STUDY PROTOCOL

Pragmatic Home-Based Exercise after Total Hip Arthroplasty - Silkeborg: Protocol for a prospective cohort study (PHETHAS-1) [version 1; peer review: 3 approved]

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Abstract

Introduction: Rehabilitation exercises are offered to patients after total hip arthroplasty (THA); however, the effectiveness and optimal type and dose of exercise remains unknown. The primary objective of this trial is to indicate the preliminary efficacy of home-based rehabilitation using elastic band exercise on performance-based function after THA, based on the relationship between the performed exercise dose and the change in performance-based function (gait speed) from 3 (start of intervention) to 10 weeks (end of intervention) after surgery. The secondary objective is to investigate if a dose-response relationship exists between the performed exercise dose and changes in: hip-related disability, lower-extremity functional performance, and hip muscle strength

Methods: In this prospective cohort study, patients scheduled for THA will be consecutively included until 88 have completed the intervention period from 3 to 10 weeks postoperatively. Participants perform the standard rehabilitation program with elastic band exercises. Exercise dose (exposure) will be objectively quantified using a sensor attached to the elastic band. The primary outcome is gait speed measured by the 40-m fast-paced walk test. Secondary outcomes include: patient reported hip disability (Hip disability and Osteoarthritis Outcome Score (HOOS)), hip muscle strength (hand-held dynamometry) and lower extremity function (30-s chair stand test).

Discussion: This trial will add knowledge concerning the relationship between performed exercise dose and post-operative outcomes after THA.
The protocol paper describes the study design and methods in detail, including the statistical analysis plan.

**Trial registration:** Pre-registered on March 27, 2017 at ClinicalTrials.gov (ID: NCT03109821).

**Keywords**
Total Hip Arthroplasty, Rehabilitation, Exercise therapy, Dose-response, Strength training

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- **Bandholm T:** Conceptualization, Funding Acquisition, Methodology, Resources, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

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Introduction

Total hip arthroplasty (THA) is offered to patients with end-stage hip osteoarthritis to reduce pain and improve function. Muscle strength and functional performance, such as walking ability, are substantially reduced early after THA; this is why postoperative rehabilitation is offered throughout the municipalities in Denmark. In some municipalities, this is organized as outpatient supervised rehabilitation, whereas in other municipalities, patients receive an initial instruction and perform rehabilitation exercise in their own homes without supervision. In Central Denmark Region (place of this trial), the current predominant clinical practice is home-based rehabilitation for most patients.

Systematic reviews with meta-analyses show that supervised, outpatient rehabilitation exercise is not superior to home-based exercise for performance-based or self-reported function outcomes. It has also been difficult to demonstrate clear superiority with relevant effect size of one type of rehabilitation exercise over another for performance-based or self-reported function outcomes. There is, however, some evidence to indicate that rehabilitation exercise may be superior to no or very little rehabilitation exercise for selected muscle-strength, gait, and function outcomes after THA. It suggests that a dose-response relationship exists for post-operative rehabilitation exercise and recovery after THA.

To be able to investigate a dose-response relationship for post-operative rehabilitation exercise and recovery after THA, objective measures that capture compliance to home-based exercise are needed. In recent work, we have validated a measure to monitor compliance to home-based exercise in healthy subjects (an in-built sensor attached to an elastic exercise band), and started using it in clinical populations for intervention research. With the PHETHAS-1 trial, we want to use this sensor technology to investigate if a dose-response relationship exists for home-based rehabilitation exercise and recovery after THA, using a prospective cohort study design. By using this technology, we will be able to not only investigate a dose-response relationship on the recovery associated with exercise practice at Elective Surgery Centre; hence, a pragmatic study design is needed.

Methods

Study design

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. The study will adhere methodologically to the STROBE guideline for prospective cohort studies and the CONSORT statement.

Study setting

All participants will be included from the Elective Surgery Centre at the public hospital, Silkeborg Regional Hospital. Exercise instruction as well as blinded outcome assessments will be performed by physiotherapists from Elective Surgery Centre. The physiotherapists are members of the staff of physiotherapists at Elective Surgery Centre and all have at least 6 months of experience working with THA.

Participants

Participants will be included by consecutive sampling. 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).

Intervention

The exercise intervention reflects the standard rehabilitation exercise practice at Elective Surgery Centre; hence, a pragmatic approach is used. During a short hospital stay (typically discharge on the day after surgery), all patients are instructed in an exercise program of unloaded exercises (not part of the intervention studied) to be performed at home during the initial 3 postoperative weeks until their scheduled follow up visit at the hospital. At this visit (3 weeks after surgery), and after the

1 Abbreviations: ADL, Activities of Daily Living; CI, Confidence Interval; HOOS, Hip disability and Osteoarthritis Outcome Score; ICME, International Committee of Medical Journal Editors; IQR, Inter Quartile Range; NRS, Numeric Rating Scale; THA, Total Hip Arthroplasty; PHETHAS, Pragmatic Home-Based Exercise after Total Hip Arthroplasty – Silkeborg; RM, Repetition Maximum; STROBE, Strengthening the Reporting of OBservational studies in Epidemiology; TIDieR, Template for Intervention Description and Replication; TUT, time-under-tension; VAS, Visual Analogue Scale; WHO, World Health Organisation
The participants will receive a thorough instruction in the strengthening exercises that they are instructed to perform without supervision in their own homes for the following 7 weeks. The instruction is conducted one-to-one by physiotherapists using approximately 20 minutes per participant and supported by an instruction booklet with written and illustrated exercise descriptions. The strengthening exercises included are: hip abduction, flexion and extension with elastic band resistance and sit-to-stand. The prescribed training load will be two sets with repetitions to contraction failure (neuromuscular fatigue) and a relative load of 10 to 20 repetition maximum (RM), performed every second day (3–4 times a week). The strengthening exercises are supplemented with daily stretching of hip flexor muscles and balance exercise (one-legged stance). Exercise compliance for the strengthening exercises will be monitored objectively (see Outcomes section). No efforts will be made to increase compliance beyond normal practice (e.g. SMS encouragements, or likewise), because we intent to measure actual, uninfluenced compliance as close to daily practice as possible. The participants will be advised to gradually increase their activity level after the operation to comply with the recommendations on physical activity from the Danish Health and Medicines Authority. Furthermore, they will be given instructions on how to handle pain during exercises and recreational activities (the pain management guide is available as Extended data). To reinforce similar treatment administration, face-to-face meetings among the participating physiotherapists will be held per need to discuss issues experienced in the clinic. The exercise intervention is described in detail according to the exercise-specific Consensus on Exercise Reporting Template (CERT) (A completed CERT checklist is available as Extended data), supplemented with the full set of strength training descriptors as suggested by Toigo and Boutellier (Table 2). Finally, the exercise intervention is described according to the Template for Intervention Description and Replication (TIDieR) checklist, which is a generic intervention-description template (a completed TIDieR checklist is available as Extended data).
<table>
<thead>
<tr>
<th>Exercise</th>
<th>Load</th>
<th>Repetitions</th>
<th>Sets per session</th>
<th>Rest between sets</th>
<th>Duration of training period</th>
<th>Contraction failure in each set</th>
<th>Rest between repetitions</th>
<th>Time under tension</th>
<th>Range of motion</th>
<th>Rest between sessions</th>
<th>Anatomical definition of the exercises</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hip abduction</td>
<td>15 RM</td>
<td>10–20</td>
<td>Week 1: 1 set (both legs)</td>
<td>Active rest while exercising opposite leg</td>
<td>3–4 (every second day)</td>
<td>Yes. The exercise is progressed (elastic band with higher load) when &gt;20 repetitions are accomplished.</td>
<td>0 sec, possible load relieve with one step between reps if needed</td>
<td>150 sec/exercise/session at 15 RM</td>
<td>Maximum possible</td>
<td>48 hours</td>
<td>The exercise is performed from standing position with the elastic band looped around both ankles and support by e.g. a solid table. The leg is elevated against resistance in a combined hip and knee flexion while keeping the trunk in upright position.</td>
</tr>
<tr>
<td>Hip flexion</td>
<td>15 RM</td>
<td>10–20</td>
<td>Week 1: 1 set (both legs)</td>
<td>Active rest while exercising opposite leg</td>
<td>3–4 (every second day)</td>
<td>Yes. The exercise is progressed (elastic band with higher load) when &gt;20 repetitions are accomplished.</td>
<td>0 sec, possible load relieve with one step between reps if needed</td>
<td>150 sec/exercise/session at 15 RM</td>
<td>Maximum possible</td>
<td>48 hours</td>
<td>Hip flexion is performed in upright standing position with the elastic band looped around both ankles and support by e.g. a solid table. The target leg is elevated against resistance in a combined hip and knee flexion while keeping the trunk in upright position.</td>
</tr>
<tr>
<td>Hip extension</td>
<td>15 RM</td>
<td>10–20</td>
<td>Week 1: 1 set (both legs)</td>
<td>Active rest while exercising opposite leg</td>
<td>3–4 (every second day)</td>
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<td>Maximum possible</td>
<td>48 hours</td>
<td>Hip extension is performed from standing position with the elastic band looped around both ankles and support by e.g. a solid table. The target leg is elevated against resistance in a combined hip and knee flexion while keeping the trunk in upright position.</td>
</tr>
</tbody>
</table>

* RM: Repetition Maximum
Patient information
The participants will be advised to gradually increase their activity level after the operation. Likewise, they will be instructed to gradually progress their exercises during the 7 weeks of training at home according to the described progression model, where the strengthening exercises are performed to failure in each set; when the possible repetitions exceed 20 in two of the three elastic band exercises they should change the elastic band so that a higher loading is possible. The participants are instructed that pain in relation to exercise is normal, and that up to 5 on a numeric rating scale (NRS) during exercise is considered acceptable based on the suggested pain monitoring system by Thomée et al.\textsuperscript{23}. However, the pain should decrease within 30 minutes after the exercise session. The participants are advised to contact the hospital if they experience increasing pain or other complications such as swelling or wound problems (the pain management guide is available as \textit{Extended data})\textsuperscript{19}.

Outcomes

\textbf{Exposure.} Performed exercise dose will be quantified as the total physiological exercise stimulus (Time under tension summary dose per week) recorded by a sensor (Bandcizer: commercially available from \texttt{www.bandcizer.com}) attached to the elastic exercise band. The sensor automatically switches on and stores data when the elastic exercise band is used\textsuperscript{13,14}. Furthermore, performed exercise dose will be quantified as the number of days with strengthening exercises being performed.

\textbf{Primary outcome}
Change in gait speed is chosen to be primary outcome, as walking ability is considered the most important function to improve by patients undergoing THA surgery\textsuperscript{24}. Furthermore, the 40-m fast-paced walk test is part of the core set of functional tests to include in clinical trials in patients with osteoarthritis in hip or knee recommended by OARSI\textsuperscript{25,26}. Furthermore, the maximal number of rises from a chair within 30 seconds. Change from 3 to 10 weeks after surgery.

\textbf{Secondary outcomes}

\begin{itemize}
\item Gait speed
  Measured by the 40-m fast-paced walk test\textsuperscript{25,26}. At 10 weeks after surgery.
\item Change in patient-reported function
  Measured by the Activities of Daily Living (ADL) subscale of HOOS\textsuperscript{27}. HOOS is a disease-specific patient-reported outcome measure. Change from 3 to 10 weeks after surgery.
\item Change in patient-reported symptoms
  Measured by the symptoms subscale of HOOS\textsuperscript{27}. Change from 3 to 10 weeks after surgery.
\end{itemize}

\textbf{Change in patient-reported pain}
Measured by the pain subscale of HOOS\textsuperscript{27}. Change from 3 to 10 weeks after surgery.

\textbf{Change in patient-reported hip related quality of life}
Measured by the quality of life subscale of HOOS\textsuperscript{27}. Change from 3 to 10 weeks after surgery.

\textbf{Change in lower extremity function.}
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\textsuperscript{28}. Change from 3 to 10 weeks after surgery.

\textbf{Change in hip abductor 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\textsuperscript{28}. Change from 3 to 10 weeks after surgery.

\textbf{Change in 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\textsuperscript{28}. Change from 3 to 10 weeks after surgery.

\textbf{Other pre-specified outcomes}

\begin{itemize}
\item Self-efficacy.
  The general self-efficacy scale\textsuperscript{29} will be used to measure self-efficacy, defined as an individual’s belief in his or her capacity to execute behaviors necessary to produce specific performance attainments. At 3 weeks after surgery.
\item 24-hour physical activity (mean upright time/day and mean number of steps/day).
  An ActivPAL movement-sensor will be used to measure mean time per day in upright position (standing and walking) based on 7 days of data collection. The sensor will be applied 3 weeks after surgery and used the following week. At 4 weeks after surgery.
\item Number of participants with adverse events.
  Number and type of adverse events will be registered by the physiotherapist 3 and 10 weeks after surgery in the following pre-defined categories: Hip dislocation, infection, fracture, wound seepage, acute myocardial
infarction, deep venous thrombosis, readmission and other.

- Mean change in pain after each exercise session.
  The visual analogue scale (VAS) will be used to assess pain before and after each exercise session. Data will be summarized as a mean change in pain per exercise session for the entire intervention period. At 10 weeks after surgery.

- Number of pain flares after exercise sessions.
  VAS will be used to assess pain before and after each exercise session. Pain flare is defined as an increase in pain of ≥20 mm\(^\text{20}\). Data will be summarized, both for the first 14 days of the intervention and for the entire intervention period. At 5 and 10 weeks after surgery.

- Motivation to perform the prescribed exercises.
  The participants will be asked about their motivation to perform the prescribed exercises. A short questionnaire comprising three questions developed for this purpose will be used (the questionnaire is available as Extended data\(^\text{19}\)). The possible responses are ordered in 4 levels of motivation on an ordinal scale. At 3 weeks after surgery.

- Evaluation of the prescribed exercises
  The participants will be asked to evaluate the exercises. A short questionnaire comprising three questions developed for this purpose will be used (the questionnaire is available as Extended data\(^\text{19}\)). The possible responses are ordered in 4 levels on an ordinal scale. At 10 weeks after surgery.

### Changes to outcomes after trial registration

- At June 28, 2017, two outcome measures were added to the study. At 10 weeks after surgery, participants will be asked both to describe their perception of the result after surgery and the change in hip problems (from preoperatively to 10 weeks after surgery). The questions will be phrased as "How would you describe the result of your operation?" with response categories "Excellent", "Very good", "Good", "Fair", "Poor". The second question will be asked as "Overall, how are the problems now in the hip on which you had surgery, compared to before your operation?" with the response categories "Much better", "A little better", "About the same", "A little worse", "Much worse". These two questions have been used as anchor questions to establish patient acceptable symptom state (PASS) and minimal clinically important improvement (MCII) cut-points for patient-reported outcomes – including some subscales of HOOS – 1 year after THA\(^\text{19}\). We will use these questions to group patients according to their perception of result of the operation and changes in hip problems, as well as for exploratory analysis of PASS and MCII cut-points for HOOS, 10 weeks after surgery.

- In April, 2019, pain flare was added as an outcome measure.

- Categories of adverse events were defined prior to study start, but they were not specifically described in the trial registration. Motivation to perform prescribed exercises was registered as outcome, but although predefined, the three items in the short questionnaire were not specifically described. Evaluation of prescribed exercises was added as outcome prior to study start.

- In April 2019, the secondary objective was added to the primary and pre-specified objective because the primary objective did not clearly outline the secondary analyses of secondary outcomes for the hypothesized dose-response relationship.

- All the changes outlined above occurred before the last participant was included and the study was unblinded (please see “Blinding” below).

### Embedded qualitative study (PHETHAS-2)

In addition to collecting quantitative data, we will also conduct an embedded qualitative study concerning the participants’ experience with performing home-based exercise and resuming general physical activities. The aim will be to understand the patients’ motivation and barriers related to home-based exercise and general physical activity after THA. The participants will be selected through theoretical sampling\(^\text{19}\), expectedly a maximum of 20. Participants will be recruited partly from the PHETHAS-1 trial, and partly from the population of standard THA patients not involved in an exercise trial. This is done to elucidate the influence of participating in a trial with extra interventions such as exercise diary, outcome assessments, etc. The embedded qualitative study is undertaken to refine the home-based intervention for future trials and clinical implementation. The embedded qualitative study will be reported in a separate paper with a clear reference to the PHETHAS-1 trial.

### Sample size

The sample size estimation is based on a minimal clinical important difference of 0.2 m/sec\(^\text{19}\) between changes in gait speed among participants with highest performed exercise dose compared to participants with smallest performed exercise dose. Based on results from a pilot study leading up to this trial, we expect a maximal difference of 4 hours in performed exercise dose (total Time under tension summary dose) during the 7-week intervention period between participants with highest and lowest exercise compliance. Also based on the pilot study, a SD of 1.06 hours for exercise dose and 0.16 m/sec for change in gait speed were used. The power is set at 0.90 to increase the power for secondary analyses, and with a 0.05 level of significance. Based on the above, the required sample size is estimated to be 88 participants.
Recruitment
The basis for recruitment makes the trial highly feasible due to the approximately 800 elective THA procedures performed annually at the Elective Surgery Centre. As there may be more eligible participants per day than for whom there is available equipment (BandCizers and ActivPAL sensors), we restrict inclusion by including consecutive participants from random sections of the department. That is, patients examined and booked for surgery in pre-specified clinics in the outpatient department. Patients are allocated to the specific clinics in the department by a secretary at random and with no influence from any personnel involved in the study. The estimated inclusion rate is approximately one to two participants per week; please see estimated participant flow and current recruitment status in Figure 1.

Blinding
The outcome assessors will be blinded to exercise compliance-data. Moreover, we will inform the participants that we measure how they perform their exercises and not how much they exercise or what the study hypothesis is. This is done with the purpose of minimizing sensor-induced influence on compliance and to reduce expectation bias.

Data collection methods
The elastic band sensor (BandCizer) automatically records and stores exercise data during elastic band exercises. It is a valid measure of date, time of day, number of repetitions and sets, total time-under-tension (TUT), and total single repetition TUT during commonly used home-based strength training exercises for the lower extremities\(^4\). The 40-m fast-paced walk test

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**Figure 1.** Estimated participant flow.
measures performance-based function and is part of the recommended core set of tests to assess physical function in people diagnosed with hip or knee osteoarthritis by the Osteoarthritis Research Society International (OARSI). A high inter-tester reliability is shown (intraclass correlation coefficient (ICC) 0.95) in a population with hip osteoarthritis. The HOOS questionnaire measures patient-reported outcome in the subscales: symptoms, pain, ADL, function in sport and recreation and hip-related quality of life. HOOS is shown valid, responsible, and reliable (ICC >0.78) when evaluating patients undergoing THA. Hip muscle strength and 30-s chair stand test will be conducted in accordance with previous published methods showing acceptable relative and absolute inter-rater reliability when used after THA (ICC 0.83-0.93 and SEM 7–10%). General Self-Efficacy Scale is a 10-item validated questionnaire holding a scale assessing optimistic self-beliefs to cope with a variety of difficult demands in life, scored between 1–4 points without any defined cut-off point. ActivPal movement-sensors measures physical activity as time spent in the sit/lie position (X-axis), standing (Y-axis) and walking (Z-axis). It has been validated in several studies in healthy adults and in older adults with a hip fracture.

Data collection will continue for participants who discontinue their training. Data collection will only be discontinued if participants explicitly withdraw from the study or any major events or diseases prevent the outcome assessments. If participants do not attend their scheduled follow ups, they will be contacted and offered a new time.

Data management

Raw data from the Bandcizer will be uploaded to a secure online database using a tablet or smartphone. Here, the investigator will be able to access and analyze data and extract the following variables: date and number of training sessions, number of repetitions, time under tension for each repetition and total time under tension for each training session. Data from the outcome measurement will be double entered in EpiData 3.1 using anonymous coding with ID numbers and relevant range checks for data values to minimize typing errors. Completed data collection forms will be stored in a locked cabinet at Silkeborg Regional Hospital. Electronic data files will be stored on a secured hospital server with access requiring personal login. The linkage between ID numbers and personal identification data (e.g. civil registration number, name, address) will be stored as an electronic file as described above.

Statistical methods

All the planned analyses are listed in Table 3.

Descriptive analyses will be performed for demographic variables, supplementary descriptive variables, adverse events, motivation to perform prescribed exercises, evaluation of prescribed exercises and pain after exercise sessions (change in pain and pain flares). Data will be presented as means with 95% confidence intervals (CI) or medians with inter quartile ranges (IQR) for continuous variables and as frequencies with percentages for categorical variables.

Primary analysis

Initially, scatterplots of outcome variables and exercise dose variables will be used to suggest starting model structures and possible more complex alternatives. The structures of the models used for the dose-response analysis will depend on the specific relationship between change in gait speed and the exercise dose variable. Because of this, and not having any prior knowledge of the structure of the relationship, multiple models will be fitted and evaluated by R-squared values to identify the models that fit data the best. As a starting point, the first model will be fitted as a fixed increase in outcome, based on exercise dose-change done by linear regression modelling. If necessary, more complex regression such as polynomial relationship and other nonlinear structures will also be evaluated.

In the case that none of the models seem to fit the data, a linear regression model with a categorical variable based on intervals of the exercise dose variable will be fitted. This model does not provide a direct dose response relationship but provides an estimate of the association between the outcome variable and the exercise dose variable within the specific intervals.

“Regression to the mean” may be present and will be evaluated by the correlation between the change and the measure at baseline. If regression to the mean is believed to be present for an outcome, the models of the outcome will additional include the baseline measure to adjust for regression to the mean.

Possible confounding variables (self-efficacy (baseline), physical activity (during intervention), and gait speed (baseline)) will also be included in the models. The confounding effect of each variable will be examined by comparison of dose response estimates in models with and without the confounder. If there is no relevant change between the estimates of the models, the confounder will be excluded from the model. Normality assumptions in the models are evaluated by QQ-plots.

Secondary analyses

For the dose response relationship between change in HOOS ADL, the analysis will be similar to the analysis for change in gait speed outlined above.

The relationship between exercise compliance and HOOS subscales (symptoms, pain, quality of life), 30-s chair stand test and hip muscle strength will be presented as means with CIs or medians with IQRs within each of the compliance quartiles, as well as graphical representation of these values.

Exploratory analyses

To better understand what may relate to how patients comply with prescribed rehabilitation exercise after THA, we will investigate how different variables relate to exercise compliance (dependent variables: time under tension summary dose and total number of exercise sessions), using uni-variable modelling. Independent variables will be: pain flares (first two weeks of intervention), pain flares (entire intervention period), HOOS pain (baseline), motivation to perform exercises, belief in effect of exercises, self-belief in compliance to exercising, satisfaction...
### Table 3. Variables, measures and methods of analysis.

<table>
<thead>
<tr>
<th>Variable/outcome</th>
<th>Hypothesis</th>
<th>Outcome measure (unit, scale)</th>
<th>Methods of analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic variables</td>
<td>Descriptive statistics, no hypothesis</td>
<td>Age, gender, height, weight, ASA status</td>
<td>Summary statistics</td>
</tr>
<tr>
<td>Supplementary descriptive variables</td>
<td>Descriptive statistics, no hypothesis</td>
<td>Prosthesis type, prior total joint replacement, length of hospital stay and self-efficacy (prior to surgery and baseline)</td>
<td>Summary statistics</td>
</tr>
<tr>
<td>Performed exercise dose of elastic band resistance training (exposure)</td>
<td>Descriptive statistics, no hypothesis</td>
<td>Time under tension summary dose/week and total (continuous), Number of exercise sessions/week and total (number, continuous)</td>
<td>Summary statistics</td>
</tr>
</tbody>
</table>

#### 1. Primary analysis

| Gait speed – measured by 40-m fast-paced walk test | Dose-response relationship | Change in score from baseline to follow up (meters/second, continuous) | (Described in more detail in section 2.12.1) Scatterplots of outcome variables and exercise dose variables will be used to suggest starting model structures and possible more complex alternatives. The analysis will depend on the specific relationship between change in gait speed and the exercise dose variable. Multiple models will be fitted and evaluated by R-squared values to identify the models that fit data the best.

1) The first model will be fitted as a fixed increase in outcome, based on exercise dose-change done by linear regression modelling.

2) If necessary, more complex regression, such as polynomial relationship and other nonlinear structures, will also be evaluated.

3) In the case that none of the models seem to fit the data, a linear regression model with a categorical variable based on intervals of the exercise dose variable will be fitted. If the measure at baseline correlates with the change, baseline measure will be adjusted for. The effect of possible confounding variables will be examined and, if having an effect, the confounder(s) will be adjusted for. |

#### 2. Secondary analyses

<table>
<thead>
<tr>
<th>HOOS ADL</th>
<th>Dose-response relationship</th>
<th>Change in score from baseline to follow up (points, continuous)</th>
<th>Similar to the primary analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOOS symptoms, pain, QOL</td>
<td>Dose-response relationship</td>
<td>Change in score from baseline to follow up (points, continuous)</td>
<td>Similar to the primary analysis</td>
</tr>
<tr>
<td>30-s chair stand test</td>
<td>Dose-response relationship</td>
<td>Change in score from baseline to follow up (repetitions, ordinal/continuous scale)</td>
<td>Summary statistics for the secondary outcomes will be presented as means with CIs or medians with IQRs within each of the compliance quartiles, and as graphical representation of these values as well.</td>
</tr>
<tr>
<td>Hip muscle strength (isometric)</td>
<td>Dose-response relationship</td>
<td>Change in score from baseline to follow up (Nm/kg), continuous scale</td>
<td>Similar to the primary analysis</td>
</tr>
<tr>
<td>Variable/outcome</td>
<td>Time under tension summary (unit, scale)</td>
<td>Methods of analysis</td>
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<tr>
<td>Exercise compliance</td>
<td>Exploratory investigation of association</td>
<td>Uni-variable regression models. Independent variables will be: pain flares (in the first two weeks of intervention and in the entire intervention period), HOOS pain (baseline), motivation to perform rehabilitation exercise, physical activity (mean upright time/day and mean number of steps/day) and self-efficacy (baseline)</td>
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<td></td>
<td>Descriptive statistics, no hypothesis</td>
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<td><strong>Final</strong>, HOOS cut points for PAS will be estimated by the mean score or mean change approach for each exercise dose quartile, the percentage of patients in each response category, will be presented (graphically).</td>
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<tr>
<td>Physical activity level</td>
<td>Exploratory investigation of association</td>
<td>Uni-variable regression models. Independent variables will be: pain flares (first two weeks of intervention), HOOS pain (baseline), motivation to perform exercises, self-belief in compliance to exercising and self-efficacy (baseline).</td>
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<td>Descriptive statistics, no hypothesis</td>
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<td><strong>Final</strong>, HOOS cut points for MCI will be estimated.</td>
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<td>Result of the operation</td>
<td></td>
<td><strong>Summary statistics</strong></td>
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<td><strong>Summary statistics</strong></td>
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<td><strong>Summary statistics</strong></td>
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<tr>
<td>Change in hip problems</td>
<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<td></td>
<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<td>Pain after exercise sessions</td>
<td></td>
<td><strong>Summary statistics</strong></td>
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<td><strong>Summary statistics</strong></td>
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<td>Pain after surgery</td>
<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<td></td>
<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<tr>
<td>Change in pain per exercise session</td>
<td>Change in pain per exercise session (score, continuous)</td>
<td><strong>Summary statistics</strong></td>
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<td><strong>Summary statistics</strong></td>
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<td>Pain flare</td>
<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<td></td>
<td>Descriptive statistics, no hypothesis</td>
<td><strong>Summary statistics</strong></td>
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<tr>
<td>Pain flare for the entire intervention</td>
<td>Pain flare for the entire intervention (number, continuous)</td>
<td><strong>Summary statistics</strong></td>
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<td><strong>Summary statistics</strong></td>
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<tr>
<td>Motivation to perform prescribed exercises</td>
<td>Motivation to perform prescribed exercises (ordinal scale)</td>
<td><strong>Summary statistics</strong></td>
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<td><strong>Summary statistics</strong></td>
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<td>Evaluation of prescribed exercises</td>
<td>Evaluation of prescribed exercises (ordinal scale)</td>
<td><strong>Summary statistics</strong></td>
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<td><strong>Summary statistics</strong></td>
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<tr>
<td>Adverse events</td>
<td>Evaluations with rehabilitation exercise adherence</td>
<td><strong>Summary statistics</strong></td>
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<td>Evalulation of bandCizer exercise adherence</td>
<td><strong>Summary statistics</strong></td>
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<td>Compliance with bandCizer exercise adherence</td>
<td><strong>Summary statistics</strong></td>
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<td>Fracture, wound seepage, acute myocardial infarction, deep venous thrombosis, hospitalization, other</td>
<td><strong>Summary statistics</strong></td>
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with rehabilitation exercise, physical activity (mean upright time/day and mean number of steps/day) and self-efficacy (baseline).

To better understand what may relate to how physically active patients are after a THA, we will investigate how different variables relate to physical activity (dependent variables: mean upright time/day and mean number of steps/day), using univariate modelling. Independent variables will be: pain flares (first two weeks of intervention), HOOS pain (baseline), motivation to perform exercises, self-belief in compliance to exercising, and self-efficacy (baseline).

In the analysis of “result of the operation”, the change in score from baseline to follow-up will be presented for each HOOS subscale (pain, symptoms, ADL, QOL) and gait speed. Data will be presented both for each response category of the anchor question, and for the subgroup of patients, who answered “excellent”, “very good” or “good” data. This subgroup is considered to be reporting a hip-specific acceptable symptom state. Data will be presented by means with 95% CI or medians and inter-quartile ranges (IQR). In each response category of the question for “change in hip problems”, the change in score from baseline to follow-up will be presented for each HOOS subscale (pain, symptoms, ADL, QOL) and gait speed. Data will be presented by mean scores with 95% CI or median and inter quartile range (IQR).

Furthermore, for each exercise dose quartile, the percentage of patients in each response category of the questions for “result of the operation” and “change in hip problems”, will be presented graphically. Finally, HOOS cut points for PASS and MCII will be estimated by the mean score or mean change approach.

Handling of missing data
Missing items within the HOOS and General Self-efficacy scale will be handled as recommended in the guidelines (HOOS: <50% missing items in each subscale is accepted, self-efficacy: ≤3 missing items is accepted). Concerning ActivPal data, a minimum of four days of data collection will be accepted as sufficient to calculate min/day upright time and steps/day. In situations where participants have to stop the physical tests due to pain, the data from the best performance are used no matter if the pre-defined number of repetitions is reached. It is noted if tests are interrupted due to pain to be able to perform sensitivity analysis if appropriate. If participants are lost to follow up (despite the before-mentioned efforts to keep every participant in the trial) they will be excluded from the analyses that include change scores. We will not use last-observation-carried-forward or other imputation procedures, as we aim to investigate relationships between performed exercise dose and observed changes in post-operative outcomes to help qualify subsequent research work.

Data monitoring
Since the study involves no major changes to current practice it is not deemed necessary to establish a data monitoring committee or perform any interim analyses. Likewise, no provisions for post-trail care will be made.

Discussion
This trial will add knowledge concerning the preliminary efficacy of home-based rehabilitation using elastic band exercises based on the relationship between performed exercise dose and outcomes after THA. We believe this is the first trial to do so, since earlier attempts have not used objective measurement of exercise dose as in the present trial. In an observational cohort study, Zech et al found no significant associations between the exercise therapy intensity or duration and improvements in patient reported function, pain, and stiffness. However, the exercise dose was dependent on the participants’ health insurance as well as individual conditions and the physiotherapist’s decision, which likely induces a risk of bias by indication.

The essential need from a clinical perspective is to be able to prescribe evidence-based exercise programs after THA. Despite the growing number of studies, a recent systematic review that included 20 studies concludes that insufficient therapeutic validity and potentially high risk of bias in the included studies limit the ability to assess the effectiveness of exercise after THA.

The new knowledge from the present study can potentially identify whether the dose of performed home-based exercise is related to changes in post-operative outcomes after THA. It will provide insight concerning the potential influence from other factors than exercise, such as general physical activity and self-efficacy. Furthermore, the embedded qualitative study will give insight to perceived motivation and barriers to perform the prescribed exercise as well as to resuming general physical activities. The results from both the quantitative and qualitative study are expected to be useful in optimizing current practice; however, the results will also be used to plan, power and execute a randomized controlled trial that compares the effectiveness of rehabilitation exercises to no rehabilitation exercises (just resuming general physical activities).

Strength and limitations
The strengths of this study include the objectively measured exercise dose, the standardized and thoroughly described intervention and the inclusion of outcome variables at all levels in the International Classification of Function, Disability and Health (ICF). We chose gait speed measured by the 40-m fast-paced walk test as the primary outcome. Walking ability is considered the most important function to improve by patients undergoing THA surgery, and the 40-m fast-paced walk test is part of the core set of functional tests to include in clinical trials in patients with osteoarthritis in hip or knee recommended by OARSI. An important candidate for the choice of primary outcome for clinical research has been suggested to be a patient-reported one. Nevertheless, we chose a performance-based measure as the primary, as we were concerned about ceiling effects on patient reported outcomes that measures function and pain, such as the HOOS questionnaire after THA.
Multiple factors can potentially affect exercise compliance; therefore, we include measurements of physical activity and self-efficacy. Also, it is not known which outcomes that is most susceptible to exercise dose which is why we include a broad range of different outcome types to be able to explore potential dose-response relationships.

Blinding of participants in randomized exercise trials are often impossible, in the present study we seek to blind the participants to the specific focus om exercise dose, they are just told that we measure “the way they exercise”. Hypothesis blinding is considered a design strength when blinding of participants regarding treatment is not possible. Furthermore, we blind the outcome assessor in the sense that they are not allowed to see the exercise diary or BandCizer data prior to the outcome assessment.

Trial status
The trial began recruiting participants in April 2017. After a period with slow inclusion, the inclusion rate is back at 1–2 participants per week, thus, inclusion is expected to be completed in July 2019. See current status on participant flow in Figure 1.

This paper is based on protocol version 5, March 8, 2019.

Declarations
Research ethics approval
The Ethics Committee of Central Denmark Region accepted initiation of the study and reviewed the study as non-notifiable (Inquiry 270/2017). The study was approved by the Danish Data Protection Agency (ref. no: 1-16-02-589-15).

Informed consent
Trained Research staff (nurse or physiotherapist) will provide presentation of comprehensible information about the research to potential participants, confirmation that they understand the research, and assurance that their agreement to participate is voluntary. Potential participants will also receive information sheets. They will be offered deliberation time and, subsequently, written consent will be obtained from those who choose to participate. The informed consent document is available as Extended data.

Confidentiality
All records that contain names or other personal identifiers, such as informed consent forms, will be stored separately from study records identified by code number to protect confidentiality before, during, and after the trial.

Future availability of trial data
The principal investigator, as well as all co-authors, will have access to the full dataset as needed. 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 recent proposal from the International Committee of Medical Journal Editors (ICMJE).

Dissemination policy
Results from the trial will be published in international, scientific peer-reviewed journals, no matter the trial outcome. The results will also be presented at relevant scientific conferences and symposiums. Authorships will be allocated according to the ICMJE recommendations. The following papers are planned:

2. Motivation and barriers to perform home-based exercise after Total Hip Arthroplasty – a qualitative embedded study within the PHETHAS-1 trial.

Data availability
Underlying data
No underlying data are associated with this article.

Extended data

This project contains the following extended data:
- WHO Trial Registration Data Set_PHETHAS.docx
- Consent document.pdf
- Managing pains associated with exercise.docx (pain management guide)
- PHETHAS Interview guide English (PHETHAS-2 interview guide, translated into English)
- Questionnaire Motivation to perform exercises.docx
- Questionnaire Evaluation of prescribed exercises.docx
- CERT Checklist.docx
- TIDieR Checklist.docx

Extended data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

Reporting guidelines

Grant information
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 Physiotherapists (37,500 DKkr), The Aase and Ejnar Danielsen Foundation (100,000 DKkr, grant: 10-002170) and The family Kjærgaard foundation (26,928 DKkr).

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.
References


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PubMed Abstract | Publisher Full Text
Open Peer Review

Current Peer Review Status: ✔ ✔ ✔

Version 1

Reviewer Report 30 August 2019

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Martin Stevens
Department of Orthopedic Surgery, University Medical Center Groningen (UMCG), University of Groningen, Groningen, The Netherlands

This is a very well-written and interesting study protocol focusing on the effectiveness of home-based rehabilitation following total hip arthroplasty. Specific strengths of the protocol are the very detailed description of the study design and the content of the home-based exercise intervention in particular, the objectively quantified exercise dose and the combination of quantitative and qualitative methods which will be used to evaluate the home-based exercise intervention. However, a few items were encountered while reading the manuscript which the authors might reflect upon:

- The different aspects of the home-based exercise intervention are described in great detail (Table 2), which enhances the understanding and replicability of the intervention. However, it is not entirely clear why these specific four strengthening exercises (hip abduction, flexion, extension with elastic band resistance and sit-to-stand) and the intervention duration of 7 weeks were chosen. Please elaborate on the rationale for these choices regarding the design on the home-based exercise intervention (e.g. based on guidelines or recommendations?).

- On page 4, it is stated that participants will be advised to comply with the recommendations on physical activity from the Danish Health and Medicines Authority. Could you give a (short) description of these recommendations?

- On page 4, it is described that all participants will receive a thorough instruction in the strengthening exercises at the baseline measurement and that face-to-face meetings among physiotherapists will be held to reinforce similar treatment administration. Will patients also be monitored during the intervention period to check whether they are still performing the strengthening exercises according to the received instructions?
• Outcome measures (1): 24-hour physical activity level will only be determined at the start of the intervention. Why will this outcome measure not be repeated at the end of the intervention as well?

• Outcome measures (2): in contrast to hip abductor and hip flexor muscle strength, hip extensor muscle strength is not specified as secondary outcome measure. However, hip extensor muscle strength is one of the four strengthening exercises of the interventions. Could you clarify why this will not be evaluated as secondary outcome?

• Self-efficacy (1): to measure self-efficacy, the general self-efficacy scale will be used. However, it has been stated that the concept of self-efficacy is most useful when it is measured for a particular behavior in a specific context (e.g. postoperative rehabilitation following total hip arthroplasty) (Bandura, 1997)¹. Could you elaborate on the decision to include a general self-efficacy scale instead of a more context-specific self-efficacy scale (e.g. The Self-Efficacy For Rehabilitation Outcome Scale, Waldrop et al. 2001)²?

• Self-efficacy (2): Table 1 shows that self-efficacy will be measured both prior to surgery (admission) and 3 weeks after surgery (baseline measurement). Literature indicates that short-term postoperative self-efficacy seems to be a better predictor of long-term outcome following total joint arthroplasty than preoperative self-efficacy (Scheek et al. 2007)³. You seem to incorporate this finding by only including the postoperative self-efficacy as possible confounding variable in the statistical analyses. What will be the additional value of including the preoperative self-efficacy measurement in your study design?

References

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Orthopedics, physical activity.
We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 14 August 2019

https://doi.org/10.5256/f1000research.21458.r50851

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This is a generally well-written, interesting, and well-designed study, on an important topic. Both from a therapeutic and health-economic perspective it is important to make the patients with THA self-reliant in their exercise management. We also consider the qualitative part of the proposed trial as an important contribution to understand the patients’ barriers and motivation for performing home-based exercises after THA.

However, we have some comments to the authors:

• It is pointed out that there is some evidence to indicate that rehabilitation exercise may be superior to no or very little rehabilitation exercise after THA (Introduction section). Can you clarify the construct ‘rehabilitation exercise’?

• The rationale for using elastic band seems a bit unclear in the section of introduction. How can the authors argue for open kinetic chain strength training with elastic band compared to functional task-oriented training? Is there any prior research indicating the effectiveness of strength training in an open kinetic chain?

• The term ‘pragmatic’ should be clarified (page 3).

• Participants: We consider the inclusion criteria very wide and unspecific (18 years and OA?). There seems to be few exclusion criteria. Why were patients with stroke, other neurological diseases, drug abuse etc., not excluded from the study?

• As walking ability is considered the most important function to improve by patients undergoing THA, why were activities of walking not included in the training? What is the rationale and link between elastic band training and improvements in walking?

• Regarding dose-response; how do you deal with the eventual problem of registration of little activity with the use of the elastic band and a high general weight-bearing activity, such as walking, without registration? In total, this can be considered as a large dose of activity that is not registered. The ActivePAL is only applied for one week.
The planned statistical analyses are well described and seem to be adequate.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Physiotherapy and rehabilitation after THA, TKA, OA, Hip fracture, elderly. Quantitative and qualitative methodology.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 02 August 2019

https://doi.org/10.5256/f1000research.21458.r50853

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Dana L. Judd
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This protocol paper details a prospective cohort study which will investigate the initial efficacy of home-based exercise program following total hip arthroplasty (THA). The authors present strong rationale for performing the study, in particular citing evidence regarding the deficits in strength and function following THA as well as the lack of consensus regarding rehabilitation following THA surgery.

The study design is described in great detail, and the proposed methods will adequately answer the research question. The strengths of the study design include objective monitoring of exercise adherence, the standardization of the exercise protocol, and the combination of validated strength measures and functional performance outcome measures. The choice of exercises for the intervention target common deficits following THA, and the choice of a gait outcome as a primary outcome measure will represent an important functional outcome for patients. A unique aspect of this proposed trial is the proposed qualitative investigation into patients’ perceived barriers to and motivations for participating in the proposed exercise program. Not only will this have potential to inform future trials, but may provide important information from the patients’ point of view to better inform clinical practice and home exercise prescription after THA.
There are also items the authors may wish to consider. First, although there are proposed training and meetings to ensure correct instruction by therapists to patients, the authors may consider including a way to objectively report fidelity data of the therapists to describe how well they adhered to the protocol. Second, due to the importance of collecting the exercise adherence data, is there a plan to handle missing data from the Bandcizer sensors? Or perhaps a way to ensure data is being collected over the weeks of intervention as expected and a plan for troubleshooting. Finally, although the choice of exercises for the protocol aligns well with common impairments following THA, it is possible the few specific exercises and proposed dosing may not yield the expected changes in gait speed without the inclusion of gait-specific training.

Overall, this is a well written manuscript describing a well-designed study and the results should be valuable to the literature regarding rehabilitation after THA.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Total Hip Arthroplasty and Rehabilitation

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.
For pre-submission enquiries, contact research@f1000.com