**WHO Trial Registration Data Set (Version 1.3.1)**

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| **1** | **Primary Registry and Trial Identifying Number** Name of Primary Registry, and the unique ID number assigned by the Primary Registry to this trial. | ClinicalTrials.gov: ID: [NCT03109821](https://clinicaltrials.gov/ct2/show/NCT03109821)  Danish Data Protection Agency: ref. no: 1-16-02-589-15 |
| 2 | **Date of Registration in Primary Registry** Date when trial was officially registered in the Primary Registry. | ClinicalTrials.gov:  First registration posted April 12, 2017.  Danish Data Protection Agency: Accepted first version October 22, 2015,  Accepted second version December 20, 2017 |
| 3 | **Secondary Identifying Numbers** | Internal registration in Central Jutland Regional Hospital, Denmark: 654894 |
| 4 | **Source(s) of Monetary or Material Support** | The study has received the following external funding: Regional Hospital Central Jutland Research Foundation (75,000 DKkr), The Danish Rheumatism Association (75,000 DKkr, grant R139-A3844), The Association of Danish Physiotherapist (37,500 DKkr), The Aase and Ejnar Danielsen Foundation (100,000 DKkr, grant: 10-002170) and The family Kjærsgaard foundation (26,928 DKkr). |
| 5 | **Primary Sponsor** | Elective Surgery Centre, Silkeborg Regional Hospital, Silkeborg, Denmark  A part of Central Jutland Regional Hospital, Denmark |
| 6 | **Secondary Sponsor(s)** | None |
| 7 | **Contact for Public Queries** | Lone Ramer Mikkelsen  e-mail: [lonemike@rm.dk](mailto:lonemike@rm.dk)  Merete N Madsen  e-mail: [meremads@rm.dk](mailto:meremads%40rm.dk?subject=NCT03109821,%20654894,%20Home-based%20Rehabilitation%20Following%20a%20Total%20Hip%20Replacement)  Postal adress, both contacts:  Elective Surgery Centre, Silkeborg Regional Hospital, Falkevej 1-3, 8600 Silkeborg, Denmark |
| 8 | 1. **Contact for Scientific Queries** | Principal investigators (see contact details above)  Lone Ramer Mikkelsen, Ass.Prof, PhD &  Merete N Madsen, MSc  Elective Surgery Centre, Silkeborg Regional Hospital, Denmark |
| 9 | **Public Title** Title intended for the lay public in easily understood language. | Home-based Rehabilitation Following a Total Hip Arthroplasty (PHETHAS-1) |
| 10 | **Scientific Title** Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available. | Pragmatic Home-Based Exercise after Total Hip Arthroplasty - Silkeborg: A prospective cohort study (PHETHAS-1) |
| 11 | **Countries of Recruitment** | Denmark |
| 12 | **Health Condition(s) or Problem(s) Studied** | Total hip arthroplasty surgery due to osteoarthritis |
| 13 | 1. **Intervention(s)** | The intervention reflects the standard rehabilitation practice at Elective Surgery Centre. 3 weeks after surgery the patients receive a thorough instruction and supervision in the strength training exercises that they are to perform without supervision at home the following 7 weeks. The instruction is conducted one-to-one by physiotherapists and supported by an instruction booklet with written and illustrated exercise descriptions. The exercises included are: hip abduction, flexion and extension with elastic band resistance and sit-to-stand and one-legged stance. The prescribed training load will be two sets with repetitions to failure and a relative load of 10 to 20 Repetition Maximum (RM), performed every second day (3-4 times a week).  Exposure: Performed exercise dose will be quantified as the total physiological exercise stimulus (Time under tension summary dose) recorded by a sensor (BandCizer) attached to the elastic exercise band. |
| 14 | **Key Inclusion and Exclusion Criteria** | The inclusion criteria are: age above 18 years, scheduled for a primary THA, at the Elective Surgery Centre due to osteoarthritis and able to understand written and spoken Danish. The exclusion criterion is: referral to supervised rehabilitation in the municipality (instead of the home-based rehabilitation exercise-program in the present study). |
| 15 | **Study Type** | The study is a pragmatic, single-center, prospective cohort study (single cohort) conducted in Silkeborg, Denmark. Outcome assessments will be performed at 3 (start of home-based strengthening exercise) and 10 weeks (after 7 weeks of home-based strengthening exercise) after surgery. Furthermore, patient-reported outcome measures will be collected pre-surgery (see the participant timeline in Table 1). It is the aim that all outcome assessments will be performed by three physiotherapists who have been thoroughly trained in performing the outcome assessments. The data collection methods, trial logistics and the intervention have been tested in a pilot study including 10 patients and adjustments have been made accordingly. |
| 16 | **Date of First Enrollment** | Date of enrollment of the first participants was: April 21, 2017 |
| 17 | 1. **Sample Size** | The required sample size is estimated to be 88 participants. To ensure 88 participants with complete dataset we continue enrollment until we are certain to reach 88 participants with completion. |
| 18 | * + **Recruitment Status** | Recruiting: participants are currently being recruited and enrolled |
| 19 | **Primary Outcome(s)** | Outcome name: Gait speed  Method and metrics: 40-m fast-paced walk test. Measured in meter/second,  Timepoint: Measured 3 and 10 weeks after surgery. Reported as change from 3 to 10 weeks after surgery. |
| 20 | 1. **Key Secondary Outcomes** | All key secondary outcomes will be reported as change from 3 to 10 weeks after surgery.  Patient-reported function. Measured by the Activities of Daily Living (ADL) subscale of Hip disability and Osteoarthritis Outcome Score (HOOS). HOOS is a disease-specific patient-reported outcome measure.  Patient-reported symptoms. Measured by the symptoms subscale of HOOS.  Patient-reported pain. Measured by the pain subscale of HOOS.  Patient-reported hip related quality of life. Measured by the quality of life subscale of HOOS. Change from 3 to 10 weeks after surgery.  Lower extremity function. Measured by the 30-s chair stand test (The maximal number of rises from a chair within 30 seconds).  Hip abductor muscle strength. Test of isometric muscle strength in hip abduction in the operated leg. The hand-held dynamometer Power Track II Commander will be used to assess this using standardized test procedure.  Hip flexor muscle strength. Test of isometric muscle strength in hip flexion in the operated leg. The hand-held dynamometer Power Track II Commander will be used to assess this using standardized test procedure. |
| 21 | 1. **Ethics Review** | The Ethics Committee of Central Denmark Region accepted initiation of the study and reviewed the study as non-notifiable (Inquiry 270/2017). |
| 22 | 1. **Completion date** | Patient enrollment is ongoing |
| 23 | 1. **Summary Results** | No results are available |
| 24 | 1. **IPD sharing statement** | A fully anonymized dataset and statistical analysis code will be made available for the scientific journal reviewing the manuscript within six months in line with the proposal from the International Committee of Medical Journal Editors (ICMJE). |