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PROJECT TITLE:

Effects of enhanced rehabilitation conditioning on the relationships between indices of sensori-motor, neuro-mechanical, psycho-physiological, and functional performance associated with patients following total knee replacement.

RESEARCHERS & COLLABORATORS:

Maria Moutzouri (Chief Investigator/PhD. Candidate)
Dr. John Gliatis (Consultant Orthopaedic Surgeon)
Prof. Elias Panagiotopoulos (Professor of Orthopaedics, Director of Orthopedic Clinic)
Dr Nigel Gleeson (Professor in Rehabilitation Science)
Dr. Fiona Coutts (Senior Physiotherapist, Dean of the School of Health Sciences)
Dr. Emad Al-dujaili

PARTICIPANT INFORMATION SHEET

You are being invited to take part in the above titled research study. Before you decide to participate, it is important for you to understand why this research is being carried out and what it will involve. Please take your time to read the following information sheet and please feel free to ask any questions if there is anything that is not explained clearly. If you would like more information, please contact the research team (contact details are provided at the end of this information sheet).

WHAT IS THE PURPOSE OF THE STUDY?

This study is part of a doctoral research programme that is currently being undertaken at Queen Margaret University, Edinburgh. The research team are investigating whether we can enhance the rehabilitation that you will be receiving following your total knee replacement surgery.

This rehabilitative programme is detailed in the total knee replacement and rehabilitation patient advice booklet you have already received. If you have not yet received this, please contact the physiotherapy team. This information guide provides you with examples of the physiotherapy programme you are to receive. This will include strength, endurance, function, balance and other related techniques used within the field of physiotherapy. It is important that you follow the instructions given to you by the physiotherapy team as they will be important for your recovery following your surgery.

The primary aim of this study will be to investigate the effectiveness of standard practice integrated with new aspects of conditioning added that might potentially enhance the clinical care of patients. It will review the overall outcomes of surgery and rehabilitation while focusing on looking for any improved capability for you to produce strength, to move precisely, to self-perceive effort during exercise and to undertake activities from everyday life.

The study will also investigate how to make best progress within your programme of rehabilitation. You might be asked to undertake a safe but slightly more intense exercise conditioning within one of your rehabilitation sessions in order for the clinical team to understand how well you cope with this slightly increased demand. This more intense conditioning that you may be asked to undertake will include some more repetitions of your usual exercises.

During your rehabilitation, you progress will be supervised by your Consultant Surgeon and your Physiotherapist. Your physiotherapist will teach you this programme of rehabilitation that will then be guided to undertake at home safely and easily with minimal equipment (e.g. elastic bands). All the exercises you will be instructed to perform will be appropriate to the stage of rehabilitation you will be in. At most cases the exercises will resemble everyday tasks such as climbing stairs that will be essential to you in order to be independent and functional in your everyday life. Some other type of exercises you will be instructed to perform will aim to facilitate your precision in moving so as to enhance your courage and minimize any risks of you getting injured (e.g. triping over an object while walking).

WHY HAVE I BEEN CHOSEN?

In this study, the research team will be investigating patients (like yourself) who have elected to undergo total knee replacement surgery and who are otherwise medically fit. The reason you are being invited to take part in this study is that you fit this description.

We are hoping to recruit 60 participants for this trial that involves random-allocation of patients to the types of rehabilitation which are being compared (randomised control trial).

DO I HAVE TO TAKE PART?

Participation in this study is entirely voluntary and you are free to decline participation or to withdraw from the study at any time. You do not need to give any reasons if you decide to leave the study. If you do decide to withdraw, you will continue your rehabilitation as normal with no prejudice.

WHAT WILL HAPPEN TO ME IF I TAKE PART AND WHAT WOULD I HAVE TO DO?

The research team would like to find out, whether or not the current way of rehabilitating patients who have had your type of surgery can be improved upon. To find this out, the research team need to make comparisons between the different styles of rehabilitation. To do this, the research team will put participants into groups that will each experience a different style of rehabilitation. The results will be compared to see which one, if any, is most beneficial. You will be randomly selected (by chance) into one of two groups. It is important to note that no matter which group you are allocated into, you will receive the same standard of care and rehabilitation that is routinely implemented as part as your physiotherapeutic treatment. You will be taught by your physiotherapist all exercises you should be doing during rehabilitation and you will be given an analytical booklet with instructions to be able to perform your program. Should you need any help you will be given contact details of your physiotherapist and orthopedic surgeon that you will be able to contact. Your physiotherapist will supervise your progress with regular weekly phone-calls.

Moreover, at some stage of your rehabilitation you may receive a session of a more intensive rehabilitative exercise task, with which you will have been familiarized within your standard rehabilitation. The research team would like to find out which are the boundaries within exercise therapy that patients can work on without fatigue.

Throughout your rehabilitation programme you will be attending the physiotherapy clinic approximately 3-4 times over the 24 week rehabilitative period to assess your progress. It is important that you attend all scheduled appointments with your physiotherapist. However, if you cannot attend for whatever reason, the

research team or physiotherapists might contact you by email, letter or telephone to discuss your rehabilitation progress.

Depending upon which group you have been randomly allocated into, you might be asked to complete a questionnaire during your scheduled physiotherapy appointment. This will take no longer than 3 minutes to complete typically. However, during your first session, its completion might take longer (up to 15 minutes) because the research team will introduce and explain about any questionnaire needing completion.

During your rehabilitation programme, you will need to attend up to four assessment sessions. The research team with gain the majority of the information required for the study from these assessment sessions, and so it will be very important that you attend. These assessments sessions will last approximately one hour and will take place on a day that you would normally attend the orthopedic clinic to visit your orthopedic surgeon. Your first appointment for assessment will be prior to your surgery.

Depending on the group to which you are allocated, you will be assessed typically when you visit hospital for your routine outpatient check-ups at 6 weeks following your surgery, a few days following that appointment and between 12 weeks following surgery. Lastly, you will be contacted for a brief phone call to answer some simple questions and when your rehabilitation is completed at 24 weeks.

Within these assessment sessions, you will be tested using advanced computerised data acquisition equipment and software. The research team hope you will find these assessment sessions informative and interesting, providing you with additional time to ask questions and to learn more about your rehabilitation.

We will be monitoring aspects of knee joint performance such as:

(1) The strength of your leg muscles and your ability to repeat brief strength tasks accurately. This allows us to check how well the muscles can produce force to protect the joint efficiently.

(2) How quickly your leg muscles can react to a brief and painless tasks. This allows us to safely check how quickly the muscles could produce force to protect the joint in an emergency, such as if you were to trip or land awkwardly from a jump.

(3) The balance you can maintain will also be tested. This allows us to check how well the rehabilitation is affecting the stability of your body and knee joint.

(4) How the above factors change following a brief fatigue task. This allows us to check the extent to which muscle fatigue could lessen your ability to protect the knee joint during exercise and helps us to gauge a safe return to functional daily-related activities.

You will also be asked to complete questionnaires about your knee, and keep a weekly diary of your rehabilitation. It is anticipated that entering information into the diary should take no longer than 10 minutes per week to complete, and recorded over the 24-week period.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS, AND WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

No matter which rehabilitation group you are allocated into, there will be no extra clinical risks or disadvantages to yourself. This is because all participants in this study will be performing the same exercises at the same stage during the rehabilitation programme. In addition, taking part might be more beneficial to your recovery, and the information the research team gathers from this study might inform and improve future clinical practice.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

The research findings may inform the research team that one way of rehabilitating patients is better than another. This will then alter the way the physiotherapy team suggest patients rehabilitate in the future.
If you wish, after the research is complete, we can disseminate the findings from the study to you.

The findings may also be written and published in medical/scientific journals to aid other clinicians and patients elsewhere. Neither you nor your data will be identifiable in these publications.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

The only purpose of this study is to assess the best way to rehabilitate patients after total knee replacement surgery. The research team will keep your name, age, sex and your results in a record that will be stored on a password-protected computer to ensure only persons involved in the study can access the information. The storage and subsequent destruction of your data is compliant with the Data Protection Act 1998. All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves this hospital will have your name and address removed so that you cannot be identified from it, and will subsequently be anonymous.

COMPLAINTS

If you believe you have been harmed in any way by taking part in this study, you have the right to pursue a complaint. Details about this are available from the research team.

CONTACT DETAILS FOR FURTHER INFORMATION:

We hope you will participate in this study, but if you have any questions or would like more information, please contact:

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moutzouri_marie@yahoo.com (preferred correspondence)

WHO HAS REVIEWED THE STUDY?

For you to have been offered participation in this study, it will have had to have been already given a favourable ethical opinion for conduct in by Queen Margaret University Edinburgh's local Ethics Committee. It will also have been approved for scientific merit by the Local Research Scientific & Ethics Committee of University Hospital in Patras.
If you would like some independent advice about whether you should take part in the study, please contact:

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Thank you for taking the time to read this information sheet and considering whether or not you'd like to participate.