Statistical analysis plan for the MovetheHip randomised controlled trial: exercise and patient education versus usual care in adults with hip dysplasia

Trial ID: Exercise and patient education compared with usual care in patients with hip dysplasia (MovetheHip)
Trial registration: ClinicalTrials.gov (NCT04795843)
Statistical Analysis Plan (SAP) version: Version 1.0 (2026-06-17)
Based on Protocol Version: Protocol Version 4, approved 25 September 2024 by the Central Regional Committee on Health Research Ethics. This version incorporates all amendments approved on 03-15-2021, 05-18-2021, 04-04-2024 and 25-09-2024.

Roles and responsibility

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- First author of the SAP
- Principal investigator of the trial
- Responsible for the overall scientific conduct of the trial
- Ensures adherence to protocol and regulatory requirements (including AE/SAE reporting)
- Responsible for the preparation of analysis datasets and data management under the supervision of the senior biostatistician; not involved in the execution of the blinded analyses

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- Co-author of the SAP
- Responsible for conducting one of the independent blinded statistical analyses according to the SAP
- Will remain blinded to group allocation until all analyses and primary result tables have been completed

Bo Martin Bibby, PhD**,** Associate Professor
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- Co-author of the SAP
- Senior biostatistician providing methodological oversight
- Reviews and approves the SAP
- Ensures methodological quality and adherence to good statistical practice
- Supervises data preparation and statistical programming before execution of analyses
- Responsible for conducting an independent, blinded statistical analysis separate from and parallel to the analysis performed by the other statistical analyst

- Will remain blinded to group allocation during all statistical oversight and until approval of the main result tables

Trial collaborators

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Signatures

Date	Name	Role and responsibility
2026-06-17	Julie Sandell Jacobsen, PhD	SAP first author; chief investigator
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2026-06-17	Bo Martin Bibby, PhD	SAP co-author; senior biostatistician; independent blinded analyst

Statement of pre-specification

This SAP was finalised prior to any unblinded comparative analyses. The statistical analysts responsible for the analyses will remain blind to the labelling of the treatment allocation (i.e., intervention versus usual care) until all analyses prespecified in this SAP have been completed and the interpretation of results for primary and secondary outcomes has been finalised.

Introduction

Hip dysplasia is a morphology of the acetabulum that may lead to insufficient femoral head coverage and hip pain in young and middle-aged adults [1–5]. Exercise and patient education have been proposed as non-surgical options for symptom management, but the existing evidence is sparse and derives primarily from studies involving individuals eligible for periacetabular osteotomy (PAO) [6,7]. To date, no trials have investigated these interventions in adults who are not eligible for or decline surgical treatment.

We conducted a feasibility study of a six-month exercise and patient education programme [8], which demonstrated clinically relevant improvements in pain and function, acceptable recruitment and adherence, and provided information on the variability of the outcome measures (e.g., standard deviations). These results supported the conduct of a full-scale randomised controlled trial, described in detail in the published protocol [9].

Objectives

The primary objective is to estimate the between-group difference in mean change in self-reported pain, measured with the Copenhagen Hip and Groin Outcome Score (HAGOS) pain subscale, from baseline to 6-month follow-up, comparing participants randomised to exercise and patient education with those randomised to usual care.

Secondary objectives are to compare the between-group differences in mean change from baseline to 6 months for the remaining HAGOS subscales, the Short Version of the International Hip Outcome Tool (iHOT-12), the performance outcome (single-leg hop for distance test), maximal isometric hip muscle strength and balance measures, comparing the same two randomised groups.

The hypothesis is that patients randomised to exercise and patient education will have a mean change score on the HAGOS pain that is at least 10 points higher than those randomised to usual care over a 6-month follow-up period.

Study methods

Trial design

The MovetheHip trial is a randomised controlled, parallel-group, assessor-blinded superiority trial comparing exercise and patient education with usual care.

The design and reporting of the protocol and the present SAP follow the Guidelines for the Content of Statistical Analysis Plans in Clinical Trials [10] and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement [11].

The trial is registered at ClinicalTrials.gov (NCT04795843). Ethical approval was obtained from the Committee on Health Research Ethics in the Central Denmark Region (project ID: 1-10-72-336-20), and data handling was authorised by the Danish Data Protection Agency (project ID: 1-16-02-678-20).

Study setting

Participants will be recruited from the Department of Orthopaedic Surgery at Aarhus University Hospital and Silkeborg Regional Hospital in Denmark. Eligibility assessment will be performed by

clinical staff at Aarhus University Hospital on all potential participants in accordance with the eligibility criteria prespecified in the trial protocol [9].

Randomisation

Following enrolment and completion of the baseline assessment, participants will be randomised to exercise and patient education or to usual care at a 1:1 ratio, using block randomisation with block sizes of 4 and 6.

An independent data manager will generate a computerised list of random numbers in the Research Electronic Data Capture (REDCap) randomisation system before participants are enrolled [12]. Group allocation will be concealed. A research assistant, not involved in the outcome assessment and blinded to block sizes and randomisation sequence, will perform the randomisation without being able to foresee the group assignment.

Intervention: exercise and patient education

Participants allocated to the intervention group are offered a six-month exercise and patient education programme as prespecified in the trial protocol [9]. The programme comprises eight supervised training sessions, during which participants are instructed in hip-strengthening exercises to be performed at least three times per week. The programme also includes structured patient education covering hip dysplasia–related pain mechanisms, the role of physical activity and exercise, and general self-management principles. Further details of the intervention content are provided in the trial protocol [9].

Control: usual care

Participants allocated to usual care receive standard self-management guidance for hip symptoms, as described in the trial protocol [9]. This includes a single consultation in which participants receive information about hip morphology, general advice on physical activity and exercise, and strategies for reducing symptom-provoking activities. Further details of usual care procedures are provided in the trial protocol.

Superiority power calculation

The sample size was determined as described in detail in the trial protocol [9]. A total of 170 participants (85 per group) provides 80% power for concluding superiority at a two-sided significance level (α) of 0.05, assuming a common standard deviation of 13 points for changes in HAGOS pain and an expected between-group mean difference of 15 points from baseline to six months [8].

A between-group mean difference of 10 points on the HAGOS pain subscale is considered the minimal clinically important difference (MCID) and defines the superiority margin [13], so that superiority corresponds to the lower limit of the 95% confidence interval for the between-group mean difference exceeding the superiority margin of 10 points for the change in HAGOS pain from baseline to 6 months [13]. Given the absence of hip dysplasia-specific data, the calculation relies on data from patients with femoroacetabular impingement syndrome [13].

The sample size allows for an anticipated attrition of up to 15%.

Analysing framework

All primary and secondary analyses will follow the intention-to-treat (ITT) principle. All randomised participants will be included in the analysis and will be analysed according to their allocated treatment group, irrespective of adherence, withdrawal or cross-over.

The ITT analysis targets the effect of assignment to the treatment strategy (exercise and patient education versus usual care). No per-protocol analysis is planned, and all conclusions will rely exclusively on the ITT analysis.

Statistical interim analysis

No interim analyses are planned. All analyses will be performed after database lock and completion of the 6-month follow-up for all participants.

Timing of final analysis

The primary statistical analysis will be conducted after the last randomised participant completes the 6-month follow-up and the 6-month dataset has been fully entered, cleaned and finalised. Database lock will occur prior to any unblinding of treatment allocation. The main trial manuscript reporting the 6-month outcomes is expected to be prepared following completion of the prespecified blinded analyses (anticipated April 2027).

Timing of outcome assessments

Outcome assessments will be conducted at baseline, 3 months and 6 months, as prespecified in the trial protocol [9]. Self-reported outcomes will be collected electronically at all three time points. Performance, strength and balance outcomes will be collected at baseline and at the 6-month follow-up.

Long-term follow-up assessments (9 months, 12 months and 2-, 5- and 10-year follow-ups) will be analysed and reported in separate secondary manuscripts. These analyses are not part of the present Statistical Analysis Plan. Prior to each long-term follow-up analysis, a dedicated statistical analysis plan will be developed to prespecify the outcomes to be analysed, the statistical methods and procedures for handling missing data.

Statistical principles

Confidence intervals and p-values

All statistical tests are two-sided with a significance level of 0.05. We will report 95% confidence intervals for the primary and secondary outcomes.

The primary result will be interpreted using the 95% confidence interval for the between-group difference in mean change in HAGOS pain.

Clinical importance will primarily be assessed against the MCID of 10 points, as prespecified in the protocol from 2022 [13]. The interpretation will be as follows (Figure 1):

Scenario 1: A confidence interval above 10 points will be interpreted as supporting a statistically significant and clinically important treatment effect.

Scenario 2: A confidence interval above 0 points, with an upper limit of at least 10 points, will be interpreted as statistically significant and may include a clinically important treatment effect.

Scenario 3: A confidence interval above 0 points, with an upper limit below 10 points, will be interpreted as statistically significant but not supporting a clinically important treatment effect.

Scenario 4: A confidence interval that includes 0 points, with an upper limit of at least 10 points, will be interpreted as statistically non-significant but may include a clinically important treatment effect.

Scenario 5: A confidence interval including 0 points and with an upper limit below 10 points will be interpreted as statistically non-significant and not supporting a clinically important treatment effect.

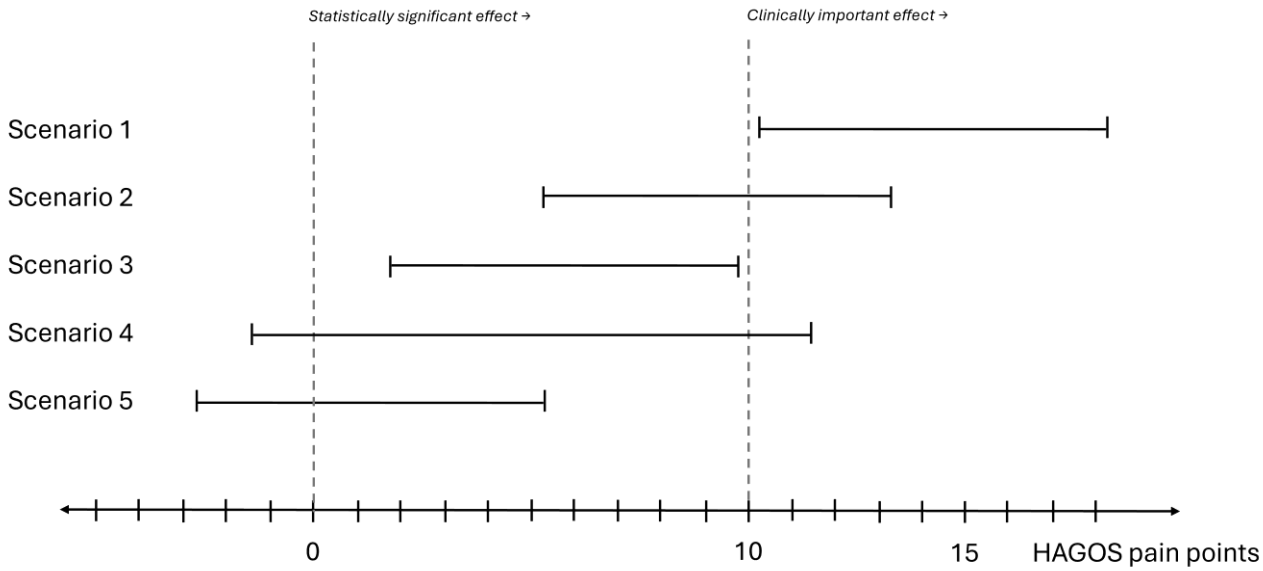

Figure 1. Different data scenarios (1-5) using the 95% confidence interval for the between-group difference in mean change in HAGOS pain from baseline to 6-month follow-up.

Blinding and independent statistical analyses

All statistical analyses and interpretation of primary and secondary outcomes will be conducted with treatment groups blinded and without access to the true allocation.

Two independent blinded statistical analyses will be performed in accordance with this prespecified SAP: one by the epidemiologist and one by the senior biostatistician. Both analysts will use the same locked analysis dataset and will work independently without access to each other's analyses.

After completion of the prespecified analyses and finalisation of the primary result tables, the two analysts will compare outputs while treatment allocation remains blinded. Comparisons will focus on numerical results, statistical model specification and adherence to the SAP.

If discrepancies arise, the analysts will:

1. Verify adherence to the SAP
2. Review differences in code, model specification or software implementation
3. Resolve discrepancies by consensus while maintaining blinding

4. Document the cause and solution.

All discrepancies and their resolution will be recorded in an internal analysis report. If discrepancies cannot be solved between the two analysts, the principal investigator will make the final decision.

Treatment allocation will not be unblinded until:

- The two independent analyses have been reconciled
- Final output tables have been approved as complete by the principal investigator. The senior biostatistician and chief investigator have authorised unblinding

All analyses will use the statistical software specified in the Analysis overview section. No analyses beyond those prespecified in this SAP are planned.

Adherence in the intervention and control groups

Adherence to the intervention is recorded in weekly training logs. In the intervention group, adherence is classified as high (≥75% of planned sessions completed), medium (50–74%) or low (<50%), as prespecified in the trial protocol. Self-reported adherence is additionally assessed using the Exercise Adherence Rating Scale (EARS) [14].

In the usual care group, adherence to the allocated treatment strategy is defined as engagement in structured hip exercises with content and frequency similar to those of the MovetheHip intervention. Participants who report performing 50% or more of such structured exercise at 6 months will be classified as having deviated from the allocated treatment strategy. Engagement below this level will be considered consistent with usual care.

Adherence will be summarised descriptively by randomisation group. Adherence will not influence the ITT analyses, which are based solely on randomised group allocation. Adherence classifications will be used only in descriptive summaries.

Analysis population

The primary analysis population is the ITT population, defined as all randomised participants analysed according to their allocated treatment group.

Participants who withdraw consent for further participation but allow continued use of already collected data will remain in the ITT population, and all available data will be included in the analyses. The number and timing of withdrawals will be reported.

Participants randomised in error will be included in the ITT population unless data use is prohibited by data protection constraints.

No per-protocol analysis set is defined.

Trial population

Screening and eligibility

All patients assessed for eligibility at Aarhus University Hospital and Silkeborg Regional Hospital will be recorded. The flow of participants through the trial will be summarised in a CONSORT flow diagram The flow diagram will display the total number of participants who were: (1) assessed, (2) excluded

(with reasons), (3) randomised, (4) received allocated treatment, (5) discontinued intervention (with reasons), (6) lost to follow-up (with time and reason), and (7) included in ITT analysis.

Eligibility criteria follow the published trial protocol [9]. In brief, inclusion requires age 18–50 years, radiographically verified hip dysplasia, hip or groin pain for at least 3 months, and fulfilment of one of the prespecified PAO-related conditions (eligible but unwilling to undergo PAO, on a prolonged PAO waiting list, or ineligible for PAO).

Key exclusion criteria include severe comorbidity, previous major hip surgery, conditions affecting hip function and inability to complete trial procedures.

Recruitment and follow-up

Participant flow from randomisation to completion of the 6-month follow-up will be presented by randomised group.

The flow diagram will report:

- Numbers allocated to each group
- Discontinued intervention and their classification (discontinued with retained data vs complete discontinued requiring data deletion)
- Loss to follow-up, including timing and reasons when available
- Numbers included in the ITT analysis

Baseline characteristics

Baseline characteristics will be summarised by randomised group using descriptive statistics. No statistical comparisons between groups will be performed. Any clinically relevant imbalances will be noted without formal testing.

Baseline variables include [9]:

- Sex
- Age
- Body mass index via height and weight
- Duration of hip symptoms
- Unilateral or bilateral hip dysplasia
- Educational level
- Employment status
- Cohabiting status
- Comorbidities
- Previous hip surgery
- Physical activity and exercise level
- Intra-articular pain (flexion–adduction–internal rotation test)
- Wiberg's centre-edge angle
- Acetabular index
- Tönnis osteoarthritis grade

Weight, physical activity and intra-articular pain will also be recorded at 6-month follow-up.

Continuous variables will be presented as means and standard deviations when approximately normally distributed and as medians and interquartile ranges otherwise. Categorical variables will be presented as counts and percentages. Baseline characteristics will be summarised in Table 1.

Analysis

Primary outcome

The primary outcome is hip pain measured with the HAGOS pain subscale.

The outcome will be analysed using a linear mixed-effects model including HAGOS pain at 0, 3 and 6 months as dependent variables.

The primary measure of association is the between-group difference in mean change in HAGOS pain from baseline to 6 months, estimated from the group×time interaction. We will report within-group mean changes in HAGOS pain scores from baseline to 6 months and between-group mean differences in the changes, along with 95% confidence intervals and two-sided p-values.

Primary outcome estimates will be presented in Table 2. Estimated HAGOS mean pain scores measured at baseline, 3 months, and 6 months will be presented in Table 2 and illustrated in Figure 2.

Secondary outcomes

Secondary outcomes include the remaining HAGOS subscales, iHOT-12, the single-leg hop for distance, maximal isometric hip muscle strength and Y-balance measures.

Continuous outcomes will be analysed using a linear mixed-effects model including measures at 0, 3 and 6 months as dependent variables, where appropriate.

The measures of associations are the between-group differences in mean change from baseline to 6 months, estimated from the group×time interaction. We will report within-group mean changes and between-group mean differences in change, along with 95% confidence intervals and two-sided p-values.

Secondary outcome estimates will be presented in Table 2. Estimated outcomes measured at baseline, 3 months and 6 months will be presented in Table 2.

Other outcomes [9]

Acceptable symptom state measured with the Patient Acceptable Symptom State at 6 months.

The following outcomes involve changes from baseline to 6 months:

- Health status measured with the EuroQoL 5- dimension (EQ- 5D- 5L)
- Productivity loss measured with the Productivity Costs Questionnaire
- Self-reported back and hip and/or groin pain intensity measured with a 100 mm VAS for pain in rest and during activity (last week and during hip muscle strength tests)
- Self-reported hip and/or groin pain intensity measured on a numerical rating scale (NRS) for pain) (during hip flexion, extension and abduction strength tests)
- Self-reported usage of analgesics (y/n/type/dose)

- Trust in the capability of the hip will be measured with a 100 mm VAS for trust during the single-leg hop for distance
- Iliopsoas-related and abductor-related muscle tendon pain
- Pain sensitisation measured as the temporal summation of pain and pressure pain threshold at the hip and forearm

Other outcomes will be summarised by randomised group using descriptive statistics at baseline and 6-month follow-up. No statistical comparisons between groups or time points will be performed.

Continuous variables will be presented as means and standard deviations when approximately normally distributed and as medians and interquartile ranges otherwise. Categorical variables will be presented as counts and percentages. These outcomes will be summarised in Table 4.

Analysing methods

Continuous outcomes will be analysed using linear mixed-effects models with a participant-specific random effect and fixed effects for group, time (categorical: 0, 3 and 6 months) and the group×time interaction. An unstructured within-subject variance-covariance matrix will be used when possible; otherwise, a simpler structure that yields stable estimates will be applied. Within and between-group mean differences in change with 95% confidence intervals will be reported.

Model assumptions will be assessed through inspection of residuals and evaluation of influential observations. If model assumptions are not met, we will consider appropriate transformations. Any deviations from the prespecified analysis plan will be documented and justified.

Binary outcomes will be analysed using binomial regression models with id link functions. Within-participant correlation arising from repeated measurements will be accounted for by using robust standard errors with participant ID specified as the clustering variable. Risk differences with 95% confidence intervals will be reported.

Missing data

For longitudinal continuous outcomes analysed using mixed-effects models, all available observations will be included under the missing-at-random assumption. No imputation will be performed for these outcomes.

For outcomes not analysed within a mixed-model framework, the amount and pattern of missing data will be summarised by randomisation group. Any method used to address the missingness of these outcomes will follow the prespecified sensitivity analyses.

Missing baseline data will not be imputed.

Sensitivity analyses

First, we will perform a complete-case analysis of the primary outcome, restricted to participants with observed HAGOS pain scores at the 6-month follow-up. Results from this analysis will be compared with those from the primary mixed-effects model.

Second, we will conduct quantile-based sensitivity analyses to explore the potential impact of missing outcome data. For participants with missing 6-month HAGOS pain values, missing outcomes will be replaced by values corresponding to the 0.10 and 0.90 quantiles of the observed distribution of 6-

month HAGOS pain scores. These values approximate the lower and upper limits of a 95 % prediction interval for the observed changes and represent conservative but plausible scenarios for the missing outcomes.

Sensitivity analyses will be restricted to the primary outcome and interpreted as supportive rather than confirmatory. Results from the sensitivity analyses will be summarised in Supplementary Table S1.

Harms

Adverse events (AEs) and serious adverse events (SAEs) will be recorded throughout the trial in accordance with the protocol [9]. All events reported by participants or observed by study personnel will be documented and categorised by type, severity and perceived relation to the intervention or usual care. SAEs will be reviewed by the principal investigator and reported to the local research ethics committee in accordance with Danish regulatory requirements.

Harms will be summarised descriptively by randomisation group. For each category of AE and SAE, we will report the number of events, the number of participants affected and the proportion of participants with at least one event. No statistical testing of between-group differences is planned.

Summaries of harms are descriptive and will not influence the interpretation of the primary or secondary outcomes. Harms will be summarised in Table 3.

Statistical software

Analyses will be conducted using statistical software (e.g., Stata or R). The specific software and version will be documented before the database lock.

Tables and figures

The following tables and figures will be prepared for the main trial publication. Formats will follow journal requirements, and no inferential results beyond those prespecified in this SAP will be produced.

Figure 1. CONSORT flow diagram

Participant flow through the trial, including (1) assessed, (2) excluded (with reasons), (3) randomised, (4) received allocated treatment, (5) discontinued intervention (with reasons), (6) lost to follow-up (with time and reason) and (7) included in ITT analysis.

Figure 2. HAGOS pain values over time

Mean HAGOS pain scores with 95% confidence intervals at baseline, 3 months and 6 months, presented by randomisation group.

Table 1. Baseline characteristics

Baseline demographic and clinical characteristics summarised by randomisation group using descriptive statistics.

Table 2. Primary and secondary outcome results

A single results table will present the primary and secondary outcomes. For each outcome, the table will report group means at baseline, 3 months and 6 months, within-group mean changes and the between-group difference in mean change from baseline to 6 months, with 95% confidence intervals

and p values. Outcomes that were not measured at 3 months will be reported only at baseline and 6 months. The primary outcome will be clearly identified.

Table 3. Harms
Adverse events and serious adverse events summarised by category, severity and relatedness. For each category, the table will report the number of events, the number of participants affected and the proportion of participants with at least one event.

Table 4. Other outcomes
Other outcomes will be summarised by randomisation group using descriptive statistics.Depending on journal requirements and space limitations, this table may be presented in the Supplementary Material.

Table S1. Sensitivity analyses
Sensitivity analyses will be presented in a supplementary table. The table will summarise results from the complete-case analysis, the quantile-based sensitivity analysis. These results will also be briefly described in the main manuscript text but will not form part of the confirmatory analyses.

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