Feasibility of Recruiting an Early Scottish Knee Osteoarthritis cOhort

Patient Information Sheet Qualitative Interview

You are being invited 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

1. Introduction to Fresko

Knee symptoms such as pain are very common (they are reported by about 1 in 5 people). Fresko is a feasibility study to determine the most efficient method for identification and recruitment of people with knee pain, identify their willingness to provide the information we need and (where relevant) undergo investigations.

2. What is the purpose of the study?

The purpose of this stage of the study is to understand patients' experiences and views of taking part in this study. It is helpful to understand both positive and negative experiences and your views on the study in order for us to develop a larger study.

3. Why have I been invited?

We are inviting a wide selection of participants who indicated that they were willing to be contacted further during the clinic appointment you attended as part of the study.

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.

5. What if I wish to withdraw at a later stage?

You can withdraw from the study at any time without giving a reason if you wish. If you do withdraw from the study we will destroy all of your identifiable data, but unless you specifically ask otherwise, we will retain and use any data collected as part of the study, up to that point.

6. What does the study involve?

You will be asked to take part in an interview to discuss your experiences and views of the FRESKO study. Before the interview starts, we will ask you to give 'verbal consent' (agreement to take part) by going through the consent form that we sent you with this information leaflet.

We will do the interview by telephone at a pre-arranged time to suit you. We anticipate that the interview will last between 30 – 45 minutes. It will be with a member of the research team. We will ask your permission to audio-record the discussion, which we will later transcribe word-for-word.

7. What are the possible disadvantages of taking part?

We do not anticipate any side-effects of taking part in the interview as we are only discussing your experiences of taking part.

8. What are the possible benefits of taking part?

There are no direct benefits to you, the aim is for us to learn from your experiences and to inform how we recruit people and what we ask of them in the future. It is possible you may find it helpful to discuss your experiences and views.

A £20 gift voucher will be provided as a thank-you and recognition of your time.

9. 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.

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

10. 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.

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

Yes. Your interview will be typed up by University of Aberdeen staff or an approved external typing company who will treat your data confidentially. When the interview is typed up it will be made anonymous, any mention of names and places will be removed. The audio-recordings will be deleted as soon as we have typed up the interview. The anonymised transcripts will be kept for 5 years from the end of the study and then destroyed. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. You will be allocated a unique Participant ID 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.

12. 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 http://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 to 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.

13. 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

14. 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.

15. 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.

16. 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