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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

Registration date
27/09/2020

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Scientific

Contact name
Dr Maria Moutzouri

ORCID ID
https://orcid.org/0000-0002-7014-892X

Contact details
Agiou Spiridonos 28
Egaleo
Greece
12243
+30 (0)6977073125
moutzouri@uniwa.gr

Additional identifiers

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

Primary study design
Interventional

Study design
Double-blind randomized controlled trial

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, particpants 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
Greece
12243

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
Protocol article		26/05/2022	27/05/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes