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Effectiveness of a combined exercise and physiotherapy intervention in improving functional activity of patients with knee osteoarthritis in Muslim prayer movements

Submission date
21/04/2021

Recruitment status
No longer recruiting

Registration date
23/04/2021

Overall study status
Completed

Last Edited
04/05/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims

Developing effective interventions for relieving pain and improving physical function of the knee in Muslim prayer movements is a critical concern in meeting their religious commitments and improving their general quality of life (QoL). However, the effects of exercise intervention duration on the functional activity of knee osteoarthritis (OA) patients in performing daily life activities, particularly Muslim praying movements, are not yet clear. Hence, an investigation was performed into the effectiveness of combined exercise and physiotherapy intervention for 6 or 12 weeks on the functional activity of individuals with knee osteoarthritis.

Who can participate?

Participate were age 50 years old and above, and both male and female participants with knee osteoarthritis were recruited.

What does the study involve?

The recruited participants were randomly divided into three groups. Group I and Group II) received combined exercise therapy intervention consisting of muscle strengthening, stationary cycling and walking exercise, and physiotherapy modalities. The combined intervention was performed for 3 sessions a week, with a duration of 60 minutes per session. Group I received intervention for 12 weeks, while Group II received intervention for just 6 weeks. Group III, as the control group, received no exercise intervention at all but performed physiotherapy modalities for 6 weeks at a rate of 3 sessions a week. During the study period, the participants' medications were standardized and remained unchanged. The study was divided into 3 stages, namely baseline, 1st follow-up and 2nd follow-up. At baseline, all of the participants were assessed by six-minute walking tests (6MWT) and chair stand tests (CST), and were asked to report their pain intensity (VAS scale), QoL (SF-36 questionnaire), and perceived health and physical function (WOMAC questionnaire).

What are the possible benefits and risks of participating?
The possible benefit of the implementation of the training activities described in the present study were improving knee function and reducing the pain intensity of individuals with knee OA when performing daily life activities, including Muslim praying movements, and there were no side effect of the intervention given.

Where is the study run from?
The physiotherapy department University of Muhammadiyah Malang (Indonesia)

When is the study starting and how long is it expected to run for?
September 2019 to February 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Rakhmad Rosadi (rakhmad21@gmail.com)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
no E.5.a/176/KEPK-UMM/IX/2019

Study information

Scientific Title
The effect of strengthening, isometric and isotonic exercise for knee osteoarthritis patients in Malang - Indonesia

Study objectives
Patients who receive a longer period of training exercise intervention (12 weeks) will exhibit better knee function, lower pain intensity and a higher QoL than those who do not

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/09/2019, Health Research Ethics University of Muhammadiyah Malang (Jl. Bendungan Sutami No.188, Sumbersari, Kec. Lowokwaru, Kota Malang, Jawa Timur 65145, Indonesia; +628125243720; patma@umm.ac.id), ref: E.5.a/176/KEPK-UMM/IX/2019

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
The participants in Group I and Group II performed combined strengthening and stationary cycling intervention, walking and physiotherapy for a total of 36 sessions (12 weeks, 3 times a week) and 18 sessions (6 weeks, 3 times a week), respectively. The participants in Group III underwent physiotherapy modalities for 18 sessions (6 weeks, 3 times a week). All of the sessions were supervised by an experienced physiotherapist. Missed sessions were compensated during the subsequent weeks such that each participant completed the full complement of sessions for their assigned group.
Randomization was by sealed envelope.

Intervention Type

Behavioural

Primary outcome measure
Functional activity measured by WOMAC at baseline, 1st follow up (6 weeks) and 2nd follow up (12 weeks)

Secondary outcome measures
1. Pain measured using the visual analogue score (VAS) at baseline, 1st follow up (6 weeks) and 2nd follow up (12 weeks).
2. Walking ability measured by 6 minutes walking test at baseline, 1st follow up (6 weeks) and 2nd follow up (12 weeks).
3. Functional fitness measured by chair stand test at baseline, 1st follow up (6 weeks) and 2nd follow up (12 weeks).
4. Quality of life measured by questionnaire SF-36 at baseline, 1st follow up (6 weeks) and 2nd follow up (12 weeks).

Overall study start date
05/09/2019

Completion date
15/02/2020

Eligibility

Key inclusion criteria
1. Clinically diagnosed with knee OA by physician
2. Treated by physiotherapist during previous 4 weeks
3. Grade 1 or higher in the Kellgren and Lawrence radiographic classification
4. Minimum age 50 years old
5. Pain level on Visual Analog Scale (VAS) greater than 4
6. Willingness to commit to a 12-week study period

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
45

Total final enrolment
30

Key exclusion criteria
1. Scheduled for joint surgery
2. Having knee injection within previous 2 months 16

3. Minimally assisted during walking
4. Diagnosed with fibromyalgia
5. Unstable heart condition
6. Physical activity more than twice a week (with a total duration of 60 minutes per week) 17
7. Unable to pedal a stationary bicycle

Date of first enrolment
06/09/2019

Date of final enrolment
15/12/2019

Locations

Countries of recruitment
Indonesia

Study participating centre
University of Muhammadiyah Malang
Physical Therapy Department
l. Bandung No.1
Penanggungan
Kec. Klojen
Kota Malang
Jawa Timur
Malang
Indonesia
65113

Sponsor information

Organisation
Universitas Muhammadiyah Malang

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Sponsor type
University/education

Website
https://www.umm.ac.id/

ROR
https://ror.org/01j1wt659

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal.

Intention to publish date
15/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			04/05/2021	No	Yes