Aqua cycling in knee osteoarthritis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24611

Source
Nationaal Trial Register

Health condition

English:
- aqua cycling
- aquatic exercise
- hydrotheray
- knee osteoarhritis

Dutch:
- aqua cycling
- watertherapie
- hydrotherapie
- knie artrose

Sponsors and support

Primary sponsor: Maastricht University Medical Centre (MUMC+)
Source(s) of monetary or material Support: Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO): Graduate Programme 2011

Intervention

Outcome measures

Primary outcome

Self-reported knee pain and physical functioning.

Secondary outcome

Secondary outcomes will be self-reported disease severity of OA symptoms, physical activity, self-efficacy, fear of movement and quality of life. Muscle strength, functional capacity and physical functioning will be assessed by a physiotherapist. Focus group interviews will be held to investigate patient satisfaction with the results of the aqua cycling training.

Study description

Background summary

Rationale:

Osteoarthritis (OA) of the knee is a common musculoskeletal disorder. Patients can exercise to alleviate pain and maximize functional abilities. In order to stabilise the increase of patients with severe limitations and high disability due to OA, it has been emphasized to focus on preventive strategies that modify the progression of the disease at an early stage.

Objective:

What is the effect of a twelve week aqua cycling course on self-reported physical functioning, knee pain, knee stiffness, quality of life, physical activity, and self-efficacy, fear of movement, muscle strength and functional capacity compared to a no intervention control group? Are patients satisfied with the set-up and impact of a twelve weeks aqua cycling programme?

Study design:

A single-blind, randomized, controlled trial
Study population: 168 patients with early knee OA, with a prescription for conservative treatment and sufficient physical and mental health, willing to participate in an aqua cycling exercise programme, will be included.

Intervention:

Patients will be randomly assigned to a control group receiving usual care of the Early OA Outpatient Clinic or to an aqua cycling programme, which will be carried out in addition to

usual care. The exercise programme will be carried out for twelve weeks with two 45-minutes sessions weekly.

Main study parameters:

The primary outcome is the difference between the aqua cycling group and the control group at baseline, twelve weeks post-intervention and three months follow-up measurements of self-reported physical functioning and knee pain.

Study objective

The combination of hydrotherapy and cycling for knee OA seems obvious. It is hypothesized that an aqua cycling training programme will be successful in improving physical functioning and reducing knee pain in patients with knee OA.

Study design

Baseline, 12 weeks post-intervention, three months follow-up.

Both the intervention and the control group will fill in a diary during four weeks at the beginning of the intervention and during the last weeks of the intervention.

Intervention

Patients will be randomly assigned to a control group receiving usual care of the Early OA Outpatient Clinic or to an aqua cycling programme, which will be carried out in addition to usual care. The exercise programme will be carried out for twelve weeks with two 45-minutes sessions weekly.

Contacts

Public
P.O. Box 616
Stefanie Rewald
Department of Epidemiology
Maastricht University
Universiteitssingel 40
Maastricht 6200 MD
The Netherlands
+31 (0)43 3883424
Scientific
P.O. Box 616

Stefanie Rewald
Department of Epidemiology
Maastricht University
Universiteitssingel 40
Maastricht 6200 MD
The Netherlands
+31 (0)43 3883424

Eligibility criteria

Inclusion criteria

1. Knee osteoarthritis (physician assessed) is the primary diagnosis;

2. Knee pain > 4 and < 7 on Numeric Pain Rating Scale (NPRS);

3. Kellgren/Lawrence score < 3;

4. Ability to cycle (on a stationary exercise bike);

5. Good mental health (score < 8 for anxiety and depression on the Hospital Anxiety and Depression Scale, HADS);

6. Sufficient mental and language skills to participate in the study (e.g. fill out questionnaires; understand instructions during testing and training).

Exclusion criteria

1. Any “yes” on the Physical Activity Readiness Questionnaire (PAR-Q), which is used to screen for contra-indications for physical training;

2. Severe, unstable co-morbidities, such as cardiac or pulmonary conditions (assessed Cumulative Illness Rating

Scale, CIRS);

3. Total knee replacement (planned within one year);

4. Current prescription of corticosteroid injections and/or hyaluron injections (because of unsatisfying results from other non-invasive interventions);

5. Corticosteroid injection < 3 months and/or hyaluron injection < 6 months;

6. Patients with serve joint complaints (other than knee joint) that interfere their ability to participate in an exercise programme;

7. Patients with symptomatic and radiological apparent hip OA;

8. Inability to safely enter and exit the pool;

9. Inflammatory joint diseases;

10. Open wounds;

11. Fear of water.

Study design

Design

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

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-03-2013
Enrollment:	168
Type:	Anticipated

Ethics review

Positive opinion
Date: 21-12-2012
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41619
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3607
NTR-old	NTR3766
CCMO	NL42617.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41619

Study results

Summary results
N/A