# Effectiveness of blended web-based rehabilitation on measures of pain, functionality and physical activity of patients with knee osteoarthritis: study protocol for a randomized control trial

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
17/09/2020		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
27/09/2020		[X] Results		
Last Edited	Condition category	Individual participant data		
08/03/2024	Musculoskeletal Diseases			

#### Plain English summary of protocol

Background and study aims

Education and exercise have been recommended for patients with knee osteoarthritis (OA). However, due to the chronic nature of pain of knee OA as well as the difficulty in access to health services, patients would benefit from a self-managed programme that encourages physical activity.

Who can participate?
Patients with knee OA, with no cognitive issues

What does the study involve?

It involves a web-based rehabilitation programme (combining both behavioural and exercise components) as well as suggested specified walk journeys within their municipality.

What are the potential benefits and risks of participating? Patients would learn how to manage their pain with confidence and be more physically active. No real risks associated, apart from the discomfort that might arise after undertaking an exercise programme lasting for 2-3 days.

Where is the study run from? University of West Attica (Greece)

When is the study starting and how long is it expected to run for? February 2020 to February 2022

Who is funding the study? State Foundation Scholarship (IKY) (Greece)

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

49238/09-07-2020

# Study information

#### Scientific Title

Effectiveness of blended web-based rehabilitation enhanced with outdoor structured walking-based activity on measures of pain, functionality and physical activity of patients with knee osteoarthritis: study protocol for a randomised control trial

#### Acronym

Webphys

#### Study objectives

Web-based rehabilitation is superior to monitored physical activity in pain levels and functionality in patients with knee osteoarthritis.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

1. Approved 20/07/2020, University of West Attica Research Ethics Committe (agiou spiridonos 28, Aegaleo, 12243, Greece; +30 210-5387.294; ethics@uniwa.gr), ref: 52650 - 20/07/2020 2. Approved 20/07/2020, Research Ethics Committee of the University of West Attica (Ag Spiridonos, Egaleo, PC 12243, Greece; +30 3105387294; ethics@uniwa.gr), ref: 49238/09-07-20

#### Study design

Double-blind randomized controlled trial

#### Primary study design

Interventional

#### Study type(s)

Quality of life

#### Health condition(s) or problem(s) studied

Knee osteoarthritis

#### **Interventions**

Group 1: This group will undertake 6 weeks of exercise, twice a week, by watching videotaped sessions and once a week attend an informative behavioural video session on how to manage pain.

Group 2: This group will follow specified, mapped green journeys by walking twice a week. Group 3 (control): This group will receive a booklet with examples of exercise and information on how to manage pain and encouragement to increase physical activity.

Randomisation is done via a computer-generated excel file. The interventions will last for 6 weeks, and we will assess patients at baseline, 6 weeks and 3 months.

#### Intervention Type

Behavioural

#### Primary outcome(s)

Self-reported functionality measured by KOOS at baseline, 6 weeks and 3 months

#### Key secondary outcome(s))

Functionality measured by Timed Up and Go Test at baseline, 6 weeks and 3 months

#### Completion date

16/02/2022

# **Eligibility**

#### Key inclusion criteria

Citizens of the municipalities of West Attica in Athens, aged between 45 and 75 years with knee osteoarthritis

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

45 years

#### Upper age limit

75 years

#### Sex

All

#### Total final enrolment

44

#### Key exclusion criteria

Participants with musculoskeletal injury or surgery in the lower limbs, participants with cardiovascular problems, participants with neurological disorders.

#### Date of first enrolment

02/11/2020

#### Date of final enrolment

20/10/2021

#### Locations

#### Countries of recruitment

Greece

#### Study participating centre Municipalities of West Attica, Peristeri and Egaleo

Kep Ygeias Peristeriou Paraskeuopoulou 23 Peristeri Athens Greece 12132

# Study participating centre University of West Attica

Agiou Spyridonos 28 Egaelo Athens

# Sponsor information

#### Organisation

University of West Attica

#### ROR

https://ror.org/00r2r5k05

# Funder(s)

#### Funder type

Government

#### **Funder Name**

State Scholarship Foundation (IKY)

## **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

#### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/02/2024	08/03/2024	Yes	No
<u>Protocol article</u>		26/05/2022	27/05/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes