Patient Information - MAXM Skate Study

Following total knee replacement surgery patients experience lower extremity muscle weakness and commonly require physical rehabilitation to enhance functional outcomes and overall recovery. Currently, various modes of rehabilitation are available and are regularly based on the hospital, surgeon or occasionally, patient specific preferences.

The aim of this clinical trial is to assess the safety, efficacy and cost-effectiveness of the Maxm Skate rehabilitation device as compared to standard rehabilitative care at Flinders Private Hospital.

The Maxm skate is a portable, lower limb post-operative and post-injury rehabilitation exercise device for individual use in a hospital or home-based setting. The Maxm Skate aims to facilitate rehabilitation and conditioning of the lower limb. It strives to allow the patient to perform strengthening exercises with minimal joint loading during their rehabilitation period. The Skate device is accompanied by two sensors and a mobile iOS Application which are designed to provide real time, objective data on exercise and rehabilitation progress following an exercise therapy session at home.

The device was primarily designed to assist patients after lower limb surgery to conduct rehabilitation exercises in the home.

The Maxm Rehabilitation device and program is an experimental treatment. This means that it is not approved for use as a rehabilitation device following total knee replacement in Australia.

This research has been initiated by orthopaedic surgeon, Dr Matthew Liptak and is financially supported by Government awarded grants, and by support from Maxm Skate Pty Ltd. The study is co-ordinated with assistance from researchers from the International Musculoskeletal Research Institute Inc.

What does participation in this research involve?

A consent form will be signed prior to any assessments being performed on you, as a potential participant.

Initial steps

You have been identified as a possible participant in this research project as you are scheduled to undergo a total knee replacement, requiring rehabilitation after surgery.

You will be randomised to receive either the novel rehabilitation device, the Maxm Skate, or standard rehabilitative care (control group).

The physiotherapist who will be conducting all functional evaluations, excluding Day 2 post-surgery, will be blinded to which rehabilitative group you have been randomised to. We ask that you <u>do not</u> disclose which rehabilitation group you are assigned to this physiotherapist, or your orthopaedic surgeon, Dr Matthew Liptak, at any time throughout the study. However, if you are concerned about your rehabilitative progress and feel it is necessary to discuss this with Dr Liptak, then please do so.

Procedures

If you are eligible and choose to participate in the study, you will undergo clinical and functional evaluations.

You will also be asked to complete an economics questionnaire at weeks 2, 4, 6, 12, 26 and 52 after surgery. This questionnaire aims to find out about the costs to you and the costs to your family across your rehabilitation journey. Questions you will be asked to complete will relate to the type of healthcare services you accessed and how the costs for these services were met. You will be queried on the mode and cost of transport used to attend these appointments and if this impacted on time-off work for you or your companion. You will also be queried on the fortnightly earnings of your companion and yourself in order to calculate the impact of lost productivity. Use of social care services and medication will also be collected. Please be advised that it is your responsibility to ensure that you have the consent of your companion before disclosing any personal information requested in the economics questionnaire.

Clinical assessments will involve completion of clinical and quality-of-life questionnaires before surgery and at 6 weeks, 12 weeks and 12 months after surgery. These will include:

Self-reported Outcome Questionnaires

- Oxford Knee Score (OKS)
- Euroqol 5 Dimensional Health Survey – Level 5 (EQ-5D-5L)
- Knee Injury and Osteoarthritis Outcome Score (KOOS)
- Patient Acceptable Symptom State (PASS)
- Satisfaction with Rehabilitation

Functional evaluations will be performed by an experienced physiotherapist and performed before surgery and at <u>Day 2</u>, and weeks 2, 4, 6, 12, 26 and 52 after surgery.

Functional measures:

- <u>Knee Range-Of-Motion (ROM)</u>

In a seated position, joint ROM will be measured with your knee when flexed and extended.

- <u>Visual Analogue Scale for Pain in Flexion and Extension</u>

This is a patient reported measure of pain.

- Isometric Knee Extensor and Flexor Strength, and Bilateral Hip Abduction

Your knee strength and hip abduction will be measured using KangaTech (Melbourne, Australia) instruments. The strength of three leg muscles will be measured while you are in a comfortable seated position and will take approximately 5 minutes. These tests have been shown to be safe for people with osteoarthritic knees and those who have had a total knee replacement. During these tests you will be asked to push against a load cell that will measure strength. You will be asked to gradually increase the force to provide your maximum pushing effort. Should you feel pain or discomfort significantly different to your resting pain, the test will be modified for you. We are testing strength of these muscles because it is important to the function of your knee. Being stronger is associated with improved function and decreased pain.

- Balance Test

This will be performed by timing your ability to stand on a single leg with your eyes open.

- Knee and Thigh Circumference
- 30s Chair-stand Test

This test will assess your ability to move from a seated position to standing.

- 4 x 10 m Fast Paced Walk Test

This test is a short distance walking activity to test your walking speed.

Time Commitments

Eligible participants who are interested in participating in the study will be invited to a consent visit with the clinical study researcher. This visit should take approximately 20 minutes, depending on your queries.

If you are willing to provide written informed consent, we will ask you to complete the self-reported questionnaires which are expected to take approximately 30-40 minutes. Following this, you will undergo the functional examination performed by the physiotherapist which will also take between 45 to 60 minutes. If it is not possible to conduct the functional assessment at this time, you may be asked to return for an additional appointment at which time you may choose to conduct the questionnaires also.

Participants randomised to receive the Maxm Skate rehabilitation device will be required to attend an additional Maxm Skate Education Session in which they will be instructed on how to safely use the device. This session will be conducted by a physiotherapist trained in the use of the device and will provide the opportunity for participants to use the device and clarify any queries. Participants in the Maxm Skate group will also be required to complete a short form titled *'Record of participation in the Maxm Rehabilitation Program'.*

All participants will be asked to take note of the physiotherapy they do receive after surgery. This will be based on the participant's ability to recall the type and number of physiotherapy sessions they have received, which will then be documented in a patient report form at a follow-up visit.

All study related appointments including the Consent Visit, Clinical Evaluations, Functional Evaluations and Maxm Skate Education Session will require your attendance at Flinders Private Hospital, Level 5, 1 Flinders Dr, Bedford Park SA 5042.

Summary of time commitments to expect over the 12 month follow-up period:

Consent Visit	Consent 20 minutes If consent provided, complete questionnaires 30-40 minutes *With Clinical Researcher*
Function Examination	45-60 minutes *With Physiotherapist*
Maxm Skate Education Session *Maxm Skate group only	30-45 minutes on a Thursday 1 week after consent visit *With Physiotherapist*
2 days post-operative	Functional Evaluations 45-60 minutes *With Physiotherapist*
2 weeks post-operative	Functional Evaluations (45-60 mins), Economics Questionnaires (5-10 mins) *With Physiotherapist + Clinical Researcher*
4 weeks post-operative	Functional Evaluations (45-60 mins), Economics Questionnaires (5-10 mins) *With Physiotherapist + Clinical Researcher*
6 weeks post-operative	Clinical Evaluation Questionnaires (30-40 mins), Functional Evaluations (45-60 mins), Economics Questionnaires (5-10 mins) *With Physiotherapist + Clinical Researcher*
12 weeks post-operative	Clinical Evaluation Questionnaires (30-40 mins), Functional Evaluations (45-60 mins), Economics Questionnaires (5-10 mins) *With Physiotherapist + Clinical Researcher*
6 months post-operative	Functional Evaluations (45-60 mins), Economics Questionnaires (5-10 mins) *With Physiotherapist + Clinical Researcher*
12 months post-operative	Clinical Evaluation Questionnaires (30-40 mins), Functional Evaluations (45-60 mins), Economics Questionnaires (5-10 mins) *With Physiotherapist + Clinical Researcher*

Randomisation

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments.

We randomly allocate participants into groups and give each group a different treatment. To ensure groups are the same, each participant is allocated a group randomly, with a 50/50 chance of receiving either the Maxm Skate device or standard rehabilitative care.

What do I have to do?

The study requires that you attend the assessments as above. If you are enrolled and randomised to the Maxm Skate group, you will be required to undertake the Maxm Skate rehabilitation program. This involves using the skate device and accompanying iOS App and sensors to complete your rehabilitation exercises, as outlined in the Maxm Skate Rehabilitation Guide which typically includes 3x 25 minute sessions daily. You will be required to download the Maxm Skate App onto your Apple phone or tablet (the Clinical Researcher will assist you at your consent visit with this). When signing in and making a profile on the App, you will be requested to report the following: *Name, email, date of birth, gender, height, weight, employment status and total knee replacement operation date.*

You will be educated on how to safety use the device, App and sensors prior to your operation during the Maxm Skate Education Session. Please note, as part of this program you will be required to wear two sensor modules on your operative leg when completing an exercise session. The sensor case is held in place with elastic hook and loop straps which can be adjusted for comfort and easy removal. If you experience any discomfort or skin response from using the sensors, please discontinue use and inform a member of the research team and your doctor.

Additionally, it is our hope that participants in the Maxm Skate group would require no further formal physiotherapy in an outpatient setting. The Maxm Skate program includes functional assessment checks to assess rehabilitation progress and confirm you are ready to progress to the next stages of exercise. These assessment checks will involve a physiotherapist coming out to your home. At 6 weeks after your surgery, your orthopaedic surgeon will assess your rehabilitation progress and advise if further rehabilitation is necessary.

Other relevant information about the research project

Data collected via the App is stored in the Google Firestore cloud database and within the i0S device itself. The database access is restricted to administration staff (currently the App developer) and the creator of the data (the user themselves). The latter can only access the data via the App. Access to the data can also be given to other parties if required. Google may also have access to the data; however, all Google Firebase services are certified under major privacy and security standard, specifically the ISO 27001 and SOC 1, SOC 2, and SOC 3 evaluation process, and some have also completed the ISO 27017 and ISO 27018 certification process.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given a Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Flinders Private Hospital.

What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you do not wish to participant in this study, this will not influence your orthopaedic or rehabilitation treatment at this hospital. You will continue to receive treatment as part of standard clinical care.

For any further study-related queries please do not hesitate to contact the Clinical Study Co-ordinator who you will see at your consent visit, Dr Kristen Georgiou on kristen.georgiou@imri.org.au or 08 7231 8452.