Task-oriented exercises and early full weight-bearing contribute to improving disability after total hip replacement: a randomized controlled trial

Marco Monticone[1], Emilia Ambrosini[1,2], Barbara Rocca[1], Chiara Lorenzon[1], Simona Ferrante[2] and Giovanni Zatti[3,4]

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[1]Physical Medicine and Rehabilitation Unit, Scientific Institute of Lissone Salvatore Maugeri Foundation IRCCS, Monza Brianza, Italy
[2]Neuroengineering and Medical Robotics Laboratory, Department of Electronics, Information, and Bioengineering Politecnico di Milano, Milan, Italy
[3]Bicocca University of Milan, Milan, Italy
[4]Orthopaedics Unit, San Gerardo Hospital, Monza Brianza, Italy

Corresponding author:
Marco Monticone, Physical Medicine and Rehabilitation Unit, Scientific Institute of Lissone (Monza Brianza), Institute of Care and Research, Salvatore Maugeri Foundation IRCCS, Via Monsignor Bernasconi 16, Lissone, MI 20035, Italy.
Email: marco.monticone@fsm.it

Introduction

Although total hip replacement is a common successful surgical procedure for relieving pain and improving function in patients with osteoarthritis of the hip, there are still doubts about the efficacy of specific types of physical exercises prescribed after operations and also about the timing, intensity, and frequency of the therapy.[1]

Traditional exercises concentrate on improving isometric muscle properties and increasing the range of motion. Recently, task-oriented exercises, which are aimed at early functional recovery, a rapid return to walking, and independence in activities of daily living (ADL), are receiving more and more interest, but their superiority has not been demonstrated yet.[1]

Moreover, although various radiological findings suggest that immediate full weight-bearing after primary uncemented total hip replacement seems to have no detrimental effect on osseous integration, subsidence, or prosthetic loosening,[2–7] there is little evidence concerning its clinical impact, and many rehabilitation protocols still advocate postoperative restrictions on weight-bearing that delay recovery times.[8,9] Full weight-bearing from day one has recently been shown to be effective in improving functional outcomes and hip range of motion in patients undergoing arthroplasty.[10] However, this study enrolled active and relative young subjects (median age of 56 years) with no comorbidities; hence, it is still unclear if these results are generalisable to patients with a more impaired preoperative condition.

We hypothesised that an in-hospital rehabilitation programme of task-oriented exercises, including closed kinetic functional activities associated with early full weight-bearing, improves disability (primary outcome), pain, ADL, and quality of life (secondary outcomes) in subjects who have undergone total hip replacement and who could not go home after discharge from the Orthopaedic Unit because of multiple comorbidities and/or insufficient home support. The aim of this randomized and controlled study was to compare this programme with a programme of traditional open chain kinetic exercises and partial weight-bearing, routinely followed by these patients during their in-hospital stay, thereby helping in the definition of evidence-based guidelines that can be used in everyday clinical practice.

Methods

This randomized, parallel-group, controlled, superiority trial was conducted at the Salvatore Maugeri Foundation's Scientific Institute in Lissone (Italy), in accordance with the CONSORT recommendations.[11]

The principal investigator randomized the subjects in two groups using a list of blinded treatment codes previously generated, and an automatic assignment system to conceal the allocation.

The principal investigator obtaining and assessing the outcome data, and the biostatisticians making the analyses, were blinded to the treatments. The physiatrists and physiotherapists could not be blinded.

The study was approved by our hospital's Institutional Review Board, and was conducted in conformity with ethical and humane principles of research.

Participants

All of the patients were operated by the same surgical team at the San Gerardo Hospital, coordinated by a highly experienced surgeon (GZ). The day

after the operation the patients were scheduled for rehabilitation and their full medical history was sent to our Rehabilitation Unit to decide on the transfer. To be eligible, the patients had to have undergone primary traditional uncemented total hip replacement because of osteoarthritis in the dominant leg 4–7 days before admission to our Rehabilitation Unit, be in the impossible-to-go-home group after discharge from the Orthopaedic Unit because of multiple comorbidities (e.g. cardiac, respiratory, or endocrine diseases), still requiring medical care and/or insufficient home support (e.g. living alone, absence of familiar, and social helps, or lack of transportation in order to access outpatient services), be aged >50 years, and have a good understanding of Italian. The exclusion criteria were cognitive impairment and all other causes of hip pain, such as previous lower limb surgery, infection, fracture, osteonecrosis or malignancy, and systemic or neuromuscular diseases. Any subjects receiving compensation for work-related disabilities were also excluded.

Participants were recruited between July 2010 and December 2011 and were asked to declare their willingness to comply with whichever treatment option they were randomly assigned to, and to attend all of the follow-up visits. To partially limit expectation bias and crossover problems, the patients were blinded to the study hypothesis by telling them that the trial was intended to compare two common rehabilitation approaches whose efficacy had not yet been established. Those who agreed gave their written informed consent, and their demographic data, symptoms, and medical history were collected.

The patients were asked to report any serious symptoms and events they experienced during the study that required further treatment.[12]

Interventional programmes

The interventional programmes involved two physiatrists and four physiotherapists.

Experimental group. The subjects performed task-oriented exercises, such as moving from a sitting to a standing position, ascending/descending stairs, climbing obstacles, and acquiring the most important functional strategies for ADL, and other exercises aimed at recovering functional abilities and balance, such as turning, sudden starts and stops, standing on an unstable surface, and walking while changing speed and direction. Sessions of stationary cycling were added to optimise hip strength and mobility. All of the exercises were performed with increasing loads on the operated limb, and included walking in place, and bilateral and unilateral knee flexion when standing. During walking training, the subjects were instructed to use their crutches reciprocally to regain a symmetrical gait pattern, but were also encouraged to abandon any walking aids by the end of their in-hospital stay. Ergonomic advice was provided in the form of a booklet given to the patients upon admission in order to help them modify their usual activities.

Control group. The subjects performed open kinetic chain exercises (e.g. hip flexion and extension; hip abduction; hip external rotations; isotonic and isometric quadriceps strengthening; hamstrings curls) in supine position on the couch aimed at improving the range of hip motion, increasing hip and lower limb muscle strength, and maintaining the length and elasticity of thigh tissues. During walking training, they were instructed to use their crutches reciprocally, allowed to use partial weight-bearing on the operated limb, and recommended to use walking aids for three months after surgery.

All of the subjects followed the exercise programmes individually. Two physiotherapists were separately responsible for each group, and arranged 90-minute sessions five times a week for three weeks. The physiotherapists were experienced at the same level.

To ensure that there was no variability in treatment administration, a fidelity check was made during each session and at the end of the intervention based on a treatment manual for administering exercise training.

No other treatments were offered once the patients had been enrolled; no major pharmacological agents were allowed, although mild analgesics (e.g. paracetamol) and non-steroidal anti-inflammatory drugs were permitted. Spouses or significant others were asked to support patient

compliance, and to inform staff promptly if any difficulty was encountered, in order to strengthen treatment adhesion and minimise the number of drop-outs.

Outcome measures and statistics

The outcome measures were disability, pain, ADLs, and quality of life.

Disability was assessed using the self-reported Western Ontario and McMaster Universities Osteoarthritis Index, a multidimensional scale consisting of three subscales (physical function, pain, and stiffness).[13] The data for each subscale were standardised to a range of 0 (best) to 100 (worst health status). We used the Italian version, which has proved to be reliable and valid.[14]

Current pain intensity was assessed using an 11-point numerical rating scale ranging from 0 (no pain) to 10 (the worst imaginable pain).[15] ADLs were evaluated by means of the Functional Independence Measure, which ranges from 18 (the greatest limitation) to 126 (no limitation).[16] We used the Italian version, which has proved to be reliable and valid.[17]

Quality of life was assessed using the self-reported Short-Form Health Survey:[18] its eight domain scores of physical function, physical role, bodily pain, general health, vitality, social function, emotional role, and mental health were calculated on the basis of the Italian version (0 = worst perceived, 100 = best perceived quality of life),[19] which has proved to be reliable and valid.[20]

The questionnaires were completed before treatment, three weeks later (posttraining), and 12 months after discharge from hospital (one-year follow-up). At baseline and posttraining, the questionnaires were administered by secretarial staff who checked them and returned any uncompleted part to the patients for completion; at follow-up, the patients were met personally or telephoned by the same secretarial staff in order to ensure the questionnaires were properly completed.

After three weeks of treatment, the patients were also asked to rate the global perceived effect of treatment using a 5-point scale (1 = helped a lot; 5 = made things worse).[21]

Osseous integration was evaluated by means of X-ray examination 12 months after surgery by an independent expert.

The primary end-point was the pre- and posttreatment difference in the Western Ontario and McMaster Universities Osteoarthritis Index – physical function subscale. It was calculated that a sample size of 45 patients per group would be capable of detecting a between-group difference of 7.9 points in the primary end-point with a standard deviation of 13.6 (effect size of 0.58), a type I error of 5%, and a power of 80%.[22,23] A total of 50 patients were included in each group to allow for a 10% drop-out rate.

Baseline comparability was assessed using Student's *t*-test for independent samples. Linear mixed model analyses for repeated measures ($p < 0.05$) were made on each of the outcome measures, with group and time entered as fixed effects. The cross-over effect of time and group was entered as an interaction term. A linear mixed model was selected because it is a robust method in the presence of missing data.[24,25]

The perceived differences in global effect were analysed using the Mann–Whitney *U*-test. The data were analysed using SPSS 20.0 software.

Results

One hundred of the 134 screened patients agreed to participate in the study, and 47 in the experimental group and 48 in the control group completed the programme. A further six patients were lost to follow-up. Figure 1 shows the CONSORT flowchart.

No crossover problems arose, as no patient asked to swap groups. The groups were comparable at baseline (Table 1).

After training, the Western Ontario and McMaster Universities Osteoarthritis Index – physical function score decreased by almost 50% in the experimental group, and by about 20% in the control group, and had further improved at follow-up in both groups. The linear mixed model revealed a significant effect of time, group, and time-by-group interaction (Table 2). Concerning the other subscales, the stiffness scores showed a significant effect of time, group, and time-by-group interaction, whereas the pain scores showed only a significant effect of time and the time-by-group interaction.

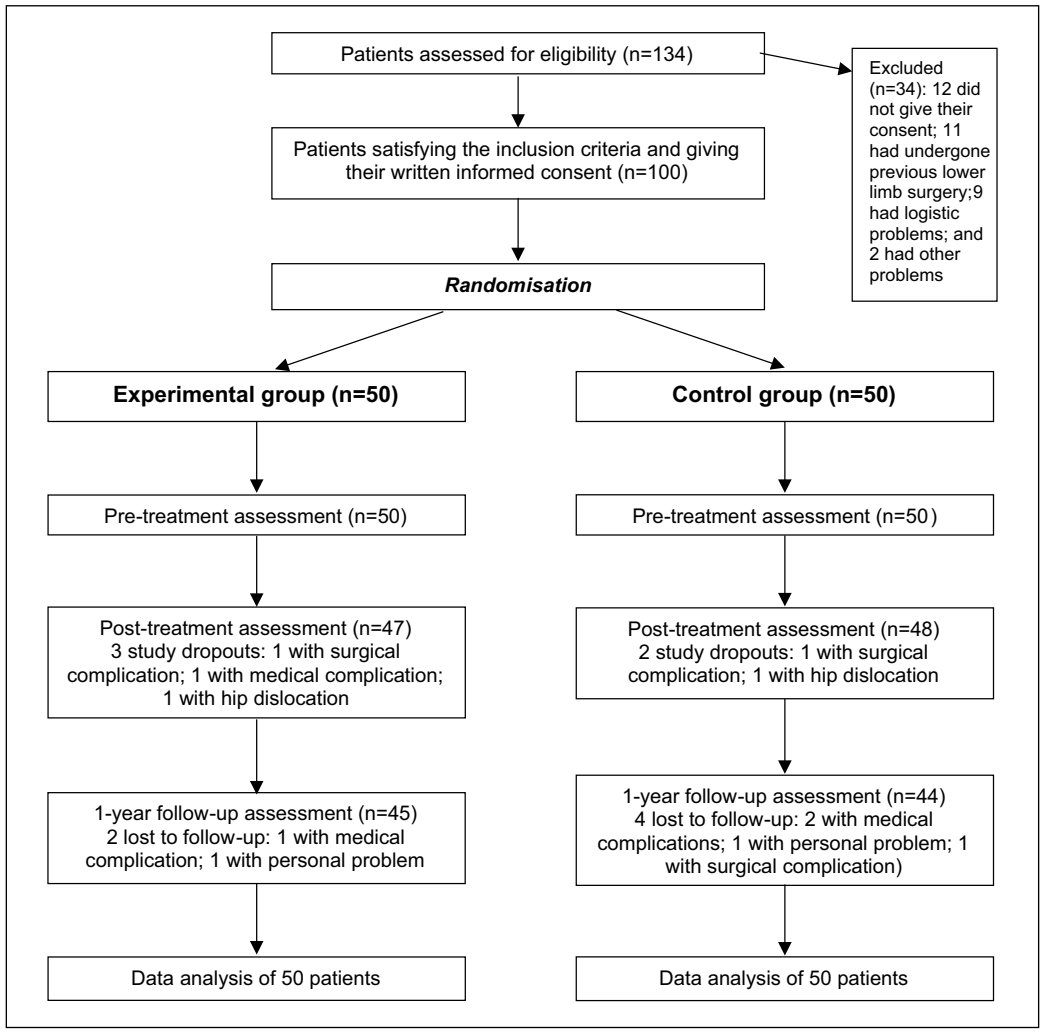

Figure 1. Participants' CONSORT flowchart.

Also the decrease in pain intensity (numerical rating scale) and the improvement in ADL performance (Functional Independence Measure) were more significant in the experimental group than in the control group (Table 2).

In terms of the quality of life (Table 3), the physical function, physical role and general health subscales revealed significant between-group differences after training.

Finally, both groups felt that the interventions had helped them a lot: the median value (interquartile range) of the global perceived effect was 1 (0) in the experimental group and 1 (1) in the control group. The scores were significantly different between the two groups ($p < 0.001$), indicating a greater perception of the efficacy of the training in the experimental group.

Satisfactory osseous integration of the femoral stem was observed in both groups at the 12-month routine surgical follow-up.

Minor adverse effects of transitory pain worsening ($n = 8$ in the experimental group and $n = 9$ in the control group) and falls ($n = 2$ and $n = 3$) were easily managed by means of symptomatic drugs and brief periods of rest.

Table 1. Patients' baseline characteristics (n = 100).

	Experimental group	Control group	P-value
Age (years)	69.5 (7.5)	68.8 (8.1)	0.683
Gender (male/female)	18/32	22/28	
Body mass index (kg/m^2)	27.7 (4.2)	27.4 (3.0)	0.472
Pain duration (months) before surgical intervention	20.5 (9.9)	17.6 (8.0)	0.112
Days after surgery at admission	5.2 (1.2)	5.3 (1.2)	0.801
Smokers (yes/no)	8/42	13/37	
Married (yes/no)	39/11	39/11	
Employed (yes/no)	8/42	13/37	
Education			
Primary school	17	16	
Middle school	20	23	
High school	9	4	
University	4	7	
Comorbidity (principal)			
Cardiac diseases	24	25	
Respiratory diseases	13	13	
Gastroenteric diseases	7	4	
Kidney diseases	1	4	
Endocrine diseases	5	4	
Use of drugs			
Antidepressants	1	2	
Analgesics	29	30	
Muscle relaxants	5	6	
Non-steroidal anti-inflammatory drugs	15	12	
Western Ontario and McMaster Universities Osteoarthritis Index			
Pain (0–100)	60.2 (20.5)	57.4 (21.5)	0.507
Stiffness (0–100)	56.5 (25.7)	57.0 (19.9)	0.914
Physical function (0–100)	48.7 (13.8)	47.6 (14.5)	0.709
Numerical Rating Scale (0-10)	5.3 (1.7)	5.2 (1.3)	0.692
Functional Independence Measure (18–126)	82.8 (8.1)	81.8 (10.2)	0.610
Short-Form Health Survey			
Physical activity (0–100)	35.4 (14.5)	35.1 (15.4)	0.920
Physical role (0–100)	35.5 (22.1)	35.3 (26.4)	0.967
Bodily pain (0–100)	31.3 (14.9)	30.4 (13.4)	0.752
General health (0–100)	48.5 (14.4)	48.9 (17.2)	0.900
Vitality (0–100)	51.4 (17.4)	52.5 (20.0)	0.770
Social function (0–100)	55.5 (16.0)	55.8 (17.5)	0.802
Emotional role (0–100)	32.0 (23.3)	33.3 (29.4)	0.973
Mental health (0–100)	59.0 (24.5)	59.2 (22.1)	0.941

Mean values (standard deviation).

Table 2. Changes over time within and between groups in terms of Western Ontario and McMaster Universities Osteoarthritis Index, Numerical Rating Scale, and Functional Independence Measure (n = 100).

	Group	Pretraining	Posttraining	Follow-up	F (p value) time effect	F (p value) group effect	F (p value) interaction effect
Primary outcome – Western Ontario and McMaster Universities Osteoarthritis Index							
Physical function (0–100)	Experimental	48.7 (13.8)	26.7 (15.1)	20.0 (11.1)	90.50	13.95	12.28
	Control	47.6 (14.5)	38.2 (13.7)	30.6 (14.9)	(<0.001)	(<0.001)	(<0.001)
Secondary outcomes – Western Ontario and McMaster Universities Osteoarthritis Index							
Pain (0–100)	Experimental	60.2 (20.5)	35.4 (19.8)	25.2 (16.1)	79.16	3.85	6.85
	Control	57.4 (21.5)	44.0 (17.8)	34.9 (18.7)	(<0.001)	(0.053)	(0.002)
Stiffness (0–100)	Experimental	56.5 (25.7)	24.0 (12.6)	19.8 (12.4)	75.54	10.46	3.42
	Control	57.0 (19.9)	37.0 (18.9)	28.8 (18.8)	(<0.001)	(0.002)	(0.037)
Numerical rating scale (0–10)	Experimental	5.3 (1.7)	1.5 (2.0)	0.8 (1.3)	147.02	5.12	3.44
	Control	5.2 (1.3)	2.5 (1.6)	1.4 (2.6)	(<0.001)	(0.026)	(0.036)
Functional Independence Measure (18–126)	Experimental	82.8 (8.1)	114.0 (5.6)	117.9 (10.3)	192.24	56.87	15.81
	Control	81.8 (10.2)	97.2 (13.1)	104.7 (14.0)	(<0.001)	(<0.001)	(<0.001)

Mean values (standard deviation).

Discussion

The results of this randomized controlled trial show that a programme of inpatient task-oriented exercises associated with early full weight-bearing is superior to a programme of traditional exercises associated with partial weight-bearing, in terms of reducing disability and pain, and improving ADLs and the quality of life in patients who have undergone total hip replacement. In terms of the Western Ontario and McMaster Universities Osteoarthritis Index, functional subscale, the difference between the two groups after training was clinically tangible (>7.9). Improvements lasted for at least 12 months after the end of the intervention in both groups.

The use of task-oriented exercises with early full weight-bearing in the rehabilitation after total hip replacement may have added value over traditional interventions. In their invaluable systematic review, Hol et al.[7] recommended early rehabilitation and walking without crutches as soon as possible, but could not clearly define the characteristics of the physical and rehabilitative interventions required, thus leaving a gap for evidence-based clinical practice. The closed chain kinetic exercises implemented in the task-oriented programme are advised in order to enhance functional outcomes, as well as a faster return to normal neuromuscular performance and to usual activities (such as sitting, standing, and ascending or descending stairs), in contrast to open chain kinetic exercises, mostly performed supine on the couch and in the absence of any functional input, that might prevent a full recovery even one year after surgery.[26–28] Furthermore, the early abandoning of walking aids by the end of their in-hospital stay (i.e. from three to four weeks after surgery) not only contributes to the satisfactory osseous integration of the femoral stem,[7] but also to additional functional outcomes such as walking with better stabilisation of the hip muscles during full loading.

At the end of the treatment period, disability and ADL performance had improved in both groups, but the improvement was significantly greater in the experimental group. Explaining to patients how to modify their functional limitations and encouraging them to walk unaided induced a greater improvement in perceived disability and the

Table 3. Changes over time within and between groups in terms of Short-Form Health Survey (n = 100).

	Group	Pretraining	Posttraining	Follow-up	F (p value) time effect	F (p value) group effect	F (p value) interaction effect
Secondary outcome – Short-Form Health Survey							
Physical function (0–100)	Experimental	35.4 (14.5)	56.8 (23.3)	73.1 (20.8)	71.99 (<0.001)	13.59 (<0.001)	3.84 (0.025)
	Control	35.1 (15.4)	45.5 (15.1)	60.9 (18.3)			
Physical role (0–100)	Experimental	35.5 (22.1)	58.5 (30.1)	76.1 (33.3)	18.08 (<0.001)	10.16 (0.002)	3.34 (0.040)
	Control	35.3 (26.4)	44.8 (38.6)	51.1 (45.1)			
Bodily pain (0–100)	Experimental	31.3 (14.9)	64.6 (16.9)	79.8 (26.1)	98.64 (<0.001)	14.11 (<0.001)	2.79 (0.067)
	Control	30.4 (13.4)	55.5 (15.9)	63.9 (25.2)			
General health (0–100)	Experimental	48.5 (14.4)	60.7 (17.5)	72.1 (18.9)	18.98 (<0.001)	14.74 (<0.001)	4.08 (0.020)
	Control	48.9 (17.2)	52.7 (13.6)	57.7 (16.8)			
Vitality (0–100)	Experimental	51.4 (17.4)	62.0 (18.2)	66.9 (17.0)	9.36 (<0.001)	4.83 (0.030)	2.25 (0.111)
	Control	52.5 (20.0)	54.8 (15.0)	58.4 (15.9)			
Social function (0–100)	Experimental	55.5 (16.0)	63.0 (25.1)	84.4 (20.5)	29.16 (<0.001)	1.26 (0.264)	0.64 (0.529)
	Control	55.8 (17.5)	60.9 (24.8)	76.7 (27.0)			
Emotional role (0–100)	Experimental	32.0 (23.3)	53.9 (42.0)	83.0 (31.5)	52.43 (<0.001)	3.25 (0.075)	1.61 (0.206)
	Control	33.3 (29.4)	41.0 (35.2)	73.5 (31.0)			
Mental health (0–100)	Experimental	59.0 (24.5)	72.0 (16.9)	74.0 (16.6)	6.821 (0.002)	6.17 (0.015)	2.11 (0.127)
	Control	59.2 (22.1)	61.7 (10.4)	66.2 (19.3)			

recovery of usual activities. Satisfactory levels were maintained until the end of the follow-up, probably because of the patients' propensity to implement functional strategies and the increasing consolidation of appropriate behaviours.

Pain perception had decreased in both groups by the end of the treatment and follow-up periods, which reflects the positive synergistic effects of surgery and active exercises.[29] The satisfactory effect of treatment on most of the Short-Form Health Survey physical subscales suggests the potential benefits of the proposed intervention, particularly in terms of improving the physical function and physical role domains. No significant between-group treatment effects were found in the mental domains of Vitality, Emotional Role, or Social Function, but given the characteristics of the experimental group, this is not surprising as the intervention did not include any specific cognitive action (e.g. cognitive-behavioural therapy).

The higher rates of treatment satisfaction in the experimental group indicate the superiority of the approach, presumably because task-oriented exercises and full weight-bearing were perceived by the subjects as providing a better solution to the functional problems experienced after total hip replacement. Remarkably, there was a limited number of drop-outs from either group, which suggests that the patients were highly motivated and determined to adhere to all of the phases of treatment. The support of staff and relatives probably played a crucial role in establishing a controlled and protected situation.

This randomized, controlled trial was internally valid, capable of distinguishing the effects in the two groups, and adequately sized. It was also based on concealed randomization, blinded data collection, and the effective masking of assessors and analysts. Concerning the generalisability issues, this sample was representative of a subset of patients with multiple comorbidities still requiring medical aids and/or insufficient home support, preventing an early discharge from the Orthopaedic Unit to home. Hence, our data are not generalisable to the general population undergoing a first total hip replacement, who is usually discharged 3–6 days after surgery.[30] Moreover, the data cannot be generalised to surgical revisions.

It is worth noting that such a rehabilitation programme is expensive, as about 5000 euros are provided from the Italian healthcare system during the in-hospital stay, and therefore it has to be reserved for patients with medical and social characteristics as described above; however, this rehabilitation programme might potentially prevent additional costs owing to long-term assistance or falls and fall-related injuries. Recommendations on earlier discharges should be advised when the management of comorbidities guarantees a safer return to home, as well as on better organised local transportation in order to allow an increasing number of patients benefiting from outpatient or home-based rehabilitation services.[31,32] This will also be of importance in order to investigate our encouraging findings in a wider population of patients undergoing total hip replacement.

This study has some limitations. First of all, we used only self-reported measures and did not investigate their relationships with physical measures and tests. Second, we did not record presurgery scores of disability, pain, ADL, and quality of life, and this may limit our interpretation of the impact of the exercise protocol.

In conclusion, our findings suggest that a three-week inpatient rehabilitation programme based on task-oriented exercises and early full weight-bearing is useful in changing the course of disability, pain, ADL, and quality of life in patients after first total hip replacement who could not go home after discharge from the Orthopaedic Unit because of multiple comorbidities and/or insufficient home support. We recommend its use in specialised secondary care settings where the staff are adequately trained.

Clinical messages

- Task-orientated inpatient rehabilitation and early full weight-bearing reduce disability and pain more quickly than open chain kinetic exercises in patients with multiple comorbidities who have undergone total hip replacement.
- These benefits were maintained for at least 12 months.

Contributors

All authors had a role in study concept and design, acquisition of subjects and data, analysis and interpretation of data, preparation of manuscript, and gave final approval of the version to be published. MM, EA, and BR drafted the article, CL, SF, and GZ revised it critically for important intellectual content. GZ surgically treated all of the patients included in the study.

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Conflict of interest

The authors declare that there was no conflict of interest.

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