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Effect of early supervised progressive resistance training compared to unsupervised home-based exercise after fast-track total hip replacement applied to patients with preoperative functional limitations. A single-blinded randomised controlled trial

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SUMMARY

Objective: To examine if 2 weekly sessions of supervised progressive resistance training (PRT) in combination with 5 weekly sessions of unsupervised home-based exercise is more effective than 7 weekly sessions of unsupervised home-based exercise in improving leg-extension power of the operated leg 10 weeks after total hip replacement (THR) in patients with lower pre-operative function.
Method: A total of 73 patients scheduled for THR were randomised (1:1) to intervention group (IG, home based exercise 5 days/week and PRT 2 days/week) or control group (CG, home based exercise 7 days/week). The primary endpoint was change in leg extension power at 10 week follow up. Secondary outcomes were isometric hip muscle strength, sit-to-stand test, stair climb test, 20 m walking speed and patient-reported outcome (HOOS).
Results: Sixty-two completed the trial (85%). Leg extension power increased from baseline to the 10 week follow up in both groups; mean [95% CI] IG: 0.29 [0.13; 0.45] and CG: 0.26 [0.10; 0.42] W/kg, with no between-group difference (primary outcome) ($P = 0.79$). Maximal walking speed ($P = 0.008$) and stair climb performance ($P = 0.04$) improved more in the IG compared to CG, no other between-group differences existed.
Conclusions: In this trial, supervised PRT twice a week in addition to 5 weekly sessions of unsupervised exercise for 10 weeks was not superior to 7 weekly sessions of unsupervised home-based exercise for 10 weeks in improving the primary outcome, leg-extension power of the operated leg, at the primary endpoint 10 weeks after surgery in THR patients with lower pre-operative function.
Trial registration: NCT01214954.

Introduction

Loss of muscle strength and functional performance as well as long term postoperative deficits has been reported after total hip replacement (THR)[1–9]. These deficits include reduced; muscle strength[1,2], walking symmetry[6,8,10], patient-reported outcomes[4,5,9] and functional performance such as walking speed and chair rise performance[3,4]. No clear evidence exists on how to reduce these deficits[11], and rehabilitation strategies after THR are often experience-based[11,12]. Given the immediate loss of muscle strength[7,13–15]

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and muscle mass post-surgery[14,16],progressive resistance training (PRT) has been advocated to be initiated shortly following surgery[2,6,7,10,17]. Studies indicate that PRT can be initiated early after THR, and that it seems to be more effective in improving muscle strength compared to less intensive training interventions[14,18]. However, these studies[14,18] have had small sample sizes (11 and 12 in the PRT group, respectively) and include few exercises (knee extension[14], leg press[14,18] and hip abduction[18]). Since loss of muscle strength has been reported for the hip flexor and extensor muscles[1,2,7,13,19] PRT should likely address these muscle groups in addition. Muscle impairment measured as leg extension power is closely related to functional performance in elderly with functional limitations and among total knee replacement patients[20,21]. Because THR patients with low levels of perceived function pre-operatively achieve inferior levels of perceived function post-operatively, it has been suggested to target supervised rehabilitation to this subgroup of patients[22,23].

Consequently, the objective of this trial was to examine if 2 weekly sessions of supervised PRT in combination with 5 weekly sessions of unsupervised home-based exercise is more effective than 7 weekly sessions of unsupervised home-based exercise in improving leg-extension power of the operated leg 10 weeks after THR in patients with lower pre-operative function.

Methods

The study is an assessor-blinded randomised controlled trial, with 1:1 allocation ratio.

Participants

Eligible patients attending the Elective Surgery Centre, Silkeborg Regional Hospital, Denmark were consecutively included in the study. Inclusion criteria were: Primary unilateral THR for hip osteoarthrosis (OA), preoperative HOOS ADL $\leq$ 67, age > 18 years, residence within 30 km from the hospital and willing to participate in training twice a week for 10 weeks. The cut off level on The hip dysfunction and osteoarthritis outcome score questionnaire (HOOS 2.0) ADL score (described in Method section) was specified according to the seventy fifth percentile in a previous study[15]. The rationale for choosing this cut-off was a settlement between including the most disabled patients while maintaining a feasible patient inclusion. Exclusion criteria were: Resurfacing hip implant, body mass index (BMI) >35, pre-planned supervised rehabilitation, pre-planned contralateral THR within 6 months, inability to speak or read Danish and mental or physical conditions impeding the intervention. Eligible patients were informed about the study during preoperative ambulant visit at the hospital and a minimum of 2 days of consideration time was offered. Written informed consent was obtained and ethical approval was obtained from the Central Denmark Region Committee on Biomedical Research Ethics (VEK M-20090231). The study was approved by the Data Protection Agency (Journal number: 2010-41-4907) and pre-registered at ClinicalTrials.gov (NCT01214954).

Randomisation

Block randomisation was performed using random block sizes of four or six patients. Stratification for contralateral THR was performed to ensure an equal distribution between the groups. Sequence in permuted blocks with equal numbers of “intervention” and “control” assignments was obtained using a simple “shuffling envelope” procedure before study initiation by a secretary not involved in the study. During admission, staff and patients were blinded to randomisation. Shortly before discharge a project nurse obtained the sequentially numbered, opaque, sealed envelope containing the patient's assigned intervention and informed the patients about group assignment.

Standard peri-operative care

All patients followed a multimodal fast-track surgical program for THR including: patient information, spinal anesthesia, optimized multimodal pain management, enforced mobilization and nutrition. All patients were prior to surgery thoroughly informed about the expected course of their operation and rehabilitation, and encouraged to take active part in the treatment and rehabilitation. On surgery day patients were admitted to hospital and the surgery was performed by one of seven experienced orthopaedic surgeons using the posterior approach[24]. Patients were subsequently discharged to their home when meeting pre-defined functional discharge criteria; independency in gait, transfer, personal care and home-based exercise and sufficient pain treatment – typically on the second postoperative day (Table II). During admission, physiotherapy was provided daily aiming at achievement of the discharge criteria. After discharge two outpatient visits with the physiotherapist was offered to all patients (four and 10 weeks after surgery).

Rehabilitation interventions

PRT

The PRT was initiated within the first week after surgery and performed twice a week for 10 weeks in the intervention group (IG). The training duration was established by balancing feasibility and effect. The PRT sessions were conducted in a public fitness centre near the hospital with one-to-one supervision by physiotherapists from the hospital sub-specialized in PRT. Patients warmed up on a stationary bike for 5–10 min and then performed unilateral PRT of the operated leg for 30–40 min. Resistance exercises consisted of hip extension, knee extension (replaced by leg press at week six), hip flexion and hip abduction in strength training machines (Technogym, Pedan A/S, DK). The relative load increased during the 10 weeks, (10–12 repetition maximum (RM) to 8 RM). The absolute training load (kilogrammes lifted) was adjusted on a set-by-set basis for all exercises, using contraction to failure in every set. The PRT training modality is documented in Table I, using the strength training descriptors suggested by Toigo and Boutellier.[25]

Home-based exercise

The standardised exercise program consisted of unloaded exercises in the movement directions: hip flexion, -extension, -abduction and knee flexion/extension. Patients were

Table I
Strength training descriptors of the exercises performed in the intervention group

Load	12 RM (week 1), 10 RM (week 2–5), 8 RM (week 6–10)
Repetitions	10–12 (week 1), 10 (week 2–5), 8 (week 6–10)
Set per session	3 sets
Rest between sets	60 s
Sessions per week	2 per week
Duration of training period	10 weeks
Contraction modes	3 s concentric, 1 s isometric, 3 s eccentric
Rest between repetitions	0 s
Time under tension	210 s/exercise/session
Contraction failure in each set	Yes
Range of motion	Maximum possible
Rest between training sessions	$\geq$48 h
Anatomical definition of the exercises	Yes

Table II
Baseline characteristics of patients allocated to intervention or control group

	Intervention ($n = 32$)	Control ($n = 30$)
Female gender, *n* (%)	14 (44)	12 (40)
Age, mean (SD)	64.8 (8)	65.1 (10)
BMI, kg/m^2, mean (SD)	27.5 (4)	25.4 (4)
Physical status* (2 missings)		
ASA I	15 (47)	15 (50)
ASA II	15 (47)	14 (47)
ASA III	1 (3)	0 (0)
Prosthesis type		
Cementless	29 (91)	28 (93)
Cemented/Hybrid	3 (9)	2 (7)
Contralateral hip		
Hip Replacement	8 (25)	7 (23)
Osteoarthritis	5 (16)	4 (13)
Postoperative days in hospital		
1 day	22 (69)	20 (67)
2 days	10 (31)	7 (23)
≥3 days	0	3 (10)

* American Society of Anesthesiologists physical status classification: I-Healthy patient, II-Patient with mild systemic disease, III-Patient with severe systemic disease.

recommended to perform one set of 10 repetitions twice a day in their maximum possible range of motion. The control group (CG) was recommended to perform the exercises 7 days a week and the IG was recommended to perform the same exercises 5 days a week and omit these exercises on the days with PRT. All patients were encouraged to supplement the hip exercises with aerobic training on a stationary bike and by walking. At the outpatient visit 4 week postoperative, the physiotherapist introduced the patients to perform the exercises with a sports rubber band to increase the relative load in the movement directions described above. Furthermore, exercises were individually adjusted if needed, for example if a flexion contracture was identified, then muscle stretching was prescribed. At the 10 week follow up visit patients in both groups were encouraged to continue their home-based training and gradually return to their usual activities. The rehabilitation in the CG reflected standard care at the hospital.

Outcome measures

Three physiotherapists collected all data (tests and questionnaires) at the hospital. Blinding of assessors was accomplished by randomising late during hospital stay, performing the PRT in other facilities than the tests and requesting the patients not to mention their group assignment to the assessors. These physiotherapists were trained and calibrated before study initiation. All outcome measurements were performed at baseline, typically 1–2 weeks prior to surgery, after the intervention period to investigate immediate effects (primary endpoint), and after 6 months to evaluate follow-up effects. Furthermore, the least demanding physical tests (isometric muscle strength and gait speed, see description below) were performed 4 weeks postoperative in order to evaluate early changes in physical performance. The methods used in the physical tests have acceptable relative and absolute inter-rater reliability (ICC > 0.8 and SEM < 10%)[26].

Primary outcome measure

The primary outcome was defined as the change in leg extension power from baseline to 10 week follow up in the unit W/kg body mass. Leg extension power was chosen as the primary outcome to capture changes in muscle performance relevant for functional performance, because it is highly correlated with functional performance, mobility and risk of falling[20,21,27,28]. Shortly after knee replacement surgery significant correlations to walking speed and chair rise performance have been reported: rho = 0.82, $P < 0.001$ and 0.74, $P < 0.001$[20]. The Nottingham Power Rig (University of Nottingham Mechanical Engineering Unit, UK) was used to measure leg extension power expressed as the product of force and velocity in a single-leg simultaneous hip and knee extension[29,30]. Subjects seated in the rig with arms folded gave maximal push against a footplate attached to a flywheel. Power output was derived from the acceleration of the flywheel and was recorded in Watts. This measurement has previously been used to assess muscle power in hip OA patients[31] and after total hip and knee replacement[20,32,33]. A sound file with the verbal command was used to avoid voice and accentuation affecting the test performance. The test was repeated with 30 s rest between trials until a plateau was reached, defined as two successive measurements below the highest. A minimum of six trials to minimize learning effect, and a maximum of 12 trials to minimize fatigue were obtained and the highest measurement in watt was normalized for body weight in kg and used as the data point. The inter-tester reliability of this measurement procedure is acceptable with ICC = 0.91 (95% CI: 0.83; 0.99) and measurement error (SEM) of 10 % (corresponding to 12.4 W)[26].

Secondary outcome measures

Maximum walking speed was measured with the 20-m walk test, which is a part of the Osteoarthritis Initiative[34], and used in recent studies on patients with hip and knee OA[33,35].

Chair rise performance was measured with the 30-s sit-to-stand test which is widely used as a functional performance measure in patients with OA and after total joint replacement[20,32,36–38].

Stair-climb performance is suggested and used when measuring functional performance in hip OA patients[39,40] and after THR[14,41,42]. Participants ascended two sections of nine steps (16.5 cm high) as fast as possible without using the handrail.

Hand-held dynamometer (HHD) testing of lower extremity muscle strength is suggested as a valid measurement for evaluating orthopaedic patients[43] and has been applied in OA patients[44] and after total joint replacement surgery[15,20]. Isometric strength in hip abduction and flexion was tested with the HHD Power Track II Commander (JTECH Medical, Salt Lake City, UT, USA). Standardised test procedures as described by Thorborg *et al.*[45] were used. Additionally, we used a sound file with the verbal command to avoid that the voice and the accentuation of the tester would affect the test performance. The measurement in Newton was normalized for leg length and body weight and used as the data point.

HOOS 2.0[46] was used to measure patient reported outcome in the following subscales; Symptoms, pain, activities of daily living (ADL), function in sport and recreation and hip related quality of life (QOL). HOOS is valid and reliable when evaluating patients undergoing THR[46]. Scores range from 0 to 100, where 100 represent the best possible score. HOOS was administered at two-, four-, six- and 10 weeks and at six- and 12 months. The subscale function in sport and recreation was not considered relevant at the earliest three measurements times after THR.

Deviations from the approved protocol and trial registration

Gait symmetry assessed by instrumented gait analysis was listed in the trial registration. These data have been collected in a subsample of patients in both treatment arms as an embedded mechanistic study, and will be reported later. Hip pain (0–100 mm VAS) and training load (kilogrammes lifted) has been recorded for all strength training exercises at every training session for the first 4 weeks in the IG only, but was not listed in the trial registration. These data were collected to indicate symptom exacerbation in the first weeks of PRT – which was not the case – and will be reported in detail later.

Sample size

Sample size calculation was based on earlier obtained leg extension power data from patients 3 months after THR (mean ± sd: 1.78 ± 0.49 Watt/kg). The expected difference in effect between intervention and CG was defined as 20% as suggested by Cochrane Musculoskeletal Group[47]. With a significance level of 0.05 and a power of 80%, the required sample size was 60. Based on an expected 15–20% drop out; 73 patients were included.

Statistical analysis

Normally distributed data are described by means and standard deviation (SD), and data not normally distributed by medians and interquartile range (IQR). The primary analysis used intention-to-treat principle including all randomised participants on the primary outcome; leg extension power. Data were analysed by a mixed model with a random person level and systematic effects of time, group and the interaction between time and group. The remaining group comparisons were extended per-protocol analysis using non-missing values only (no imputations). Patients who discontinued the intervention were encouraged to participate in the follow up test anyway, and those who accepted were included in the analyses according to their original group assignment (see Fig. 1). Groups were compared regarding changes over time using multivariate repeated measurement ANOVA with group and time as factors. The assumption of homogeneity in SDs and correlations was tested, and approximate test allowing for heterogeneity was used when appropriate. For model validation, histograms and probability plots of the data distribution at each measurement time and differences in each group were inspected and approved. The within-group changes between baseline and 10 week follow up were tested using Student's *t*-test (one-sample). Data were double entered and validated in EpiData 3.1 (Epidata association, Odense, Denmark). The statistical analyses were performed using STATA 12.1 (StataCorp, College Station, TX) software package. The significance level was set at 0.05.

Results

In the period September 2010 to November 2012, eligible patients were consecutively enrolled in the study. The participant flow is shown in Fig. 1. In total, 73 patients were randomised to either IG ($n = 36$) or CG ($n = 37$). After randomisation, two patients

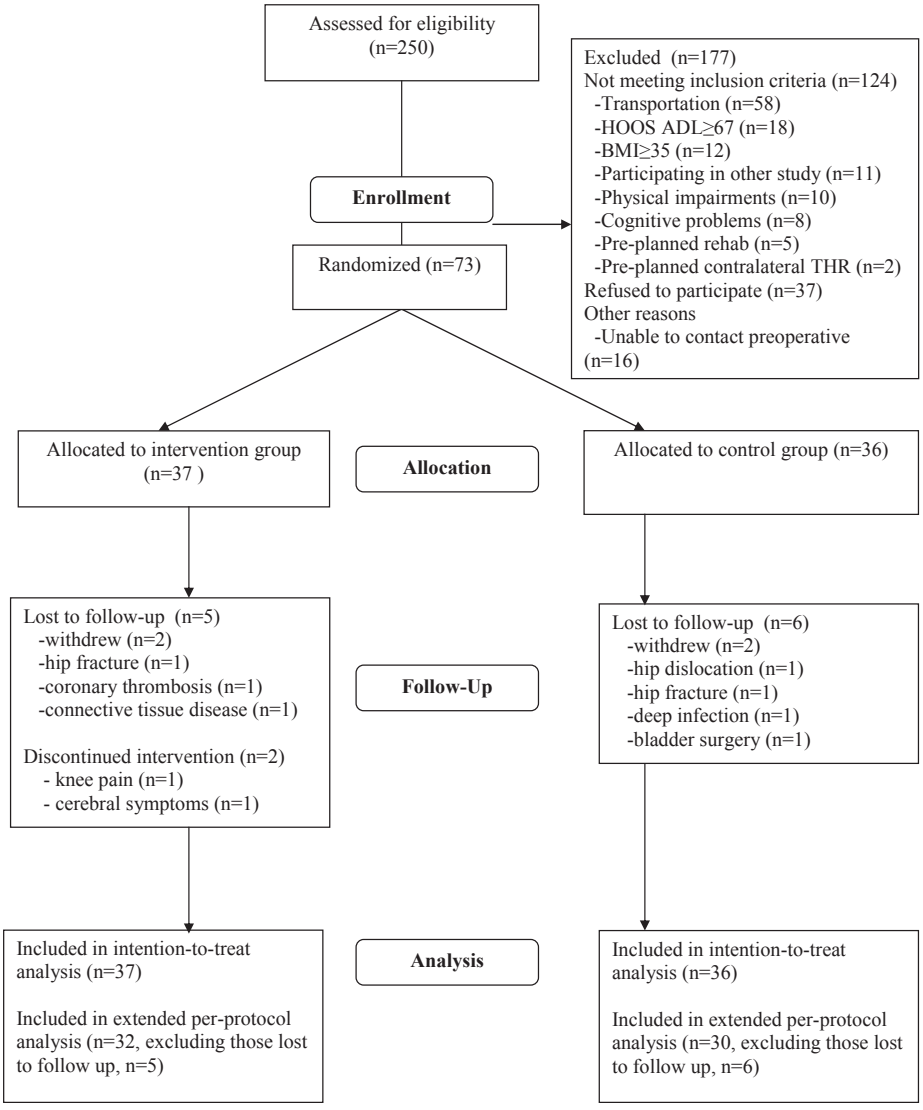

Fig. 1. Participant flow throughout the study.

in each group withdrew consent, and seven were excluded due to major events such as hip fracture. None of these events were associated with the rehabilitation (Fig. 1).

The baseline characteristics were comparable in the two groups, however three patients in the CG were hospitalized 3 days or more and none in the IG (Table II). In eight cases (=13%) the assessor-blinding failed, due to the patient revealing their group assignment during test.

Primary outcome measure

The intention-to-treat analysis on the primary outcome showed no statistically significant between-group difference at 10 week follow when adjusting for the baseline value ($P = 0.79$, Table III). In both groups, statistically significant increases in leg extension power were achieved: mean [95% CI] IG: 0.29 [0.13; 0.45] and CG: 0.26 [0.10; 0.42] W/kg, corresponding to relative improvements of 21% and 17%, respectively.

Secondary outcome measures

For the secondary outcomes, there were statistically significant effect of group over time in maximal walking speed ($P = 0.008$) and stair climb performance ($P = 0.04$) in favour of the IG, and no difference in the remaining outcomes (Table III). The relative improvements in the IG at 10 week follow up reached 18–26% in isometric muscle strength and 21–26% in the functional performance tests. The corresponding improvements in the CG were 4–12% and 11–20%. The scores on the HOOS subscales at each measurement time are presented in Table IV. There was no significant difference between groups over time in any of the subscales (P-value range: 0.31–0.90). Ceiling effect, defined as score = 100 in ≥20% of patients, was present in the pain subscale at 10 week follow up and in the other subscales at 6 month follow up, except from the subscale sport/recreation where ceiling effects appeared only at 1 year follow up. All secondary outcomes improved significantly from baseline to 10 week follow up in both groups except for hip flexion strength in the CG (Tables III and IV).

Table IV
Results from the questionnaire: Hip osteoarthritis outcome scale (HOOS) in the IG, ($n = 32$) and CG, ($n = 30$). Values are mean (SD)

Measurement time		HOOS subscale				
		Symptoms	Pain	ADL	Sport/rec	QOL
Baseline	**IG**	43.0 (13)	46.3 (8)[1]	49.6 (10)	29.5 (16)	32.6 (13)
	CG	43.7 (15)	48.1 (17)	49.9 (17)	32.8 (21)	37.5 (16)
2 week	**IG**	62.9 (16)[4]	68.2 (15)[4]	63.8 (11)[4]		51.8 (16)[4]
	CG	64.6 (16)[2]	67.7 (15)[2]	65.8 (16)[3]	Not	55.1 (16)[3]
4 week	**IG**	72.8 (12)	74.9 (13)	74.9 (11)	measured	61.9 (16)[1]
	CG	73.3 (16)	78.8 (15)[1]	76.5 (14)		62.3 (18)[1]
6 week	**IG**	76.2 (14)[2]	82.5 (15)[2]	81.1 (13)[2]	62.6 (25)[3]	67.6 (21)[3]
	CG	74.6 (17)[5]	81.9 (15)[5]	82.0 (14)[5]	69.5 (24)[5]	69.5 (21)[5]
10 week	**IG**	82.9 (12)[1]*	88.7 (12)[1]*	89.1 (10)[1]*	77.0 (18)[1]*	79.0 (16)[1]*
	CG	80.3 (17)*	86.3 (16)[1]*	86.5 (13)*	74.4 (21)[1]*	75.6 (20)[1]*
6 month	**IG**	85.0 (15)	91.7 (10)[1]	90.4 (11)	80.1 (17)	83.8 (18)
	CG	86.2 (13)	91.4 (13)[1]	91.7 (10)	83.7 (17)	86.7 (17)
12 month	**IG**	90.7 (11)[1]	94.0 (8)[1]	93.4 (8)[1]	81.9 (20)[1]	86.7 (16)[1]
	CG	90.0 (14)	92.2 (14)	92.1 (12)	82.8 (19)	86.0 (20)
***P* value**†		0.90††	0.31††	0.82††	0.39	0.47††

Subscale abbreviation: Sport/rec: Function in sport/recreation.
Superscript numbers indicate the number of missing values.
* Significant within group difference from baseline to 10 week follow up ($P < 0.05$).
† Multivariate repeated measurement analysis, testing the difference between groups over time.
†† Approximate test, allowing for heterogeneity.

Training compliance

The patients in the IG attended a median of 19 PRT sessions (IQR: 18; 20). The resistance training was initiated median 5 (IQR: 5; 6) days after surgery, postponed initiation was due to readmission for blood transfusion ($n = 1$), wound oozing ($n = 1$) and lack of energy ($n = 1$). Home-based exercise was self-reportedly performed median 5 (IQR:4–7) days a week in the IG as prescribed and 6 (range: 4–7) days a week in the CG, where 7 days a week was prescribed.

Table III
Results from the physical outcome measures in the IG and CG at all measurement times. Values are mean (SD), change scores are mean [95% CI]

Primary outcome	Baseline		10 week		6 month		Change baseline-10 week		Difference	*P*-value
	IG	CG	IG	CG	IG	CG	IG	CG		
Leg extension power (W/kg)†										
Intention-to-treat analysis (IG: $n = 37$, CG: $n = 36$)	1.41 (0.6)	1.50 (0.7)	1.72 (0.6)*	1.78 (0.6)*	2.04 (0.7)	1.97 (0.6)	0.29 [0.13; 0.45]	0.26 [0.10; 0.42]	0.03 [−0.20; 0.26]	0.79††
Extended per-protocol analysis (IG: $n = 32$, CG: $n = 30$)	1.44 (0.6)	1.55 (0.7)	1.72 (0.6)*	1.78 (0.6)*	2.04 (0.7)	1.97 (0.6)	0.28 [0.12; 0.44]	0.25 [0.02; 0.48]	0.03 [−0.24; 0.31]	0.23§

Secondary outcomes (IG: $n = 32$, CG: $n = 30$)	Baseline		4 week		10 week		6 month		Change baseline-10 week		*P*-value§
	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	
Maximum walking speed (seconds)	14.02 (4.8)	13.57 (3.5)	13.85 (3.7)	13.72 (3.0)	11.08 (2.4)*	11.99 (2.6)*	10.81 (2.8)	11.02 (2.6)	2.94 [1.8; 4.1]	1.58 [0.7; 2.4]	0.008‖
Hip abduction strength (Nm/kg)	0.82 (0.3)	0.92 (0.4)	0.87 (0.3)	0.90 (0.3)	1.03 (0.3)*	1.03 (0.3)*	1.08 (0.3)	1.15 (0.3)	0.21 [0.1; 0.3]	0.11 [0.0; 0.2]	0.26‖
Hip flexion strength (Nm/kg)	1.07 (0.3)	1.27 (0.4)	1.11 (0.3)	1.21 (0.3)	1.25 (0.3)*	1.32 (0.4)	1.33 (0.3)	1.41 (0.4)	0.19 [0.1; 0.3]	0.05 [−0.1; 0.2]	0.29
Sit-to-stand test (repetitions)†	11.56 (3.9)	11.90 (4.6)	Not measured		14.41 (3.9)*	13.13 (4.3)*	15.47 (4.5)	15.07 (5.1)	2.84 [1.8; 3.9]	1.34 [0.2; 2.5]	0.12
Stair climb test (seconds)	12.83 (7.9)	13.12 (7.2)	Not measured		9.49 (3.2)*	10.54 (4.0)*	9.07 (3.0)	9.03 (2.8)	3.32 [1.0; 5.7]	2.58 [0.6; 4.6]	0.04‖

Abbreviations: diff: difference, W/kg: Watt/kilogram bodyweight, Nm/kg: Newton*meter/kilogram bodyweight.
* Significant within group difference from baseline to 10 week follow up ($P < 0.05$).
† One missing at baseline, the patient was not able to perform the test due to pain.
†† Mixed effect model comparing between-group changes with adjustment for baseline values.
§ Multivariate repeated measurement analysis, testing the difference between groups over time.
‖ Approximate test, allowing for heterogeneity.

Adverse effects

During PRT, five patients experienced adverse effects during or after training sessions. Two patients had discomfort and dizziness due to hypotension; regulation of their anti-hypertensive medication solved the symptoms. In one patient, an accumulation of blood burst during the third training session, the bandage was changed and no further complications were observed. One became nauseous and vomited after the training session; this was a well-known phenomenon for her during physical exertion due to an earlier tumour in the brain, and led to discontinuation of the PRT. Knee pain in the contra-lateral leg also led to discontinuation of the PRT in one patient. In total, two patients discontinued the intervention due to adverse effects; they participated in follow up visits and are included in the analysis.

Discussion

Primary outcome: leg extension power

The main finding of the present study was no superior effect of 2 weekly sessions of supervised PRT in combination with 5 weekly sessions of unsupervised home-based exercise in improving leg-extension power of the operated leg 10 weeks after surgery, when compared to 7 weekly sessions of unsupervised home-based exercise in patients with THR, who had lower pre-operative function. Results from the intention-to-treat and extended per protocol analysis on leg extension power were similar, indicating no systematic bias due to drop outs.

The result is in contrast to earlier smaller studies that have reported substantial additional effect of supervised resistance training compared to CGs performing home-based exercise with no external resistance and weekly supervision for 12 weeks[14] or supervised exercises with low or no external resistance 3–5 times a week for 4 weeks[18] on muscle performance – but not on leg extension power, specifically[14,18]. It may be explained by the implementation of fast-track THR surgery, involving early mobilisation and enhanced recovery of patients included in the present study, as opposed to the patients included in the previous studies. This study demonstrated changes in muscle strength and power after PRT (18–26%) comparable to changes in isokinetic quadriceps strength after 12 weeks of PRT after THR (22–28%)[14]. In that study, as well as the study by Husby *et al.*[18], the CG showed a reduction or no change in muscle strength during the intervention period. That is opposite to the CG in the present study, where muscle strength and power increased by 4–16%, reaching statistical significance in leg extension power and hip abduction strength (Table III). Furthermore, recent studies that have not applied PRT indicates that hip strength does not improve from the preoperative level during the first two to 3 months after THR[1,7]. Hence, the CG in the present study showed larger improvements in muscle power and strength during 10 weeks of home based exercises than expected based on the current literature, despite the inclusion criteria of HOOS ADL $\leq$ 67 points. However, our results are in line with earlier findings of 21–23% improvement in hip abduction strength during 12 weeks of home based exercise after THR using fast-track procedures[15]. It is possible that faster improvements than those already obtained by fast-track surgery and home-based exercise are not conceivable or requires more comprehensive interventions. Another theoretical explanation of the lack of additional effect of PRT is surgery-induced inhibition of muscles close to the operated hip, preventing strength gains beyond that of the CG. Such arthrogenic muscle inhibition is well known after total knee replacements[48], and has been indicated after THA as well[49].

Secondary outcomes

All secondary outcomes improved significantly from baseline to 10 week follow up in both groups, except from hip flexion muscle strength in the CG (Tables III and IV). There was a statistical significant difference between groups over time in maximum walking speed ($P = 0.008$) and stair climb performance ($P = 0.04$) (Table III). We question the clinical relevance of these findings, due to the small differences and the diminishing of the effect after 6 months (Table III). The functional performance improvements after PRT in the present study (21–26%) correspond well with the findings from Suetta *et al.*[14] of 28–30% improvements in functional performance after 12 weeks of PRT. The increase in maximum walking speed (IG: 21%, CG: 12%) is comparable to results from a recent study with preoperative neuromuscular training and outpatient physiotherapy post discharge (18%)[33]. Likewise, HOOS ADL scores showed slightly larger improvement in the present study at 10 week follow up (IG: 40, CG:37 points) than their 3 months follow up (~30 points) with comparable baseline values[33]. There were no significant between-group differences on the HOOS subscales in the present study (Table IV). The HOOS results indicate a rapid and substantial recovery in both groups in the present study, comparable with IGs in other studies[33,50]. However, ceiling effect was observed for all HOOS subscales from the 6 months follow up and forward.

Strength and limitations

The qualities of this study encompass the assessor-blinded, randomised controlled design, the exclusion of the preoperative best functioning patients and the controlled, well-described intensity and execution of the exercises. PRT as used in this study is simple to apply and is based on identified muscle deficits documented in the existing literature. We excluded the patients reporting least disability preoperative as an attempt to address the intervention to the patients with greatest rehabilitation needs (stratified medicine), as advocated in previous studies[13,22]. A very high compliance to the PRT in combination with one-to-one supervision verifies that the intended exercise intervention was implemented.

The limitations of this study encompass potential selection bias and risk of attention bias. We possibly included motivated patients with a positive attitude towards training as they had to be willing to attend 2 -weekly training sessions which might weaken the external validity of the trial. We aimed at including patients with lower pre-operative function, but the cut-off level (seventy fifth percentile) might have been too high to actually reflect the patients with low function only. However this was deemed necessary for completion of the trial, since non-consenters tend to be more disabled than those participating in clinical studies[51]. To comply with the possible risk of attention bias it would have been optimal to perform supervised placebo training in the CG, but this was not deemed feasible. The results must be interpreted with this potential attention bias in mind.

Implications

The findings from this study suggest no clinically relevant additional effect of PRT compared to home-based exercise after fast-track THR. These findings do not claim being exhaustive, but needs to be confirmed or contradicted in future research. There might be a subgroup of patients profiting from PRT and maybe different timing and dosage could change the conclusions. Considering the rapid and substantial improvements in this study (despite of group assignment) the persisting deficits stated in the literature needs to be further studied in patients following a fast-track course of treatment and compared to healthy peers as well. It is required to identify

patients needing supervised rehabilitation and those recovering well by unsupervised home-based rehabilitation. Today, there is a large variation between rehabilitation procedures after THR, ranging from no supervised physiotherapy after discharge to all patients being referred to outpatient physiotherapy or even rehabilitation unit stay. This emphasizes the need for further knowledge to achieve optimal allocation of health care resources.

Conclusions

In this trial, supervised PRT twice a week in addition to 5 weekly sessions of unsupervised exercise for 10 weeks was not superior to 7 weekly sessions of unsupervised home-based exercise for 10 weeks in improving the primary outcome, leg-extension power of the operated leg, at the primary endpoint 10 weeks after surgery in THR patients with lower pre-operative function.

However, it is currently unknown whether PRT is effective in other subgroups of patients, at higher training dosage (e.g., increased longevity of the training), different timing or on different outcomes.

Contributions

LRM, KS, TB, AKP and IM all contributed to the conception and design of the study. LRM, LBJ and SM contributed to data acquisition. LRM was responsible for analysis and interpretation of data and drafting the article with all co-authors contributing with critical revision for important intellectual content. All authors approved the final version to be submitted. First and last authors take responsibility for the integrity of the work as a whole, from inception to finished article. E-mail last author: annempte@rm.dk.

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Competing interest statement

All authors declare that they have no competing interest.

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Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.joca.2014.09.025.

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