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The effect of the Mulligan mobilization with movement approach following knee replacement surgery

Submission date
31/10/2018

Recruitment status
No longer recruiting

Registration date
15/11/2018

Overall study status
Completed

Last Edited
07/03/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Total knee replacement surgery is used to replace worn and painful knee joints that have been damaged by osteoarthritis (inflammation and destruction of bone and cartilage in joints) with an artificial knee joint. However, many patients experience loss of motion after surgery. The Mulligan mobilization with movement approach is a type of physiotherapy in which the patient's body is moved by a therapist. This approach has been found to reduce pain and improve range of motion for various conditions. This study aims to investigate whether it improves pain, range of motion and the ability to stand up and walk in patients who have had total knee replacement.

Who can participate?
Women aged 40-80 years with advanced knee osteoarthritis who have been scheduled for total knee replacement surgery.

What does the study involve?
The participants will be randomly allocated into two groups: Control and Mulligan. Both groups will receive the standard physiotherapy programs offered to people who have had knee replacement surgery for up to 3 months including exercises, walking, cycling and stair training. The Mulligan group will additionally receive six sessions of Mulligan mobilization to improve knee range of motion, which will be done manually with a Mulligan-certified physiotherapist.

What are the possible benefits and risks of participating?
The examinations which will be done at the four stages can be considered a benefit for the patients as they will be kept informed about the recovery of their knee. The standard physiotherapy program will be delivered to the two groups as usual, so there are no additional risks. The Mulligan group might benefit from receiving the individualized Mulligan mobilizations.

Where is the study run from?
Al-Razi Orthopedic and Rehabilitation Hospital, which is the main governmental hospital specializing in orthopedics (bone, muscle and joint medicine) in Kuwait.

When is the study starting and how long is it expected to run for?
February 2018 to September 2022

Who is funding the study?
This study is currently funded by the investigator; however, other funding will be sought in the near future.

Who is the main contact?
Dr. Najla Alsiri, dr.alsiri@outlook.com

Contact information

Type(s)
Scientific

Contact name
Dr Najla Alsiri

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
698/2018

Study information

Scientific Title
The Effect of Mulligan knee Mobilization with Movement Approach on pain and movement in patients who have undergone Total Knee Arthroplasty for osteoarthritis (EMMATKA): a randomized clinical trial

Acronym
EMMATKA

Study objectives
Mulligan's mobilization with movement approach is effective for patients with acute total knee arthroplasty in terms of impairments, activity and participation.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Kuwait Ministry of Health ethics committee, 14/05/2018, 698/2018

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact dr.alsiri@outlook.com to request a participant information sheet.

Health condition(s) or problem(s) studied
Acute total knee arthroplasty

Interventions
Current intervention as of 10/12/2018:
Patients will be randomized using an online research randomizer to either Mulligan or control group. Both groups will receive the standard physical therapy rehabilitation program from week 2 post-operation which will include cryotherapy, range of motion and strengthening exercises, full-weight-bearing gait training and this will be carried on daily in the in-patient department for 1 week, then carried on twice per week in the out-patient physical therapy department, where open kinematic chain exercises, cycling and stair training will be introduced. This program will be provided to the two groups up to 3 months. However, patients assigned to the Mullligan group will additionally receive Mulligan mobilization with movement approach for knee flexion which will start on the week 3 post-operation, during 3 weeks for six sessions, or fewer or more than six sessions depending on the clinical decision of the Mulligan practitioner. The practitioner could also decide to delay the start day of the application of the Mulligan Approach or reduce the repetitions and pressure in order to maintain the safety of the intervention for patients in the acute post-surgical period. Three certified Mulligan practitioners will conduct the intervention. According to the Mulligan approach, a pain-free mobilization technique will be used which could be medial rotation, lateral rotation, anterio-posterior, medial or lateral glide with knee flexion following Mulligan approach guidelines. Patients will be followed up for 6 months. Examinations will be performed at four timepoints by a blinded assessor; pre-operation, 3rd week post-operation when the Mulligan approach will be introduced, 6th week post-operation when the patient receives 6 sessions of Mulligan approach during 3 weeks, and at 6 months post-operation.

Previous intervention:
Patients will be randomized using concealed envelopes to either Mulligan or control group. Both groups will receive the standard physical therapy rehabilitation program from week 2 post-operation which will include cryotherapy, range of motion and strengthening exercises, full weight bearing gait training and this will be carried on daily in the in-patient department for 1 week, then carried on twice per week in the out-patient physical therapy department, where open kinematic chain exercises, cycling and strain training will be introduced. This program will be provided to the two groups up to 3 months. However, patients assigned to the Mullligan group will additionally receive Mulligan mobilization with movement approach for knee flexion which will start on the week 3 post-operation, during 3 weeks for six sessions. Three certified mulligan practitioners will conduct the intervention. According to the Mulligan approach, a pain-free mobilization technique will be used which could be medial rotation, lateral rotation, anterio-posterior, medial or lateral glide with knee flexion following Mulligan approach guidelines. Patients will be followed up for 6 months. Examinations will be performed at four timepoints by a blinded assessor; pre-operation, 3rd week post-operation when the Mulligan approach will be introduced, 6th week post-operation when the patient receives 6 sessions of Mulligan approach during 3 weeks, and at 6 months post-operation.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Knee range of motion measured using the standard 12-cm goniometer in supine position
2. Knee pain intensity measured using a Visual Analogue Scale during both rest and movement
3. Knee mechanical axis measured using the scanogram
All outcomes will be measured before surgery, and at 3 weeks, 6 weeks and 6 months after surgery.

Secondary outcome measures
1. Mobility assessed using timed up and go (TUG) test timed using a stopwatch
2. Walking speed assessed using 15-m walk test timed using a stopwatch
3. Effect of OA on knee pain, stiffness and function assessed using Western Ontario and McMaster Universities osteoarthritis (OA) index (WOMAC)
All outcomes will be measured before surgery, and at 3 weeks, 6 weeks and 6 months after surgery.

Overall study start date
01/02/2018

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Diagnosis of knee osteoarthritis according to American College of Rheumatology criteria
2. Scheduled for TKA due to symptoms of OA
3. Aged 40-80 years

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
80

Total final enrolment
84

Key exclusion criteria
1. Secondary OA
2. Inflammatory joint disease, including inflammatory arthritis
3. Trauma to knee joint, including history of fractures in or adjacent to the joint
4. Peripheral vascular disease
5. Cardiac disease
6. Cannot understand, read and write Arabic
7. Neurological deficits

Date of first enrolment
28/10/2018

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Kuwait

Study participating centre
Al-Razi Orthopedic and Rehabilitation Hospital
Jamal Abdul Nasser St
Sulaibikhat
Kuwait City
Kuwait
13001

Sponsor information

Organisation

Kuwait Ministry of Health

Sponsor details
Jamal Abdul Nasser St
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13001
00965-24877219 ext 2996
healthresearch@moh.gov.kw

Sponsor type
Hospital/treatment centre

Website
https://www.moh.gov.kw/en

ROR
https://ror.org/036njfn21

Funder(s)

Funder type
Other

Funder Name
self-funded

Results and Publications

Publication and dissemination plan
The study will be published in high-impact journals and will be presented at international conferences.

Intention to publish date
31/07/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Najla Alsiri, dr.alsiri@outlook.com. The data will be stored in SPSS files for 3 years after data collection completion. Patient personal information will not be shared. Each patient will be assigned an ID number to anonymize them. Only the results of the measured outcomes will be analyzed and shared.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2021	13/10/2020	Yes	No