


BMJ Open Better before–better after: efficacy of prehabilitation for older patients with osteoarthritis awaiting total hip replacement – a study protocol for a randomised controlled trial in South-Eastern Norway

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ABSTRACT

Introduction Health professions need to prepare for the increase of older patients with osteoarthritis requiring health services including those requiring total joint arthroplasty (TJA). The primary objective of this study is to assess the effect of a tailored prehabilitation programme of older patients awaiting primary surgery for total hip replacement on physical function measured by walking speed within 1 week after intervention as well as 6 weeks and 3 months after TJA surgery.

Methods and analysis This is a single-blinded randomised controlled trial. The participants are 70 years or older, scheduled for primary total hip replacement due to late stage osteoarthritis. The intervention group will receive patient education and exercise for 6–12 weeks. The control group will receive care as usual. The primary outcome is gait speed. Secondary outcomes are lower body strength, mobility, aerobic capacity, activity of daily living, length of stay at the hospital, referral to an inpatient rehabilitation clinic, pain, quality of life and cost-effectiveness. Estimated sample size is 150 participants randomised into the two arms. The data will be analysed following the intention-to-treat principle with methods for repeated measurements.

Ethics and dissemination The project proposal has been approved by The Regional Committee for Medical Research Ethics in South Norway (ref no. 2018/503). The results will be published in peer-reviewed articles.

Trial registration number NCT03602105

INTRODUCTION

Around 275 000 Norwegians above 20 years of age have hip osteoarthritis (OA), affecting 5.5% of the general population.¹ There has been a significant increase in the prevalence of OA over the decades.² OA is associated with a high economic and personal burden, largely attributable to the effects of disability, comorbid disease and the expense of treatment.³ The prevalence of OA is higher in

Strengths and limitations of this study

- This study will add to the body of current knowledge and guide clinical practice in whether a tailored prehabilitation program prior to surgery is an effective approach for older patients awaiting total hip replacement.
- The prehabilitation intervention adheres to general recommendations for dosage and progression of exercise and will be tailored to meet individual needs and targeted to the level of difficulty relevant for each participant.
- The study setting, criteria for inclusion, intervention and outcomes has a pragmatic approach to ensure external validity.
- The outcome assessor is kept blinded for the group allocation and the performance-based outcome measures used are valid, reliable and relevant to the end users of the intervention.
- Due to short waiting list for elective hip joint replacement in Norway, some of the study participants may exercise for only 6 weeks prior to surgery, which may challenge the dose–response aspect for exercise efficacy.

females than males, and ranked as the 11th highest contributor to global disability and 38th highest in disability-adjusted life years.⁴ Longitudinal data from six European countries showed that clinical OA is associated with frailty and prefrailty in community dwelling older adults above 65 years.⁵ Studies have also shown that hip OA is associated with morbidity, poor physical and mental health^{6 7} and frequent use of healthcare providers.⁷

Worldwide, more than 1.4 million total hip replacement (THR) procedures are performed annually.⁸ In 2017, the annual numbers in Norway were 9097 for primary

THR. ⁹ Given the ageing population, the number of THRs is likely to increase substantially and these surgical procedures are costly. ¹⁰ Patients' expectations of good outcomes after total joint arthroplasty (TJA) are high. ¹¹ These expectations include reduction of pain, increased physical function and general well-being. ¹¹ However, recent studies have shown that patients' expectations are not always met. ^{12 13} Beswick *et al* ¹⁴ reported that 20% among those having hip arthroplasty had worse or no improvements in pain.

Impaired muscle strength, gait speed, agility and dynamic balance, seems to be predictor of delayed postoperative functional recovery from total hip replacement. ¹⁵ For the older patients surgery is a stressful event, ¹⁶ and in light of poor physical function prior to surgery and the likelihood of further decline during the hospitalisation it is hypothesised that a prehabilitation programme could improve outcomes after surgery. ^{17 18}

Several systematic reviews on prehabilitation for patients awaiting TJA are available, but they disagree on the effect. ^{18–23} A possible explanation for the lack of effect of exercise training prior to TJA may be that most of the randomised controlled trials (RCTs) are performed on generally healthy adults yielding small effect sizes. ²⁴ In addition, former RCTs within this field are based on trials with small sample sizes. The 22 RCTs in the review by Wang *et al* ²³ had sample sizes ranging from 21 to 165 patients, median sample size was 54, and only 5 studies included more than 100 patients. Further, assessments of methodological quality of former studies have shown that most of them have moderate to high risk of bias, with lack of outcome assessor blinding and high drop-out rates being the most common risks. ^{20 22 23} Finally, most trials are skewed towards interventions of low-to-moderate intensity exercise, ^{20 21 23 24} and may therefore fail to show effectiveness of exercise.

For treatment of hip OA in general, the current guidelines universally suggest exercise and physical activity in combination with patient education as first-line treatments to reduce pain and improve function. ^{25–28} For older people and people with chronic disease, current guidelines adopt the general recommendations for dosage and progression of exercise put forward by the American College of Sports Medicine. ^{29 30} For aerobic training of moderate-intensity training, this involves at least 30 min/day or up to 60 min for greater benefit. For progressive strength training for this patient group, this involves exercises for major muscle groups at least 2 days/week at a level of moderate to high intensity, at around 40%–60% of one repetition maximum for 8–12 repetitions, resulting in volitional fatigue. ³¹ Studies have shown that moderate to high-intensity training is necessary to achieve improvements in physical function, activities of daily living (ADLs) and quality of life (QOL), and further that frail and older patients can tolerate the programmes. ^{32–34}

No firm conclusion can be drawn about the efficacy of prehabilitation for patients awaiting TJA. Further research of high methodological and interventional quality is

therefore warranted. ^{20 22 23} Last, but not least there is a need for studies that include older people with increased risk of disappointing outcomes after surgery. ^{24 35}

Aims

The primary aim of this study is to assess the effect of a prehabilitation programme over 6–12 weeks on gait speed among older patients awaiting primary surgery for total hip replacement when measured after the intervention is finished as well as follow-up measures 6 weeks and 3 months after THR surgery.

The secondary aim of the study is to examine the effect of a prehabilitation programme on transitory ambulation, pain, need for assistance, QOL, physical function and consumption of health services for older patients awaiting primary surgery for THR.

METHODS

Study design

This is a single-blinded RCT evaluating the effect of a prehabilitation programme prior to THR. The study protocol will adhere to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement, ³⁶ and the most recent reporting guidelines for non-pharmacological trials will be followed. ³⁷

Study setting

The proposed project will be carried out in collaboration with hospitals in the municipalities within the region of South-Eastern Norway Regional Health Authority, and the prehabilitation programme (preoperative intervention) will take place in the primary healthcare within these municipalities. The intervention will be delivered by physiotherapists who have attended the 8-hour AktivA course for physical therapists, as part of a national model for implementation of evidence-based guidelines for patients with OA (www.aktivmedartrose.no). The physiotherapists delivering the intervention will have access to appropriate training facilities for our study participants.

Recruitment and study population

The participants will be recruited from collaborating hospitals. In this study, we will target older people with poor function and severe symptoms due to late stage hip arthrosis, as they are assumed to have increased risk for poorer postoperative outcome. ^{24 35} Orthopaedic surgeons in Norway commonly use the Harris Hip Score to assess hip function. In order to target those with poor function and severe symptoms, the cut-off point for inclusion is set to a score <60, a score that would be considered poor. ³⁸ The orthopaedic surgeons at the collaborating hospitals will screen the patients' hip function by using the Harris Hip Score. Collaborating hospitals will make arrangements in order to ensure that this study project is continuously informed about eligible patients scheduled for TJA surgery.

Inclusion criteria

We will include participants 70 years or older living at home with residential address in the municipalities within the region of South-Eastern Norway Regional Health Authority scheduled for elective primary THR due to end-stage OA. Patients with Harris Hip Score <60 will be included. The participants are required to be mentally capable to receive and comprehend instruction during the exercise sessions, as well as being capable to read, understand and fill out the questionnaires on their own.

Exclusion criteria

We will exclude participants with known rheumatoid arthritis or medical contraindications for exercise or those who are scheduled for revision of hip arthroplasty or are unable to speak and understand the Norwegian language. Participants with neurological conditions affecting gait and participants already participating in the AktivA programme elsewhere will also be excluded.

Randomisation

Participants will be stratified on hospital performing the procedure and thereafter randomly assigned to the intervention or control group with allocation ratio 1:1. To ensure allocation concealment, the randomisation to groups will be done by an investigator not involved in recruitment and outcome assessment. A computer-generated random number sequence with randomly permuted block sizes and opaque sealed envelopes will be used. The applied randomisation procedure will keep the outcome assessors blinded for group allocation throughout the study.

Intervention

Participants in the intervention group will prior to surgery receive an educational and exercise programme, in which the therapeutic exercise intervention is the main component. Supervised training with an experienced physiotherapist will be offered two times per week, either as one-to-one or as group exercises. Additionally, the participants will perform home training or self-training at the clinic with a training programme provided by their physiotherapist. The exercise programme consists primarily of progressive resistance training, neuromuscular training and cardiovascular training.³⁹ The training programme will be tailored to meet individual needs and targeted to the level of difficulty relevant for each participant. Functional training will be emphasised. The education part of the intervention will consist of a thorough introduction to what OA is, causes, and practical advices and measures on how to master the condition in the best possible way. Exercise intensity is guided by the recommendations put forward by the American College of Sports Medicine.^{29 30} The intervention programme will be carried out for 6–12 weeks with 3–4 training sessions weekly lasting 45–60 min. Resistance training will be performed at 40%–60% of one repetition maximum for 8–12 repetitions for 1–3 sets. For progression, the load

will be increased within the prescribed zone of 8–12 repetitions, rather than increasing the number of repetitions. For cardiovascular training, we will in the current study monitor the perceived exertion throughout the intervention period by using the Borg Scale,⁴⁰ and the participants will perform cardiovascular exercises with an perceived exertion of 13–14. The study by Hoogeboom⁴¹ *et al* showed that exercising with moderate intensity and a perceived exertion at 13–14 on the Borg Scale was feasible for older patients awaiting THR. Aerobic training can be used both as a warm-up and as a whole exercise intervention if appropriate. Aerobic training includes exercise modes such as treadmills, cycling ergometer, walking, stair-climbing and elliptical machine. Resistance training will emphasise functional exercises and neuromuscular training. Examples of exercises can be loaded abduction for m.gluteus medius, squats, balance exercises, loaded knee extension and deadlifts. The physiotherapist will continuously monitor training and tailor the exercises to the individual participant, maintaining progression and adjusting exercises to pain levels. If the patients have difficulties to reach out to the primary healthcare clinic, the training will be offered as supervised home training. This will be done in order to avoid sample selection and drop-out.⁴² Physiotherapists in the primary healthcare in the South-Eastern Norway who have attended the 8-hour AktivA course for physical therapists, as part of the national model for implementation of evidence-based guidelines for patients with OA will deliver the intervention in this study. So far, 40 physiotherapists are standing by to receive project participants, making sure that all participants can start the intervention as soon as possible. For patients awaiting THRs, studies have shown that these patients seem to tolerate progressive resistance training without suffering from side effects or adverse events.²² The pain level during the intervention period will also be monitored. A pain rating after exercise indicating unacceptable pain, set as >5 on a 0–10 Numeric Rating Scale, will indicate the need for reduction in training dosage.⁴³ The home exercise programme will include a prescribed set of functional leg exercises and balance exercises.

The control group will receive standard usual care and will not start supervised prehabilitation intervention prior to surgery. Participants from both the intervention group and the control group will participate in the standard usual care given by the recruiting hospitals.

Time plan of the study

Participant recruitment started June 2019. Recruitment is expected to be completed by the end of 2020 and participant flow is described in figure 1. Data collection will last for 18–24 weeks after recruitment is completed. Thereafter, we will write up and publish peer-reviewed articles.

Outcome measures

Baseline testing will be performed within 1 week before the start of intervention and will include sociodemographic variables, clinical assessments of performance-based physical

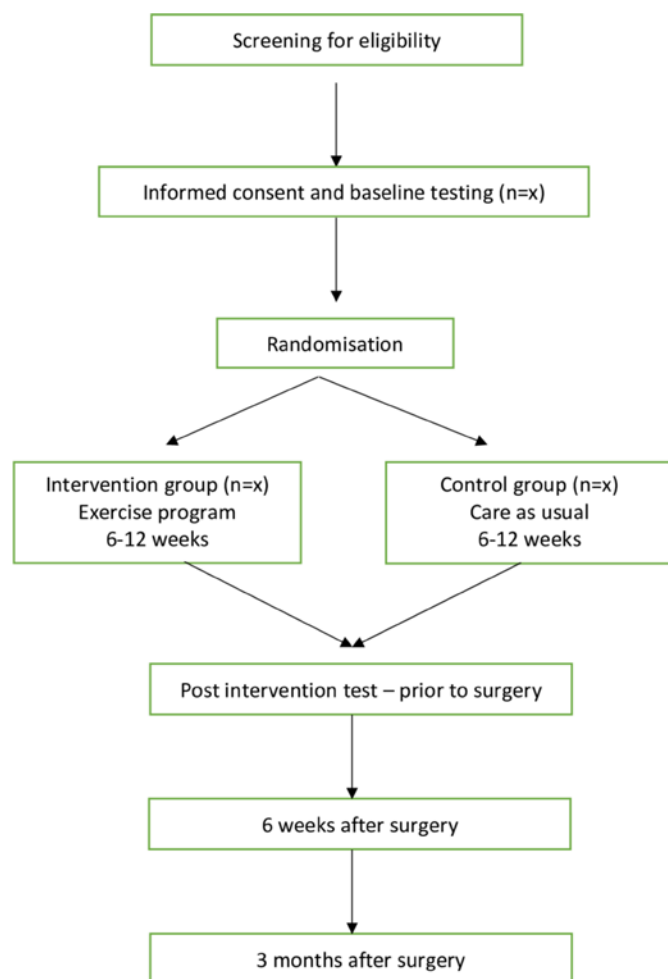


Figure 1 Planned flow of participants in the study.

function (see Primary and Secondary outcome measures sections). Self-reported outcomes (see Secondary outcome measures section) will be collected through questionnaires at the location of testing prior to the physical tests (primary and secondary outcomes). The same data collection will be performed within 1 week after the intervention is finished and with follow-up assessments 6 weeks and 3 months after surgery. Due to postoperative movement restrictions set by the collaboration hospitals, such as being cautious with flexion of the hip joint beyond 90° as well as movements involving rotation and adduction, the Timed-Up-and-Go Test (TUG) and Sit-to-Stand Test will not be performed at 6 weeks postsurgery. The clinical assessments are performed by a research assistant employed by OsloMet—Oslo Metropolitan University and will be kept blinded for group allocation. Before the study starts, the research assistant will take part in an educational programme regarding testing procedures in order to secure that testing is performed consistently in the same manner. This will ensure high inter-rater test reliability on the physical performance measures.

Primary outcome measures

The primary outcome measure of this study is gait speed at 3 months after TJA surgery. It is chosen as the primary outcome of this study because gait speed in older people

predicts 3-year incidence of bathing or dressing dependence, mobility difficulty, and is further a composite outcome of disability and mortality.⁴⁴ Osteoarthritis Research Society International further recommend gait speed as a core measure when assessing performance based function in patients with hip OA.⁴⁵ Gait speed will be measured by the 40 m (4×10 m) Fast-Paced Walk Test.⁴⁶ The participants are asked to walk as quickly but as safely as possible along a 10 m walkway. Timing will be recorded for each 10 m (4×10 m). Gait speed will be expressed as m/s by dividing 40 m by total time. Regular walking aids are allowed and recorded.⁴⁶

Secondary outcome measures

Lower extremity muscle strength will be measured by the Sit-to-Stand Test.⁴⁷ Scoring is the maximum number of chair stand repetitions possible in a 30 s period. Patients, who cannot stand even once, can place the arms on their legs or use their regular mobility aid, and scored as an adapted test score. Aerobic capacity/walking long distances will be measured by the 6 min Walk (6 MW) Test.⁴⁸ On a flat walking area, participants are asked to walk as quickly as possible for 6 min to cover as much ground as possible. The maximal distance is recorded. Rest periods are allowed, but included in the time. Transitory ambulation will be measured by the TUG.⁴⁹ Scoring is the time needed to stand up from a chair, walk 3 m at their normal pace, turn, walk back and sit down again is measured. The participants will also be tested in stair ascending and descending with the Stair Climb Test.⁵⁰ For all tests, the participants will use the assistive device they normally would use to perform the activity irrespective of how they performed it previously.

Length of stay at hospital will be measured as number of days spent at the hospital from postsurgery until discharge. Referral to inpatient rehabilitation clinic after stay at hospital will be recorded based on the hospitals referral. Self-reported outcomes, such as pain, symptoms, ADL, physical activity and QOL, will be measured on the Hip disability and Osteoarthritis Outcome Score (HOOS) questionnaire.⁵¹ Harris Hip Score and the use of medication, such as pain killers will be recorded and may be used as a possible covariates in our multiple regression modelling. Health status will also be measured by the Norwegian version of the EuroQol-5D (EQ-5D) questionnaire, and data obtained by this questionnaire will provide data to the cost-utility analysis (CUA) (see separate paragraph).

Adherence

Training adherence at home will be recorded by the participants using a training diary, whereas the physical therapist will record supervised session adherence. Adherence to the programme will be reported as the percentage of the total planned exercise sessions conducted. Participants attending 80% or more of their scheduled exercises will be recorded as adherent.

Cost–utility analysis

Cost-effectiveness of the intervention will be estimated using a patient-level CUA.⁵² Health benefit will be measured by using EQ-5D. This will in turn be used to calculate the score of quality-adjusted life year (QALY). Data about resource use will mainly be collected by using survey data. Some of the relevant types of cost included in the CUA are the actual time used for training (both the physical therapists and participants), travel expenses, hospitalisation, medicine, home help service, informal care and other health services. Information on costs will be obtained by using the validated instrument Client Service Receipt Inventory covering costs of health, social and informal services. The treatment cost will be calculated and included. The unit costs will be based on marked prices, the reimbursement systems in Norway and literature. The results will be reported as incremental cost-effectiveness ratios and its CI, scatter plot in the cost-effectiveness plane and cost-effectiveness acceptability curves.⁵³ Additionally, we will aim to perform sensitivity analysis for changes in unit cost and uncertainty related to generalisability and extrapolation.⁵⁴ By using multiple regression models, we will examine which characteristics of the participants contribute to costs (or QALY) and which do not.⁵⁵

Adverse events

Adverse events, such as falls and increased pain, will be recorded by the physiotherapist during the exercise sessions and by the participants through the training diary provided to them at the start of the intervention. The research staff will record adverse events should these occur during testing. The risk level in this study is regarded as low. The study follows the SPIRIT 2013 checklist regarding plans for collecting, assessing, reporting and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct. Examples of adverse events include falls, increased pain and fractures.

Sample size estimation

The sample size analysis is based on a substantial meaningful difference in 40m gait speed at 3 months after hip surgery between the randomised groups. A substantial meaningful mean difference between the two groups for this study is defined as 0.1 m/s and the expected SD in habitual gait speed is assumed to be 0.2 m/s based on findings by Perera *et al.*⁵⁶ We performed the sample size calculation based on assessed mean difference between the randomised groups using an analysis of covariance (ANCOVA) model. Our primary statistical analysis will be linear mixed models for repeated measurements, which should give somewhat higher statistical power compared with an ANCOVA model. However, power and sample size analysis using an ANCOVA model is methodologically better implemented and gives a robust approximation of required sample size. The dependent variable in the ANCOVA model is the outcome variable measured at

follow-up and the independent variables are the respective outcome variable measured at baseline and a dummy variable for randomised group. To obtain 80% statistical power at 5% significance level with an expected mean difference between the groups of 0.1, a correlation between baseline and follow-up measurement for the outcome variable of 0.5 and SD in the groups of 0.2, we require a study sample of 96 patients, 48 in each group. We will aim to include 150 in order to compensate for dropouts and to ensure statistical power. The power and sample size analysis was conducted with the `sampsi` command in Stata V.15 (StataCorp, College Station, Texas, USA).

Statistical procedure

The level of significance is set to 5%. Descriptive statistics will be reported for variables of interest. Linear mixed models for repeated measurements will be our primary assessment of differences between randomised groups for continuous outcome variables. The model will include a random intercept to account for within subject correlation of repeated measurements and the following independent fixed effects: the respective outcome variable at baseline, the follow-up times (ie, end of intervention, and 6 weeks and 3 months after TJA surgery), the randomised groups, the interaction term between outcome variable at baseline and randomised groups, and the interaction term between follow-up times and follow up times. We will assess mean differences between randomised groups at each follow-up time with 95% CI and p value using estimated marginal means from the maximum likelihood estimated models. Categorical variables will be assessed with Pearson χ^2 tests. Secondary outcomes will be assessed using similar statistical procedures as for the primary outcome. However, due to the many multiple comparisons, the results from secondary outcomes will be interpreted with caution. Intention to treat (ITT) will be the principal analysis assessing effect of the intervention. If data are missing at random, the linear mixed model for repeated measurements is considered robust. In addition, we will use multiple imputation to assess its robustness for missing data at random. If data are assumed to be not missed by random, we will apply Bayesian modelling. If the data are missing completely at random, the primary statistical methods are robust. We will also perform a 'per-protocol analysis' including those completing the trial with an exercise adherence $\geq 80\%$. All statistical analyses and the corresponding software commands will be prespecified before the data analysis.

Data entry will be performed by a researcher blinded for group allocation and range checks for data values will be performed. The data set will be stored in a secure server unavailable for any person not connected to the project.

Patient and public involvement

Patient representatives were involved in the process of developing the research questions and gave input on which outcomes most relevant for them.

DISCUSSION

Being able to live at home as long as possible is a political goal and is seen as a right.⁵⁷ As no firm conclusion can be drawn about the efficacy of prehabilitation for patients awaiting THR, further research of high methodological and interventional quality is warranted. In contrast to former RCTs predominately performed on generally healthy adults,⁴¹ the current study will investigate the effectiveness of a prehabilitation programme for older people having poor function ahead of THR surgery.

A strength of the current study is that the exercise intervention will adhere to general recommendations for dosage and progression of exercise.^{29 30 34} We anticipate exercising prior to surgery may be beneficial for the patients in the study and that they may shorten the rehabilitation period and help make rehabilitation less problematic and uncomfortable. The study and its tailored prehabilitation programme has the potential to create a norm for treatment of these patients, providing substantial benefits for each individual patient and also the society in general as the THR procedures are costly.¹⁰ The need for faster and better rehabilitation for patients with THR is widely accepted as important for the individual patients and their QOL.⁵⁸ The intervention and study will have potential to support evidence-based decision-making and empower patients awaiting THR.

The use of standardised and validated performance-based tests of physical function is important as they complement self-report in a valid and reliable way.^{59 60} Performance-based tests may more accurately capture changes over time. Additionally, they are to a lesser extent influenced by cognitive function and education when compared with self-reported, subjective assessments. Objective outcome measures may, therefore, strengthen comparability across studies.⁶¹ Gait speed is the primary outcome measure in this study. Gait speed is a robust health measure that can be used to identify persons at risk of functional impairment, cognitive impairment and falls and may also be used as a goal of change.^{62–65} To the authors knowledge, this is the first study to directly aim at elderly awaiting THR with gait speed as the primary outcome measure.

Pain is a construct that patients expect improvements in when they get their THR.¹¹ According to Zeni *et al*,⁶⁶ pain is the primary predictor of self-reported scores in the HOOS questionnaire among patients. Severity of pain is associated with increased score on the times to complete TUG test and for less distance walked in 6MW.⁶⁶ Monitoring pain will enable the therapist to adjust exercise during the intervention and may increase treatment efficiency and increase QOL for the patients.

Regarding quality of the study, issues, such as internal and external validity,^{67 68} are to be discussed. The internal validity may be influenced by methodological issues such as allocation, blinding, outcome measures, drop-outs, sample size and adherence to the intervention.^{69 70} The hospitals recruiting participants to this study may differ somewhat in their procedures when performing THR,

the study participants will, therefore, be stratified by hospital performing the procedure and thereafter be randomly assigned to the intervention or control group. This is done in order to secure comparable groups.

Perceptions about the advantages of one treatment over another might influence outcomes, leading to biased results.⁷¹ In this study, blinding of patient and physiotherapists delivering the intervention is not possible. However, all performance-based outcomes will be assessed by an outcome assessor blinded for the group allocation. This will reduce the risk of detection bias.⁶⁷

Adherence to the intervention will be of importance for the internal validity of the study.⁷⁰ Adherence to the study protocol can be increased with high-quality treatments tailored to the individual patient concerning exercise intensity and pain level during the training. The physiotherapists providing the treatment are invited to seminars where study information is given, strengthening the possibilities for good adherence. The participants will use exercise diaries in order to record their completed home training, as well as training sessions with their physiotherapist. We will perform ITT analysis, which will reduce the attrition bias caused by drop-out. However, we will also perform a 'per-protocol analysis', in which participants with an exercise adherence of less than 80% and drop-outs will be excluded. This will be done in order to explore whether adherence and drop-out might influence the results.

This study does have some limitations. As the participants are recruited from the municipalities within the region of South-Eastern Norway Regional Health Authority it could be argued that, we can only generalise for this population, despite the population of the area being very varied. In studies using self-reported outcome measures, it should also be noted that there is some risk of the Hawthorne effect.⁷² Another weakness of this study is the length of the intervention period. Regarding the dose–response issue, a 6-week intervention period is perhaps too short to expect increased functional status and muscle strength levels for the patients in the intervention group. For the older patients, it can be a challenge to be able to attend to the course twice a week for 6–12 weeks. In particular, this can be challenging for the frailest of the participants. The intervention period of 6 weeks is coherent with the average period of waiting time for surgery at the hospitals, with waiting times varying from 2 weeks up to 16 weeks.

CONCLUSION

Previous research does not agree on the effect of prehabilitation exercises for patients awaiting THR. The proposed study will examine whether an approach combining tailored exercise with patient education can have positive impacts on physical function as well as QOL and cost-effectiveness for older having poor function prior to THR. The effect of prehabilitation will be compared with standard care for patients awaiting THR.

The study will assess effect on gait speed at end of the intervention as well as after 6 and 12 weeks after THR. This study will add to the body of knowledge and support clinicians in providing the best possible management of people awaiting hip replacement.

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Contributors All authors have participated in the development of study design. GH was responsible for grant applications for the project. OES administers the data collection and coordination of the intervention programme. AHP contributed to the statistical plan and sample size calculations. OES wrote the first draft of the manuscript. AB, MAR, AHP and GH critically revised and approved the final version of this manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The project proposal has been approved by The Regional Committee for Medical Research Ethics in South Norway (ref no. 2018/503). The researchers ensure that written informed consent is obtained from all participants included in the analyses, and the project is conducted according to the WMA Declaration of Helsinki. Consent form is also approved by the REC. Any protocol modifications will be communicated to REC and updated on ClinicalTrials.gov.

Provenance and peer review Not commissioned; externally peer reviewed.

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