Original Article

Sports Therapy Interventions Following Total Hip Replacement

A Randomized Controlled Trial

Heidrun Beck, Franziska Beyer, Franziska Gering, Klaus-Peter Günther, Cornelia Lützner, Achim Walther, Maik Stiehler

University Center of Orthopedic and Trauma Surgery, TU Dresden, Section Sports Medicine and Rehabilitation, Dresden: Dr. med. Heidrun Beck, Dr. rer. medic. Achim Walther

University Center of Orthopedic and Trauma Surgery, TU Dresden, Dresden: Franziska Beyer, Franziska Gering, Prof. Dr. med. Klaus-Peter Günther, Dr. rer. medic. Cornelia Lützner, PD Dr. med. Maik Stiehler

Summary

Background: Sport rehabilitation is a reimbursable intervention assisting reintegration and self-help. In this study, we measured the effects of sport rehabilitation on muscle strength around the hip joint at 1 year after surgery, as well as cardiopulmonary endurance performance and stability of stance, in patients who had undergone a first implantation of a total hip endoprosthesis (total hip replacement, THR) as a treatment for osteoarthritis of the hip.

Methods: 160 patients were randomly allotted either to an intervention group with intensive sport rehabilitation for the first year or to a control group. At three time points (baseline, six and twelve months after surgery), measurements were made of muscular strength around the hip joint (with isokinetic dynamometry), stability of stance, and endurance performance. The primary endpoint was the change in strength of the hip extensors, abductors, flexors, and adductors at twelve months after surgery.

Results: With respect to the primary endpoint, the results were not significantly better in patients who had received sport rehabilitation than in those who had not. At one year, the patients in the intervention group had less pain as measured by the WOMAC pain score ($p = 0.023$), though the size of this effect was small ($r = 0.27$). Health-related quality of life was higher in the intervention group at six months, albeit with a small effect size ($p = 0.036$, $r = 0.25$); this was no longer demonstrable at one year. The other parameters studied displayed no significant changes.

Conclusion: This trial did not demonstrate any significant benefit of sports rehabilitation on functional outcomes in patients who had undergone total hip replacement. Nonetheless, positive trends after the intervention were seen in some parameters. The unexpectedly high dropout rate had been underestimated in the planning phase of the trial; further trials with larger numbers of patients should be performed.

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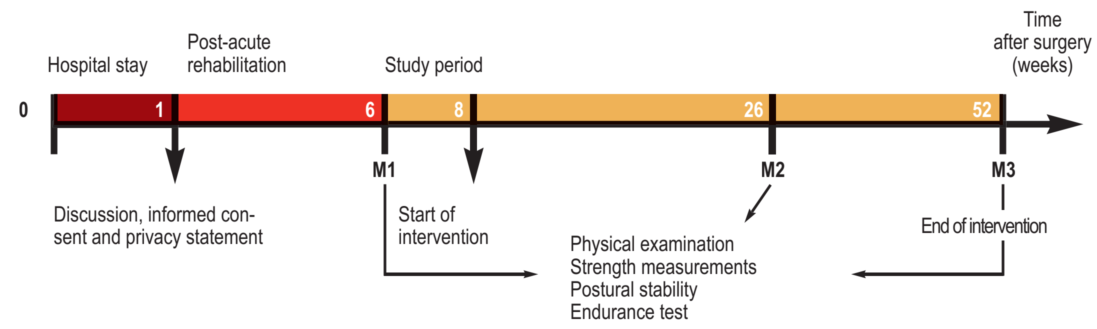
Osteoarthritis is one of the most common conditions in industrialized nations (1). According to a survey of the Robert Koch Institute conducted in 2010, the lifetime prevalence of degenerative joint disease (osteoarthritis), is 27% for women and 18% for men, with the knee and hip joints being the most common sites (2). Joint replacement is indicated in patients with advanced osteoarthritis of the hip in the presence of relevant functional impairments and joint pain when conservative treatment options have failed. Registry studies have shown that total hip replacement resulted in significant pain reduction, improved day-to-day functioning and better health-related quality of life (3–6).

In many patients, decreases in muscle strength are already noted years before surgery. Exercise physiological testing revealed that patients with osteoarthritis of the hip frequently experience significant deficits with regard to strength, mobility, coordination, and cardiopulmonary fitness (7–10).

While the effectiveness of total hip arthroplasty (total hip replacement, THR) with regard to pain reduction and functional improvements has been clearly demonstrated in numerous trials, currently there is a lack of scientific evidence demonstrating improvements in strength capacity and cardiopulmonary fitness during the first postoperative year (8, 11).

Since 2001, the rehab sports therapy program (*Reha-Sport*) has been offered in Germany as a supplementary measure paid for by pension insurances, health insurances and accident insurances

FIGURE 1



Sport medicine measurements (M1, M2, M3) were obtained during 3 examination visits

TABLE 1

Sports therapy interventions, aims and exercise examples of the hip rehab sports therapy program

Sports therapy intervention	Aims	Exercise examples
Warming-up	Activation of metabolism, increasing psychological, cardiopulmonary und neuromuscular performance capacity	Walking slowly in circles, toe/heel walking, potential walking exercises with tire
Endurance training	Improvement of cardiopulmonary endurance	Fast walking, Nordic walking with walking poles, training on cycle ergometer
Coordination training	Training of body perception, gait improvements, proprioception, joint stability, and neural muscle control	Leg axis training from various start positions and on unstable bases
Strengthening	Improvement of trunk stability, strengthening of the muscles surrounding the hip	Squats with adapted movement amplitude, traction exercises with TheraBand
Stretching	Improvement of flexibility of iliopsoas and leg muscles	Exercises with porcupine ball, loosening-up exercises, fascial training
Theory	Hip-appropriate behavior in everyday life & leisure time	Correct sitting, lifting and lying
Concluding game type	Improvement of orientation and response capacity, movement-related fun and motivation sharing	Team circle games with tires/ribbons/balls, basket ball
End	Session close	Farewell, brief patient feedback

pursuant to section 64 of Book IX of the German Social Code (SGB) to support return to the workplace and reintegration into society. The aim is to motivate participants to continue exercising independently after completion of the group training program. The rehab sports therapy program is a supplementary measure in the rehabilitation process and can be prescribed for patients after total hip replacement (hip rehab sports therapy program) (12, 13). The specific goals of the rehab sports therapy program are the improvement of

- endurance
- strength
- coordination
- flexibility (14).

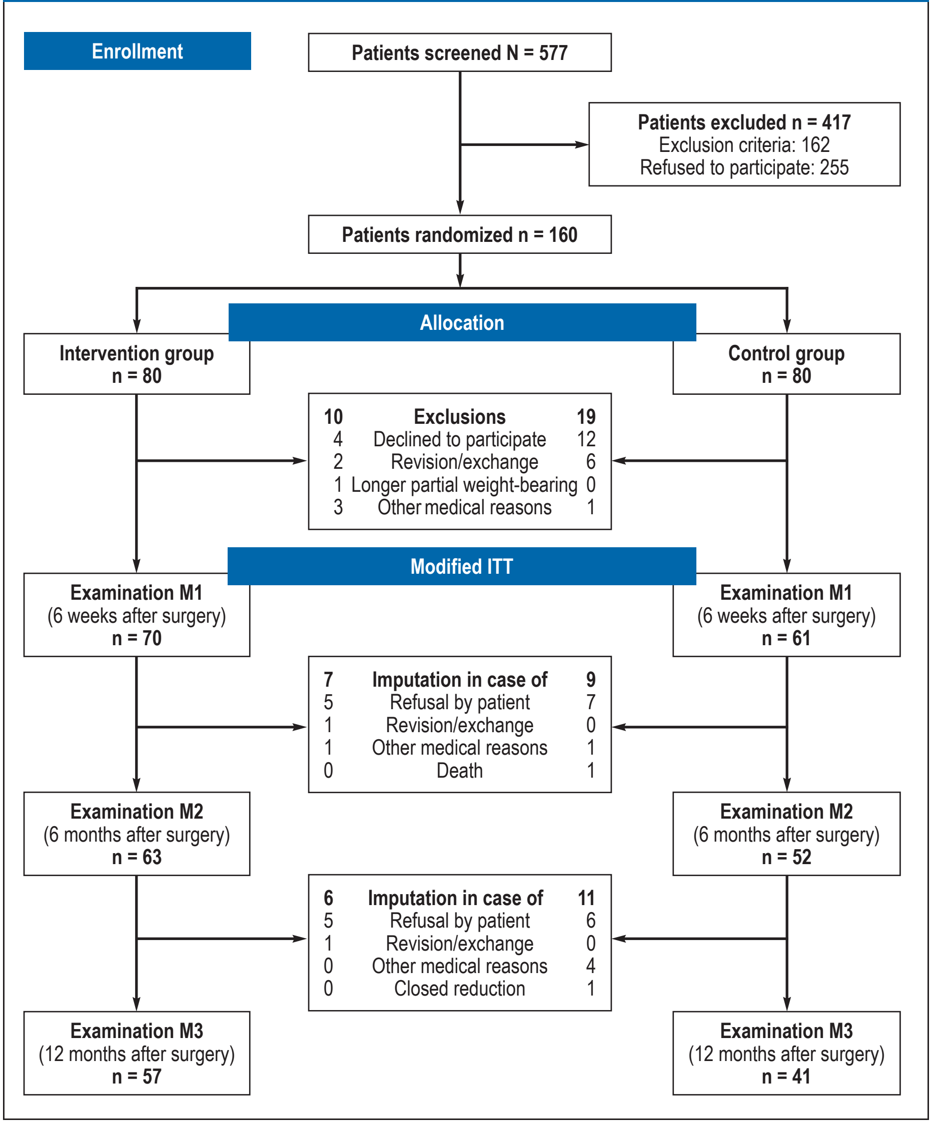
However, scientific studies evaluating the efficacy and long-term effect of the rehab sports therapy program after total hip replacement are scarce.

The primary endpoint of this study was the comparison of changes in strength capacity of hip extensor muscles and hip abductor muscles as well as hip flexor muscles as the result of the hip rehab sports therapy program 12 months after surgery. The secondary endpoints were changes in strength capacity after 6 months, the effects on postural stability and cardiopulmonary endurance as well as the patient-reported outcomes after 6 and 12 months, respectively. The starting hypothesis was that the muscle strength required for normal gait and for postural stability can be improved by hip rehab sports therapy.

Materials and methods

This prospective, randomized clinical trial (ethics committee approval EK 152042014, Clinical Trials no. NCT03584451) was conducted between January 2015 and July 2017 in the Department of Sports Medicine

FIGURE 2



CONSORT flow diagram
ITT = intention to treat; M1/2/3, measuring visit 1/2/3

and Rehabilitation of the University Center of Orthopedic and Trauma Surgery (OUC) at the Carl Gustav Carus University Hospital, Dresden, Germany. Patients who underwent total hip replacement at the OUC were invited to participate in the study. The inclusion criteria were general medical eligibility for hip rehab sports therapy, a stable implant, age 18 years or older, and written consent to participate in the study. The exclusion criteria included acute or chronic diseases and severe pain in the affected hip joint. Sample size planning was based on strength measurements obtained in a pilot study with 122 patients which found a mean torque for extension/flexion of 377 Nm with a standard deviation of 165 Nm. In the literature, a hip muscle strength increase of 20% was reported after sports therapy interventions (15). To detect an increase of 20% compared to the control group at a significance level of 0.05 and a power of 0.80, a size of 75 patients per group would be required. Eighty patients per group (N = 160 patients) were randomized.

Patients were randomized, using a randomization list (without blinding), into the following two groups:

- Intervention group: group with hip rehab sports therapy (80 subjects)
- Control group: group without hip rehab sports therapy (80 subjects)

The sports medicine measurements were obtained at 3 visits (*Figure 1*): The baseline examination (measurement visit 1 [M1]) was performed at week 6 (±1 week) after surgery; between the time of surgery and M1, patients had the chance to participate in post-acute rehabilitation (*Anschlussheilbehandlung*, AHB). Further examinations were performed at month 6 (±1 months) (M2) and month 12 (±3 months) (M3) after surgery. During these visits the measurements described below were obtained.

TABLE 2

Change in strength capacity compared with baseline examination (M1 = 6 weeks after surgery)*

	6 months (ΔM2–M1)					12 months (ΔM3–M1)				
	Intervention	Control	Effect r	p value	adjusted p value	Intervention	Control	Effect r	p value	adjusted p value
Operated leg										
Extension	0.69 (0.44; 0.96)	0.55 (0.06; 0.79)	0.12	0.171	1.000	0.86 (0.46; 1.11)	0.93 (0.42; 1.07)	0.01	0.956	1.000
Flexion	0.31 (0.19; 0.43)	0.26 (0.09; 0.35)	0.12	0.188	1.000	0.55 (0.31; 0.69)	0.42 (0.31; 0.58)	0.15	0.077	0.616
Abduction	0.18 (0.09; 0.26)	0.13 (0.04; 0.17)	0.21	0.014	0.112	0.22 (0.16; 0.30)	0.20 (0.12; 0.24)	0.11	0.201	1.000
Adduction	0.17 (0.09; 0.29)	0.14 (0.03; 0.24)	0.11	0.206	1.000	0.23 (0.14; 0.35)	0.19 (0.15; 0.28)	0.09	0.291	1.000
Non-operated leg										
Extension	0.33 (0.06; 0.64)	0.26 (−0.06; 0.52)	0.13	0.125	1.000	0.39 (−0.02; 0.83)	0.49 (0.14; 0.72)	0.09	0.328	1.000
Flexion	0.17 (−0.01; 0.25)	0.10 (−0.04; 0.19)	0.15	0.087	0.696	0.23 (0.06; 0.38)	0.24 (0.08; 0.28)	0.07	0.425	1.000
Abduction	0.08 (0.02; 0.18)	0.11 (0.05; 0.16)	0.04	0.612	1.000	0.12 (0.02; 0.20)	0.10 (0.04; 0.16)	0.11	0.203	1.000
Adduction	0.08 (0.00; 0.18)	0.10 (0.01; 0.18)	0.05	0.558	1.000	0.11 (0.05; 0.23)	0.18 (0.08; 0.22)	0.07	0.419	1.000

* In the Intervention and Control columns, the median and, in brackets, the 25th and 75th percentiles are listed.
ΔM2−M1, difference of the results of the second and first measurement visit; ΔM3−M1, difference of the results of the third and first measurement visit

Medical history and physical examination

To document the current state of health, study participants underwent a sports medicine examination before each visit.

Measuring strength capacity using isokinetic dynamometry

In order to obtain objective bilateral strength capacity measurements of hip extension/hip flexion and hip abduction/hip adduction, instrument-based isokinetic assessments were performed using the ISOMED2000 dynamometer (D&R Ferstl GmbH, Hemau/Germany).

These tests recorded the various force-joint angle curves during maximum concentric muscle work. A range of motion of 0–80° and an angular velocity of 60°/s was used for measuring extension and flexion.

The abduction and adduction measurements were obtained for a range of motion of −8° to +30° at an angular velocity of 45°/s. The isokinetic data set was analyzed using the DualAthletic software (D&R Ferstl GmbH, Hemau/Germany). For each part movement, the work was calculated in Joule (J) and the relative work (J/kg body weight) determined.

Postural stability measurement on the Kistler force plate

The Kistler force plate type 9287A (Kistler Instrumente GmbH, Wintherthur, Switzerland) is a static, piezoelectric measuring platform for registration of the center of pressure (COP) (16, 17). Bilateral and unilateral postural stability were measured four times, each time for 15 seconds, on the operated and non-operated side. The measurements (COP track in cm) and potentially incorrect performance or external support (holding) were recorded.

Lactate threshold test

Cardiopulmonary endurance capacity was measured with a cycle ergometer test and exercise protocols were adapted to each individual patient. The goal was to reach the lactate threshold of 3 mmol/L; the absolute or relative workload (in Watts) achieved was used as an individual reference value for cardiopulmonary endurance.

Patient-reported outcomes

At M2 and M3, hip-specific pain and function (McMaster Universities Osteoarthritis Index

[WOMAC] and Harris Hip Score) (18–20), current pain levels of the operated hip (visual analog scale [VAS], 0–10 points), physical activity (UCLA activity scale) (21, 22) and health-related quality of life (EuroQol, EQ-5D) (23, 24) were measured.

Hip rehab sports therapy program

Following post-acute rehabilitation, the patients of the intervention group received hip rehab sports therapy once a week at a rehab sports therapy facility close to their home. For this purpose, they were issued a prescription for 50 units, each of 45 min duration, and information material (25, 26). The details of the requested hip rehab sports therapy are listed in *Table 1* and were communicated to the rehab sports therapy providers.

Statistical analysis

Data were analyzed using the IBM SPSS (version 25) software package. A modified intention-to-treat analysis (mITT analysis) was performed with single median imputation for missing data.

To compensate for differences between the groups which may already have been present at the baseline examination, the sports medicine data were adjusted for the baseline data, i.e. the differences (ΔM2−M1 and ΔM3−M1) were used for the comparison. Since the data presented were not normally distributed, significance testing between the groups was performed with the Mann–Whitney U test. The results are shown as medians (25th percentile; 75th percentile). The chi-square test was used for the analysis of dichotomous variables (support during postural stability testing). The significance level was $p < 0.05$ for all tests. To compensate for alpha error accumulation due to multiple testing, the Bonferroni correction, with adjustment of p values, was performed.

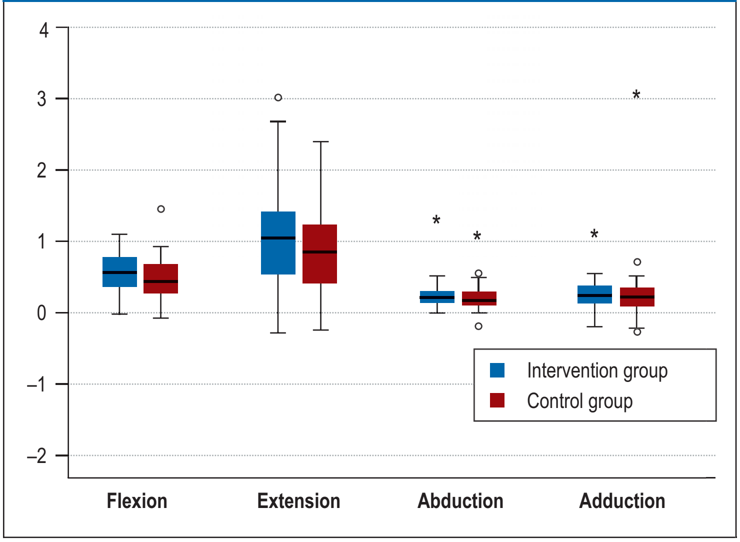
The effect size (r) of not normally distributed variables was calculated by comparison of the medians (Bravais–Pearson correlation coefficient). Values for $r < 0.3$ represent a small effect, $0.3 < r < 0.5$ a moderate effect and $r \geq 0.5$ a large effect. The effect size of support during postural stability testing was expressed with Cramer's V. Here, a value of V = 0.1 represents a small effect, of V = 0.3 a moderate effect and of V = 0.5 a large effect.

Results

After randomization, the intervention group comprised of 42 (52.5%) women and 38 (47.5%) men. The control group included 51 (63.8%) women and 29 (36.2%) men. In the intervention group, the median age was 59.0 years (51.1; 69.7) and the median body mass index (BMI) was 26.4 kg/m² (23.8; 28.6). In the control group, the median age was 61.9 years (52.5; 70.0) and median BMI was 25.9 kg/m² (23.7; 30.4). No significant differences with regard to sex distribution, age and BMI were found between the intervention group and the control group.

Figure 2 shows that 29 patients already dropped out of the study before the first measurement (M1) for personal or medical reasons. After 6 months and 12 months, a further 16 and 17 patients, respectively, were excluded.

FIGURE 3



Boxplot of the change in strength capacity after 12 months compared with the baseline examination (six weeks after surgery) in the operated leg

Strength capacity

For the primary endpoint—the change in strength capacity after 12 months—no significant difference was found (*Table 2, eFigure 1*). The patients in the intervention group achieved a greater increase in abductor strength 6 months after surgery compared with the control group (p = 0.014); however, after adjustment of the p value, the difference is no longer significant (*eFigures 2, 3*). The effect size achieved of r = 0.21 represents a small effect. *Figure 3* shows the boxplots of the changes in strength capacity of hip abduction.

Postural stability

No significant differences were found with regard to changes in postural stability. After 1 year, patients in the intervention group required less support during single-leg stance. In the control group, approximately 40% of patients required support compared to only 16% in the intervention group. The effect size of the result, which was no longer significant after Bonferroni correction, is at the level of Cramer's V = 0.26; this represents a small effect.

Endurance performance

With regard to the cycle ergometer performance measured at a lactate level of 3 mmol/L, no significant difference in cardiopulmonary endurance performance were found at any time point measured.

Patient-reported outcomes

Six months after surgery, a significant difference in health-related quality of life (adjusted p = 0.036) was

TABLE 3

Patient-reported outcomes, 6 and 12 months after surgery, respectively*

	Intervention	Control	Effect r	p value	Adjusted p value	Intervention	Control	Effect r	p value	Adjusted p value
	6 months	6 months	6 months	6 months	6 months	12 months	12 months	12 months	12 months	12 months
Pain VAS	1.0 (0.0; 2.0)	1.0 (0.0; 2.0)	0.07	0.402	1.000	0.0 (0.0; 1.0)	0.0 (0.0; 2.0)	0.15	0.098	0.882
WOMAC Pain	95.0 (90.0; 100.0)	92.5 (90.0; 100.0)	0.14	0.113	1.000	100.0 (95.0; 100.0)	95.0 (90.0; 100.0)	0.27	0.003	0.023
WOMAC Stiffness	87.5 (75.0; 100.0)	87.5 (75.0; 100.0)	0.00	0.960	1.000	87.5 (75.0; 100.0)	100.0 (75.0; 100.0)	0.08	0.373	1.000
WOMAC ADL	92.7 (85.2; 95.6)	92.6 (89.7; 95.6)	0.03	0.522	1.000	95.6 (89.7; 100.0)	95.6 (92.7; 97.1)	0.11	0.214	1.000
WOMAC Total	92.7 (86.5; 95.8)	92.7 (85.4; 96.9)	0.01	0.943	1.000	95.8 (91.7; 100.0)	95.8 (88.5; 96.9)	0.10	0.523	1.000
Harris Hip Score	93.0 (86.0; 96.0)	95.0 (88.0; 96.0)	0.12	0.171	1.000	96.0 (93.0; 98.0)	96.0 (90.0; 97.0)	0.08	0.384	1.000
UCLA Activity Scale	7.0 (6.0; 7.0)	7.0 (6.0; 7.0)	0.14	0.112	1.000	7.0 (7.0; 7.0)	7.0 (6.0; 7.0)	0.18	0.042	0.378
EQ-5D index	1.00 (0.89; 1.00)	0.89 (0.89; 1.00)	0.25	0.004	0.036	1.00 (0.89; 1.00)	1.00 (0.89; 1.00)	0.14	0.099	0.891
EQ-5D VAS	85.0 (80.0; 90.0)	85.0 (75.0; 90.0)	0.01	0.899	1.0000	90.0 (80.0; 90.0)	85.0 (70.0; 90.0)	0.13	0.149	1.000

* In the Intervention and Control columns, the median and, in brackets, the 25th and 75th percentiles are listed.
ADL, activities of daily living; EQ-5D, health-related quality of life questionnaire; Harris Hip score, functional evaluation of hip;
UCLA Activity Scale, activity scale of the University of California, Los Angeles; VAS, visual analog scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis index

found, with a small effect size (r = 0.25) in favor of the intervention group; 12 months after surgery, this was no longer the case *(Table 3)*. The WOMAC pain score one year after surgery was found to be significantly better in the intervention group (adjusted p = 0.023), with a small effect size (r = 0.27). The significant difference in the UCLA activity scale is no longer present after p value adjustment.

Discussion

The primary endpoint was the strength capacity of the muscles surrounding the hip joint 12 months after surgery. Regardless of the intervention, no significant increase in strength was achieved.

Even though 6 months after surgery a significant increase in strength of the abductor muscles of the operated side was found in the intervention group, with a small effect size, the difference was no longer significant after adjustment of the p value. Horstmann et al. reported similar results for patients with hip osteoarthritis who received preoperative sports therapy once weekly over a period of 6 months (27). They found an increase of isometric hip abductor strength of approximately 10%, while the rehab sports therapy program did not increase isometric extensor strength (27, 28).

With regard to postural stability, a reduced need for support during single-leg stance was found in the intervention group one year after surgery; however, this difference was also not significant. Besides the hip extensor muscles, the hip abductor muscles are essential for a normal gait pattern and maintaining postural stability while standing. Ikutomo et al. found in female patients an almost threefold increase in the risk of falling during the first year after total hip replacement (29).

Our study was the first randomized prospective study to evaluate over a period of one year the effect of a sports therapy rehabilitation program with sessions once per week on the strength of the muscles surrounding the hip and the patients' fitness, using methods of performance assessment which are well-established in sports medicine to objectively determine treatment success.

The scientific evidence with regard to the effect of sports therapy, especially in the form of joint-specific sports medicine programs, after total joint replacement surgery is scarce (30, 31).

Krakor et al. evaluated the effect of weekly one-hour training units in patients with osteoarthritis of any type over a period of 3 and 6 months, respectively

(32). At the start and at the end of the program, the patients were assessed using sports medicine motor tests and a questionnaire; positive effects were found for motor function and subjective bodily pain. Gilbey et al. and Horstmann et al. showed in their prospective studies that training programs of 8 weeks and 6 months duration, respectively, had a positive effect on maximum hip abductor muscle strength in patients with osteoarthritis of the hip (9, 33).

Several studies on joint-specific sports medicine interventions, evaluating the effects of independent home-based training, have been published. However, hip rehab sports therapy and home-based interventions are only comparable to a limited extent because they differ in duration, frequency and intensity (34–37). In the literature, significant improvements in the strengths of hip flexor, extensor and abductor muscles as well as in postural stability have been reported for home-based training (28, 35–38).

The results of our study suggest that with sports rehabilitation faster increases in the strength of the abductor muscles, which stabilize the pelvis, can be achieved—an effect also reflected by improved single-leg stance stability. However, our study did not demonstrate the statistical significance of this change. This and other capabilities are highly important from a clinical perspective as they help to prevent falls and their potential negative consequences.

This study has some methodological limitations. These include the high number of 29 patients who already dropped out of the study after randomization before the first measuring visit M1. Thirteen patients dropped out early for medical reasons, while 16 patients decided against participating in the study after having completed the post-acute rehabilitation program. Some patients in the control group decided before M1 to undergo sports rehabilitation and withdrew from the study. During the course of the study, 33 further patients dropped out, in 10 cases for medical reasons. Sample size planning underestimated the effective drop-out rate, which was not significantly different between the two groups. To us, the primary reasons for this seem to be that the enrolled patients were comparatively old and the measuring technologies used demanded considerable patient effort. The high drop-out rate resulted in incomplete datasets, making it difficult to perform the planned modified ITT analysis so that a single imputation had to be performed.

Protocol violations occurred because 10 patients did not participate in the sports rehabilitation program on a regular basis. On the other hand, 14 patients of the control group privately joined a rehabilitation sports group during the one-year study period. According to the intention-to-treat principle, this was not taken into account in the analysis and is reflective of the clinical reality in our opinion.

The Bonferroni correction of the p value is known to be conservative, especially if numerous outcome parameters are assessed. This may increase the likelihood that the null hypothesis is not rejected even if it is actually incorrect. However, if statistically significant differences had been demonstrated, we would have been able to generalize the results of the study.

The hip rehab sports therapy program is not a standardized intervention program and consequently the offerings of different providers may vary. To order to ensure comparability, we created an information sheet for rehab sports therapy providers, detailing the required sports therapy interventions and giving examples of exercises (*Table 1*). Due to limited time, it was not feasible to document the contents of the training during the training units. Consequently, no conclusions can be drawn on the effects of individual training modules; however, the overall result reflects the reality in the various facilities.

Conclusion

In summary, this study showed that sports rehabilitation after total hip replacement did not significantly improve the primary endpoint. However, a positive trend was noted for some outcomes. There is a need to optimize the frequency of the sports rehabilitation sessions. A second weekly training unit and an additional home exercise program could increase the training effects. Some studies have already demonstrated the effects of home-based exercise programs with several training sessions per week (28, 29, 34–38). Here we can look forward to further studies evaluating the feasibility and effectiveness of telerehabilitation, because especially by using telerehabilitation the benefits of standardization could be evaluated (34).

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Conflict of interest statement
The authors declare that no conflict of interest exists.

Data sharing
The authors are prepared to share the data underlying this study for scientific purposes, once further analyses of the data have been completed. Please direct enquires regarding the dataset to Dr. Heidrun Beck.

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Translated from the original German by Ralf Thoene, MD.

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Key messages

- In this study, the hip rehab sports therapy program did not increase the strength capacity measured 12 months after surgery more than no intervention.
- Of the 160 randomized patients, 29 discontinued the study prior to the first measurement. After 6 months, a further 16 patients and after 12 months an additional 17 patients dropped out of the study. Protocol violations were noted in 10 subjects of the intervention group and 14 subjects of the control group.
- Possible reasons for the high drop-out rate include the comparatively old age of the patients (approximately 60 years) and the considerable patient effort that was required due to the measurement methods used.
- A second weekly training unit and an additional home exercise program could increase the effects.

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Corresponding author
Dr. med. Heidrun Beck
OUC Uniklinikum Dresden, Sportmedizin,
01307 Dresden, Germany
Heidrun.Beck@uniklinikum-dresden.de

► Supplementary material

eFigures:
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Supplementary material to:

Sports Therapy Interventions Following Total Hip Replacement

A Randomized Controlled Trial

by Heidrun Beck, Franziska Beyer, Franziska Gering, Klaus-Peter Günther, Cornelia Lützner, Achim Walther, and Maik Stiehler

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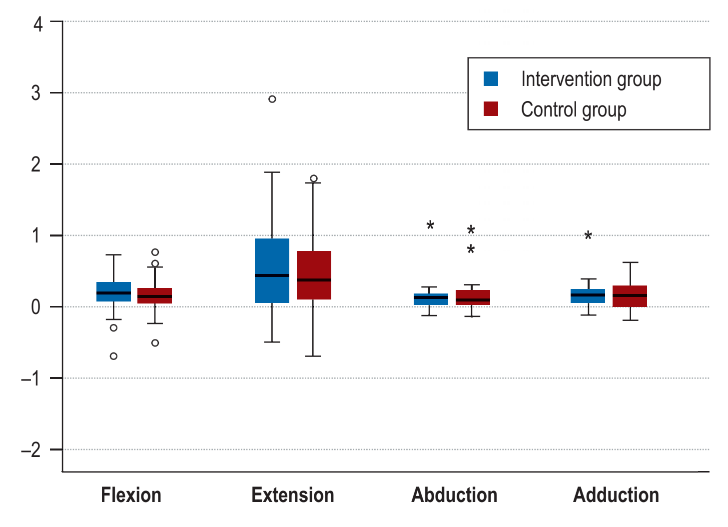
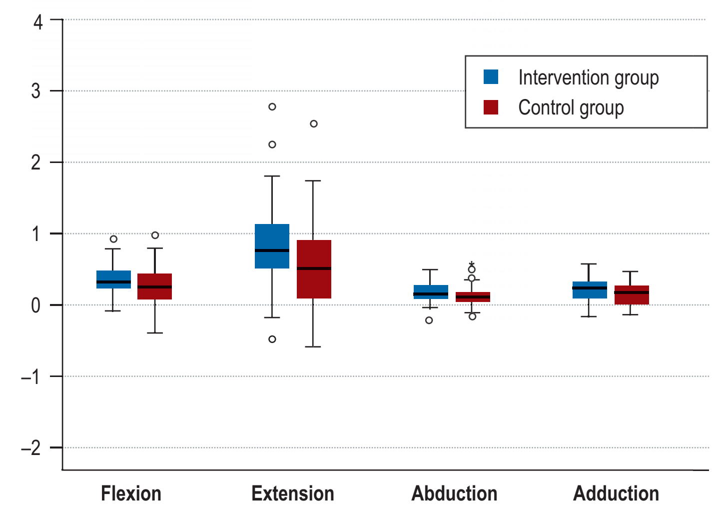
eFIGURE 1



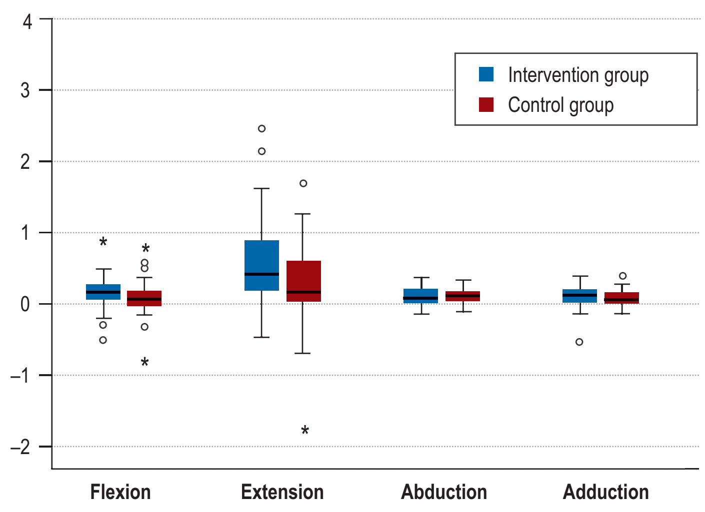
Boxplot of the change in strength capacity after 12 months compared with the baseline examination (six weeks after surgery) in the non-operated leg

eFIGURE 2



Boxplot of the change in strength capacity after 6 months compared with the baseline examination (six weeks after surgery) in the operated leg

eFIGURE 3



Boxplot of the change in strength capacity after 6 months compared with the baseline examination (six weeks after surgery) in the non-operated leg