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Cycling in water to improve pain and movement in people with knee osteoarthritis

Submission date
29/05/2018

Recruitment status
No longer recruiting

Registration date
31/05/2018

Overall study status
Completed

Last Edited
31/05/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) of the knee is a common disorder that involves damaging and thinning of the cartilage of the knee joints. It is also known as wear and tear arthritis. Symptoms of knee osteoarthritis include knee pain, swelling and stiffness of the knee joint. Furthermore, patients with knee OA often experience problems with activities of daily living such as getting in and out of a chair, walking or using stairs. Regular and low-impact exercise like walking, cycling or strength training can help to reduce pain and improve physical functioning. In addition, to land-based exercises many patients with knee OA enjoy exercising in water because water's buoyancy significantly reduces the impact on the joints.
Recently, aquatic cycling has emerged as a trendy fitness activity. Aquatic cycling takes the typical spinning class and submerges the fitness bikes in a pool. During a typical aquatic cycling session participants pedal against water resistance in seated as well as outof-saddle positions and combine the cycling exercises with exercises for the upper body.
The combination of cycling and aquatic exercise seems promising for patients with knee osteoarthritis. However, studies about the effects of aqua cycling are scarce. Therefore, the aim of our study was to evaluate the effect of an aquatic cycling programme on self-reported physical functioning and knee pain in patients with knee OA.

Who can participate?
Patients with mild to moderate knee OA with a prescription for physical therapy could participate. Furthermore, potential participants had to be able to safely participate in an aquatic exercise therapy.

What does the study involve?
To evaluate the effects our 12-week aquatic cycling programme was compared to the usual care of an early OA outpatient clinic. The early OA outpatient clinic provides information on knee OA and a personalised treatment plan including lifestyle advices, pain medication management, and prescriptions for physical therapy (if needed). Patients were randomly allocated to one of the two groups.
Patients in the usual care group continued with the treatment plan and could start with physical therapy. After their study participation these participants were invited to 12 free aquatic cycling sessions.

The aquatic cycling group received a 12-week aquatic cycling exercise program. Participants exercised twice a week for 45 minutes in a therapy pool. The training included cycling in a sitting position, leg exercises, cycling in out-of-saddle positions, and upper body exercises.
All participants were asked to fill in questionnaires that assessed their knee OA symptoms and more general health outcomes such as level of physical activity or quality of life. In addition, participants' walking ability and lower leg muscle strength were assessed by a physical therapist.

What are the possible benefits and risks of participating?
The proposed study will contribute to help patients with knee OA and increase scientific knowledge about the effects of aqua cycling. If the intervention aquatic cycling turns out to be effective it can be implemented as an option to delay total joint surgery and as prevention of inactivity within this patient group.
The content of the aquatic cycling intervention is comparable to existing physical activity programmes on land. Research has shown that these programmes provide no additional harm or risk to the patient. A previous pilot of aquatic cycling in OA patient was evaluated as safe and feasible because of immediate pain reduction, progression in training level and no adverse reactions. In addition, there is adequate evidence that aquatic training and stationary cycling are beneficial and safe activities for patients with knee OA.

Where is the study run from?
The study is being run by Maastricht University.

When is the study starting and how long is it expected to run for?
March 2013 to March 2016.

Who is funding the study?
Netherlands Organisation for Scientific Research (NWO). The NWO grant number is 022.003.036.

Who is the main contact?
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Contact information

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Scientific

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EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR3766

Study information

Scientific Title
Efficacy of aquatic cycling on pain and physical function in patients with mild to moderate knee osteoarthritis.

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Board of Maastricht University Medical Centre, 06/03/2013, 12-2-075

Study design
Two-arm single-centre single-blind parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Participant information sheet only available in Dutch. Please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
After obtaining written informed consent participants were randomised with a constant block size of 8 and an allocation ratio of 1:1 by an independent research assistant. Patients will be randomly assigned to a control group receiving usual care of an early osteoarthritis outpatient clinic or to an aquatic cycling programme, which will be carried out in addition to usual care.

Usual care included the indication of personal risk factors and a tailored treatment plan including pain medication and a referral for primary care physical therapy. During the active trial period, the usual care group continued with the tailored treatment plan and could decide if they wanted to start with physical therapy. After the last measurement at 24 weeks, people in the usual care group were invited to 12 try-out sessions of aquatic cycling.
The intervention group received a 12-week aquatic cycling exercise program (low to moderate intensity) consisting of two 45-minutes sessions weekly in a therapy pool (32°C). The patients exercised in small groups of maximally four patients and were supervised by a physical therapist. Participants cycled in an upright position on an aquatic bike throughout the whole session. The main part of the training consisted of cycling in a sitting position with good postural control. In addition, out-of-the-saddle positions, leg exercises, and upper body exercises were incorporated.

Intervention Type
Behavioural

Primary outcome measure
Self-reported scores on knee pain and physical functioning assessed with the Knee Injury and Osteoarthritis Outcome Score (KOOS, http://www.koos.nu), assessed at baseline, 12 weeks post-intervention and 24 weeks follow-up.

Secondary outcome measures
1. Symptoms, sport activity and disease-related quality of life assessed using KOOS subscales
2. Physical functioning on the test day was assessed with the LEFS (Lower Extremity Function Scale)
3. Knee pain assessed using a 10-point Numeric Pain Rating Scale, assessed after the 6-minute walking test
4. Patient-rated general health assessed using Patient Global Assessment (PGA)
5. Level of physical activity assessed using the Short QUestionnaire to ASsess Health-enhancing physical activity (SQUASH)
6. Quality of life was measured with the Rand 36-item Health Survey
7. Fear of movement was assessed with the Tampa Scale for Kinesiophobia (TSK)
8. Self-efficacy for physical functioning assessed using four questions of the Arthritis Self-Efficacy Scale (ASES)
9. Performance measures of physical functioning were assessed under supervision of a physical therapist using the 6-minute walking test (6-MWT) and the timed-up-and-go test (TUG)
10. Isometric and isokinetic muscle strength of the affected leg was measured with the Biodex® System 3 Pro
All secondary outcomes will be assessed at baseline, 12-weeks post-intervention and 24-weeks follow-up.

Overall study start date
06/03/2013

Completion date
09/03/2016

Eligibility

Key inclusion criteria
1. Knee osteoarthritis (physician assessed) as 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)

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
168

Key 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 using Cumulative Illness Rating Scale, CIRS)
3. Total knee replacement (planned within 1 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. Severe joint complaints (other than in the knee joint) that interfere with ability to participate in an exercise programme
7. Symptomatic and radiological apparent hip osteoarthritis
8. Inability to safely enter and exit the pool
9. Inflammatory joint diseases
10. Open wounds
11. Fear of water

Date of first enrolment
16/04/2013

Date of final enrolment
17/08/2015

Locations

Countries of recruitment
Netherlands

Study participating centre

Maastricht University Medical Centre+
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Sponsor information

Organisation
Maastricht University

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Not defined

Funder Name
Nederlandse Organisatie voor Wetenschappelijk Onderzoek

Alternative Name(s)
Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, Dutch Research Council, Netherlands, NWO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Netherlands

Results and Publications

Publication and dissemination plan

Intention to publish date
31/10/2018

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Stored in repository