

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/04/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 04/05/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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?

Participants 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

ROR

<https://ror.org/01j1wt659>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes