Feasibility of Recruiting an Early Scottish Knee Osteoarthritis cohort (FRESKO)

Patient Information Sheet Clinical Examination

We would like to invite you to take part in a research study. Before you decide 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 us 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.

Prof. Gary Macfarlane
(Chief Investigator)

Funder: Chief Scientist Office of the Scottish Government

Contact details: Laura Moir (Study Co-ordinator) by phone 01224 437421 or email: fresko@abdn.ac.uk

Chief Investigator Prof Gary Macfarlane

Participant Information Sheet - Stage II (Clinical Examination and X-ray)

1. Introduction

Knee symptoms such as pain are very common, they are reported by about 1 in 5 people. In the future we want to recruit people across Scotland with knee pain. Studying such people will allow us to study what happens over the course of time to these symptoms and specifically study people whose symptoms do or do not get worse and to understand why that is and what may be causing the symptoms. Ultimately our aim is to develop new and more effective treatments for those with knee pain.

2. What is the purpose of the study?

Before we can start such a large and expensive study, we need to make sure all our methods work and that enough people with knee pain are willing to take part. We need to make sure that they find acceptable what we are asking them to do and the time it takes them to take part in the study. That is what this current study is about (we call it a "pilot study")

3. Why have I been invited?

You have reported some symptoms in relation to your knee in the health questionnaire your GP practice sent you recently. You also indicated that you were willing to be contacted again.

4. Do I have to take part?

No. It is up to you to decide whether to take part. 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 the standard of care you receive.

5. What does the study involve?

A researcher will contact you by telephone. They will explain what is involved and answer any questions you may have. If you are agreeable, they will then arrange a time for you to attend the clinical research facility (CRF) at the Foresterhill Health Campus. During your visit to the CRF the research nurse will again explain about the study and will answer any questions you have. If you are still happy to take part, you will be asked to sign a consent form. We will ask you to complete a questionnaire, have an examination of the knee, a measurement of your height and weight, and an X-Ray of your knee. We think that the study visit will last up to 2 hours.

6. What happens to my results?

Once the x-ray is taken, the results will be transferred to your hospital records. Clinical

members of the study team will look at the x-ray results, together with your questionnaire answers and results of your knee examination, to decide if you have any signs of knee osteoarthritis. We will send you the results by letter, and we will send a copy to your GP.

If you are found to have signs of knee osteoarthritis, we will give you information about the condition, and will give you the chance to speak with one of the clinical members of our research team to ask any questions you may have.

7. What are the possible disadvantages of taking part?

An X-ray is quick and painless and is commonly used to produce images of the inside of the body. You will only be exposed to a very low level of radiation for a fraction of a second. The amount of radiation you will received will be much lower than the daily level of radiation we receive from the environment.

You will also undergo a knee examination, this will involve you standing, sitting or lying, while a research nurse moves and examines it. This should not involve any pain, and if any part of the examination is uncomfortable you will be able to speak to the nurse and ask them to stop.

8. What are the possible benefits of taking part?

You and your GP will learn if your knee pain symptoms might be a result of osteoarthritis. If they are, you will receive information on the condition and what you can do help, along with being given the chance to discuss the condition with one of the clinical members of our research team.

Our long-term ambition is to develop treatments for individual patients with signs of early knee osteoarthritis, and we hope our research will help in making this possible.

There is no payment for participation in this part of the study, although we can pay your travel costs.

9. Can I bring a relative or friend?

Yes, you can bring someone with you if you wish. They will not be able to enter the x-ray with you, however, and will be asked to stay in reception while you have your x-ray.

10. What if something goes wrong?

If you have any concerns about any aspect of this study, you should speak directly to the researchers who will do their best to answer your questions, details are at the bottom of this information sheet (section 16).

If you still remain unhappy and wish to complain formally, you can contact NHS Grampian Feedback service on Tel: 0345 337 6338 or by email: nhsgrampian.feedback@nhs.net

11. What will happen if I can't or don't want to carry on with the study?

You can withdraw from the study at any time without having to give a reason. This will not affect the standard of care you are receiving. With your permission will use the anonymised data collected in the study, up until the point that you withdrew.

If at any point you become incapacitated (no longer able to express your own wishes) or if you are unable participate to due to ill health, you will be withdrawn from the study. Again, with your permission, we will use any anonymised data collected in the study, up until the point that you were no longer able to continue participating in the study.

12. Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital or university will have your name and address removed, so that you cannot be recognised. Identifiable information will only be accessible to the local research team and regulatory authorities for auditing and monitoring purposes. You will be allocated a unique identification number and staff not directly involved with you will know you only by this number. When the results of the study are reported, individuals who have taken part will not be identified in any way.

13. How do we look after your information

The University of Aberdeen is the sponsor for this study. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen will keep identifiable information about you for 5 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information https://www.abdn.ac.uk/privacy

NHS Grampian will collect information from you and your medical records for this research study in accordance with our instructions.

NHS Grampian will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from The University of Aberdeen and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS Grampian will pass these details to The University of Aberdeen along with the information collected from you and your medical records. The only people in The University of Aberdeen who will have access to information that identifies you will be people who need to contact you or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

NHS Grampian will keep identifiable information about you from this study for 5 years after the study has finished

14. What will happen to the results of the research study?

The results from this pilot study may be published in the form of a scientific manuscript but mainly will be used to inform the development of a future Scotland-wide study which would recruit and follow-up people over a number of years.

15. Who is organizing and funding the research?

This research study is funded by the Chief Scientist Office for Scotland. The study is being coordinated by the University of Aberdeen and NHS Grampian.

16. Who has reviewed the study?

This study has been reviewed and approved by the North of Scotland Research Ethics Committee (2) and by the Chief Scientist Office for Scotland

17. Contact for further information

For further information please contact the study coordinator Mrs. Laura Moir Tel: 01224-437421 Email: fresko@abdn.ac.uk

Thank you for considering taking part in this study