com]. You and your nominated health care professionals will need to log onto this website. This will give you access to information about your condition.

Finally, as this trial involves your treating health professionals, we will also ask them what treatments they provided. They will need your permission to release this information.

Being involved in the study will not influence any involvement you have with third parties (such as insurance or legal firms) nor will it affect the way in which your treating practitioner communicates with these third parties. That is, your primary healthcare professional and/or specialist healthcare professional will continue to be bound by the same rules and regulations as they normally are and which are dictated by the Australian Health Practitioner Regulation Agency (AHPRA) (https://www.ahpra.gov.au/registration/registers-of-practitioners.aspx).

How much of my time will the study take?

This project requires a 12-month commitment from you, should you wish to volunteer. The initial questionnaire will take up to an hour to complete. At 3, 6 and 12 months after injury, the questionnaires will take about 35 minutes to complete.

Who can take part in the study?

People who have low back pain, neck pain, whiplash, or knee osteoarthritis can take part in this study. They should be intending to seek care for their pain, or have sought care within the past month.
People with low back pain, neck pain, whiplash, need to be aged 18 to 65 (as children and older adults need to be managed differently). People with knee osteoarthritis need to be aged above 45 years. People should be proficient in written and spoken English because our questionnaires have not been translated into every language.

People will be excluded if their pain does not come from a musculoskeletal cause. Examples of this are known disease (e.g. cancer or infection), or known bony injury like a fracture. Patients with knee osteoarthritis will be excluded if they have stiffness in their knee in the morning for more than 30 minutes or if they are scheduled for surgery.

(6) Do I have to be in the study? Can I withdraw from the study once I’ve started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate or not will not affect your current or future relationship with the researchers or anyone else at The University of Sydney, University of Queensland, The Melbourne University or Curtin University.

The decision whether to participate or not in the study will also not affect your medical treatment or your relationship with the staff who are caring for you.

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by contacting the investigator identified in section 11.

You can withdraw your responses if you change your mind about having them included in the study, up to the point that we have analysed and published the results.

If you decide to withdraw from the study, we will not collect any more information from you. Any information that we have already collected, however, will be kept in our study records and may be included in the study results.

(7) Are there any risks or costs associated with being in the study?

The treatments provided in this study are usual treatments provided to people with musculoskeletal pain conditions and should not cause you any harm. Although a minority of participants may experience a temporary increase in symptoms following physical examination, treatment or exercise that may be prescribed, these symptoms generally settle within a few hours. You will be able to take your usual medication if you so wish.

The physical exercises that may be prescribed will be low intensity and therefore the risk of any potentially serious events is extremely rare. There have been no adverse events reported from participation in the same physical exercise treatments undertaken by over 1000 participants with similar conditions in our previous studies. If you do experience an adverse event during exercise such as shortness of breath, chest pain or palpitations, you will be immediately referred to emergency care.

Travel reimbursements will be covered by the study and we will also provide a token gift voucher after you have completed the follow up questionnaires (total = $50). The ‘usual care’ costs are not covered by this study, and would be provided and paid for as usual for public and private patients. If you are compensated by an insurer, primary care costs are usually covered under your insurance claim. If you are randomised to receive specialist care, these costs are met by the study, and the specialist will be paid directly.
(8) Are there any benefits associated with being in the study?

You may benefit from being in either of the groups in this study. However, it is possible that you may receive no direct benefit but the knowledge gained from your participation may benefit others in the future. Remember there is no obligation to take part in the study and you are free to withdraw from the study at any time, with or without stating a reason.

(9) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future projects. By providing your consent you are allowing us to use your information in future projects. We don’t know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

As per the Australian Code for the Responsible Conduct of Research, the data will be stored for 20 years for a clinical research trial.

(10) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(11) What if I would like further information about the study?

When you have read this information, Mr. Johnny Kang (kwangil.kang@sydney.edu.au, or 0435589971) or Dr. Kerrie Evans (Kerrie.evans@sydney.edu.au, or 0755611810) will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact any of the following people:

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(12) Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by ticking the relevant box on the consent form. This feedback will be in the form of a one page summary. You will receive this feedback after the study is finished.

(13) What if I have a complaint or any concerns about the study?

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project Number: 2018/926]. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:
- Telephone: +61 2 8627 8176
- Email: human.ethics@sydney.edu.au
- Fax: +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep