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**Efficacy of patient education and supervised exercise versus patient education alone in patients  
with hip osteoarthritis. A single blind randomized clinical trial.**

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## ABSTRACT

**Objective** To compare the efficacy of patient education and supervised exercise with that of patient education alone for the management of pain in patients with hip osteoarthritis.

**Design** Single blind randomized clinical trial.

**Setting** Recruitment of patients from hospitals, primary health care and advertisement, Oslo, Norway.

**Participants** 109 patients with radiographic and symptomatic hip osteoarthritis with mild to moderate symptoms.

**Interventions** Patient education (PE). Patient education and supervised exercise (PE+SE).

**Primary outcome measure** The pain subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC pain).

**Results** No significant between group differences were found for WOMAC pain over the 16 month follow-up. Significant improvements were found for the secondary outcome WOMAC physical function ( $p=0.011$ ) in the group receiving PE+SE compared to the group receiving PE only. No significant differences were found for WOMAC stiffness, the SF-36 subscales or the activity scale. The effect sizes (95% confidence interval) for WOMAC pain were -0.26 (0.11, -0.64), -0.35 (0.07, -0.77), and -0.30 (0.15, -0.75), and for WOMAC physical function -0.29 (0.09, -0.67), -0.48 (-0.06, -0.91), and -0.47 (-0.02, -0.93) at 4, 10 and 16 months, respectively, in favor of the group receiving both PE and SE. All patients attended the three-session PE program, and 75% performed  $\geq 16$  sessions of the 12 week SE program.

**Conclusion** The study could not demonstrate a significant difference in pain reduction over time between PE+SE versus PE alone. Adding SE to PE may improve physical function, but the magnitude of possible benefit is unknown as the 95% confidence intervals around the mean difference were wide.

**Trial registration** Clinical Trials NCT00319423

**Key words** Osteoarthritis, Hip, Patient education, Exercise

## INTRODUCTION

Osteoarthritis (OA) is reported to be one of the most disabling diseases in high-income countries<sup>1, 2</sup>. OA predominantly affect hip and knee joints with pain, stiffness, and limitation in physical function. For the purpose of reducing pain and improving physical function in patients with hip and knee OA, 28 out of 34 clinical guidelines recommended patient education and 27 out of 34 recommended strengthening exercises<sup>3</sup>. Since the evidence upon which these guidelines primarily comes from randomized controlled trials (RCTs) including patients with either knee or multiple-site OA, the evidence level for the recommendations in patients with isolated hip OA has been considered to be low<sup>4-6</sup>. In a recent meta-analysis, in which the authors accessed hip joint specific data from RCTs evaluating the effect of exercise in patients with both hip and knee OA, it was concluded that exercise had a moderate effect on pain in patients with hip OA<sup>7</sup>. The authors also emphasized that as only one RCT exists that restricted recruitment to patients with hip OA, more RCTs evaluating the effect of exercise for this cohort are needed. Hence, the purpose of the present study was to compare the benefits of adding a supervised exercise program to a patient education program, on pain, physical function, health-related quality of life, and activity level in patients with isolated hip OA over a 16 month period.

## METHODS

## Participants

Patients aged between 40 and 80 years who had experienced hip pain for the past three months or longer were screened for inclusion. Inclusion criteria were a radiographically verified minimum joint space <4 mm for patients <70 years old and <3 mm for patients ≥70 years old<sup>8</sup>, and a Harris Hip Score (HHS)<sup>9</sup> between 60-95 points. Thus, the included patients had both radiographic and symptomatic hip OA. At our institution, a HHS below 60 points has been used as criteria for total hip replacement (THR) surgery. In cases with bilateral OA the most painful hip was chosen as the index joint. Patients were excluded if they had a THR in the index joint, had been diagnosed with knee OA, had knee pain, low back pain, rheumatoid arthritis, osteoporosis, cancer, cardiovascular disease and not tolerate exercise, dysfunction in lower extremities due to accident or disease, were pregnant, or did not understand Norwegian. The study was carried out according to the Helsinki Declaration and was approved by the regional medical research ethics committee. Written informed consents were obtained from all patients.

The patients were recruited by one university hospital, one local hospital, one rehabilitation center, general medical practitioners, and by advertisement in a local newspaper in Oslo, Norway. The inclusion was performed at the Department of Orthopedics at the Oslo University Hospital, by one orthopedic surgeon (LN) examining all radiographs<sup>8</sup>, and one physical therapist (LF) rating the patients' symptoms (HHS)<sup>9</sup>.

#### Interventions

The patients were randomized to either a group receiving patient education only (PE) or to a group that received patient education and supervised exercise (PE+SE) (Fig.1). Education was therefore

offered to all patients. The PE given was in the form of a previously described “Hip School” developed for patients with hip OA<sup>10</sup>. This comprised three group-based sessions and one individual physical therapy visit, two months after completing the group sessions. The SE given was a therapeutic exercise program specially designed for patients with hip OA<sup>11</sup>. The patients randomized to the PE+SE group started exercising within a week after completing the PE group sessions. The exercise program consisted of 26 different exercises, including warm-up, strengthening exercises, functional exercises and flexibility exercises<sup>11</sup>. The patients in the PE+SE group were offered individual supervision of the exercise program twice a week and had access to the gym any other week-day for a period of 12 weeks. They were instructed to perform the exercise program two to three times a week and were supervised during the exercise program at least once weekly. The supervision was performed by a physical therapist in order to individualize the exercise program to each patient’s ability. This included selecting exercises from the 26 predetermined exercises, and setting the training dose and progression accurately<sup>11</sup>. Both the education and the exercise program were conducted at our rehabilitation center (Hjelp24NIMI) in Oslo, Norway, and led by physical therapists specialized in orthopedic and/or sports physiotherapy.

#### Outcome measures

The primary outcome measure was the pain subscale of the Western Ontario and McMaster Universities Osteoarthritis Index with visual analogue scales (WOMAC pain). The WOMAC is a self-administered and disease-specific outcome specially designed for patients with hip or knee OA. A normalized subscale score was calculated for each dimension and expressed best to worst on a 0-100 scale<sup>12</sup>. Psychometric studies have shown moderate to high validity and reliability for the WOMAC<sup>13</sup>.

Secondary outcomes were the stiffness and physical function subscales of the Western Ontario and McMaster Universities Osteoarthritis Index with visual analogue scales (WOMAC stiffness and WOMAC physical function), the health related quality of life questionnaire SF-36v2 and the modified Norwegian version of Physical Activity Score for Elderly (PASE)<sup>16, 17</sup>. The SF-36 consists of eight multi-item scales; physical function, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. All items were normalized to a scale from worst (0) to best (100). The SF-36 has been found to be valid and have high reliability in patients with OA and rheumatoid arthritis<sup>15, 18</sup>. The PASE registers physical activities performed over the week preceding testing and the score is calculated from weight and frequency values for the activities. The modifications done for the Norwegian version of PASE consisted of both adapting the questionnaire to Norwegian conditions and excluding question number 1 and 2 from the original PASE, as the questions were considered redundant<sup>17</sup>. The modified Norwegian PASE ranges from 0-315, where "0" represents no activity at all during the past week and "315" represents an extremely active week. The PASE is considered reliable and valid for the registration of activities among older people<sup>19-21</sup>. The patients filled in the self-administered questionnaires at baseline, and at the 4, 10 and 16 month follow-ups.

#### Sample size calculation

Based on previous studies on patients with OA we postulated a mean difference of at least 15 mm on the of the WOMAC pain score between the treatment groups at follow-up and a standard deviation of 23<sup>22, 23</sup>. When comparing mean pain scores between the groups, a two-tailed student t-test with a 5% significance level was used<sup>24</sup>. In order to have 90% test-power at least 49 patients per group

needed to be included in our trial, however we decided to include at least 54 patients per group to allow a drop-out rate of 10%.

#### Randomization and blinding

A blocked randomization list with 10 patients in each block was computer generated by a statistician (LS) before the inclusion started. Blocking was used to ensure approximately equal group sizes. We maintained allocation concealment until written consent was obtained, baseline assessments were completed, and the patient had completed the PE group sessions. A research coordinator who was not involved in testing or interventions, opened sealed envelopes containing the randomization allocation and assigned subjects to the PE group or PE+SE group accordingly. The number on the envelope, containing group allocation, corresponded to the consecutive number of the patient. The researchers were blinded to group allocation throughout the whole trial and analysis period. No patient in the PE group had access to the SE program during the intervention period, and could subsequently not cross over to the PE+SE group during that period of time. Once the 4-month follow-up was completed, the patients were free to visit any physical therapy department or training center they wanted.

#### Statistical analyses

Intention to treat analyses were performed when comparing the PE group and the PE+SE group on efficacy variables for all participants enrolled in the study, regardless of adherence to the PE or the PE+SE<sup>25</sup>. A linear mixed model (variance component model) was used when comparing the groups on



efficacy variables with time and the interaction of time and group as fixed effects and time as random effect intercept and slope (SPSS 16.0, Chicago, IL). Model assumptions were checked by residual plots (normally distributed errors) and were found to be adequately fulfilled. Mean difference estimates (95% confidence interval) between groups at 4, 10, and 16 month follow-ups for the WOMAC sub-scores were extracted from the linear mixed model analysis and presented in a table. Median (inter-quartile range) was used for the description of adherence to the exercise program, and sub-group per-protocol analysis on the main outcome was performed using  $\geq 20$  sessions as cut-off for satisfied adherence. Comparisons at baseline were performed with independent samples t-test and chi-square test. A significance level of 5% was used. Standardized effect size, known as Cohen's *d*, was estimated for effect size measures for the pain and physical function subscales of the WOMAC<sup>26, 27</sup>. The effect sizes were calculated based on the collected data and for sensitivity analysis also based on the last observation carried forward principle. A negative effect size represented a value in favor of the PE+SE group, as compared to the PE group.

## RESULTS

Two-hundred and two patients were screened for inclusion during the period April 2005 to October 2007. Of these, 109 fulfilled the inclusion criteria and were randomized (Fig. 1). Recruitment channels of the included patients are presented in Table I. All included patients attended the three-session PE. The patients allocated to the PE+SE performed a median of 20 (inter-quartile range 16-24) sessions over the 12 week intervention period, with a mean of 1.6 exercise sessions per week. Three patients performed  $< 8$  exercises during 15% of their sessions. During all other sessions the patients in the PE+SE group performed  $\geq 8$  different exercises. One patient in the PE+SE group discontinued exercise after three sessions because of aggravation of hip pain. No other adverse events were registered. At

the 4, 10, and 16 month follow-up, drop-out rates were 0%, 22%, and 33% for the PE group and 0%, 15%, and 24% for the PE+SE group, respectively (Fig. 1). At 16 months, 11 patients (20%) in the PE group and six patients (11%) in the PE+SE group had undergone THR surgery, explaining 55% of the drop-outs. The patients who were lost to follow-up at 16 months had, at the last observation before drop-out, a mean(SD) WOMAC pain score of 39.4(23.5) and 35.2(20.1) mm in the PE and PE+SE group, respectively.

At baseline, all variables were similarly distributed with no significant differences between the treatment groups (Table I and III). At this time, the patients had significantly lower SF-36 physical function and bodily pain scores than an age matched general Norwegian population<sup>28</sup> (Table II). No significant differences in PASE scores were seen between the included patients and a representative elderly Norwegian population at baseline<sup>17</sup> (Table II).

Over the 16 month period, no significant difference between the PE group and the PE+SE group was found for the WOMAC pain score ( $p=0.15$ ) (Table III). The per-protocol analysis of WOMAC pain score could not detect any significant differences between the two groups over the 16 month period ( $p=0.30$ ). The standardized effect sizes (95% confidence interval) for WOMAC pain scores were -0.26 (-0.64 to 0.11), -0.35 (-0.77 to 0.07), and -0.30 (-0.75 to 0.15) at the 4, 10 and 16 month follow-ups, respectively. The standardized effect sizes (95% confidence interval) using the last observation carried forward principle were -0.33 (-0.71 to 0.05) and -0.31 (-0.69 to 0.07) for 10 and 16 months, respectively.

The PE+SE group improved significantly compared to the PE group in WOMAC physical function score over the 16 month follow-up period ( $p=0.011$ ) (Table III). Mean differences between the treatment groups at the follow-ups disclosed significant differences in favor of the PE+SE group at 10 and 16 months for WOMAC physical function score (Table IV). The standardized effect sizes (95% confidence interval) for WOMAC physical function scores were -0.29 (-0.67 to 0.09), -0.48 (-0.91 to -0.06), and -0.47 (-0.93 to -0.02) during the 4, 10 and 16 month follow-ups, respectively. The standardized effect sizes (95% confidence interval) using the last observation forward principle were -0.47 (-0.85 to -0.08) and -0.44 (-0.82 to -0.06) for 10 and 16 months, respectively. No significant differences between the groups were found for WOMAC stiffness scores, SF-36 subscales, or PASE over the 16 month follow-up period (Table III).

## DISCUSSION

No significant difference between the PE and the PE+SE group was found for the main outcome, the WOMAC pain score, over the 16 month follow-up period. The effect sizes of -0.29 to -0.35 for the WOMAC pain score in this study were not significant and were lower than previously reported. Hernandez-Molina et al., reported a significant effect size of -0.47 in patients with hip OA attending exercise programs<sup>7</sup>. The mean values for the WOMAC pain score in the PE and the PE+SE groups indicated a small reduction of pain from baseline to 10 and 16 months in both groups (Table III). However, no significant differences could be detected between groups over time. The lower mean scores of pain seen at 10 and 16 months might be a consequence of people requiring THR surgery dropped out from the study. Presumably, the 11 patients in the PE group and the six patients in the PE+SE group dropping out due to THR surgery experienced more hip pain and limitations in physical function at the time for surgery than at inclusion of the present study. The mean WOMAC pain score

for the drop-outs (at the last observation for the 31 patients) revealed a higher mean value than for patients still in the study. Accordingly, patients with severe symptoms requiring surgery between the 4 and 16 month follow-ups were not included in the analysis. The mean values for the 10 and 16 month follow-ups (Table III) represented patients with hip OA that were not eligible for surgery within a 16 month period. Thus, based on intention-to-treat, per-protocol, and effect size analyses, no significant differences in pain could be detected between the two interventions for patients with hip OA not requiring THR surgery. From a bio-psychosocial perspective, the experience of pain in patients with OA has been suggested to be a product of a complex interaction between internal traits and external influences affecting perception, beliefs and behavior<sup>29</sup>. For the management of OA, educational interventions containing information for the enhancement of coping strategy and self-efficacy have been recommended<sup>29</sup>. The PE program, offered to both treatment groups in our study, contained information with the purpose of increasing the patients' beliefs in their own ability to control their situation, and thereby potentially improve their coping strategy<sup>10</sup>. A follow-up study evaluating the same PE program that we have used in our study found a significant difference in pain scores between the group receiving PE and the control group<sup>10</sup>. Since our study did not contain a control group that did not receive education, it cannot be ascertained if the PE alone could reduce pain.

Whilst the improvement found for the WOMAC physical function score in the PE+SE group was significant, the clinical importance of this is uncertain. The minimal difference in WOMAC sub-scores thought necessary to achieve clinical significance for rehabilitation studies has been suggested to be 0.67-0.75 points (scale 0 to 10) for absolute values and 11-26% for relative values<sup>30, 31</sup>. In our study, WOMAC physical function score between group mean difference at 10 and 16 months were 8.4 and 7.7 mm (scale 0 to 100) and changes from baseline to 10 and 16 months were 25% and 28%, respectively (Table IV). A relationship has been found between baseline WOMAC physical function

scores and the perception of improvement in patients with knee OA, where a low score at baseline required a smaller improvement to be considered an improvement by the patient than would a high score at baseline<sup>32</sup>. When applying the differences reported by Tubach et al. to our study, the mean differences of absolute values of 8.4 and 7.7 mm between the groups at the 10 and 16 month follow-ups would be small but of clinical importance. A plausible explanation of low baseline values (mild to moderate symptoms) in our study could be the inclusion criteria of a HHS of 60-95 points, representing a patient group seeking primary health care<sup>33, 34</sup>. Twenty patients (18%) in our study scored  $\leq 10$  mm on WOMAC pain<sup>33</sup>, and 31 patients (28%) scored  $\leq 10$  mm on WOMAC physical function. However, the significant differences seen in WOMAC physical function score (Table III) were supported by significant and robust effect sizes for WOMAC physical function score at 10 and 16 months, respectively. The mean effect sizes found at 10 and 16 months are considered to be moderate<sup>35</sup>. But, the wide ranges of the 95% confidence intervals for the effect sizes imply a large inter-individual variance and the magnitude of improved physical function can range from small to large between individuals.

#### Strength and limitations

One strength of the present study was the design; the study was randomized and the outcome assessor was blinded. Moreover, we included patients solely with hip OA and used interventions specially designed for hip OA patients<sup>10, 11</sup>. The included patients had hip OA with mild to moderate symptoms which is a commonly seen patient group in primary health care<sup>33, 34</sup>, but this patient group in particular lacks evidence for treatment modalities<sup>5</sup>. Although the patients scored mild to moderate symptoms on the WOMAC, they sought medical care for their symptoms and at baseline they

differed significantly in SF-36 physical function and bodily pain to a general Norwegian population (Table II). In addition, a total of 17 patients (16%) had THR surgery within the 16 month period. Thus, indicating that the included patients were patients with manifested symptoms in need of efficient treatment modalities. Some limitations need to be addressed in our study. Firstly, OA has shown to be a disease with fluctuating pain<sup>36</sup> and the small mean changes observed in the study could be an effect of patients seeking care in a flare period and the results being a consequence of natural course or regression to the mean. Secondly, the observed results could be a consequence of patients changing their behavior when entering study, i.e. the Hawthorne effect. Thirdly, a common problem in long-term follow-up studies are increasing drop-out rates as time passes, which was particularly seen at the 16-month follow-up in our study (Fig. 1). The 16-month results must therefore be interpreted cautiously. We calculated the sample-size based on 90% power and a drop-out rate of 10%, but ended up with a higher drop-out rate than expected (28%). Knee pain or diagnosed knee OA were among the exclusion criteria for this study, which was the reason for excluding 16 of the initial 220 screened patients. The results must therefore be limited to patients with hip OA, but with no concomitant knee pain or knee OA.

The majority of studies evaluating exercise as treatment for patients with OA encounter difficulties in compliance with treatment. Over the 12 week exercise intervention in our study, the patients in the PE+SE group performed a median of 20 sessions, where 75% of the patients performed  $\geq 16$  sessions. Because of a wide variety in exercise prescription in both knee and hip OA studies, no recommendation on optimal dosage (intensity, frequency, duration) exists for patients with hip or knee OA<sup>31, 37</sup>. However, the general recommendation on the prescription of strength training is to perform 8-10 types of exercises twice a week<sup>38, 39</sup>. In our study, almost all patients in the PE+SE group performed a minimum of 8 different exercises per session, and performed a mean of 1.6 exercise sessions per week for 12 weeks. The duration of the exercise period and the amount of exercises

performed per session would be sufficient in terms of evaluating the potential effects of exercising<sup>39</sup>,<sup>40</sup>. The average of 1.6 exercise sessions performed per week, on the other hand, is less than recommended. One patient in the PE+SE group discontinued exercise because of pain, but no other adverse events occurred. The exercise program and its progression model<sup>11</sup>, may therefore be considered feasible for patients with hip OA with mild to moderate symptoms.

#### Comparison with other studies

The latest Cochrane review comparing land-based exercise with no exercise found five RCTs including patients with hip and knee OA, all with fewer than 50 participants per treatment allocation<sup>37</sup>. Fransen et al.<sup>37</sup> concluded that the meta-analysis results should be considered inconclusive because of small samples of the RCTs and heterogeneity both in outcome measures and content and duration of the interventions. The present study is the first to include patients with isolated hip OA and to follow-up more than 50 patients per treatment allocation for the evaluation of a land-based exercise program. Compared to effect sizes of -0.40 for pain and -0.37 for physical function from a meta-analysis evaluating exercise among patients with knee OA<sup>31</sup>, the effect sizes of -0.26 to -0.35 for pain and -0.29 to -0.48 for physical function in our study would be considered less for pain and similar for physical function. At baseline, the activity level measured with PASE did not show any differences between the patients with hip OA in our study and elderly Norwegians<sup>17</sup>, nor did the PASE scores show any significant differences over the follow-up period between the two treatment groups (Table II and III). Consequently, the observed significant results found for WOMAC physical function scores could not be explained by the patients' general activity level but they may possibly be an effect of the performance of specific exercises that stimulate muscles and joint motion needed for daily activities, such as stair walking, rising from a chair and putting on socks<sup>6, 41</sup>. The SE program focused on

strengthening of lower extremities with the goal of performing the exercises at an intensity level of 70-80 % of maximum<sup>11</sup>. The patients performing this exercise program may therefore have increased their lower extremity strength, which is a possible explanation for their improvement in physical function.

The present study is the first to evaluate a supervised exercise program in addition to patient education versus patient education alone in patients with isolated hip OA. For the reduction of pain, the combination of patient education and supervised exercise showed no differences compared to attending patient education only. However, adding supervised exercise to patient education may be useful in improving physical function.



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**Author contributions:** LF contributed to the study design, data collection, analysis and interpretation, drafting and revising of the manuscript. KS and MAR contributed to the concept, study design, data interpretation, and critical revising of the manuscript. LS contributed to data analysis and interpretation, statistical expertise and critical revising of the manuscript. LN contributed to study design, provision of patients, data collection, data interpretation, and critical revising of the manuscript. All authors approved of the final version of the manuscript.

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**Competing interests:** None

**Ethical approval:** The study was carried out according to the Helsinki Declaration and was approved by the regional medical research ethics committee.

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Fig. 1. Study flow diagram of participants enrolled in the study. THR=Total hip replacement; HHS=Harris Hip Score; PE=Patient Education; SE=Supervised Exercise.

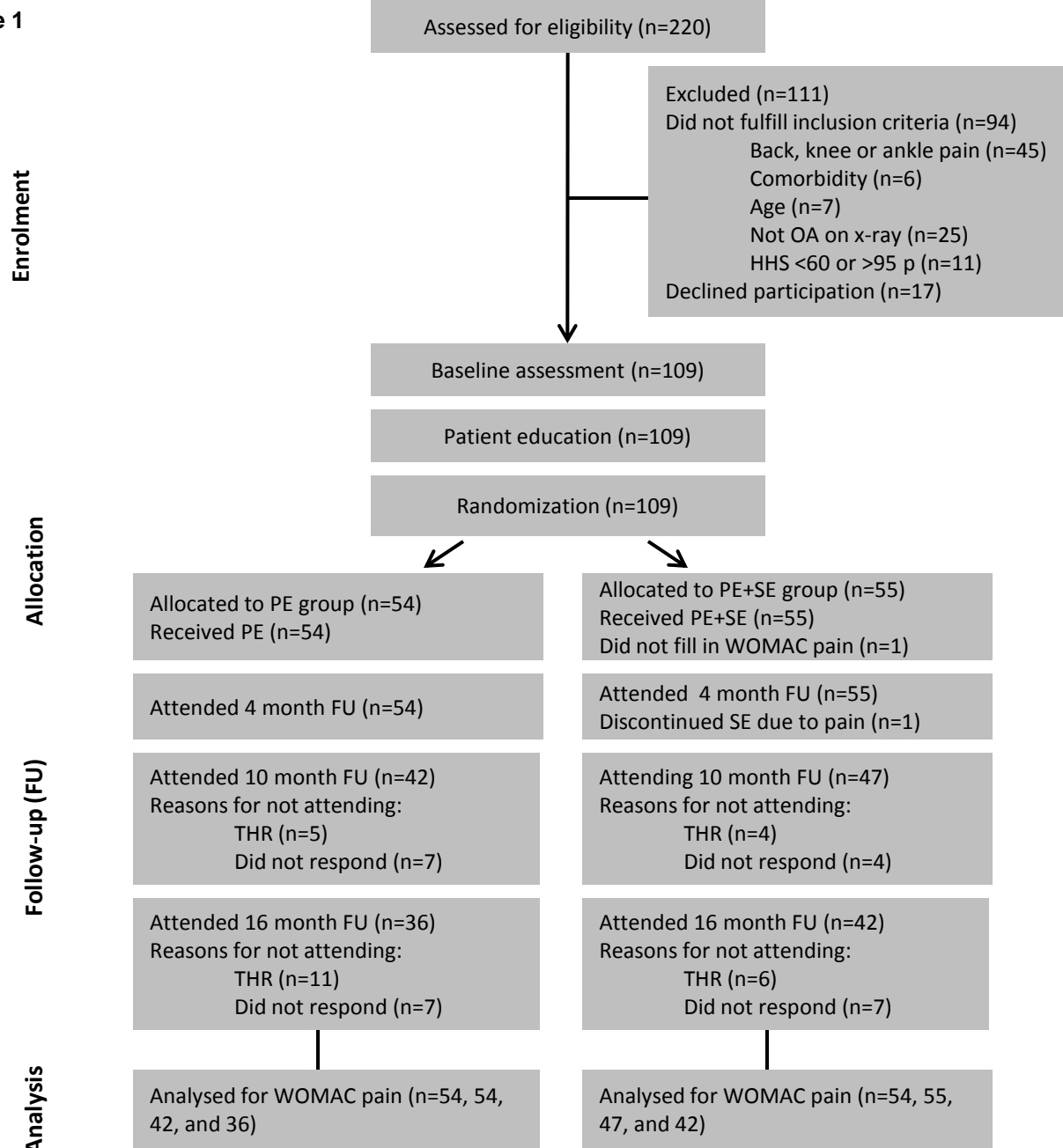
**Figure 1**

Table I

Baseline characteristics ACCEPTED MANUSCRIPT

(mean $\pm$ SD)	PE (n=54)	PE+SE (n=55)
Age (years)	57.2 $\pm$ 9.8	58.4 $\pm$ 10.0
Men/Women	26/28	24/31
BMI (kg/m <sup>2</sup> )	24.9 $\pm$ 3.8	24.6 $\pm$ 3.2
MJS in target joint (mm)	1.9 $\pm$ 1.1	2.1 $\pm$ 1.0
Harris Hip Score (0-100)	76.9 $\pm$ 8.2	79.6 $\pm$ 7.7
Pain duration (months)	49.5 $\pm$ 50.9	47.3 $\pm$ 53.3
Uni-/bilateral JSN number (%)	16/38	17/38
THR in contralateral hip	2 (3.7)	4 (7.3)
>12 years education	35 (67.3)	43 (78.2)
Employed	36 (66.7)	35 (63.6)
Retired	9 (16.7)	11 (20.0)
Sick-leave	5 (9.3)	8 (14.5)
NSAIDs	9 (16.7)	13 (23.6)
Paracetamol	5 (9.3)	4 (7.2)
Glucosamine	19 (35.2)	13 (23.6)
Other medication	14 (25.9)	10 (18.2)
Recruitment:		
Hospitals	12 (22.2)	4 (7.3)
Primary care	24 (44.4)	31 (56.4)
Advertisement	7 (13.0)	7 (12.7)
Patients' friends	3 (5.6)	5 (9.1)
No data on recruitment	8 (14.8)	8 (14.5)

Table II				
<i>Baseline scores for SF-36 and PASE of included patients and Norwegian population<sup>17,28</sup></i>				
(mean ± SD)	Patients with hip OA		General Norwegian population <sup>28</sup>	
	Men (n=50)	Women (n=59)	Men (n=175)	Women (n=174)
<b>SF-36 (0-100)</b>				
Physical function	71.9 ± 16.1	70.7 ± 19.1	87.2 ± 17.4**	85.6 ± 16.6**
Role physical	80.7 ± 23.6	74.6 ± 25.7	78.0 ± 35.9	77.6 ± 36.2
Bodily pain	63.3 ± 18.8	57.4 ± 16.4	73.2 ± 25.5*	73.8 ± 27.1**
General health	71.3 ± 16.9	67.2 ± 21.8	74.1 ± 22.5	74.7 ± 22.4*
Vitality	62.4 ± 20.3	54.6 ± 19.7	62.4 ± 21.6	62.0 ± 21.0*
Social functioning	91.2 ± 18.4	84.8 ± 22.7	86.5 ± 24.1	86.0 ± 21.3
Role emotional	94.6 ± 14.0	91.5 ± 18.2	87.5 ± 27.9	84.3 ± 30.9
Mental health	83.2 ± 13.8	81.0 ± 14.5	79.7 ± 16.0	79.5 ± 17.3
Included patients with hip OA Men and women (n=107)			Elderly Norwegian population <sup>17</sup> Men and women (n=343)	
<b>PASE (0-315)</b>	118.5 ± 47.2		126.9 ± 73.0	

Analysis took into account independent samples t-test. \*significant level <0.05. \*\*significant level <0.001.



(mean $\pm$ SD)	PE group								PE+SE group								p-value
	n	Baseline	n	4 months	n	10 months	n	16 months	n	Baseline	n	4 months	n	10 months	n	16 months	
WOMAC																	
Pain	54	27.3 $\pm$ 17.9	54	25.3 $\pm$ 18.5	42	23.4 $\pm$ 19.6	36	22.3 $\pm$ 18.4	54	26.0 $\pm$ 16.1	55	20.6 $\pm$ 17.2	47	16.8 $\pm$ 17.7	42	17.3 $\pm$ 14.5	0.150
Stiffness	54	34.3 $\pm$ 20.5	54	32.4 $\pm$ 22.5	42	32.0 $\pm$ 22.2	36	35.5 $\pm$ 26.9	54	34.8 $\pm$ 23.7	55	28.9 $\pm$ 22.4	46	25.7 $\pm$ 20.9	42	24.4 $\pm$ 21.4	0.133
Physical function	54	23.6 $\pm$ 15.7	54	22.5 $\pm$ 17.0	42	24.2 $\pm$ 18.4	36	22.8 $\pm$ 18.6	54	21.1 $\pm$ 15.3	55	17.9 $\pm$ 14.3	47	15.8 $\pm$ 15.9	41	15.1 $\pm$ 13.7	0.011
SF-36																	
Physical function	54	71.6 $\pm$ 17.1	52	69.8 $\pm$ 20.1	43	72.9 $\pm$ 22.3	35	71.3 $\pm$ 20.8	51	70.9 $\pm$ 18.5	55	76.1 $\pm$ 18.4	49	77.2 $\pm$ 19.0	40	75.5 $\pm$ 20.5	0.307
Role physical	54	74.3 $\pm$ 26.3	53	74.9 $\pm$ 24.8	44	74.7 $\pm$ 26.2	37	75.7 $\pm$ 29.0	54	80.4 $\pm$ 23.2	55	81.5 $\pm$ 24.4	48	83.2 $\pm$ 20.0	41	82.3 $\pm$ 25.5	0.110
Bodily pain	50	57.4 $\pm$ 19.1	48	59.3 $\pm$ 20.3	44	60.8 $\pm$ 21.5	37	61.4 $\pm$ 24.3	52	62.8 $\pm$ 16.0	53	68.6 $\pm$ 19.3	49	68.9 $\pm$ 18.2	41	70.5 $\pm$ 18.6	0.056
General health	53	68.5 $\pm$ 17.7	53	69.4 $\pm$ 17.4	44	70.0 $\pm$ 19.2	36	67.6 $\pm$ 22.1	53	69.5 $\pm$ 21.8	54	68.1 $\pm$ 18.2	47	69.6 $\pm$ 19.1	38	71.3 $\pm$ 20.7	0.927
Vitality	53	58.3 $\pm$ 20.4	52	59.6 $\pm$ 22.3	44	60.5 $\pm$ 20.9	37	61.7 $\pm$ 20.6	55	58.0 $\pm$ 20.3	53	57.3 $\pm$ 20.3	48	63.4 $\pm$ 17.4	41	59.0 $\pm$ 21.0	0.889
Social function	48	85.9 $\pm$ 23.4	48	88.8 $\pm$ 19.0	44	85.2 $\pm$ 23.4	37	84.1 $\pm$ 26.9	54	89.4 $\pm$ 18.6	53	90.3 $\pm$ 17.3	49	92.7 $\pm$ 12.5	41	91.2 $\pm$ 15.9	0.150
Role emotional	53	91.5 $\pm$ 19.3	53	91.5 $\pm$ 17.0	43	93.6 $\pm$ 12.3	37	90.5 $\pm$ 21.7	53	94.3 $\pm$ 13.1	55	89.1 $\pm$ 21.3	49	92.7 $\pm$ 13.1	41	90.7 $\pm$ 15.5	0.854
Mental health	53	82.2 $\pm$ 13.1	53	82.7 $\pm$ 13.5	44	81.9 $\pm$ 16.7	37	82.8 $\pm$ 15.4	52	81.8 $\pm$ 15.4	55	82.3 $\pm$ 15.2	49	84.8 $\pm$ 13.5	40	81.8 $\pm$ 14.9	0.905
PASE	54	123.1 $\pm$ 50.6	54	121.3 $\pm$ 45.4	45	125.6 $\pm$ 48.3	36	133.3 $\pm$ 57.3	53	113.8 $\pm$ 43.5	53	114.9 $\pm$ 52.9	47	118.2 $\pm$ 48.6	41	123.1 $\pm$ 50.7	0.607

Analysis took into account linear mixed model (variance component model) with time and time\*group as fixed effects, and time as random effect intercept and slope.

Table IV

Mean difference (95% confidence interval) between PE and PE+SE groups at 4, 10 and 16 months

WOMAC	4 months	10 months	16 months
Pain	-4.7 (-11.3, 1.9)	-6.5 (-13.9, 0.7)	-4.9 (-12.8, 2.9)
Stiffness	-3.5 (-12.0, 4.9)	-6.3 (-15.8, 3.1)	-11.1 (-21.1, -1.0)*
Physical function	-4.6 (-10.6, 1.5)	-8.4 (-15.1, -1.7)*	-7.7 (-14.9, -0.5)*

Linear mixed model (variance component model) with time and time\*group as fixed effects, and time as random effect intercept and slope. \*Significance level  $p < 0.05$ .