

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 17/09/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/03/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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)

Who is the main contact?

Maria Moutzouri

Study website

<http://westwalks.uniwa.gr/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 Committee (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

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Not available in web format. please use contact details to request a participant information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

16/02/2020

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

Age group

Adult

Lower age limit

45 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

60

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

Agiau Spyridonos 28

Egaleo

Athens

Greece

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Sponsor information

Organisation

University of West Attica

Sponsor details

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Greece

12243

+30 210 5387475

gioftsos@uniwa.gr

Sponsor type

University/education

Website

<http://www.uniwa.gr/en/>

ROR

<https://ror.org/00r2r5k05>

Funder(s)

Funder type

Government

Funder Name

State Scholarship Foundation (IKY)

Results and Publications

Publication and dissemination plan

1. Planned publication in a high-impact peer-reviewed journal.
2. Participants desiring to know the outcomes of the study will be informed by email.

Intention to publish date

16/12/2023

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?
Protocol article		26/05/2022	27/05/2022	Yes	No
Results article		06/02/2024	08/03/2024	Yes	No