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Comparing exercise and patient education with usual care in the treatment of hip dysplasia: a protocol for a randomised controlled trial with 6-month follow-up (MovetheHip trial)

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ABSTRACT

Introduction Surgery is not a viable treatment for all patients with hip dysplasia. Currently, usual care for these patients is limited to a consultation on self-management. We have shown that an exercise and patient education intervention is a feasible and acceptable intervention for patients not receiving surgery. Therefore, we aim to investigate whether patients with hip dysplasia randomised to exercise and patient education have a different mean change in self-reported pain compared with those randomised to usual care over 6 months. Furthermore, we aim to evaluate the cost-effectiveness and perform a process evaluation.

Methods and analysis In a randomised controlled trial, 200 young and middle-aged patients will be randomised to either exercise and patient education or usual care at a 1:1 ratio through permuted block randomisation. The intervention group will receive exercise instruction and patient education over 6 months. The usual care group will receive one consultation on self-management of hip symptoms. The primary outcome is the self-reported mean change in the pain subscale of the Copenhagen Hip and Groin Outcome Score (HAGOS). Secondary outcomes include mean changes in the other HAGOS subscales, in the Short Version of the International Hip Outcome Tool, in performance, balance and maximal hip muscle strength. Between-group comparison from baseline to 6-month follow-up will be made with intention-to-treat analyses with a mixed-effects model. Cost-effectiveness will be evaluated by relating quality-adjusted life years and differences in HAGOS pain to differences in costs over 12 months. The functioning of the intervention will be evaluated as implementation, mechanisms of change and contextual factors.

Ethics and dissemination The study protocol was approved by the Committee on Health Research Ethics in the Central Denmark Region and registered at ClinicalTrials. Positive, negative and inconclusive findings will be disseminated through international peer-reviewed scientific journals and international conferences.

Trial registration number NCT04795843.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This trial is the first to compare exercise and patient education with usual care in patients with hip dysplasia.
⇒ A feasibility study including qualitative and quantitative data preceded this trial.
⇒ The investigation includes a clinical evaluation, a health-economic evaluation and a process evaluation.
⇒ The intervention is designed to fit into the patients' everyday life with a potential for large-scale use.
⇒ A limitation of this trial is the inability to blind participants and intervention providers.

INTRODUCTION

Hip dysplasia is the medical term for a hip joint with a reduced acetabular weight-bearing area.[1] The prevalence proportion of radiographic findings is 3–20% in the general population[2 3] and 19–32% in adults with hip pain.[2 4] Hip dysplasia can present in infancy or in young adulthood,[5] and hip dysplasia is associated with early osteoarthritis.[6–9] The joint disease affects mainly young to middle-aged women,[10] and many have a familial predisposition.[11] The most common symptom is groin pain, which is associated with high day-to-day variation in pain intensity,[10 12 13] and this unpredictability is perceived as the most challenging aspect to cope with.[14]

Young and middle-aged adults with hip dysplasia are often exposed to daily physical demands due to occupational and family-related responsibilities.[15] Physical limitations imposed by hip problems challenge their perception of being physically active and independent, which may affect their personal

identity, confidence and self-esteem.[10 14 16–18] This bio-psycho-social impact of hip dysplasia call for effective and individualised treatment options.[14] Periacetabular osteotomy (PAO) is a well-accepted surgical treatment for patients with pain.[19] Yet, a PAO is not always a viable treatment option for all patients. Patients with a body mass index (BMI) above 25, age above 45 years or hip osteoarthritis may not be offered a PAO since worse outcomes are associated with these characteristics.[20–22] Besides, a subgroup of the patients offered a PAO are not willing to undergo surgery. Currently, usual care for these patients is limited to a single consultation on self-management of hip symptoms.

We recently completed a feasibility study on an exercise and patient education intervention for patients not receiving a PAO. The results showed a high willingness to be recruited and acceptable retention. We found clinical relevant improvements in pain, physical function and maximum hip muscle strength with a high intervention acceptance.[15] The feasibility study contributed to refinement of the intervention, the data collection and the recruitment procedures. Thus, it seems feasible to conduct a full-scale randomised controlled trial (RCT) to investigate the effectiveness of exercise and patient education on pain, physical functioning and maximum hip muscle strength.

The primary aim of this effectiveness trial is to investigate whether patients with hip dysplasia who are randomised to exercise and patient education have a different mean change in self-reported pain measured by the Copenhagen Hip and Groin Outcome Score (HAGOS) compared with those randomised to usual care over a 6-month follow-up period. Secondary aims are to compare mean changes between the two groups on the other HAGOS subscales over a 6-month follow-up period. Similar comparisons will be made on self-reported mean changes in the Short Version of the International Hip Outcome Tool (iHOT-12) and mean changes in performance, balance and maximum hip muscle strength. We hypothesise that patients randomised to exercise and patient education will have a between-group 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.

In a health-economic evaluation, we will investigate the cost-utility and cost-effectiveness of exercise and patient education compared with usual care over 12 months. Furthermore, in a process evaluation, we will explore the functioning of the intervention by evaluating the implementation, mechanisms of change and the contribution of contextual factors over 6 months.

METHODS AND ANALYSIS

Trial design

This study is a parallel-group superiority RCT following the Standard Protocol Items: Recommendations for Interventional Trials statement.[23] The treatments are described according to the Consensus on Exercise Reporting Template.[24] Permuted block randomisation will be used with a 1:1 ratio with the primary end points after 6 months. The first participant was enrolled in April 2021, and enrolment is expected to be completed by December 2025.

Study setting

We will recruit participants from the Department of Orthopaedic Surgery at Aarhus University Hospital in Denmark. Orthopaedic surgeons, specialised in hip dysplasia, will apply eligibility criteria and will provide oral and written information to patients with hip dysplasia as part of an initial screening. Following an initial screening, the principal investigator (PI) will contact patients willing to participate by phone and will verify the eligibility criteria. The PI will provide detailed oral information about the trial objective, clinical implication, procedures, funding and possible adverse events (AEs). Following this, the PI will obtain informed consent by sending a personal electronic letter to the individual patient's eBoks, which is a national secure electronic mailbox for encrypted digital communication between citizens, private companies and public authorities in Denmark.

Eligibility criteria

Inclusion criteria: (1) 18–50 years of age, (2) radiographically verified hip dysplasia (Wiberg's centre edge (CE) angle of 10–25°[25] and an acetabular index (AI) angle >10°[26]), (3) hip and/or groin pain (primary pain complain) for at least 3 months, (4) eligible but unwilling to undergo PAO or not eligible for PAO (negative impingement test, BMI >25, Tönnis hip osteoarthritis score >1, age >45 years or reduced hip range of motion (<95° flexion or <30° abduction)). Exclusion criteria: (1) HAGOS pain score >80 points, (2) any major planned surgery (arthroplasty or discectomy surgery), (3) BMI >35, (4) acetabular retroversion defined by crossover sign and posterior wall sign, (5) Calvé Legg Perthes or epiphysiolysis, (6) previous pelvic/hip surgery in index limb, (7) previous pelvic/hip surgery within 2 years in contralateral limb, (8) previous surgery due to herniated disc or spondyloses, (9) previous arthroplasty in the lower limb, (10) previous trauma, neurological, medical or rheumatological conditions affecting the hip function, (11) inadequacy in written and spoken Danish, pregnancy, mental illness or other conditions affecting the ability to follow mandatory stages for participation.

Randomisation

Following enrolment and a baseline assessment, participants will be randomised to exercise and patient education or usual care at a 1:1 ratio through permuted block randomisation with randomly varying block sizes of 4–6 (figure 1). An independent data manager will set up a computer-generated list of random numbers in the Research Electronic Data Capture (REDCap) randomisation system before the inclusion of participants. The

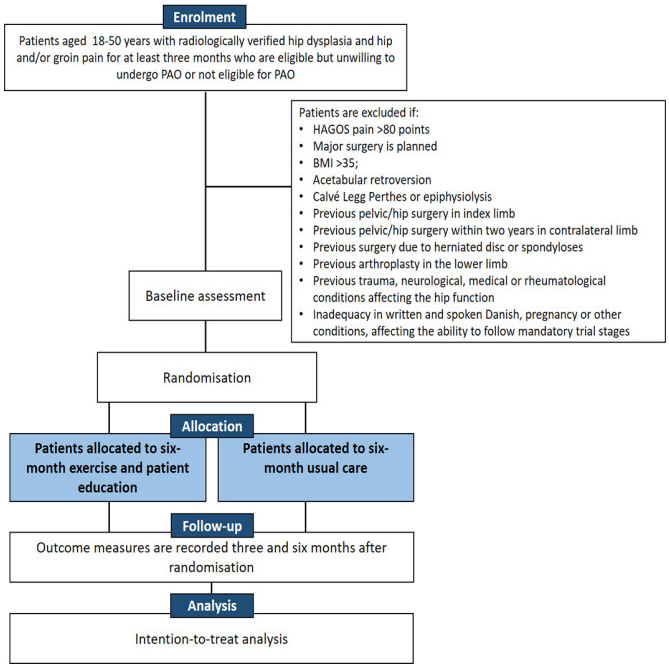

Figure 1 Flow of participants through the trial. BMI, body mass index; HAGOS, Copenhagen Hip and Groin Outcome Score; PAO, periacetabular osteotomy.

group allocation will be concealed since a research assistant not involved in the outcome assessment will perform the randomisation without being able to foresee the group assignment. The research assistant will inform the PI about the group allocation, and the PI will assign participants to one of the two groups. The participants will start treatment closely thereafter.

Blinding

Neither the participants nor the intervention providers will be blinded to the treatment allocation. Outcome assessors will be blinded to the treatment allocation, and the participants will be instructed not to disclose their allocation when outcomes are assessed. The primary outcome is self-reported. Therefore, we will blind participants to previous testing scores and the trial hypothesis. A data analyst blinded to the treatment allocation will perform all predefined analyses on coded data. Only the PI will have the key access to the electronically stored data with information about the treatment allocation.

Patient characteristics

The following will be registered at baseline: sex, age, height, weight, duration of hip symptoms, unilateral or bilateral hip dysplasia, educational level, employment status, cohabiting status, comorbidities, previous surgery, level of physical activity (PA) and exercise, intra-articular pain using the Flexion-adduction-Internal-rotation test, CE angle,[25] AI angle[26] and osteoarthritis grade evaluated with the Tönnis osteoarthritis classification.[26] A hip surgeon (SSJ) will measure the radiological characteristics using standardised standing anteroposterior radiographs. Weight, PA level and intra-articular pain will additionally be recorded at 6-month follow-up.

Exercise and patient education (intervention)

The intervention was designed to reduce pain,[10 27] reduce physical limitations[16 28 29] and help patients cope with their pain and limitations in their everyday life.[14] In addition, it was designed as a flexible intervention requiring little time in order to motivate intervention adherence despite daily occupational and family-related responsibilities.

The intervention will follow a previously described protocol[15] and will be running over a period of 6 months (table 1). The participants will be offered eight individual supervised training sessions. In these sessions, participants will be instructed in four exercises. Each of these exercises can be completed at three levels of difficulty, and all participants will start at the lowest level. The participants will be instructed to perform exercises on a perceived exertion level of 5–7 based on the Borg CR10 scale, that is, somewhat hard (level 5), hard (level 6) or very hard (level 7),[30] and to perform a minimum of three training sessions at home each week. Additionally, participants will receive oral patient education about the mechanisms of pain in hip dysplasia,[27 31] the importance of regular PA and exercise,[32] the consequences of inactivity,[33] the importance of exercise adherence, the advice to lose weight if relevant and that muscle soreness is to be expected. The intervention providers will use written treatment and exercise manuals, and the participants will be provided with paper-based exercise instructions.[15]

Usual care (control)

Usual care will include one oral consultation provided by the PI on self-management of hip symptoms, including advice about staying physically active and exercising and, if relevant, advice to lose weight. Moreover, self-management of hip symptoms will include information about the hip morphology and advice to reduce symptoms by focusing on symptom-lowering activities and sports. The content of the information provided as usual care will be similar to the patient education provided to the participants in the intervention group. However, usual care will be limited to one session over 6 months and will not include instruction in specific hip exercises. In contrast, the participants in the intervention group will receive oral patient education in all supervised training sessions.

Adherence

Adherence to exercise and patient education will be self-reported and documented by weekly logbook recordings in the intervention group. At 6-month follow-up, participants in the control group will be asked to report if they have performed specific hip exercises in the last month and how often and for how long (concomitant treatment). *High* adherence in the intervention group is defined as completing a minimum of 75% of scheduled training sessions (supervised and self-managed), *medium*

Table 1 Treatment delivery according to the Consensus on Exercise Reporting Template (CERT) for both groups

Topic	Item	Exercise and patient education intervention	Usual care
WHAT	1	The intervention does not require any equipment.	Usual care does not require any equipment.
WHO	2	Physical therapy students deliver the intervention under supervision by an expert team of physical therapists (UGB, KT and JSJ). Physical therapy students receive an hour of supervision per participant and four meetings with the expert team during the trial period. More details on this are provided in the online supplemental material in Jacobsen *et al*[15]	An experienced physical therapist delivers usual care (JSJ).
HOW	3	Exercise is provided one-to-one and delivered face-to-face.	Usual care is provided one-to-one and delivered face-to-face or by phone with video call as an option (optional to participants).
	4	Eight supervised training sessions are scheduled, including exercise instruction, correction of exercise performance, regression or progression of exercises and patient education. Sessions are scheduled as two sessions each month in the first 2 months and as one session each month in the last 4 months.	After one oral consultation, usual care is unsupervised.
	5	Adherence is documented by weekly logbook recordings and by completing the EARS at 3-month and 6-month follow-up.	At 6-month follow-up, adherence is registered by completing a standardised form on whether specific hip exercises were performed in the last 6 months and, if relevant, how frequent.
	6	Improvements in difficulty level of exercises, repetitions, pain or function are identified at the supervised training sessions to motivate participants to adhere to the intervention. Moreover, the rationale of exercising and the importance of regular and consistent training are given as part of the patient education.	Participants can call the usual care provider at any time for support to adhere to usual care. Moreover, rationale of physical activity, exercise and weight reduction (if relevant) will be delivered.
	7a	Participants are instructed in four exercises. Each of these exercises can be completed at three levels of difficulty (levels A, B, C; A being the highest level), and all participants start at level C. *First 4* weeks: increase the number of repetitions up to 20 if the Borg CR10 scale is below three. *After 4* weeks: progress to higher difficulty level of exercises and/or increase repetitions up to 20 if the Borg CR10 scale is below five. To progress to higher difficulty levels, the following criteria are mandatory: (1) an exercise is performed correct, (2) an exercise must be acceptable to participants with regard to pain and/or discomfort, (3) a minimum of 10 repetitions in three sets on the lower difficulty level can be completed.	N/A
	7b	One set on the lower (usual) difficulty level is done. If 1–3 are fulfilled, a higher level is probed. To exercise on the higher level, criteria 1–2 must be fulfilled, and the participant must be able to complete a minimum of five repetitions in sets of three on the higher difficulty level. Regression or progression is done at the supervised training sessions. At home, regression to lower difficulty level or fewer sets or repetitions are done if unacceptable pain or discomfort is experienced.	N/A
	8	Four exercises, a supine plank exercise, a side-lying plank exercise, a squat exercise and a one-leg stability exercise.[15]	One oral consultation on self-management of hip symptoms and advice on exercising and staying physically active. If relevant, advise to lose weight.
	9	Perform the four exercises at 3 weekly home-based training sessions	Perform regular physical activity and exercise and, if relevant, lose weight.
	10	Patient education: explain what hip dysplasia is, the rationale and importance of being physically active and exercising on a regular basis, education on tissue tolerance and pain mechanisms in hip dysplasia, knowledge about gains of specific exercise regimens and knowledge of the relation between overweight and pain.	Patient education: explain what hip dysplasia is, the rationale and importance of being physically active and exercising on a regular basis, education on tissue tolerance and pain mechanisms in hip dysplasia, gains of a physically active lifestyle, and knowledge of the relation between overweight and pain.

Continued

Table 1 Continued

Topic	Item	Exercise and patient education intervention	Usual care
	11	SAE and AE are registered at 3-month and 6-month follow-up (self-reported). Any SAE or AE during supervised training sessions are registered by intervention providers. Participants are encouraged to contact the intervention providers or GP if a health problem occurs. In case a medical evaluation is required, participants are referred to the Medical advisor (SSJ), who will decide if participation is safe. Exercise performance must be acceptable (ie, pain or discomfort) to participants. If sudden joint-related pain flares beyond muscle soreness appear, exercises are regressed to fewer repetitions, sets or lower level until performance is acceptable. If one or more exercises are unacceptable regardless of regression, the exercise is not performed.	SAE and AE are registered at 3-month and 6-month follow-up (self-reported). Participants are encouraged to contact the usual care providers or the GP if a health problem occurs. In case a medical evaluation is required, participants are referred to the medical advisor (SSJ), who decides if participation is safe.
WHERE	12	Exercises are performed unsupervised at home and at the supervised training sessions located in a fitness room at a University College in Denmark.	N/A
WHEN, HOW MUCH	13	Exercises should be performed three times a week over a period of 6 months. The exercises should be repeated minimum five times, be performed in sets of three and with a break of 15–30 s between each set.	N/A
TAILORING	14 a	Exercises are tailored to each participant based on response to the intervention through difficulty level, repetitions and acceptability. Patient education is tailored to each participants based on challenges in everyday life, experiences, confidence and self-esteem.	Advice is tailored to each participant (ie, challenges in everyday life, experiences, confidence and self-esteem).
	14b	Exercises are individually tailored based on: (1) difficulty level (level C to A) and (2) repetitions. Moreover, (3) exercise performance has to be acceptable to participants with regard to pain and/or discomfort. Patient education is tailored based on: (1) pain and challenges, (2) pain cooping, (3) preferred physical activities or sports and (4) BMI with respect to experiences, confidence and self-esteem.	Advice is tailored based on: (1) pain and challenges, (2) pain cooping, (3) preferred physical activities or sports and (4) BMI with respect to experiences, confidence and self-esteem.
	15	The starting level of each difficulty level is: (1) correct performance, (2) performance is acceptable and (3) a minimum of five repetitions in sets of three can be completed.	N/A
HOW WELL	16 a	Fidelity is registered by the intervention providers after finalisation of each participant. Fidelity describes to which extent the following categories were possible to deliver as intended: (1) Borg CR10 to determine difficulty level and repetitions, (2) participant acceptability to determine difficulty level and repetitions, (3) correct performance to determine difficulty level and repetitions, (4) patient education on rationale of regular exercise, physical activity and weight loss, if relevant.	N/A
	16b	N/A	N/A

AE, adverse events; EARS, Exercise Adherence Rating Scale; GP, general practitioner; SAE, serious adverse events.

adherence as completing 50–74% and *low* adherence as completing less than 50%.[34] Acceptable adherence to exercise and patient education is defined as completing at least 70% of scheduled training sessions. Acceptable adherence to usual care is defined as completing less than 50% of similar training (eg, concomitant treatment by own initiative). In addition, self-reported adherence to the intervention will be measured by the 6-item Exercise Adherence Rating Scale (EARS).[35] The EARS measures non-adherence to complete adherence on a score of 0–24 points (24 highest score). Concomitant care will be registered.

Outcomes

At baseline, 3-month, 6-month, 9-month and 12-month follow-up, self-reported outcomes will be entered electronically by the participants using a survey option in REDCap (table 2). The other outcomes will be collected at a clinical assessment at baseline and at 6-month follow-up.

Primary outcome

The primary outcome will be the self-reported mean change in the pain subscale of the HAGOS from baseline to 6-month follow-up (figure 2). The HAGOS pain subscale measures the degree of hip and/or groin pain through ten questions.[36] The minimal clinically important difference (MCID) of the between-group difference of the HAGOS pain subscale is considered to be equal to the within-group minimal important change of 10 points reported by Thomeé *et al*.[37] The pain subscale has a high responsiveness, reported as effect sizes of 1.12–1.37.[36–38] The HAGOS is a valid and reliable outcome questionnaire, which is associated with correlation coefficients of 0.2–0.7 across subitems when correlated to relevant constructs.[36 37 39] The HAGOS consists of six subscales, including pain, symptoms, activities of daily living (ADL), sport and recreation (sport/rec), participation in PA and hip-related quality of life (QOL).[36] The measurement

Table 2 Baseline characteristics and outcome measures

Measure	Baseline	3 months	6 months	9 months	12 months
Patient characteristics					
Sex, age, height	X				
Weight	X		X		
Duration of hip symptoms	X				
Unilateral/bilateral affection	X				
Educational level, employment status, family status	X				
Comorbidities	X				
Previous surgery (ankle, knee, hip, back)	X				
Physical activity and exercise	X		X		X
FADIR test	X		X		
Radiological measures					
Centre-edge angle	X				
Acetabular index angle	X				
Tönnis' osteoarthritis grade	X				
Self-reported measures					
Copenhagen Hip and Groin Outcome Score (HAGOS)	X	X	X	X	X
Short Version of the International Hip Outcome Tool (iHOT-12)	X		X		X
Patient Acceptable Symptom State (PASS)			X		X
Hip/groin pain intensity in rest within the last week on a VAS for pain	X		X		X
Hip/groin pain intensity in activity within the last week on a VAS for pain	X		X		X
Back pain intensity in rest within the last week on a VAS for pain	X		X		X
Back pain intensity in activity within the last week on a VAS for pain	X		X		X
Hip and/or groin pain intensity during hip flexion, extension and abduction strength tests on the Numeric Rating Scale for pain	X		X		
Usage of analgesics (y/n/type/dose)	X		X		X
European Quality of Life-5 Dimensions with 5 Levels (EQ-5D-5L)	X	X	X	X	X
iMTA Productivity Cost Questionnaire (iPCQ)	X	X	X	X	X
Outcome measures on physical function (most painful hip)					
Single-leg Hop for Distance Test (HDT)	X		X		
Trust in capability of the hip during the HDT on a 100 mm VAS for trust	X		X		
Y-balance test, anterior, posteromedial and posterolateral	X		X		
Isometric hip muscle strength in flexion, extension and abduction with a fixed dynamometer	X		X		
Other treatment-related outcomes					
Iliopsoas and abductor-related muscle-tendon pain	X		X		
Pain sensitisation at the forearm and hip (temporal summation of pain and pressure pain threshold)	X		X		
Concomitant care and treatments*	X		X		X
Adverse events and serious adverse events		X	X		
Adherence to the intervention using the six-item Exercise Adherence Rating Scale (EARS)			X		
Adherence to intervention measured as number of completed training sessions	←	—	→		

*For baseline, concomitant care and treatments during the last year; for other time points, over the previous 6 months.
FADIR, flexion-adduction-internal rotation test; iMTA, Institute for Medical Technology Assessment; NRS, numerical rating scale; VAS, visual analogue scale.

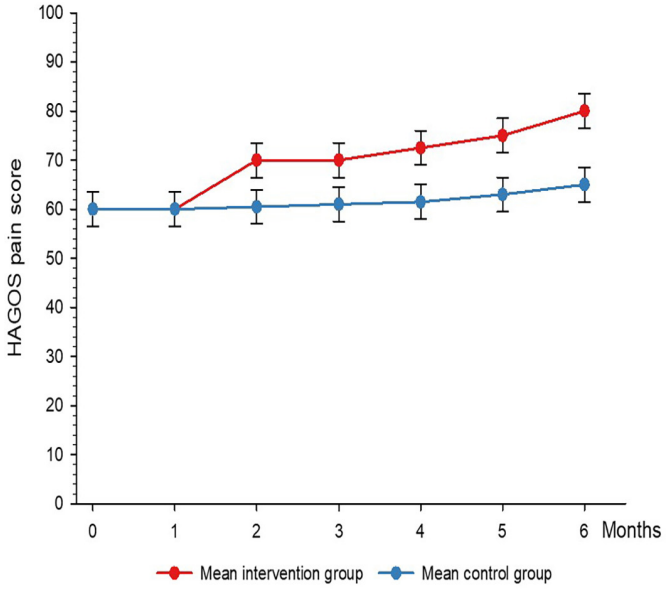

Figure 2 Illustration of anticipated changes in the Copenhagen Hip and Groin Outcome Score (HAGOS) over a 6-month follow-up period. Values are mean (95% CIs). The mean score of the intervention group (exercise and patient education) is anticipated to change from 60 to 80 points, corresponding to an improvement of 20 points over 6 months. In contrast, the mean score of the control group (usual care) is anticipated to change from 60 to 65 points, corresponding to an improvement of 5 points over 6 months. These group-based improvements lead to a hypothesised between-group change difference of 15 points (95% CI 10 to 20). The lower limit of the 95% CI between-group change difference of 10 points represents the minimal clinically important difference (MCIC), which is described in our hypothesis and included in our power calculation.

error ranges from 1 to 5 points across subscales at group level in patients with hip pain.[36 37 39]

Secondary outcomes

Secondary self-reported outcomes will be the mean change in the four remaining HAGOS subscales, i.e. symptoms, ADL, sport/rec, participation and QOL,[36] and the mean change in the score of the iHOT-12.[40]

The iHOT-12 consists of 12 questions scored on a visual analogue scale (VAS) from 0 points (worst) to 100 points (best). It is considered valid and reliable tool to measure change in young and active patients with hip disorders.[40]

Other secondary outcomes will be mean changes in performance, balance and maximal hip muscle strength (online supplemental material 1, performance, balance and muscle strength), which will be measured by two blinded outcome assessors in the most painful hip. The single-leg hop for distance test (HDT) is a measure of performance[41] (online supplemental figure 1) and the Y Balance Test is a measure of dynamic balance[42] (online supplemental figure 2). Maximal hip muscle strength will be measured isometrically in hip flexion, extension and abduction with a fixed dynamometer (Commander Echo MMT, JTECH Medical, Salt Lake City, Utah, USA) using a standardised test protocol and external belt fixation[43 44] (online supplemental figure 3). We will consider changes to be clinically relevant if they are above 15 cm in HDT,[41] above 15 cm in the Y Balance Test[45] and above 0.15 Nm/kg in hip muscle strength.[44 46]

Other outcomes

Health status will be measured with the EuroQoL 5-dimension (EQ-5D-5L),[47] and productivity loss will be measured with the Productivity Costs Questionnaire.[48]

Acceptable symptom state will be measured with the Patient Acceptable Symptom State[49] by the question: 'Taking into account all the activities you are doing in your daily life, your level of pain and also your functional impairments, do you consider that your current state of symptoms is acceptable (yes/no)?'

Self-reported change in back and hip and/or groin pain intensity will be measured with a 100 mm VAS for pain in rest and during activity within the last week. Change in self-reported usage of analgesics will be registered, including usage of paracetamol/acetaminophen, ibuprofen and other NSAIDs and morphine/opioids.

Change in self-reported hip and/or groin pain intensity during the hip muscle strength tests will be measured using a numerical rating scale, and trust in the capability of the hip will be measured with a 100 mm VAS for trust during the HDT.[15]

The blinded outcome assessors will assess Iliopsoas-related and abductor-related muscle tendon pain[27] and pain sensitisation. Pain sensitisation will be measured as temporal summation of pain[50] and pressure pain threshold[51] at the hip and forearm.

Adverse events

Any serious AE (SAE) and AE related to the conduct of the trial within the intervention period will be reported to the local research ethics committee. SAEs will be defined according to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.[52] AEs will be defined as sudden joint-related pain flares beyond muscle soreness in the hip/groin or other parts of the body. The intervention providers and test physical therapists will report any SAE and AE during training sessions or outcome assessments. Furthermore, at 3-month and 6-month follow-up, participants will be asked to report any SAE or AE. In case a medical evaluation is required, participants will be referred to the hip surgeon (SSJ), who will decide if participation is safe.

Health-economic evaluation

A health-economic evaluation with 12-month follow-up will be conducted alongside the RCT to incorporate a societal perspective. The 12-month follow-up is chosen for this analysis because costs of the treatments are expected to be delayed compared with the endpoint of the primary and secondary outcomes. Quality-adjusted life years (QALYs) will be the outcome in a cost-utility analysis, and the HAGOS pain will be the outcome in a

cost-effectiveness analysis. QALYs will be calculated as the area under the curve using the EQ-5D-5L[47] and Danish preference weights.[53 54] Intervention and usual care costs will be calculated using microcosting. Visits to primary healthcare services will be extracted from the Danish National Health Service Register for Primary Care and valued using the activity-based tariffs that are used for remuneration. Secondary healthcare services will be extracted from the National Patient Registry and costs will be calculated using the associated diagnosis-related grouping tariff. The productivity costs per participant will be calculated using the Human Capital method and age and gender-matched average gross salaries from Statistics Denmark.

Incremental cost-effectiveness ratios (ICER) will be calculated by dividing the difference in costs by the difference in effects. The uncertainty around the ICER and 95% CIs surrounding the cost differences will be estimated with 95% bootstrapped CIs based on non-parametric bootstrapping (10 000 replicates)[55] and will be graphically presented on cost-effectiveness planes and cost-effectiveness acceptability curves. These graphs will indicate if the intervention is cost-effective compared with usual care at different values of willingness to pay for a gain in outcome.

Process evaluation

A process evaluation will be conducted alongside the RCT to explore the functioning of the intervention by evaluating implementation, mechanisms of change and contextual factors.[56 57] Implementation includes the implementation process, fidelity, dose and reach (online supplemental table 1). The implementation process will evaluate structures and resources through which delivery is achieved. Fidelity aspects will evaluate the extent to deliver each component as planned and registered during the intervention period using self-report questionnaires. Dose will evaluate how much intervention is delivered and registered during the intervention period using routine monitoring forms, and reach will be evaluated as patterns in uptake and adherence by baseline patient characteristics registered before and during the intervention period. Mechanisms of change include interactions between the intervention, the intervention providers and the participants. Interactions will be evaluated through focus group interviews and by quantitative data on reasons for not receiving surgery. Contextual factors will include events, personal understandings and interactions and their possible influence on the implementation. Contextual factors will be evaluated through one-to-one semistructured interviews during and after the intervention period. Findings from quantitative and quantitative analyses will be merged, interpreted and reported jointly. The results from the process evaluation will be used to refine the programme theory, including a logic model to be used in a potential full-scale implementation of the intervention (online supplemental figure 4).

Long-term follow-up

Participants will be invited to complete the HAGOS and iHOT-12 after 2, 5 and 10 years to investigate predictors of long-term outcome and progression to hip-preserving surgery or hip replacement. In addition, we plan to evaluate if hip osteoarthritis progresses over 5 and 10 years by assessing the degree of osteoarthritis with the Tönnis osteoarthritis classification.[26]

Data management

Once a participant is enrolled, efforts will be made to collect all outcomes despite deviations from the intervention or usual care. All participants will receive a text message reminder for the 6-month follow-up assessment. If a participant is not able to attend or cancels the appointment, the participant will be offered to reschedule. If a participant does not attend the 6-month follow-up assessment, the participant will be asked to complete the self-reported outcomes. Moreover, if a participant does not complete self-reported outcomes at any follow-up, one reminder will be sent. Reasons for dropping out and non-adherence to planned training sessions will be registered. All data collected in this trial are directly entered into REDCap for safe storage and will be treated confidentially by the research staff. The PI will perform checks of protocol adherence and data completeness. No formal data monitoring committee will be established. The authors will discuss any SAE yearly, classify these into subcategories and monitor recruitment, treatment and retention. No interim analysis will be performed.

Sample size

The power calculation was based on a clinical superiority calculation.[58] The expected mean difference between groups was 15 points in the change in HAGOS pain over a 6-month follow-up period.[15] The superiority margin was a MCID of 10 points in the between-group change in the HAGOS pain over 6 months,[37] representing the lower end of the 95% CI of the expected mean difference between groups. Given these assumptions, a sample size of 200 participants (n=100 in each group), a common SD of 13 HAGOS pain points[15] for the change in each group and an alpha level of 5%, we will reach a power of 86%. Based on an expected dropout of 15% during the 6-month follow-up period,[15] our sample size will be 170 participants (85 in each group), and the power of the trial will be 80%.

Statistical analysis

All primary and secondary outcomes will be analysed with the intention-to-treat principle. Between-group differences from baseline to 3-month and 6-month follow-up of continuous outcomes will be estimated using repeated measurement analysis in a mixed-effects model, including participant as random effect, with a fixed factor for group and time and the corresponding interaction (Group × Time), adjusted for baseline values. Between-group differences of continuous outcomes from baseline

to 6-month follow-up will be analysed with an unpaired t test, where between-group differences of categorical data from baseline to 6-month follow-up will be analysed with a binominal regression model using risk difference as a measure of association. All results will be presented with 95% CIs and associated p values. A two-sided p<0.05 will be considered as statistically significant. A prespecified statistical analysis plan will be made publicly available prior to inclusion of the final participant. The statistical analyses and the data interpretation will be blinded to group allocation. Data analysis will be performed with Stata V.16 software package (StataCorp, College Station, Texas).

Ethics and dissemination

The trial will be conducted and reported in accordance with the WMA declaration of Helsinki, and the data will be handled in accordance with the General Data Protection Regulation. This trial has been approved by the Committee on Health Research Ethics in the Central Denmark Region (project ID: 1-10-72-336-20). The Danish Data Protection Agency authorised patient data handling (project ID: 1-16-02-678-20), and the study protocol has been registered at ClinicalTrials. Any protocol amendments will be registered at ClinicalTrials, reported to the Committee on Health Research Ethics in the Central Denmark Region and addressed in the primary trial paper. Results will be published in international peer-reviewed scientific journals with open access. Authorship will adhere to the Vancouver conventions as outlined by the International Committee of Medical Journal Editors.[59]

Explorative analyses

By using subgroup stratification, we will explore if muscle-tendon pain[27] and pain sensitisation modify between-group changes of the primary and secondary outcomes over 6 months. Furthermore, we plan to conduct an instrumental variable analysis on primary and secondary outcomes in an attempt to investigate the efficacy of the intervention.[60] These analyses will be reported in secondary papers with clear reference to the primary trial paper.

Patient and public involvement

A qualitative study of 17 patients[14] and a feasibility study of 30 patients[15] collected information on expectations, needs and opinions about content, frequency and outcome of treatment as well as burden to participate. This information has been used to refine the intervention and the study procedures.

DISCUSSION

The majority of patients with hip dysplasia are treated non-surgically in primary care, and data exist on changes after surgical treatment.[1 16 27 61–63] Nevertheless, there is limited evidence on what constitutes effective primary care for patients with hip dysplasia. By highlighting the benefits, harms, costs and processes of exercise and patient education, the MovetheHip trial will provide valuable evidence for patients, health professionals and decision-makers.

Strengths and limitations

The strengths of this trial are the preceding feasibility study[15] and the parallel health-economic and process-evaluation studies. Another strength is the development of a well-described flexible intervention designed to require little time to fit into the daily life of young to middle-aged patients, as this holds a potential for large-scale implementation.[14] Additional strengths are the use of assessor blinding and the randomised controlled design with blinded intention-to-treat analyses.

A limitation is that intervention providers and participants are not blinded to treatment allocation. However, blinded assessors will assess all clinical outcomes, and a blinded data analyst will perform all predefined analyses. Moreover, the participants will be blinded to the trial hypotheses, and both participants and assessors will be blinded to previous testing scores at all follow-ups. Another limitation is the heterogeneity of the participants, which might make it difficult to show between-group differences. Finally, participants may choose various concomitant care, which may add to changes in outcomes. However, any concomitant care or treatment will be registered and reported as part of the health-economic evaluation.

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Contributors JSJ is the PI. IM, KT and JSJ designed the preliminary version of the present trial. RON contributed with methodological and statistical aspects, whereas DS and LGO provided input to the design of the intervention and to the design

of the process evaluation study. LGO and MWvT contributed to the design of the health-economic evaluation. SSJ and CF provided imported insights on the clinical implication of the trial and recruited participants. All authors contributed to the drafting of this manuscript and approved the final version.

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