Statistical Analysis Plan for the Snappy Hip Trial

A randomised trial comparing clinical and cost-effectiveness of progressive resistance training compared to no intervention on pain for adults with external snapping hip

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Trial registration, version of statistical analysis plan and protocol

This trial is registered at www.ClinicalTrials.gov with the number NCT06924164 and the Statistical Analysis Plan is version 1.

Signatures

Role	Name	Date	Signature
The person writing the SAP	Lisa Urup Tønning	29/9-26	Lisa Tønning
Senior statistician responsible	Bo Martin Bibby	30/9-2026	
Chief investigator/clinical lead	Inger Mechlenburg	30/9/2026	Inger Mechlenburg

INTRODUCTION

Background

External snapping hip is a musculoskeletal condition causing a painful snapping sensation during hip movement, most commonly affecting physically active individuals aged 15–40 years [9, 14]. The snapping is attributed to extra-articular structures moving over the greater trochanter [9]. Although conservative management is recommended as first-line treatment, a substantial proportion of patients report persistent symptoms despite treatment. This underscores the need for targeted exercise-based interventions, such as progressive resistance training (PRT) that may address the underlying biomechanical impairments associated with the condition[12-14].

Rationale for this study

High-quality randomised evidence evaluating the effect of PRT for external snapping hip is lacking. This trial compares a 12-week PRT programme with no treatment to assess its effect on hip pain and related outcomes. This statistical analysis plan pre-specifies the analytical methods to be applied, thereby ensuring transparency and minimizing analytical bias.

Objectives

The primary objective of the trial is to compare the effect of the 12-week PRT programme with no intervention on hip pain in individuals aged 18–40 years with external snapping hip (Aim I). The primary outcome is the between-group difference in change in the pain subscale of the Copenhagen Hip and Groin Outcome Score (HAGOS) [17] from baseline to 12 weeks after randomisation . The secondary objective is to compare the effect of immediate versus delayed initiation of PRT on hip pain (Aim II). This will be assessed by comparing the change in HAGOS pain scores after 12 weeks of PRT in the immediate treatment group (baseline to week 12) with the corresponding change after 12 weeks of PRT in the delayed treatment group (baseline to week 24). For both aims, additional analyses will assess treatment effects of the intervention on patient-reported, functional, health-economic and safety outcomes.

STUDY METHODS

Trial design

The SnappyHip trial is a national, multicentre, randomised controlled trial designed to evaluate the effect of a 12-week PRT programme for individuals with external snapping hip. Participants are

randomised in a 1:1 ratio to either immediate initiation of PRT or a no-intervention period of 12 weeks followed by delayed initiation of the same PRT programme (Figure 1) [18]. Outcome assessments are conducted at baseline (week 0), after the initial 12-week period (week 13), and after completion of the delayed intervention period (week 25). The primary randomised comparison relevant to the primary aim is limited to the period from baseline to week 13, during which participants in the control group have not yet received the intervention. The delayed-start design further allows evaluation of the effect of intervention timing by comparing outcomes following 12 weeks of PRT in the immediate and delayed intervention groups. Due to the nature of the exercise intervention, neither participants, treating physiotherapists, nor outcome assessors are blinded to treatment allocation. Statistical analyses will be conducted according to this prespecified statistical analysis plan to minimise the risk of analytical bias.

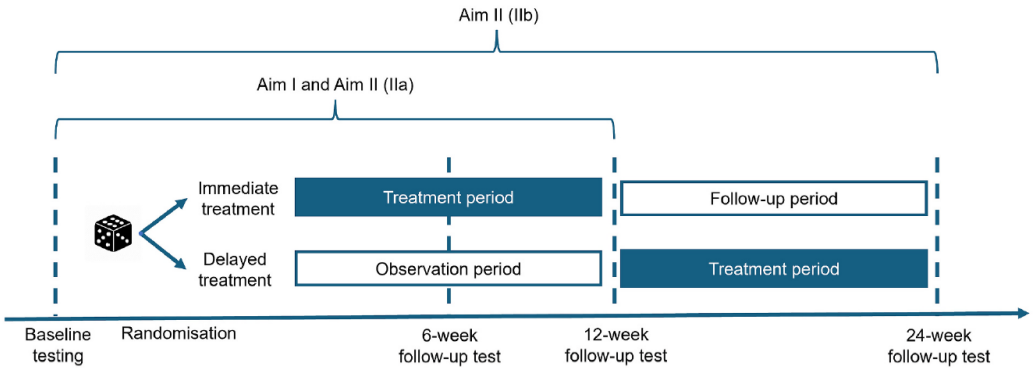


Fig. 1. Overview of the trial design. The trial has two aims: (I) to compare the change between the first and the third assessments for both groups, and (II) to compare the change between the first and third assessments for the immediate treatment group (IIa) with the change between the first and the fourth assessments for the delayed treatment group (IIb).

Randomisation and blinding

Participants are randomised in a 1:1 ratio to either immediate initiation of the 12-week PRT programme or a no-intervention period followed by delayed initiation of the same intervention. Randomisation is performed after completion of all baseline assessments using the Research Electronic Data Capture (REDCap) system hosted at Aarhus University [6, 7]. The randomisation sequence is generated using blocks of varying sizes to ensure balance between groups during recruitment. Due to the nature of the exercise intervention, participants and treating physiotherapists are not blinded to treatment allocation. Baseline assessments are conducted prior to randomisation and are therefore performed blinded to group allocation. Follow-up outcome assessments are not blinded. All statistical analyses and interpretation of trial data will be conducted with treatment

groups masked and blinding will be maintained until the interpretation of results has been completed and made publicly available.

Sample size

The sample size calculation is based on the primary efficacy objective, comparing the effect of the 12-week PRT programme with no intervention on hip pain measured using the pain subscale of HAGOS. A between-group difference in the effect of 9.7 points on the HAGOS pain subscale is considered the minimal clinically important difference [16]. In the prior feasibility study [12], participants improved by 30.8 points (95% CI: 19.2;42.5, SD 14.6) after the intervention. Accounting for a potential dropout bias in the feasibility study, the expected mean improvement in the immediate PRT group is conservatively estimated to be approximately 20.5 points, while a smaller improvement of 2.5 points is assumed in the delayed treatment group. With an expected between-group difference of 18 points, a two-sided significance level of 0.05, and a statistical power of 80%, a total of 78 participants per group is required to detect a clinically meaningful difference in the primary outcome. To account for potential dropout during the trial, estimated at approximately 28%, the total required sample size is increased to 100 participants, corresponding to 50 participants in each randomised group. The trial is powered exclusively for the primary randomised comparison. Analyses addressing the secondary aim regarding timing of intervention are considered exploratory and are not separately powered.

Framework

The SnappyHip trial is designed within a superiority framework. The primary objective is to determine whether a 12-week PRT programme is superior to no intervention with respect to change in hip pain. Superiority will be assessed based on the between-group difference in change from baseline, with statistical inference conducted at a two-sided significance level of 0.05.

Statistical interim analyses and stopping guidance

No formal interim analyses are planned for the SnappyHip trial. The trial is not designed with stopping rules for efficacy, futility or harm.

Timing of final analysis and outcome assessments

Outcome assessments are conducted at four predefined time points: baseline (week 0), week 6, week 13, and week 25 (Figure 1). The primary outcome for the primary efficacy objective (Aim I) is assessed over the randomised comparison period from baseline to week 13. Outcomes related to the secondary efficacy objective (Aim II) are assessed by comparing changes following 12 weeks of PRT in the immediate intervention group (baseline to week 13) with corresponding changes in the delayed intervention group (baseline to week 25). The final statistical analyses will be performed after completion of all scheduled outcome assessments and after the study database has been locked.

STATISTICAL PRINCIPLES

Confidence intervals and P values

All estimates will be reported with two-sided 95% confidence intervals (95% CI). For both the primary efficacy objective (Aim I) and the secondary efficacy objective (Aim II), statistical inference will be conducted using a two-sided significance level of 0.05. A p-value less than 0.05 will be considered statistically significant for analyses related to each aim. Secondary and other outcome analyses will be evaluated using the same significance level of 0.05, and no formal adjustment for multiple comparisons will be applied. Consistent with contemporary statistical guidance, interpretation of results will not rely solely on dichotomisation based on statistical significance. Instead, emphasis will be placed on effect estimates, confidence intervals, and clinical relevance alongside reported p-values (13).

Adherence and protocol deviations

Adherence is defined as the ability to follow the allocated PRT intervention. Adherence will be described using the number of supervised PRT sessions attended, the number of supervised sessions in which all prescribed exercises were completed, and the number of self-reported training sessions during the study period. These adherence measures will be summarised descriptively and compared between the randomised groups. Good adherence is predefined as participation in at least 70% of the supervised PRT sessions. This definition will be used to identify participants eligible for the prespecified per-protocol analysis.

Protocol deviations, including deviations from the planned PRT exposure or from the scheduled outcome assessments, will be summarised descriptively. Major protocol deviations will be considered in sensitivity analyses where relevant.

Analysis populations

All efficacy analyses for Aim I and Aim II will follow the intention-to-treat principle and will include all randomised participants in the groups to which they were allocated. A per-protocol analysis will be conducted as a prespecified sensitivity analysis and will include only participants with good adherence to the PRT programme, defined as participation in at least 70% of the supervised PRT sessions. The per-protocol analysis will be used to assess the robustness of the findings from the intention-to-treat analyses. The per-protocol analysis will be adjusted for age and gender.

TRIAL POPULATION

Screening data, eligibility and recruitment

All individuals assessed for potential participation in the SnappyHip trial will be screened according to the predefined inclusion and exclusion criteria. Screening data will be summarised descriptively to document the flow of participants through the trial. Participants are recruited from orthopaedic departments at hospitals, physiotherapy clinics, and through public advertisements. Eligible individuals who provide informed consent are enrolled and randomised after completion of baseline assessments. The number of individuals screened, eligible, randomised, and included in the intention-to-treat population will be reported and illustrated in a CONSORT flow diagram. Reasons for non-eligibility and withdrawal, when available, will be summarised descriptively.

Baseline patient characteristics

Baseline demographic and clinical characteristics will be summarised descriptively for all randomised participants by treatment group. Continuous variables will be presented as means with standard deviations (SD) for approximately normally distributed data, or as medians with interquartile ranges (IQR) for data that are not normally distributed. Categorical variables will be

presented as counts and percentages. Baseline characteristics will be reported for the intention-to-treat population. No formal statistical testing will be performed to compare baseline characteristics between groups, as any observed differences will be considered attributable to random variation.

Withdrawal

Participants may withdraw from the trial at any time. Participants who discontinue the allocated intervention will be encouraged to complete all scheduled outcome assessments. Withdrawals will be summarised descriptively, including the number of participants who withdraw from the intervention while continuing outcome assessments and the number of participants who withdraw from both the intervention and further assessments. The timing of withdrawal will also be reported where available. A CONSORT flow diagram will be used to illustrate participant flow throughout the trial, including withdrawals and loss to follow-up.

ANALYSIS

Outcome definitions

The primary outcome is hip pain measured using the pain subscale of HAGOS (14). The pain subscale consists of ten items evaluating pain related to hip and groin problems. Item responses are transformed to a score ranging from 0 to 100, where higher scores indicate less pain. The minimal clinically relevant difference in HAGOS pain has been found to be 9.7 points (15). HAGOS is a valid and reliable questionnaire to collect patient-reported outcomes regarding hip and groin pain among young to middle-aged patients (15,16). For Aim I, the primary endpoint is the change in the HAGOS pain subscale from baseline to week 13, comparing immediate PRT to no intervention. For Aim II, the primary endpoint is the change in the HAGOS pain subscale comparing immediate versus delayed initiation of PRT. In the immediate PRT group, this is defined as the change from baseline to week 13. In the delayed PRT group, this is defined as the change from baseline to week 25.

Secondary patient-reported outcomes include the remaining HAGOS subscales assessing symptoms, physical function in daily living, physical function in sport and recreation, and hip and groin-related quality of life. All HAGOS subscales are scored from 0 to 100, with higher scores

indicating better status. Additional secondary patient-reported outcomes include physical activity level assessed using the University of California Los Angeles Activity Scale [2] and global perceived change assessed using the Global Perceived Effect (GPE) questionnaire [10]. Objective hip function is assessed using the single leg hop for distance test [1, 11] and the 30 second single leg sit to stand test [4].

Health-related quality of life is assessed using the European Quality of Life 5 Dimensions 5 Levels instrument (EQ-5D-5L) [8]. EQ-5D-5L data will be used both as a clinical outcome and as input for the health economic analyses. Productivity loss is assessed using the Productivity Costs Questionnaire (iPCQ) [3] and healthcare resource utilization and medication use is assessed using the Health Utilisation Questionnaire (HUQ) [5]. These outcomes are analysed descriptively and used for cost-effectiveness and cost-utility analyses. Adverse events reported during the trial period are recorded and summarised descriptively by type and frequency. All secondary outcomes are analysed as change scores over the relevant assessment periods corresponding to Aim I and Aim II.

Analysis methods

Descriptive statistics will be used to summarise baseline characteristics and outcome measures at each assessment time point. Continuous variables will be reported as means with standard deviations when approximately normally distributed, or as medians with interquartile ranges when distributions are skewed. Categorical variables will be reported as counts and percentages.

The primary and secondary continuous outcomes will be analysed using linear mixed-effects models to account for the repeated measurements within participants. For the primary outcome, the dependent variable will be the HAGOS pain score. Fixed effects will include treatment group, time, and the interaction between treatment group and time. Participant identifier will be included as a random effect. Secondary continuous outcomes will be analysed using the same modelling strategy as the primary outcome.

The health economic evaluation will be conducted from a societal perspective. Differences in total costs and effects between groups will be estimated using seemingly unrelated regression (SUR) models, in which cost and effect equations are estimated simultaneously, allowing for correlation between their residuals [20]. Analyses will be adjusted for age, sex, and baseline HAGOS pain score. Incremental cost-effectiveness ratios (ICER) will be calculated as the ratio between adjusted

differences in costs and adjusted differences in effects. Uncertainty around cost-effectiveness estimates will be assessed using non-parametric bootstrapping with 5000 replications. Results will be presented using cost-effectiveness planes and cost-effectiveness acceptability curves across relevant willingness to pay thresholds. Interpretation of cost effectiveness will be based on the probability of cost effectiveness at the National Institute for Health and Care Excellence (NICE) willingness to pay threshold of €22,665 per quality adjusted life year [15].

Missing data

Analyses for Aim I and Aim II will be based on all available data under the assumption that data are missing at random. No single-value imputations will be applied for these aims. Missing cost and utility data in the health economic evaluation will be handled using multiple imputation under the assumption that data are missing at random, with pooled estimates obtained using Rubin's rules [19].

Additional analysis

As described above, a per-protocol analysis will be performed as a sensitivity analysis, including only patients with good adherence who participated in ≥70% of the supervised training sessions. Patients who do not comply with the randomised treatment will be excluded from this analysis. For the health economic evaluation, sensitivity analyses will be conducted using alternative analytical specifications, including analyses without covariate adjustment and without imputation.

Harms

Adverse events will be recorded by the physiotherapist throughout the study period, including during supervised training sessions and follow-up assessments. Adverse events will be summarised descriptively as numbers and percentages by type of event.

Statistical software

All statistical analyses will be performed in the newest version of Stata (StataCorp LLC, College Station, TX, USA).

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FIGURES AND TABLES

As the project cotains two aims, the following figures and tables will be presented for each aim separately.

AIM I

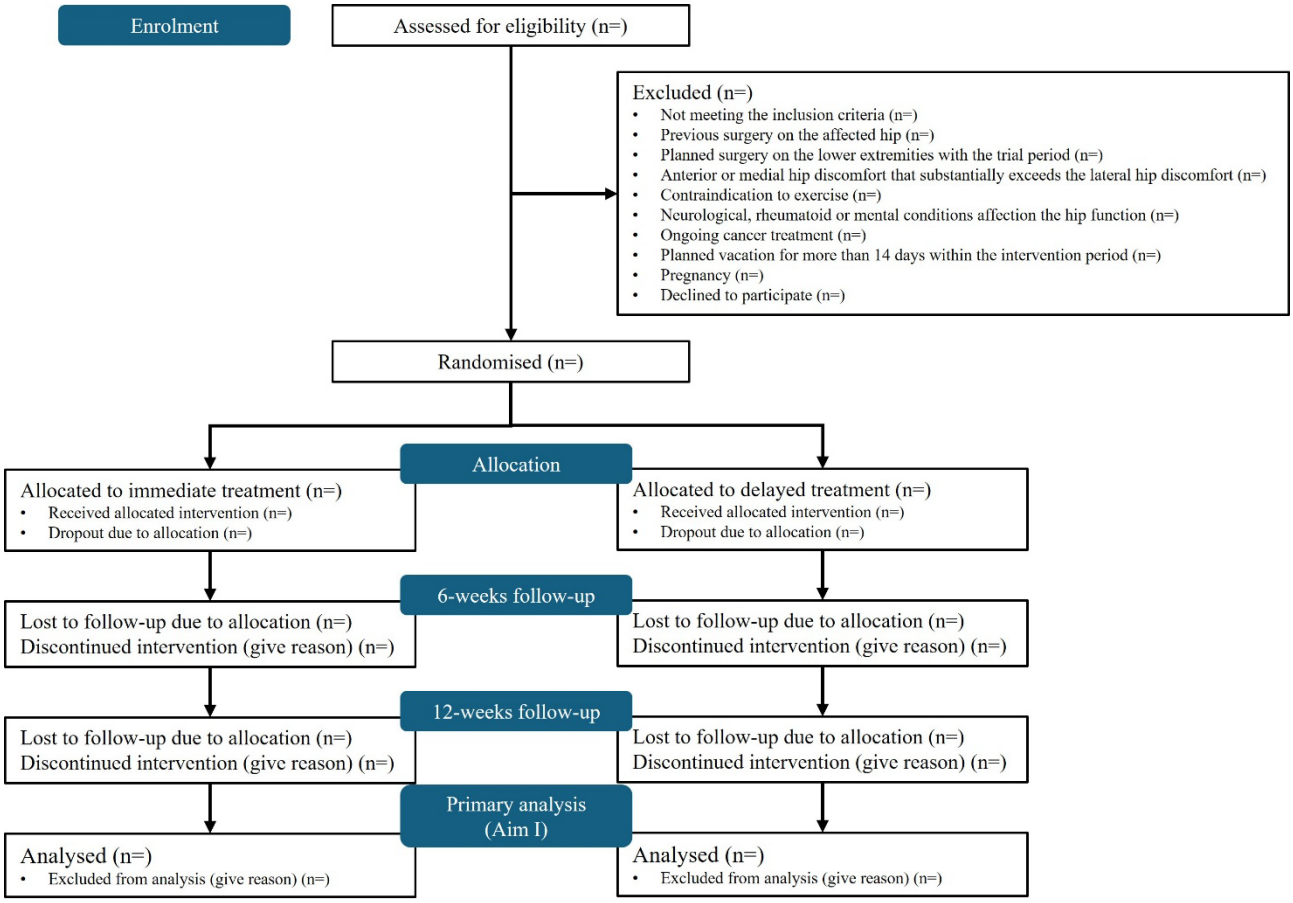


Figure 1 – Aim I. *Flow chart of the participants in the SnappyHip trial randomised to either immediate initiation of progressive resistance training (PRT) or a no-intervention period of 12 weeks followed by delayed initiation of the same PRT programme.*

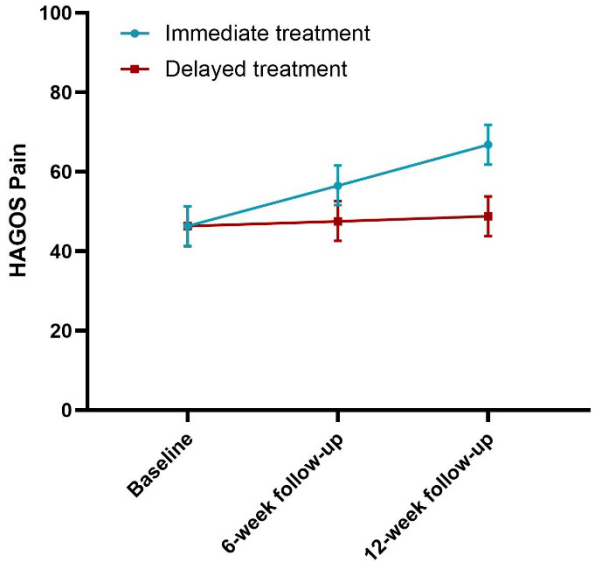


Figure 2 – Aim I. *Intention-to-treat analysis of the difference between the immediate treatment group and the delayed treatment group in improvement from baseline to 12-week follow-up, in the subscale Pain on the Copenhagen Hip and Groin Outcome Score (HAGOS). This figure is an example and is based on results from the feasibility study* [12].

Table 1 – Aim I. Baseline characteristics for the two treatment groups.

	Immediate treatment n =	Delayed treatment n =
Gender		
Age		
Height		
Weight		
Previous big hip surgery		
Bilateral external snapping hip		
Duration of hip symptoms		
0-6 months		
6-12 months		
1-2 years		
2-5 years		
5-10 years		
More than 10 years		
Civil status		
Married		
Cohabiting		
Single		
Divorced		
Widow/widower		
Not informed		
Educational level		
Primary school		
Vocational education		
High school or similar		
Short higher education		
Medium higher education		
Long higher education		
Other education		
Employment status		
During education		
In work		
In activation, sick leave, available, etc.		
Outside the labor market		
Other		
Alcohol consumption		
Under 2 items per week		
2-7 items per week		
8-14 items per week		
15-21 items per week		
22-30 items per week		
Over 30 items per week		
Smoking behaviour		
Never smoked		
Quit smoking		
Sometimes		
Daily		
Co-morbidities		

Table 2 – Aim I. Intention-to-treat analysis of the difference between the immediate treatment group and the delayed treatment group in improvement from baseline to 12-week follow-up.

	Immediate treatment			Delayed treatment			Improvements between the two groups	
	Baseline	6-week follow-up	12-week follow-up	Baseline	6-week follow-up	12-week follow-up	Crude	Adjusted
HAGOS								
Pain								
Symptoms								
Activities of daily living								
Sport and recreation								
Participation in activity								
Hip and groin-related quality of life								
UCLA-AS								
Physical function test								
Single-leg hop for distance test								
30-second single-leg sit-to-stand test								

Outcomes presented as mean with 95% confidence interval. Adjusted: the analysis will be adjusted for time. HAGOS: Copenhagen Hip and Groin Outcome Score. UCLA-AS: University of California Los Angeles Activity Scale.

Table 3 – Aim I. Usage of painkillers.

	Immediate treatment			Delayed treatment		
	Baseline	6-week follow-up	12-week follow-up	Baseline	6-week follow-up	12-week follow-up
Type of painkillers, n (%)						
Paracetamol						
NSAID						
Morfin/opiods						
Other painkillers						
Usage of painkillers, n (%)						
Never						
Monthly						
Weekly						
Daily						

Outcomes presented as numbers and percentages.

AIM I

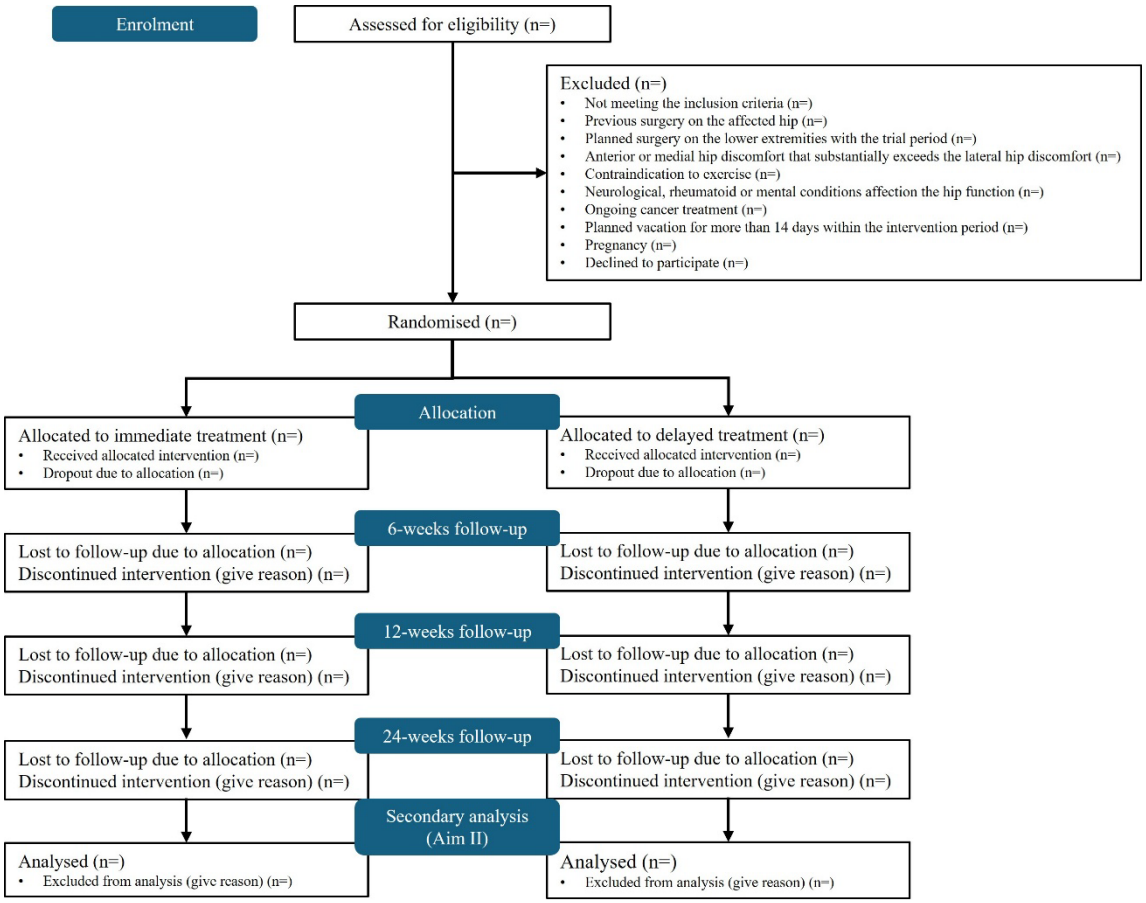


Figure 1 – Aim II. *Flow chart of the participants in the SnappyHip trial randomised to either immediate initiation of progressive resistance training (PRT) or a no-intervention period of 12 weeks followed by delayed initiation of the same PRT programme.*

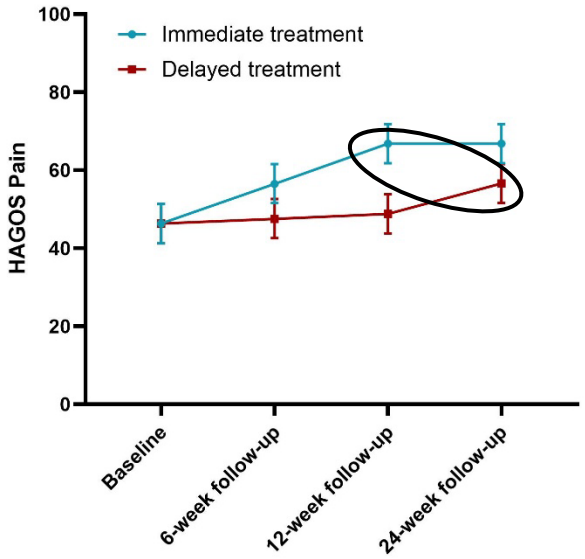


Figure 2 – Aim II. *Intention-to-treat analysis of the difference between the immediate treatment group and the delayed treatment group in improvement from baseline to 12-week follow-up for the immediate treatment group and the improvement from baseline to 24-week follow-up for the delayed treatment group, in the subscale Pain on the Copenhagen Hip and Groin Outcome Score (HAGOS). This figure is an example and is based on results from the feasibility study [(12)].*

Table 1 – Aim II. Baseline characteristics for the two treatment groups.

	Immediate treatment n =	Delayed treatment n =
Gender		
Age		
Height		
Weight		
Previous big hip surgery		
Bilateral external snapping hip		
Duration of hip symptoms		
0-6 months		
6-12 months		
1-2 years		
2-5 years		
5-10 years		
More than 10 years		
Civil status		
Married		
Cohabiting		
Single		
Divorced		
Widow/widower		
Not informed		
Educational level		
Primary school		
Vocational education		
High school or similar		
Short higher education		
Medium higher education		
Long higher education		
Other education		
Employment status		
During education		
In work		
In activation, sick leave, available, etc.		
Outside the labor market		
Other		
Alcohol consumption		
Under 2 items per week		
2-7 items per week		
8-14 items per week		
15-21 items per week		
22-30 items per week		
Over 30 items per week		
Smoking behaviour		
Never smoked		
Quit smoking		
Sometimes		
Daily		
Co-morbidities		

Table 2 – Aim II. Intention-to-treat analysis of the difference between the immediate treatment group and the delayed treatment group in improvement from baseline to 12-week follow-up for the immediate treatment group and the improvement from baseline to 24-week follow-up for the delayed treatment group.

	Immediate treatment				Delayed treatment				Improvements between the two groups	
	Baseline	6-week follow-up	12-week follow-up	24-week follow-up	Baseline	6-week follow-up	12-week follow-up	24-week follow-up	Crude	Adjusted
HAGOS										
Pain										
Symptoms										
Activities of daily living										
Sport and recreation										
Participation in activity										
Hip and groin-related quality of life										
UCLA-AS										
Physical function test										
Single-leg hop for distance test										
30-second single-leg sit-to-stand test										

Outcomes presented as mean with 95% confidence interval. Adjusted: the analysis will be adjusted for time. HAGOS: Copenhagen Hip and Groin Outcome Score. UCLA-AS: University of California Los Angeles Activity Scale.

Table 3 – Aim II. Usage of painkillers.

	Immediate treatment			Delayed treatment		
	Baseline	6-week follow-up	12-week follow-up	Baseline	6-week follow-up	12-week follow-up
Type of painkillers, n (%)						
Paracetamol						
NSAID						
Morfin/opiods						
Other painkillers						
Usage of painkillers, n (%)						
Never						
Monthly						
Weekly						
Daily						

Outcomes presented as numbers and percentages.