Statistical analysis plan for the study «Effects of Patient Education and Basic Body Awareness Therapy, compared to Patient Education alone. A Randomized Controlled Trial of patients diagnosed with hip osteoarthritis".

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This statistical analysis plan has been developed in accordance with published guidelines[1,2], in order to reduce the risks of outcome reporting bias and data-driven results.

Roles and responsibility

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Background

Musculoskeletal disorders are reported to be the second largest contributor to years lived with disability worldwide [3], and the largest contributor in Norway [4]. Osteoarthritis (OA) of the hip is among the most common with a prevalence rate of 5.8%, increasing with age[5]. Pain, structural joint degeneration and compensational movement adjustments commonly seen in this condition have consequences for patients' daily movement and functioning, as well as for social life and self-confidence[6].

There is insufficient high-quality evidence regarding non-pharmacological and nonsurgical interventions of hip OA, but clinical guidelines are rather similar in their general recommendations[7,8]. A broad range of means to improve functioning are recommended, such as patient education, lifestyle changes, exercise modalities, weight loss, assistive technologies and adaptations, footwear and work modification[9,10]. A, biopsychosocial approach to assessment is recommended, as well as an individualized treatment plan[11]. However, the guidelines do not provide concrete suggestions of how psychological or social perspectives should be implemented into physiotherapy.

The scientific evidence for recommending therapeutic exercises for hip OA has been examined in several systematic reviews and meta-analyses, and strong evidence is claimed for beneficial short-term effects of both land and water based aerobic and strengthening exercise programs[12,13]. Adherence to dosage recommended by the American College of Sports Medicine (ACM) may enhance the effect from exercise on pain[14]. Recommendations are made that therapeutic exercise programs for hip or knee OA should focus on the entire lower limb, and that weight bearing exercises should be preferred[15]. Neuromuscular training is also recommended, aiming to restore neutral functional alignment of the lower extremities by improving dynamic motor control and functional stability[16].

Disease processes and pain in osteoarthritis are known to have an impact on the patients´ movement pattern, leading to dysfunctional habits with additional strain on the joint and other body parts[17]. Although physiotherapists observe and attend to the quality of patients' movement performance during exercise, correcting guidance is mainly focused on maintaining physiological joint angles or activating specified muscles[18]. From qualitative studies, it is well-known that patients with hip osteoarthritis, similar to other long-lasting pain conditions, experience changes in the way they perceive their body in movement and at rest[19,20]. Their sensitivity to nuanced body perceptions may be disturbed and reduced by sensations of pain. Patients' way of coping with the disease is also influenced by how they interpret and act on bodily perceptions. For example is it likely that flares of increased pain is understood by patients as a sign for increased disease severity, and that they consequently develop negative beliefs and/or feelings of helplessness. The present study will investigate effects from Basic Body Awareness Therapy (BBAT), a movement learning program that aims to address patients movement habits based on enhanced movement awareness[21]. Revealing and utilizing own resources for movement under physiotherapy guidance is regarded to help patients understand and handle bodily signals in such a way that they develop functional movement patterns as well

as constructive ways of dealing with their disease. Hence, BBAT aims to address health aspects described in the bio-psycho-social model, based on the patients' active involvement, their movement experiences and their movement learning process[22,23].

Objectives and hypotheses

The purpose of this study is to examine the supplementary short- and long-term effects of BBAT in patients with hip OA, by comparing the outcomes (pain, functioning, and quality of life) of Patient Education (PE) alone with PE and BBAT combined. It is hypothesized that patients that participate in BBAT group therapy following PE show more short-term (4-5 months) and long-term (12-13 months) improvements compared to patients that participate in PE only.

Design and methods

The trial is a single-centre, block-randomised, single-blinded, parallel-group trial conducted in collaboration between primary- and secondary health care in Bergen, Norway. It is a study of superiority, aimed to investigate whether PE followed by BBAT is more effective than PE alone.

Patients with verified (by x-rays and clinical symptoms) hip osteoarthritis referred to a 3,5 hours Patient Education (PE) course offered by Haukeland University Hospital, were invited to participate in the trial. *Inclusion criteria*: Women and men with primary OA according to the American College of Rheumatology Clinical Criteria [24], living in Bergen or within a reasonable travelling distance (judged by the patients) , commonly 1 hour. *Exclusion criteria*: Other known major physical or mental problems or disease that precludes movement training and participation in an educational program, known drug abuse, not speaking or understanding Norwegian language, pregnancy 5-9 months.

Between October 2015 and January 2019, 101 patients were enrolled. After given written informed consent to participate in the study, but before attending to the PE, the patients filled in questionnaires and were tested by a blinded assessor in accordance with the study protocol. Immediately after the PE course, they were randomized to one of two groups; A - intervention group, participating in 12 weekly sessions of BBAT, and B – comparison group, recommended to follow advice given in the PE course concerning self-training and/or guided physiotherapy in primary health care. A computer-generated block randomization schedule was used to allocate participants. A research coordinator not involved in the randomization procedure prepared opaque envelopes with allocation to groups and administered the distribution of envelopes immediately after each PE course.

Interventions

Patient Education was offered and led by an orthopaedic surgeon and an orthopaedic physiotherapist from Haukeland University Hospital, inspired by an educational program

developed in Sweden and further developed for use in Norway (AktivA)[25]. Emphasis was on describing the dynamic nature of joint structures and the importance of optimal loading, and giving advice on weight bearing and physical activity, adjusted to functional limitations and pain. Exercises addressing typical movement problems in hip osteoarthritis were demonstrated. Shock-absorbing materials in shoe soles were recommended, and weight reduction in overweight. Patients were advised to be physically active and to obtain guidance from physiotherapists in primary health care if needed. The patients' own experiences with hip osteoarthritis and sharing in the PE group were in the forefront.

Basic Body Awareness Therapy (BBAT) in groups was led by an experienced physiotherapist in primary care. Specific strategies promoting movement awareness and movement quality in daily life movements; lying, sitting, standing, relational and walking, were applied for the group as well as individually. The learning process in BBAT is illustrated as a cycle of seven steps; coming in contact with, exploring, experiencing, integrating, creating meaning of, mastering and conceptualizing movement aspects for more functional movement strategies[21]. Participants were to attend 12 weekly group sessions, each consisting of about 70 minutes of guided movements and 20 minutes of reflective talk in the group. Between the group sessions, patients were to practice movements regularly at home, and to implement experienced movement aspects into daily life activities and settings. They were to use a log-book for personal notes on movement experiences and reflections. As the PE course was organized once monthly, new patients were enrolled and joined the running BBAT group every month, meaning that the group consisted of new and old members at all times.

Data collection and outcomes

Electronic collection data is made through InfoPad, approved by the Data inspectorate. All participating patients were assessed according to the protocol described below at baseline and at 4-5 months' follow-up. The data collected are similar to those collected in the Norwegian osteoarthritis register (AktivA). The included tests are recommended by the Osteoarthritis Research Society International (OARSI) (40). Patients in the comparison group are asked to report any treatment or training activities that they have attended to during the intervention period.

Demographic data and data from assessments at baseline were collected on the same day for each of the participants. Follow-up data from all baseline assessments, additionally Patient Global Impression of Change (PGIC), were collected 4-5 months after enrolment.

Follow-up data limited to self-reported questionnaires were collected 12-13 months after enrolment. Questionnaires were distributed per e-mail using the web-based program InfoPad, and all questionnaires are to be filled out in one single session.

Primary Outcomes

1) Numeric Rating Scale (NRS) for pain during walking is a primary outcome, scale 0-10. A change $\geq$ 15.3 mm on a 0-100 scale is considered clinically important in hip OA [26,27].
2) Hip Osteoarthritis Outcome Score (HOOS) is an instrument to assess the patients' opinion about their hip and associated problems, as perceived during the last week

before measurement [28]. It contains questions of five domains; pain (P) - 10 items, symptoms (S), - 5 items, Activities of Daily Life (A), - 17 items, sport and recreation (SP) - 4 items, and hip related quality of life (QL) - 4 items [29]. Each item is answered on a Likert scale (no, mild, moderate, severe, extreme) and scored from 0-4. The sum score of each domain is transformed to a normalized 0-100 scale, where 0 indicates extreme problems and 100 no problems. HOOS has shown high test-retest reliability (ICC for subscales ranging from 0.78 to 0.91) [28]. Construct validity has been supported by high correlations with the Oxford Hip Score ($r_s = 0.822$) and the SF-36 ($r_s = -0.664$)[30]. The HOOS ADL subscale is a primary outcome.

Secondary outcomes:

1) **Chairs test**

The chairs test is a quantitative test of a functional activity. The patient repeats rising up from a chair and sitting down during 30 seconds, and the number is counted. Intra-rater and inter-rater reliability is high in patients with hip or knee OA, with ICC = 0.85 and 0.86, respectively [31]. A minimal clinical important improvement of 2.0 – 2.6 stands have been reported (Wright, 2011)

2) **Stairs test**

The stairs test is a quantitative test of a functional activity. The time by number of seconds used to walk up and down 18 steps x 3 is measured[32].

3) **6-minutes walking – test (6MWT)**

Walking as far as possible during the course of 6 minutes without running. Distance is measured in meter. Minimal detectable change is 61.34 meters[32].

4) **University of California Los Angeles activity score (UCLA)**

UCLA is used to assess the self-reported level of physical activity during the last month on a 10 point ordinal scale from totally sedentary (dependent on other persons) to participating regularly in high intensity physical activities (running, tennis, skiing, ballet, heavy work, hiking) [33]. Criterion validity of UCLA was indicated as it was strongly correlated with steps per day as recorded by pedometer [34]. Excellent test-retest reliability has been reported (kw = 0.80,95% CI 0.70-0.90), and UCLA was able to discriminate between active and inactive patients with hip OA[33].

5) **Hip Osteoarthritis Outcome Score (HOOS)**

See description above (primary outcomes). Subscales pain (P) - 10 items, symptoms (S), - 5 items, sport and recreation (SP) - 4 items, and hip related quality of life (QL) - 4 items.

6) **Arthritis Self-efficacy Scale (ASES)**

ASES is a questionnaire about self-efficacy regarding pain, symptoms and physical function[35] for patients with arthritis. In the present study, only the subcategories Pain and Symptoms were included. The sub-category Pain consists of 5 questions, each to be answered on a 5-point Likert scale (1-5) from very unsure to very sure (sum-score from 5 (worst) to 25 (best). Sub-category Symptoms consists of 6 questions, with a sum-score from 6 (worst) to 30 (best). High test-retest reliability have been reported, r=0.87 for pain and 0.90 for symptoms[35], as well as validity [36].

7) **EuroQol (EQ-5D-5L)**

EuroQol (EQ-5D-5L) is a generic health index comprising a five-part questionnaire and a visual analogue self-rating scale[37]. The five dimensions concern mobility, self-care, usual activities, pain/discomfort and anxiety/depression and each is scored on a five-point scale from no problem (score 1) to extreme problems (score 5). An EQ index is calculated, ranging from 0.0 (worst health) to 1.0 (best health).The EQ VAS records the respondents' self-rated health on a vertical, visual analogue 0-100 scale with the endpoints 'Best imaginable health state' and 'Worst imaginable health state'. Test-retest reliability has been reported in patients referred for hip or knee replacement, ICC for the 5 items ranging from 0.61 to 0.77[38].

8) **Patient Global Impression of Change** (PGIC)

PGIC is used to collect the patients' own impression of change after 4 months and 1 year. Change is scored on a 7-point ordinal scale: 1 very much improved, 4 no change, 7 very much worse[39].

9) **Harris Hip Score (HHS)**

HHS is used to assess hip disabilities and effect of treatment on four domains. Grading of scores: <70=poor, 70-79=fair, 80-89= Good, 90-100 Excellent. A successful result: >20 points[40].

10) **Body Awareness Rating Scale–Movement Quality and Experience (BARS-MQE)**

BARS-MQE consists of two intertwining parts. In Part 1, the physiotherapist observes, evaluates and scores the patient's MQ in 12 daily-life movements and actions: lying, sitting, standing, walking and moving in relation to another person [41]. Each movement is followed by Part 2), an open-ended question on the patient's immediate experiences from exploring the movement[20]. Part 2 is not included in the present study. The observed MQ in each of the 12 movements is scored on an ordinal scale from 1 (dysfunctional MQ, described as unstable, mechanical, stiff and with a lack of unity), to 7 (functional MQ, described as balanced, free, centered, unified, rhythmic and synchronous) [23]. The sum score of the 12 movements ranges from 12 to 84. In a study of patients with long-lasting musculoskeletal disorders and mental health problems, reliability of the BARS-MQE was found highly satisfactory. Internal consistency by Cronbach's alpha was 0.92, and ICCs of inter-tester and test-retest reliability 0.99 and 0.96, respectively. BARS-MQE was found to correlate moderately with most subscales of the Short-Form Health Survey (SF-36) and with the General Perceived Self-Efficacy Scale (GPSES), and to discriminate between patients and healthy persons[42].

Statistical methods

Sample size

The necessary sample size was estimated based on the two primary outcomes; hip pain and function in daily life activities. Pain was assessed by the 0-100 Numeric Rating Scale (NRS). The expected difference in change between the groups was 18 points on the NRS, which is considered the minimum important difference in improvement[43]. Based on previous studies

[26,27], we assumed a between-participant standard deviation of change of 30 points. The required sample size, with 80% power and the significance level of 0.05 was 44 in each group. Allowing for a 15% drop-out, a total of 100 patients was required. Disability was assessed by the Hip disability and Osteoarthritis Outcome Score (HOOS). Referring to power calculation of a previous relevant study, 74 patients are needed to detect a clinically relevant change of 10 points on the subscale in patients with hip pain (SD ± 15, power =0.80 and $\alpha = 0.05$)[15]. A total of 100 patients were, accordingly, a sufficient sample size for both measures.

The intervention, BBAT, has been tried out in a pilot study showing promising results and has shown positive results in other patient groups[44]. No adverse effects have been reported. Plans for interim analyses or stopping guidance were therefore not considered relevant.

Adherence and protocol deviations

Definition of adherence to the intervention and how this is assessed including extent of exposure

The physiotherapist leading the BBAT group kept a record over patient attendance. Patients that participate at least 10 times in BBAT groups are regarded to having completed the intervention. A table will show the number of BBAT group sessions attended to during the intervention period.

Definition of protocol deviations for the trial

No deviations from the original protocol.

Definition of analysis populations

All participants (n = 101) will be included in an intention to treat (ITT) analysis investigating the effectiveness of BBAT groups in clinical and practical settings; a real life situation.
Patients who have completed the treatment (10 BBAT group sessions) and have been available for all baseline and 4-5 month follow-up measurements, are included in a per protocol analysis (PPA) investigating the maximum treatment efficacy in perfect compliers.

Withdrawal/follow-up

A flow-chart will be made to show the level of patient participation throughout the study, illustrating withdrawals/lost to follow-up data in both groups separately, with timing and reasons for withdrawal/lost to follow-up.

Statistical analysis plan

The present statistical analysis plan will be made publicly through registration in ClinicalTrials before any analysis is performed. The statistical analyses will be performed in close collaboration with an independent statistician who is unaware of group assignment.

Intention-to-treat analysis of short-term follow-up data (4-5) months is performed during the fall 2019. To reduce the risk of bias during interpretation, blinded study results will be presented

to all authors. A researcher not involved with the study is asked to add A and B to the data sheet in line with the list of randomized participants, but without breaking the randomization code. Per protocol analysis of short-term data will be carried out after breaking the randomization code (spring 2020).

The long-term and final analyses of primary and secondary outcomes, as well as subgroup analyses related to cartilage thickness and additional treatment, will be conducted after data collection at 12-month follow-up is completed, the database is closed and the randomization code is broken (spring 2020).

Demographic data and characteristics of participants (e.g. age, height, weight, cartilage thickness, comorbidities, work status, type of work and medications) will be presented using descriptive statistics. Normality of continuous variables will be inspected visually on Q-Q plots. Mean and standard deviation will be used to describe normally distributed continuous variables, and median and upper and lower limits of the interquartile range to describe non-normally distributed continuous variables. Counts and percentages will be used to present categorical variables. No statistical testing will be performed to investigate differences in baseline characteristics between groups.

Differences between groups at both follow-up time points will be investigated separately using analysis of covariance (ANCOVA). Additionally, we will estimate a linear mixed effects model, including all time points, effect of treatment and their interaction.

In line with a patient-centred perspective, the clinical meaningful interpretation of change scores on the two primary outcomes, NRS Pain during walking and HOOS subscale ADL, will be discussed. A responder analysis will be conducted, based on values of minimal clinically important improvement (MCII) as anchors. No studies have, so far, calculated a MCII value for NRS Pain during walking or HOOS ADL in relation to physiotherapy. The values will therefore be defined as the mean change in scores in the category of patients who report to be "slightly improved" in pain and function on the PGIC [45]. The proportions of responders in the intervention- versus control group will be analysed.

The general significance level is set to 0.05. Using Bonferroni adjustment for 2 tests (2 primary outcomes; NRS and HOOS A), 0.025 is set as a marginal level. Residual plots will be used to check for normality assumptions and homoscedasticity. A per protocol analysis (PPA) will be used for sensitivity analysis for all outcomes. Subgroups related to cartilage thickness (0 versus > 0) will be investigated using a stratified ANCOVA as described above, if sufficient number of observations is available in both groups.

Missing data

Missing data will be investigated for any relations to the intervention or outcomes of interest (missing at random). Assuming the data missing at random, multiple imputation methods (MIM) will be used to generate random estimates, if necessary.

Missing items in patient reported questionnaires will be handled in accordance with guidelines for the questionnaire. If no guideline is available, mean imputation will be used if less than 10% of the items are missing.

Additional analyses
ANCOVA adjusted for concomitant treatments reported by participants will be conducted.

Harms

No adverse effects or risks of harm are documented from studies on PE or BBAT groups. If adverse events should occur, they will be categorized as treatment related or not, and treatment related events will be summarized and compared between groups.

Statistical software

IBM SPSS 24[46] and R [47] will be used for data handling and analyses.

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