Promotion and support for physical activity maintenance post total hip arthroplasty (PANORAMA).

A pragmatic, randomized, controlled, trial.

Statistical Analysis Plan for The PANORAMA trial

SAP version 01, 14. December 2023

Clinicaltrials.gov Trial registration identifier: NCT04471532

Department of Physical and Occupational Therapy, Bispebjerg and Frederiksberg Hospital

Administrative information

Title and Trial Registration

Promotion and support for physical activity maintenance post total hip arthroplasty (PANORAMA).

A pragmatic, randomized, controlled, trial.

Clinicaltrials.gov Trial registration identifier: NCT04471532

Research ethics committee registration identifier: H-19050820

Data Protection Agency registration identifier: P-2020-75

Statistical Analysis Plan Version and Date

Version 1.

Date: 14. December 2023

Protocol Version and Date

This document has been written based on information in the study protocol version 1 31.07.2019 and the study protocol article Bieler T, Magnusson PM, Siersma V, Rinaldo M, Schmiegelow MT, Beck T, Krifa A, Kjær BH, Palm H and Midtgaard J. "Effectiveness of promotion and support for physical activity maintenance post total hip arthroplasty—study protocol for a pragmatic, assessor-blinded, randomized controlled trial (the PANORAMA trial) Trials (2022) 23:647 https://doi.org/10.1186/s13063-022-06610-4

Statistical Analysis Plan Author

Theresa Bieler (Principal investigator)
Post Doc, PhD, Physiotherapist
Department of Physical and Occupational Therapy, Copenhagen University Hospital - Bispebjerg and Frederiksberg

Volkert Siersma (Statistician)
PhD, Statistician
The Research Unit for General Practice and Section of General Practice, Department of Public Health, University of Copenhagen

Christian Have Dall
Senior researcher, PhD, Physiotherapist
Department of Physical and Occupational Therapy, Copenhagen University Hospital - Bispebjerg and Frederiksberg

Morten Tange Kristensen
Professor, PhD, Physiotherapist
Department of Physical and Occupational Therapy, Copenhagen University Hospital - Bispebjerg and Frederiksberg

Søren Overgaard
Professor of Orthopedic Surgery, PhD, Orthopedic surgeon
Department of Orthopedic Surgery, Copenhagen University Hospital - Bispebjerg and Frederiksberg

S. Peter Magnusson
Professor, DMSc, Physiotherapist
Department of Physical and Occupational Therapy, Institute of Sports Medicine Copenhagen, Department of Orthopedic Surgery, Copenhagen University Hospital - Bispebjerg and Frederiksberg

Julie Midtgaard
Professor, PhD, Psychologist
Department of Clinical Medicine, University of Copenhagen and 7Centre for Applied Research in Mental Health Care (CARMEN), Mental Health Centre Glostrup

Signatures

Theresa Bieler Signature:  Date: 18-12-23

Volkert Siersma Signature:  Date: 14-12-2023

Christian Have Dall Signature:  Date: 18-12-23

Morten Tange Kristensen Signature:  Date: 18-12-2023

Søren Overgaard Signature:  Date: 18-12-23

S. Peter Magnusson Signature:  Date: 18-12-2023

Julie Midtgaard Signature:  Date: 17-12-2023

Purpose

This statistical analysis plan (SAP) describes detailed aspects of data preparation and analysis according to the guidelines for the content of statistical analysis plans in clinical trial (Gamble et al., 2017) and was set up before starting the final analysis. The SAP is based on the final trial protocol (version 1 31.07.2019) and the study protocol article Bieler T, Magnusson PM, Siersma V, Rinaldo M, Schmiegelow MT, Beck T, Krifa A, Kjær BH, Palm H and Midtgaard J. "Effectiveness of promotion and support for physical activity maintenance post total hip arthroplasty—study protocol for a pragmatic, assessor-blinded, randomized controlled trial (the PANORAMA trial) Trials (2022) 23:647 https://doi.org/10.1186/s13063-022-06610-4.

Introduction

Synopsis

Background and rationale: Total hip arthroplasty (THA) is considered an efficacious procedure for relieving pain and disability, but physical activity level is unchanged compared to pre-surgery and still considerably lower than that of a healthy age and sex-matched population 6-12 months post-surgery. Increasing physical activity after THA may enhance the outcome of the THA because a graded relationship between physical activity level and functional performance has been documented.

Objectives: 1) primary: to investigate the effectiveness of a physical activity behavior change intervention, initiated three months after THA complementary to usual rehabilitation care compared to control (i.e., usual rehabilitation care with no further attention) on the proportion of participants that complete on average ≥8,000 steps per day six months after surgery in persons who have undergone THA because of osteoarthritis. 2) secondarily: to investigate the effectiveness of the intervention on changes from baseline in core outcomes (i.e., physical function, hip pain, and global

perceived effect) and health-related quality of life six months after THA and the long-term effectiveness on changes in these outcomes together with the number of steps per day and the proportion of participants that complete on average ≥5,000 steps respectively 8,000 steps per day twelve months after THA.

Outcomes: 1) primary: the proportion of participants that complete on average ≥8,000 steps per day six months post-surgery. 2) secondary: number of steps per day and the proportion of participants that complete on average ≥5,000 steps per day six and twelve months after THA and on average ≥8,000 steps per day twelve months post-surgery and changes from baseline to six and twelve months in: physical function using both performance-based and patient-reported outcome measures, hip pain, global perceived effect (change from pre-surgery) and health-related quality of life.

Trial design: The trial is designed as a pragmatic, parallel group, two-arm, assessor-blinded, superiority, randomized (1:1), controlled trial with post intervention follow-up six and twelve months after THA.

Statistical considerations: the assessment of the primary outcome as well as all other outcomes will be based on an intention-to-treat (ITT) principle.

Background and rationale

Total hip arthroplasty (THA) is considered an efficacious procedure for relieving pain and disability, but objectively measured physical activity level remains unchanged compared to pre-surgery and is still considerably lower than that of a healthy age- and sex-matched population 6–12 months post-surgery (Arnold et al., 2016, Hammett et al., 2018). Six to eight months after THA, physical function is recovered to about 80% of that of healthy peers (Vissers et al., 2011) and since there is a graded relationship between physical activity level and functional performance (Dunlop et al., 2011), increasing physical activity may enhance the outcome of the procedure. Physical

interventions using wearables have shown promising results for in increasing physical activity e.g. steps per day in persons who have undergone total hip or knee arthroplasty (Master et al., 2022). The current study aims to investigate whether a multimodal, minimal contact, pedometer-driven, behavior change intervention, initiated three months after THA because of hip osteoarthritis, that promotes and supports physical activity complementary to usual rehabilitation care can increase objective measured physical activity six months post-surgery. Furthermore, if physical activity can be maintained one year after THA and whether improvements in physical activity translate into improvements in physical function. For more details about the background and rationale see the protocol article (Bieler et al., 2022).

Objectives

The primary objective is to investigate the effectiveness of a physical activity behavior change intervention, initiated three months after THA because of osteoarthritis complementary to usual rehabilitation care compared to control (i.e., usual rehabilitation care with no further attention) on the proportion of participants that complete on average ≥8,000 steps per day six months after surgery. Secondary objectives are to investigate the effectiveness of the intervention by comparing change from baseline to six and twelve months after THA in core outcomes (i.e., physical function, hip pain, and global perceived effect (change from pre-surgery)) and health-related quality of life.

We hypothesize that the intervention will increase the proportion of participants that complete on average ≥8,000 steps per day six months post-surgery to 50% compared to 30% after usual rehabilitation care.

Study methods

Trial design

The PANORAMA trial is designed as a pragmatic, parallel group, two-arm, assessor-blinded, superiority, randomized (1:1), controlled trial with post intervention follow-up six (primary endpoint and twelve months after THA (secondary endpoint) (figure 1). The patients are provisionally enrolled in the study prior to surgery and re-screened about 2–3 months after surgery to confirm eligibility (figure 1 and 2).

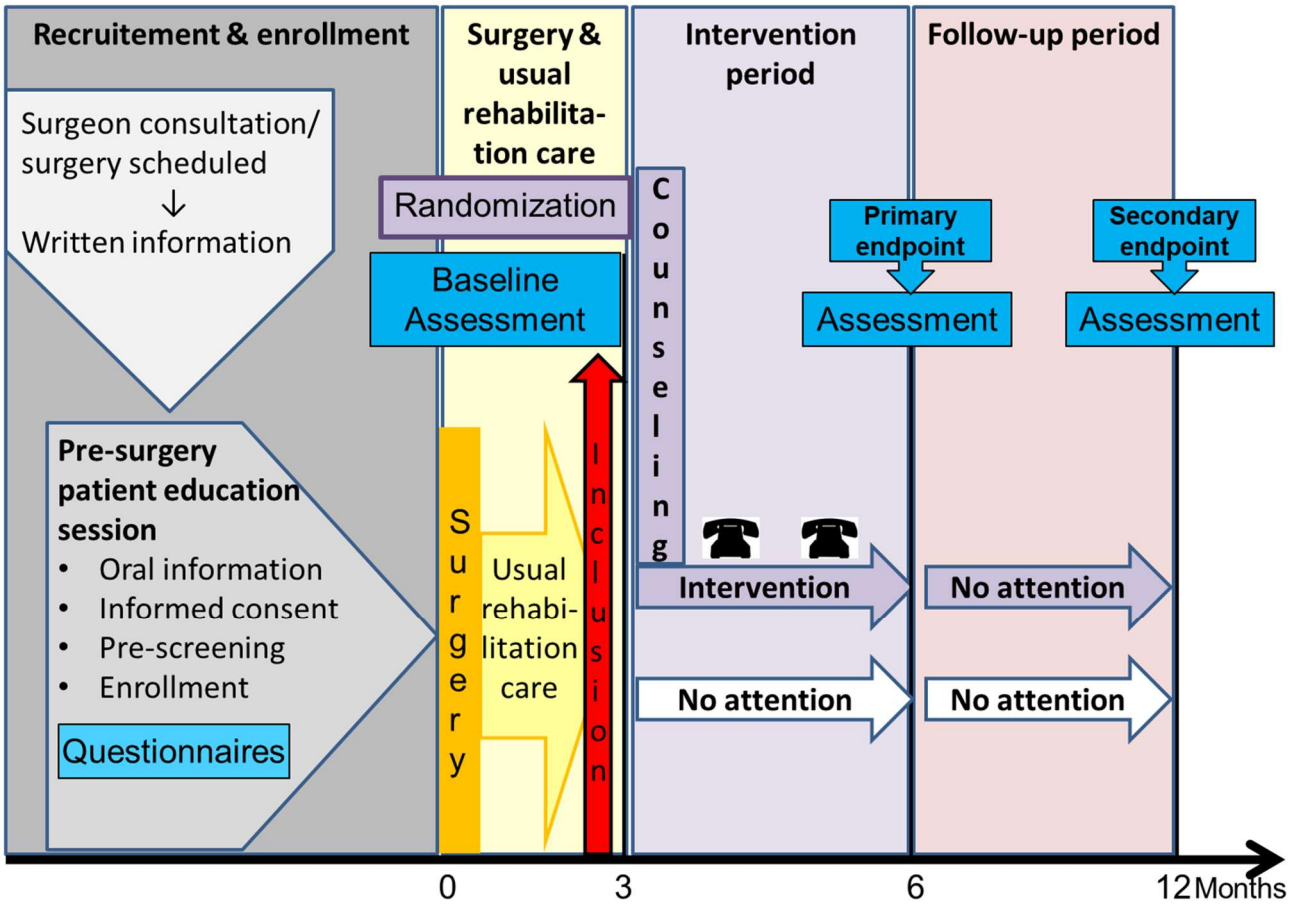

Figure 1. Graphical illustration of the study design

Baseline assessment is conducted three months after THA and subsequently the patients are randomized to a physical activity behavior change intervention or control (no further attention)

(Bieler et al., 2022) (figure 1 and 2). In brief, the intervention is a 3-month package consisting of one 45-minute face-to-face physical activity counselling immediately after randomization followed by two 20-minute telephone-assisted counselling, respectively three weeks (± 1 week) and seven weeks (± 1 week) later; for further details see the protocol article (Bieler et al., 2022).

Randomization

Randomization (1:1 by using envelope-based randomization) is performed according to the order in which the participants have completed baseline test. To control for potential imbalance in the randomization, stratification for self-reported pre-surgical physical activity level (high pre-surgical physical activity level Yes/No), age (≥75 years/<75 years), and total joint replacement in the lower extremities within the last 12 months (yes/no) is employed; for further details see the protocol article (Bieler et al., 2022).

Sample size

For sample size calculation (n=200, 100 in each group) see the protocol article (Bieler et al., 2022).

Framework

The trial is designed as a pragmatic, superiority trial.

Statistical interim analyses and stopping guidance

No statistical interim analysis has been planned and there is no guidance for stopping the trial.

Timing of outcome assessments

Data are collected on four occasions at Bispebjerg and Frederiksberg Hospital: once prior to THA (some days before or at the day of surgery) and three times after THA (three months (baseline), six months (post intervention/primary endpoint), and twelve months after surgery (follow-up/secondary endpoint)).

	STUDY PERIOD				
Visits	**Enrol-ment**	**Surgery**	**Baseline assessment & allocation**	**Post-allocation assessments**	
TIMEPOINT	***-t_1***		**0**	***t_1: primary endpoint***	***t_2: secondary endpoint***
Weeks after THA	***Patient seminar***		**12+2**	***26±2***	***52±3***
ENROLMENT:		**usual rehabi-litation care**			
Provisional eligibility/ Confirmation eligibility[#]	X				
Informed consent	X				
Allocation			X		
INTERVENTIONS:					
Behavior change intervention			X[##]		
Control					
ASSESSMENTS:		**Surgery and usual care rehabilitation**			
Demographics & patient characteristics	X				
Primary outcome *Accelerometer-based PA*			←	X	X
Core outcomes					
Physical function (PF): *Functional performance test: 6MW, 30sCS, TSC*			X	X	X
HOOS[§] PF subscale	X		X	X	X
Hip pain *HOOS[§] Pain subscale*	X		X	X	X
Patient global assessment[§]			X	X	X
Quality of life					
EQ-5D-3L[§]	X		X	X	X
HOOS[§] QOL subscale	X		X	X	X
Self-rated health					
EQ-VAS[§]	X		X	X	X

Figure 2. Timing of outcomes

[#]Telephone-based 10 weeks +2 after surgery; [##]two telephone-assisted counselling 3 weeks±1 respectively 4 weeks±1 after the initial face-to-face counselling; [§]questionnaire.
Abbreviation: PA: physical activity; the 6MW: 6-minute walk test; the 30sCS: 30s chair stand test; TSC: timed stair climbing; HOOS: the Hip disability and Osteoarthritis Outcome Score; PF: physical function/function in daily living; EQ-5D-3L: the EuroQol 5-Dimension Questionnaire (3 level); QOL: Quality Of Life; EQ-VAS: the visual analog scale form the EuroQol 5-Dimension Questionnaire.

Timing of final analysis

All primary and secondary outcomes will be analyzed collectively. The first and main publication of the trial will be prepared for comparison of results between the intervention-group and the control-group when all trial participants have completed the 12-month assessment (anticipated February 2024) and data for the primary and secondary outcomes have been received and cleaned. When this statistical analysis plan was signed all assessors/testers and the statistician (VS) who performs the data analyses were still blinded to group allocation and the database management was not finished. Statistical analyses will start when the database is closed.

Statistical principles

Confidence intervals and P values

Two-sided p values of less than 0.05 will be considered statistically significant and 95% confidence intervals will be presented for all effect estimates. Additionally, for the full collection of hypothesis tests it will be indicated which p values are to be deemed significant controlling the false discovery rate at 5% using the method of Benjamini-Hochberg (Benjamini and Hochberg, 1995).

Adherence and protocol deviations

Immediately after baseline assessment three months after THA, the patients were randomized. Patients randomized to the behavior change intervention received the initial face-to-face physical activity counselling directly after randomization (Bieler et al., 2022) (figure 1 and 2). Thus, all the patients randomized to the behavior change intervention have received the initial face-to-face

physical activity counselling. The number of patients who have received each of the two telephone-assisted counselling, respectively three weeks (± 1 week) and seven weeks (± 1 week) later will be reported.

There has been no deviation from the protocol except that the average number of steps per day, the proportion of participants that on average complete ≥ 5,000 steps per day and the EQ-5D index at follow-up six and twelve months after THA have been added as secondary outcomes at www.clinical trials.gov.

Analysis populations

The analysis executed is based on the ITT principle, thus all randomized patients will be included in the analysis.

Trial population

Screening data

It will be reported how many patients have undergone primary THA during the recruitment period and how many of those have been invited to participate.

Eligibility

Inclusion criteria

1. Patients who undergo primary THA because of hip osteoarthritis
2. Patients who are home-dwelling, independent and self-reliant adults
3. Patients who have signed informed consent to participate

Exclusion criteria

1. Patients with planned joint arthroplasty in the lower extremities within the first six months after their THA

2. Patients who are unable to read, understand and speak Danish
3. Patients who develop complications in relation to THA e.g. dislocation, fracture or infection (within the first six months after THA)
4. Any other condition, which by investigator determination, makes a potential participant unfit for participation (within the first six months after THA)

Recruitment

The following information will be included in the CONSORT flow diagram (figure including level and timing in withdrawal from follow-up and lost to follow-up) (Figure 3).

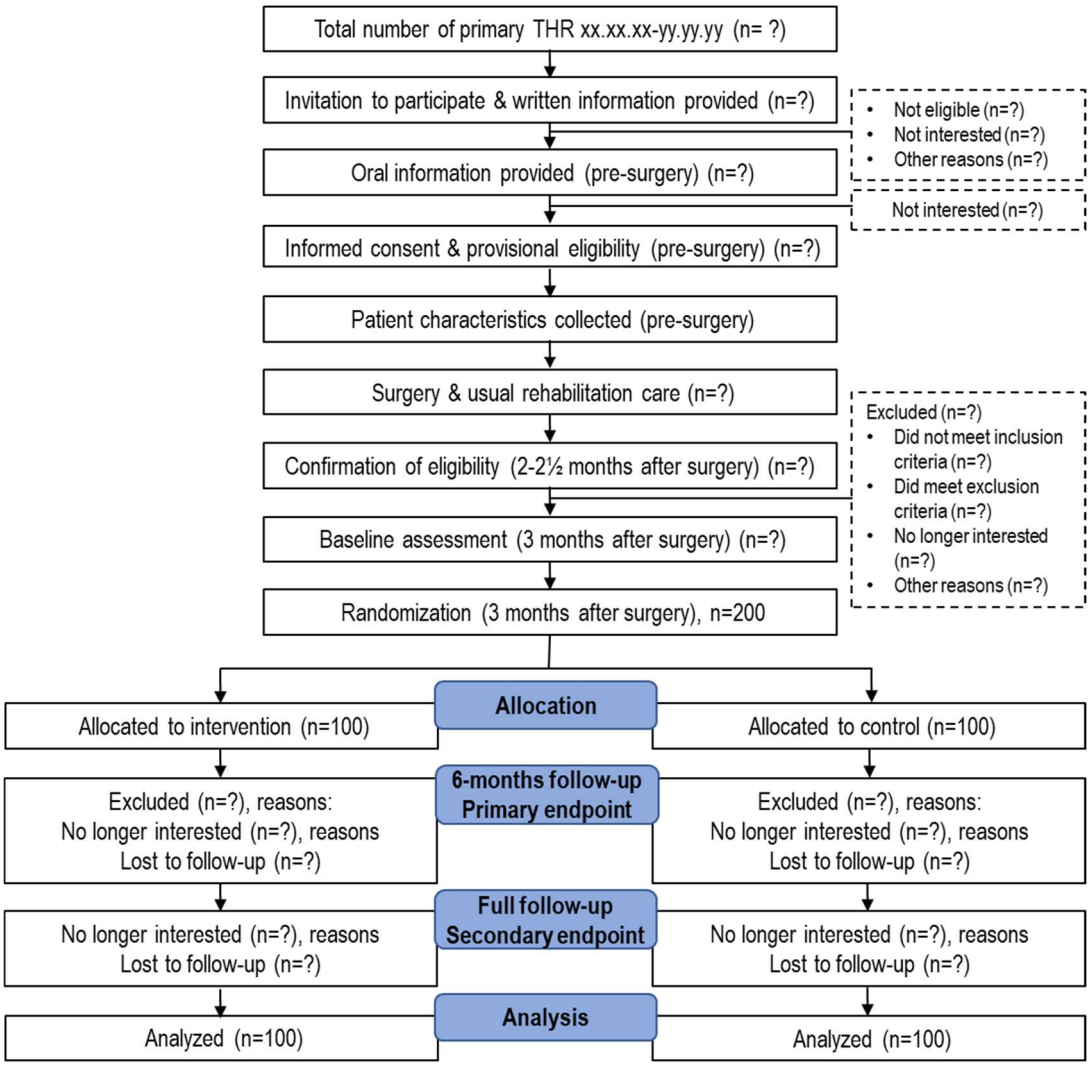

Figure 3. The CONSORT flow diagram

Baseline patient characteristics

The patients are provisionally enrolled in the study prior to surgery, where we collected demographics & patient characteristics, and re-screened about 2–3 months after surgery to confirm eligibility and baseline tested three months after surgery (Figure 1, 2 and 3). The following information regarding patients' characteristics will be included in Table 1.

Table 1. Participant characteristics.

Characteristics	**Provisional enrolled**	**Enrolled/ baseline**	**Intervention baseline**	**Control baseline**
Time point	**Prior to surgery**	**3 months after surgery**	**3 months after surgery**	**3 months after surgery**
Number				
Sex (Male/Female)				
Age (years)¤				
Stratification factor				
High pre-surgical PA (CCHS level 3-4) [e]				
≥75 years¤				
TJR ≤ 1 year [e]				
Body weight (kg)				
Height (cm)				
BMI (kg/m^2)				
Retired [e]				
Education [e]				
9-10 years				
10-12 years				
13-15 years				
15-17 years				
Living together/alone [e]				
Pain-comorbidity				
Non-index hip				
Knees				
Back				
Prior THA/TKA [e]				
Comorbidity [e]				
Cardiovascular disease[a]				
Lung disease[b]				
Metabolic disease[c]				
Prior cancer				
Mental illness[d]				
GPE (p)				

HOOS (0-100)				
Hip pain				
Symptoms				
Function in ADL				
Sport and Recreation Function				
QOL				
EQ5D-3L index score (p)				
EQ-VAS (0-100)				
PA level				
PASE (0-400) (p)				
CCHS (1-4)(l)				

Note. Values are mean ±SD, or number [%]. [¤]Age when provisional enrolled in the study. [a]Including high blood pressure; [b]Including COPD and asthma; [c]Including hypothyroidism and diabetes; [d]Mainly depression; [e]Self-reported prior to surgery.

Abbreviation's: TJR=total joint replacement in the lower extremities; THA=total hip arthroplasty; TKA= total knee arthroplasty; GPE: the patients' assessment of global perceived effect compared to the pre-surgery state; HOOS= the Hip disability and Osteoarthritis Outcome Score; ADL=function in Daily Living; QOL= hip related Quality Of Life; EQ5D-3L=the EuroQol 5-Dimension Questionnaire, the three level version; EQ-VAS=the EuroQol 5-Dimension Questionnaire visual analog scale for self-rated health; PA=physical activity; PASE= the Physical Activity Scale for the Elderly; p=points; CCHS=question from the Copenhagen City Heart Study; l=level.

Analysis

Outcome definitions

For more detailed description of the outcomes see the protocol article (Bieler et al., 2022).

Primary outcome

- The proportion of participants that on average complete ≥ 8,000 steps per day six months after THA determined on the mean number of steps per day during the last week (7 days).

Secondary outcomes

<u>Secondary outcomes at the primary and secondary endpoint</u>

Physical activity/steps per day:

- The average number of steps per day at follow-up six and twelve months after THA determined on the mean number of steps per day during the last week (7 days) respectively one week (7 days).
- The proportion of participants that on average complete ≥ 5,000 steps per day at follow-up six and twelve months after THA determined on the mean number of steps per day during the last week (7 days) respectively one week (7 days).
- The proportion of participants that on average complete ≥ 8,000 steps per day twelve months after THA determined on the mean number of steps per day during the one week (7 days).
- The proportion of participants that on average complete ≥ 10,000 steps per day at follow-up six and twelve months after THA determined on the mean number of steps per day during the last week (7 days) respectively one week (7 days).

Core outcomes/physical function:

- Change from baseline to follow-up six and twelve months after THA in objective measured physical function: the 6-minute walk test (walking distance in meters).
- Change from baseline to follow-up six and twelve months after THA in objective measured physical function: the 30-s chair-stand test (number of chair stands).
- Change from baseline to follow-up six and twelve months after THA in objective measured physical function: the stair-climb test (seconds).
- Change from baseline to follow-up six and twelve months after THA in self-reported physical function measured by the Hip disability and Osteoarthritis Outcome Score (HOOS) (Klassbo et al., 2003, Nilsdotter et al., 2003) function in daily living (ADL) subscale, (A normalized score 0-100; 100 indicates no problems).

- Change from baseline to follow-up six and twelve months after THA in self-reported physical function in sport and recreation measured by the HOOS (Klassbo et al., 2003, Nilsdotter et al., 2003) the function in sport and recreation subscale (A normalized score 0-100; 100 indicates no problems).

Core outcomes/hip pain:

- Change from baseline to follow-up six and twelve months after THA in hip pain measured by the HOOS (Klassbo et al., 2003, Nilsdotter et al., 2003), the pain subscale (A normalized score 0-100; 100 indicates no problems).

Core outcomes/global perceived effect:

- Change from baseline (in this case the pre-surgery state) to follow-up six and twelve months after THA in the patients' assessment of global perceived effect measured as a transition rating of global perceived effect (a 200 mm visual analog scale with anchors being: -100 = "Much worse"; 0 = "No changes"; 100 = "Much better") based om the participants comparison of their current global wellbeing and the pre-surgery state.

Health related quality of life:

- The EQ-5D index measured by the EuroQol 5-Dimension Questionnaire (EQ-5D-3L) (1990) at six- and twelve-months follow-up and calculated based on the Danish EQ-5D Time Trade-Off (TTO) value set (Wittrup-Jensen et al., 2009).
- Change from baseline to follow-up six and twelve months after THA in the health-related quality of life index from EQ-5D-3L (1990) and calculated based on the Danish EQ-5D TTO value set (Wittrup-Jensen et al., 2009).

- Change from baseline to follow-up six and twelve months after THA in hip-related quality of life measured by the HOOS (Klassbo et al., 2003, Nilsdotter et al., 2003), the hip-related quality of life subscale (A normalized score 0-100; 100 indicates no problems).

Self-rated health

- Change from baseline to follow-up six and twelve months after THA in the patients self-rated health measured by the visual analog scale (EQ-VAS) form the EuroQol 5-Dimension Questionnaire (1990) a separate 20cm visual analog scale with anchors being: 0=”worst imaginable health state”; 100=”best imaginable health state”).

Other symptoms

- Change from baseline to follow-up six and twelve months after THA in hip-related quality of life measured by the HOOS (Klassbo et al., 2003, Nilsdotter et al., 2003), the other symptoms subscale (A normalized score 0-100; 100 indicates no problems).

Management of the accelerometer data

When all participants have reached the secondary endpoint (figure 1 and 2), the physical activity data will be exported from the SENS’ database through SENS innovation service and entered in the study database and the data will be cleaned. All participants have been asked to wear the accelerometer continuously during the entire intervention period (3 to 6 months after THA, figure 2), but only the mean number of steps per day during the last week (7 days) will be used for data analysis of the primary outcome (Bieler et al., 2022). We will always use accelerometer data from the last week (7 days) of this monitoring period. Also in cases where the participant has canceled (illness, etc.) the follow-up test and it therefore has been conducted later than originally planned. In general, we will report the number of patients/proportions where the follow-up assessments are conducted beyond the follow-up windows (primary endpoint 26 ± 2 weeks, secondary endpoint 52

± 3 weeks). At follow-up (secondary endpoint; figure 1 and 2), all participants have been asked to wear the accelerometer for one week (7 days) after the 12-month follow-up visit (Bieler et al., 2022). A 1-weeks data is only determined valid if ≥ 5 days with 24 hours of wear-time are available. In case of < 7 days but ≥ 5 days the mean of the available days will be used for the mean number of steps per day during the week. In case that <5 days with 24 hours of wear-time are available for the last week of the 3-month continuously measured period (figure 2), we will select the last week with valid data in that period. In all other cases <5 days with 24 hours of wear-time during a week are considered as missing data.

Analysis methods

A description of the study population and an assessment of the randomization success is provided by tests for the difference between the randomization groups of baseline values for the outcomes and the selected covariates (self-reported pre-surgical physical activity level (high pre-surgical physical activity level Yes/No), age (≥75 years/<75 years), and total joint replacement in the lower extremities within the last 12 months (yes/no) and sex).

The primary effectiveness analyses performed are ITT assessments of the between-group difference in the outcomes at six months after surgery, beyond a difference already present at baseline three months after surgery; similar analyses assess the between-group differences at twelve months. These analyses are performed in longitudinal logistic regression models for binary outcomes - such as the primary outcome - and longitudinal linear regression models for continuously valued outcomes. For correct inference, the covariance matrix is adjusted for repeated measurement with the method of generalized estimating equations (GEE).

We have not planned any sensitivity or subgroup analyses.

Missing data

Potential differential dropout and other types of missing value mechanisms between the groups is adjusted for with weighting the analyses with the inverse of the probability that an observation is not missing (Dufouil et al., 2004); these weights estimated by multivariable logistic regression models including baseline variables and outcomes. Also, the weighting is adjusted for with GEE.

Additional analyses

We do not expect that any additional statistical analyses are required

Statistical software

The analysis will be carried out using the statistical software SAS v9.4 and R v4.3.1.

References

1990. EuroQol--a new facility for the measurement of health-related quality of life. *Health Policy,* 16**,** 199-208.

ARNOLD, J. B., WALTERS, J. L. & FERRAR, K. E. 2016. Does Physical Activity Increase After Total Hip or Knee Arthroplasty for Osteoarthritis? A Systematic Review. *J. Orthop. Sports Phys. Ther,* 46**,** 431-442.

BENJAMINI, Y. & HOCHBERG, Y. 1995. Controlling the false discovery rate: a practical and powerful approach to multiple testing. *Journal of the Royal Statistical Society, Series B,* 57**,** 289–300.

BIELER, T., MAGNUSSON, S. P., SIERSMA, V., RINALDO, M., SCHMIEGELOW, M. T., BECK, T., KRIFA, A. M., KJAER, B. H., PALM, H. & MIDTGAARD, J. 2022. Effectiveness of promotion and support for physical activity maintenance post total hip arthroplasty-study protocol for a pragmatic, assessor-blinded, randomized controlled trial (the PANORAMA trial). *Trials,* 23**,** 647.

DUFOUIL, C., BRAYNE, C. & CLAYTON, D. 2004. Analysis of longitudinal studies with death and drop-out: a case study. *Stat. Med,* 23**,** 2215-2226.

DUNLOP, D. D., SONG, J., SEMANIK, P. A., SHARMA, L. & CHANG, R. W. 2011. Physical activity levels and functional performance in the osteoarthritis initiative: a graded relationship. *Arthritis Rheum,* 63**,** 127-136.

GAMBLE, C., KRISHAN, A., STOCKEN, D., LEWIS, S., JUSZCZAK, E., DORE, C., WILLIAMSON, P. R., ALTMAN, D. G., MONTGOMERY, A., LIM, P., BERLIN, J., SENN, S., DAY, S., BARBACHANO, Y. & LODER, E. 2017. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. *JAMA,* 318**,** 2337-2343.

HAMMETT, T., SIMONIAN, A., AUSTIN, M., BUTLER, R., ALLEN, K. D., LEDBETTER, L. & GOODE, A. P. 2018. Changes in Physical Activity After Total Hip or Knee Arthroplasty: A Systematic Review and Meta-Analysis of Six- and Twelve-Month Outcomes. *Arthritis Care Res. (Hoboken.),* 70**,** 892-901.

KLASSBO, M., LARSSON, E. & MANNEVIK, E. 2003. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. *Scand. J. Rheumatol,* 32**,** 46-51.

MASTER, H., BLEY, J. A., CORONADO, R. A., ROBINETTE, P. E., WHITE, D. K., PENNINGS, J. S. & ARCHER, K. R. 2022. Effects of physical activity interventions using wearables to improve objectively-measured and patient-reported outcomes in adults following orthopaedic surgical procedures: A systematic review. *PLoS One,* 17**,** e0263562.

NILSDOTTER, A. K., LOHMANDER, L. S., KLASSBO, M. & ROOS, E. M. 2003. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. *BMC. Musculoskelet. Disord,* 4**,** 10.

VISSERS, M. M., BUSSMANN, J. B., VERHAAR, J. A., ARENDS, L. R., FURLAN, A. D. & REIJMAN, M. 2011. Recovery of physical functioning after total hip arthroplasty: systematic review and meta-analysis of the literature. *Phys. Ther,* 91**,** 615-629.

WITTRUP-JENSEN, K. U., LAURIDSEN, J., GUDEX, C. & PEDERSEN, K. M. 2009. Generation of a Danish TTO value set for EQ-5D health states. *Scand J Public Health,* 37**,** 459-66.