Efficacy of aqua cycling on pain and physical function in patients with early knee osteoarthritis.

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Does a 12-week aqua cycling program result in a significant difference in self-reported severity of knee osteoarthritis symptoms, quality of life, physical activity and tested muscle strength and physical capacity in patients with early knee...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON41619

Source
ToetsingOnline

Brief title
Aqua cycling in patients with knee OA.

Condition

- Joint disorders

Synonym
degenerative joint disease, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: NWO Graduate Programme 2011

Intervention

Keyword: aqua cycling, aquatic exercise, hydrotherapy, knee osteoarthritis

Outcome measures

Primary outcome

Self-reported physical function and knee pain.

Secondary outcome

Secondary outcomes will be self-reported disease severity of OA symptoms,

physical activity and quality of life. Muscle strength, functional capacity and

physical functioning will be assessed by a physiotherapist.

Study description

Background summary

Pain, limited physical function and stiffness are typical symptoms of knee osteoarthritis that restrict patients* abilities in activities and participation. The existing evidence in the area of aqua cycling is still scarce and there is a lack of knowledge concerning the use of aqua bike in a therapeutic setting for knee osteoarthritis patients.

Study objective

Does a 12-week aqua cycling program result in a significant difference in self-reported severity of knee osteoarthritis symptoms, quality of life, physical activity and tested muscle strength and physical capacity in patients with early knee osteoarthritis compared with a control group receiving the standard care of early osteoarthritis outpatient clinic?

Study design

Randomized, controlled trial inclusive assessments at three different time points (baseline, post-intervention, three months follow-up).

Intervention

The patients will participate in an exercise programme, supervised by a physiotherapist, which also includes strategies to improve self-management skills of the patient. Patients exercise twice a week for 45 minutes. Patients take part in an aqua cycling program over a period of 12 weeks.

The program will be carried out in the therapy pool (32 ° Celsius) of the physiotherapy department of the Academic Hospital Maastricht. The AquaCruiser will be used to cover almost all parts of the training:
- Global and local muscle strength
- Endurance
- Knee range of motion
- Balance exercises

Every session consists of: warming-up, conditioning phase and cool-down.

During a five minute warming-up participants will cycle with an individually chosen cadence and a low pedalling resistance. Participants focus on a good posture and ergonomic pedalling. Furthermore the upper body will also be included to acclimatize the whole body to the aquatic environment and to support customization to the different handle-bar positions on the AquaCruiser.

The conditioning phase will last 30 minutes and will be divided in alternate parts of upper and lower body strength exercises. Due to the fact that patients will cycle continuously during the whole session the training automatically includes an aerobic training part.
Exercises for the upper body patients will always be accompanied by continuous cycling with individually preferred pedalling frequency and low pedalling resistance to train range of motion of the knee.

The cool-down will consist of slow cycling forward and backward to decrease heart frequency, ROM exercises for the knee, balance exercises and static stretching of the lower limbs.

Study burden and risks

The risk in relation to participation is similar to usual physiotherapy (group) sessions. The design of the intervention (training parameters and types of exercise) is based on international guidelines for exercise in osteoarthritis and the measurements are part of usual care or comparable to it. The additional burden consists of a measurement after twelve weeks of training and after three months. However, these measurements equal the previous assessments in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Knee osteoarthritis (physician assessed) is the primary diagnosis
* Knee pain > 4 and < 7 on a numeric pain rating scale (NPRS)
* Kellgren/Lawrence score < 3
* Ability to cycle (on a stationary exercise bike)
* Good mental health (score < 8 for anxiety and depression on the Hospital Anxiety and Depression Scale, HADS)
* Sufficient mental and language skills to participate in the study (e.g. fill out questionnaires; understand instructions during testing and training)
* Indication for physiotherapy in conjunction with impairments due to OA

Exclusion criteria

* Any *yes* on the Physical Activity Readiness Questionnaire (PAR-Q), which is used to screen for
contra-indications for physical training
* Severe, unstable co-morbidities, such as cardiac or pulmonary conditions (assessed Cumulative
Illness Rating Scale, CIRS)
* Total knee replacement (planned within one year)
* Current prescription of corticosteroid injections and/or hyaluron injections (because of unsatisfying results from other non-invasive interventions)
* Corticosteroid injection < 3 months and/or hyaluron injection < 6 months
* Patients with serve joint complaints (other than knee joint) that interfere their ability to participate
in an exercise programme
* Patients with symptomatic and radiological apparent hip OA
* Inability to safely enter and exit the pool
* Inflammatory joint diseases
* Open wounds
* Fear of water

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2013
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-01-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24611
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42617.068.12
Other	NTR (TC = 3766)
OMON	NL-OMON24611

Study results

Date completed:	09-03-2016
Actual enrolment:	111

Summary results

Trial ended prematurely