

Aqua cycling in knee osteoarthritis.

Gepubliceerd: 21-12-2012 Laatste bijgewerkt: 19-03-2025

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24611

Bron

NTR

Aandoening

English:

- aqua cycling
- aquatic exercise
- hydrotheray
- knee osteoarthritis

Dutch:

- aqua cycling
- watertherapie
- hydrotherapie
- knie artrose

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre (MUMC+)

Overige ondersteuning: Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO): Graduate Programme 2011

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Self-reported knee pain and physical functioning.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 severe 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelnemers

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2013
Aantal proefpersonen:	168
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	21-12-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41619
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A