Corka

REC Reference 15/SC/0019

Participant Information Sheet – Main Study

Community Based Rehabilitation after Knee Arthroplasty (CORKA)

What is the purpose of the study?

This study will determine the difference in outcome for people undergoing knee arthroplasty (knee replacement), between a community based rehabilitation programme and usual care. Participants in this study will be randomly assigned to either usual care or a community based rehabilitation programme. The programme will consist of exercises and practice of functional activities. It will be set up by a Physiotherapist and supervised by a Rehabilitation Assistant with occupational therapy involvement. The study will help to inform the way rehabilitation after knee replacement is delivered, determining whether a home based rehabilitation programme is different from usual care physiotherapy.

Why have I been asked to participate?

You have been invited to take part in this study because you are due to undergo a knee replacement and you will require physiotherapy after the surgery.

Do I have to take part in the study?

It is up to you whether or not to take part. If you decide not to take part then your future medical care will not be affected in any way. You are also free to ask the researchers any questions you may have at any time during the study. If you decide to take part you would be given this information sheet to keep and be asked to sign a consent form. The study team will be looking for 620 participants to take part.

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NHS National Institute for Health Research

Who can take part in the study?

Men and women aged 55 or above can take part in the study if they:

- Have undergone a primary knee replacement (not a revision)
- Are identified as having the potential to benefit from increased rehabilitation
- Are not scheduled for any further lower limb surgery in the next year
- Do not have rheumatoid arthritis

What will happen if I take part in this study?

At your pre-op assessment appointment, if you are considered eligible for the trial, you will be given information on the study. After this if you consent to take part in the study. A research staff member will visit you at home to complete a baseline assessment. This consists of some paper questionnaires and three physical tests, looking at your balance and walking and standing from sitting.

Three days after your knee replacement surgery, a member of the research team will visit you in hospital to check how the surgery went and ensure you are still happy to continue to take part in the research. At this point if you have developed any post-operative complications you may no longer be eligible to take part in the study.

If you are still eligible you will be allocated to one of two groups of physiotherapy rehabilitation and the allocation will be decided entirely by 50:50 chance, like a toss of a coin. A computer programme is used to generate the allocation.

The two treatments are:

- Usual physiotherapy care - This consists of written advice, a home exercise programme and the provision of any essential equipment on discharge from hospital. You will then be referred for further outpatient physiotherapy which will consist of between 1-6 sessions depending on your ability and availability in your hospital.

- Community based rehabilitation - This consists of 7 sessions of a rehabilitation programme, set up by a Physiotherapist and supervised by a Rehabilitation Assistant in your own home. The programme will consist of practice of functional activities such as walking or climbing stairs, in addition to an exercise training programme consisting of gentle stretches, strengthening and balance exercises. The rehabilitation assistant will guide you through this and the programme will be tailored to you. If needed you may also be loaned equipment to make functional tasks at home easier, such as a grabber. You will also be asked to carry out the exercise programme on your own a further 3 times in the week. You will need to allow the rehabilitation team to attend your home to deliver the rehabilitation programme.

To be able to compare the treatments we need to repeat the questionnaires and physical assessments after you have received treatment. We will invite you to be re-assessed at 6 months and 12 months after you have joined the study. This can be undertaken in your home or at your local hospital.

Diary

We will ask all participants in both intervention groups to complete a diary. The diary will record the exercise you have undertaken, any medication you have used, any additional health care you have received. In addition to any problems that have occurred following your knee replacement. There will be a diary for the first 6 months that you are in the study, followed by another diary for 6 months to 12 months. Although this diary covers a number of areas, it has been designed to be easy to fill in and it will be explained to you by a clinician at one of your appointments.

As part of the study a small number of participants will be invited to take part in a one to one discussion with a member of the research team. Questions will focus on what they thought about taking part and the treatment they received. Your participation in

the discussion is completely voluntary and if you are invited to take part further information will be provided.

Expenses and payments

If you attend the research clinic at the hospital for research assessments additional to your usual care travel expenses (public transport, car mileage, car parking) will be reimbursed.

What are the benefits of taking part in the study?

We do not expect any particular benefits from taking part for you as an individual. The information we get from this study will help us to treat future patients with knee replacement. However, it is known that rehabilitation can improve outcomes after knee replacement

Is there any risk of taking part in this study?

There are no "new" treatments included in this study. The treatments are those already used with patients after knee replacement. There should be no more risk in the community based rehabilitation group as in standard care.

What happens when the study ends?

When the study ends we will provide you with a summary of the study findings. Your clinical follow up by your consultant will not be affected by your participation in the study and will continue according to their wishes for you.

What if I have any concerns?

If you have a concern or problem about any aspect of the study please speak to any one of the researchers who will do their best to answer your questions. Their contact details at the Physiotherapy Research Unit are at the top of this patient information sheet. You may also contact the hospital's Patient Advice and Liaison Service (PALS)

INSERT LOCAL PALS NUMBER or email INSERT PALS LOCAL EMAIL ADDRESS.

Will my taking part in this study be kept confidential?

All information that is collected about you during the study will be kept strictly confidential. Information will be held in a secure place and questionnaire and assessment information sent from your local clinical site to the trial team will have your name and address removed first. Every person that takes part will be given a unique study number to make sure they cannot be identified outside of the study.

Once assigned to a treatment group you will be allocated a unique ID which will be used in the trial database and that any identifying information will be kept separately. All information will be securely stored for five years after the study has ended and then be destroyed. A copy of your signed and dated consent form will be sent to the Trials Office, for monitoring purposes. The consent form and the contact details you provide will contain your name and other identifying details and we ask your permission to use this information for study purposes on the consent form.

All information collected during the course of the study is centrally managed by the research team at the University of Oxford who will receive your anonymised study data. All study data will be stored in a restricted-access study database managed by the Oxford Clinical Trials Research Unit in the University of Oxford. The study database will be password protected and will only be used by named researchers working on this study under the direct supervision of the senior scientific investigators.

Responsible members of the University of Oxford or the local NHS Trust may be given access to data and or medical records for monitoring and/or audit of the study to ensure we are complying with regulations.

How long will my data be stored?

Anonymised study data is kept for at least 5 years from the end of the study by the University of Oxford both as a paper copy and on a secure database.

Personal identifiable information (such as your name, contact details and NHS number) will be held securely and separately to the anonymised data collected in the study.

What if new relevant information becomes available?

If new relevant information about physiotherapy treatments for knee replacement becomes available then your physiotherapist or a member of the study team will tell you about it and discuss with you whether you want to continue in the study. If the study team believed it would be in your best interest to withdraw from the study they would also discuss this with you. Your hospital/GP would be informed. If you decided to continue with receiving a study treatment you would be asked to sign an updated consent form.

What would happen if I don't want to continue with the study?

You can withdraw from the study at any point. You would be asked how your information is managed – you can choose between leaving the study and allowing the information already given to be used by the study team OR leaving the study and asking for the information already given by you to be destroyed. If you withdraw from the study this will not affect your future NHS care in any way.

Would anyone else know if I was taking part?

We would ask for your permission to write to your GP to tell them you are taking part in this study.

What happens to the results of the study?

The results will be used to write a report and health journal articles so that health care professionals can use the results to help other patients in the future. In any report or publication we will not use your name or give any information that could identify you. We will send out a summary of the results to people who take part in the study when the study is complete.

What if something goes wrong?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact *<name of investigator><contact details (phone number & email)>* or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk

Who is organising and funding the research?

The study is being set up by researchers in The University of Oxford and organised by the CORKA Trial Office (University of Oxford). Funding has been provided by the National Institute of Health Research's Health Technology Assessment Programme.

Who has reviewed and approved this study?

The study was reviewed by independent experts when the study was being considered for funding. All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, which is there to protect your safety, rights, wellbeing and dignity. The CORKA study has been reviewed by the South Central Oxford B Ethics committee, REC number 15/SC/0019 and has given its approval along with the Research & Development Department based at your hospital.

Who do I contact for further information?

If you would like any further details about this study or would like to ask us any questions then please do not hesitate to contact us. You may speak to the local CORKA team by telephoning:

Principal Investigator: Insert PI Name,Title	Insert PI Contact Details

Research Team: Insert Local Research Team Name	Insert Local Research Team Contact Details

If you would like to write to the person in charge of the study please send your letter to:

Dr Karen Barker
Physiotherapy Research Unit
Nuffield Orthopaedic Centre
Oxford, OX3 7HE
Tel: 01865 737526
Email:Karen.barker@ouh.nhs.uk

Or contact the CORKA Study Research Team in Oxford:
Tel no. 01865 737526
Or email us on CORKA@ndorms.ox.ac.uk

You may also contact the University of Oxford's Clinical Trials and Research Governance Office: Tel: 01865 572221

What do I do now?

If you would like to take part in this study then please fill in the reply slip and post it to us in the pre-paid envelope provided. If you have received this invitation in the post and we do not hear from you we will send you one further invitation.

Thank you for taking the time to read this Patient Information Sheet and considering Participation in this study.