

Patient Information Sheet

Study of Communication Between Patients and Musculoskeletal Physiotherapists

We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why this research is being done and what it will involve;
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish;
- You are free to decide whether or not to take part, this will not affect the quality of care you receive from your physiotherapist;
- Ask us if there is anything that is not clear or if you would like more information.

Why are we doing this study?

- We want to improve how we communicate with our patients and service users;
- We have been trialling a new type of communication training with our physiotherapy staff, we want to know if this is improving the patient experience or if we need to review this

Why have I been invited?

All adult patients referred to the musculoskeletal physiotherapy service have been invited to take part.

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How to contact us?

If you have any questions about this study, please contact the physiotherapists who organise it:

Dr. Grant Syme, Mr. Mark Fergie
Mrs. Morag Watson or Mr. David Reynolds
01592 648106

What will I need to do?

- If you are willing to take part please indicate this when asked by the Administrator when you contact the Booking Office to make your first appointment. You are under no obligation to take part and not taking part will not affect your appointment in any way.
- If you agree to take part you will be asked to sign a consent form at your first physiotherapy session and consultation (please allow 60 to 90 minutes for this process). This initial session only will be digitally *audio taped (not video)*. The audio tape will be transcribed and analysed.
- You will also be asked to complete four brief questionnaires at both the initial and final consultation;
- You will receive your normal physiotherapy treatment and care;
- A number of patients (40%) will be invited (if willing) to take part in a further 30 minute audio taped interview at their last treatment session to explore how they found their physiotherapy experience.
- You will be contacted by telephone at one year after completion of your participation in the study to see how you are progressing with your condition.
- No treatment is changed or withheld.
- Only the four members of the NHS Fife the research team will have access to the audio tapes. The audio tapes will be kept securely and confidentially until the completion of the study or for a maximum of 2 years from the collection date.

Are there any risks or disadvantages to taking part?

Your initial consultation may take 15 to 30 minutes longer than usual in order to complete the research paperwork. Any communication or clinical interaction with patients may reveal sensitive psychological issues that may become evident during the consultation. In the event of any unforeseen overtly sensitive or distressing issues the audio taping will be terminated. Your feelings/thoughts in that moment will be discussed and in collaboration with the physiotherapist, either the consultation would continue, be ended and/or your withdrawal from the study agreed.

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. The audio file will be anonymised and analysed by the physiotherapy research team at NHS Fife. Any published work will contain no patient identifiable information.

Further Information About Taking Part

What are the possible benefits to taking part?

We hope that in time we can improve the experience and outcomes for patients receiving physiotherapy as there is some evidence that advanced communication training may improve patient outcomes.

What happens when the research stops?

You will continue to receive any physiotherapy care that you require. The study does not involve a trial or comparison of different types of physiotherapy treatments.

What will happen to the results of this research study?

The results of this study will form a report for NHS Fife and be made available through the Patient Partnership Forum. Papers from this research may be published in physiotherapy or medical journals.

Who is organising and funding the research?

No physiotherapist or doctor is being paid for including you in this study. The research is organised by NHS Fife.

What if something goes wrong?

If in the unlikely event this research harms you there are no special compensation arrangements. If you are harmed due to someone's negligence then you may have grounds for legal action, but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of the study the normal National Health Service complaints mechanisms are available to you. Please contact NHS Fife Patient Relations Service.

NHS Fife Patient Relations

Telephone: between 9.00am and 4.30pm Monday to Friday on: 01592 648153 Ext: 28153

Email: Patientrelations.fife@nhs.scot

This mail box is manned twice a day (Monday to Friday). NHS Fife will acknowledge receipt of your email.

Address:

Patient Relations Department
Fife NHS Board
Room 104
Hayfield House
Hayfield Road
Kirkcaldy
KY2 5AH

What happens next?

When you contact the Physiotherapy Central Booking Office you will be asked if you

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received the study information and whether you are willing to participate in the study. The Administration staff at the Central Booking Office are not directly involved in the study, although are aware of it. If you do not wish to take part, then this will not affect your physiotherapy appointment or management in any way. We expect you to have a positive experience in participating in this study. If you do agree to take part, you are free to withdraw from the study at any time.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East of England, Cambridge and Hertfordshire NHS Research Ethics Committee.

Review by Regulatory Bodies

The Sponsor NHS Fife has approved all the study protocol and materials, which have also been reviewed and approved by the East of England, Cambridge and Hertfordshire NHS Research Ethics Committee. The Lead Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

The Lead Investigator shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

General Data Protection Regulation (GDPR)

All investigators and study site staff will comply with the requirements of General Data Protection Regulation (GDPR) and the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information. The study information once collected from patients at the study site will be coded and uploaded to NHS Fife secure electronic information storage systems.

Access to any patient data prior to data being anonymised will be restricted to the NHS Fife employed staff for quality control, audit and analysis purposes. Patient data will be stored for 7 years as per NHS Fife Physiotherapy Records retention procedures.

Insurance and Indemnity

Insurance - NHS Fife will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

NHS Fife will maintain its membership of the Clinical Negligence and Other Risks Insurance Scheme ("CNORIS"), which covers the legal liability of NHS Fife in relation to the study.

Indemnity - The Sponsor does not provide study participants with indemnity in relation to participation in the Study, but has insurance for legal liability as described above.

Contact for further information

Should you require any further information about the study please contact:-

Lead Researcher

Dr. Grant Syme
Consultant Physiotherapist
Department of Physiotherapy
Victoria Hospital, Kirkcaldy
Hayfield Road
Kirkcaldy
Fife
KY2 5AH

Tel: 01506 717828

Local independent advisor

Should you wish to discuss this study with a local independent advisor not connected with the study please contact:

Ms. Amanda Leech
Primary Care Physiotherapy Services Manager
Department of Physiotherapy
Queen Margaret Hospital
Whitefield Road
Dunfermline
Fife
KY12 0SU

Tel: 01383 627036

NHS Fife provides accessible communication in a variety of formats including for people who are speakers of community languages, who require Easy Read versions, who speak BSL, read Braille or use Audio formats. NHS Fife SMS text service number 07805800005 is available for people who have a hearing or speech impairment. To find out more about accessible formats contact: fife-UHB.EqualityandHumanRights@nhs.scot or telephone 01592 729130.

Many thanks for your help and consideration