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Is formal physical therapy necessary after reverse total shoulder arthroplasty? A single-blinded, randomized controlled trial

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Background: Formal, supervised physical therapy (SPT) is a mainstay in the postoperative rehabilitation protocol after reverse shoulder arthroplasty. However, recent studies have called into question its superiority over alternative approaches. The purpose of this study was to compare, in a randomized controlled trial, the effectiveness of an unsupervised home therapy (UHT) program to SPT on patient-reported outcomes for patients undergoing reverse shoulder arthroplasty.
Methods: In this prospective, single-center study, 59 patients aged 60-85 undergoing primary reverse shoulder arthroplasty were randomly assigned to either SPT (n = 30) or UHT (n = 29) groups. The UHT group followed a detailed physical therapy manual provided before discharge. Exclusion criteria included a history of ipsilateral shoulder infection, autoimmune or neuromuscular disease, and a need for postdischarge rehabilitation facility care. The primary outcome measure was the American Shoulder and Elbow Surgeons score at 1 year postoperatively. Secondary outcomes included Simple Shoulder Test, Constant score, visual analog scale, patient satisfaction, and range of motion at 3 months and 1 year postoperatively. An independent examiner blinded to group assignment evaluated these outcomes.
Results: Results showed no significant difference in American Shoulder and Elbow Surgeons scores between the SPT group (mean 77.6) and UHT group (mean 81.1) at 1 year postoperatively ($P = .501$). Despite limited in-person follow-up rates, range of motion measurements showed no significant differences between groups at either 3 months (41 patients) or 1 year (25 patients) postoperatively. Both groups demonstrated comparable results in Constant scores, visual analog scores, and patient satisfaction measures. Neither group required any reoperations during the study period.
Conclusion: This study suggests that self-directed home therapy following reverse shoulder arthroplasty may be a viable alternative to formal SPT. Although the findings were limited by reduced in-person follow-up rates, which may have underpowered certain comparisons, the results consistently showed no significant differences between the two approaches across multiple outcome measures. These findings have important implications for patients who face barriers to accessing formal physical therapy due to circumstances, cost, or comorbidities, suggesting that a well-structured home exercise program may provide comparable outcomes. Future research with larger sample sizes and higher follow-up rates would be valuable to confirm these findings.

Reverse total shoulder arthroplasty (rTSA) is a well-established surgical procedure now utilized for a variety of shoulder pathologies.[1] Its popularity has steadily increased, and it is now the most common form of shoulder arthroplasty performed in the United States.[4] The postoperative rehabilitation protocol, typically involving formal supervised physical therapy (SPT), has been

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viewed as critical for optimizing functional recovery and improving range of motion (ROM).[2,4,6,10] Despite a marked increase in the utilization of rTSA, there is no clear consensus as to the proper postoperative rehabilitation protocol.

Numerous studies have demonstrated the benefits of SPT programs in enhancing shoulder function, ROM, and overall quality of life postsurgery.[2,4,6,10] Romano et al found that formal physical therapy is vital for patients after rTSA, noting that patients had improved clinical outcomes and decreased complication rates.[9] Physical therapy after shoulder surgery has been proposed to serve as a guide for patients through the recovery period, with the goal of ultimately improving outcomes and satisfaction.[8] The findings from these early studies have established a conventional belief in the necessity of SPT for optimal recovery. Despite its widespread acceptance, the rigid framework of formal SPT may not be accessible or feasible for all patients. Factors such as geographical limitations, financial constraints, and unexpected healthcare disruptions (eg, the COVID-19 pandemic) may impede consistent SPT attendance. Coverage of physical therapy has become increasingly limited by insurance companies, leading to alternatives including telerehabilitation, internet-based physical therapy, and home-based physician-guided physical therapy.[11]

Despite the plethora of literature on postoperative physical therapy, the necessity of formal SPT in this context has seldom been rigorously compared to alternative rehabilitation methods.[1-6] A recent randomized controlled trial suggested that unsupervised or home-based exercise programs or unsupervised home therapy (UHT), designed to be patient-friendly and cost-effective, could serve as viable alternatives.[12] These programs, when structured appropriately, have shown potential in achieving comparable outcomes to SPT, especially in contexts where formal therapy is impractical. For example, a study by Schick et al on rehabilitation following rTSA demonstrated similar postoperative improvements in American Shoulder and Elbow Surgeons (ASES) scores in both formal therapy and home-based therapy groups.[12] Furthermore, Mulieri et al found that home therapy directed by the surgeon had favorable outcomes compared to formal physical therapy after anatomic TSA.[7]

As value-based care becomes increasingly important in healthcare, these studies raise the possibility of equivalent outcomes without the cost of multiple physical therapy visits. The purpose of this study was to compare, in a randomized controlled trial, the effectiveness of an UHT program to outpatient SPT. We hypothesized that there would be no significant difference in ROM, ASES scores, or patient satisfaction between the SPT and UHT groups.

Materials and methods

Study design

This study was a prospective, single-center, two-arm, parallel-group randomized controlled trial. The primary aim was to compare the effectiveness of an unsupervised home exercise program (UHT) to formal SPT in restoring function in patients undergoing unilateral reverse shoulder arthroplasty (rTSA).

Power analysis

A power analysis was performed to estimate the necessary sample size for detecting a significant difference in the ASES score between the two groups: those receiving outpatient physical therapy (SPT) and those following an UHT regimen. A two-sided test with a significance level of 0.05 was employed. The analysis assumed a 10-point mean difference in ASES score between the groups, with a standard deviation of 10. To achieve a nominal power of 90% and accounting for a potential attrition rate of 30%, the study estimated that a total of 30 participants per group would be required. This calculation was performed using a standard sample size formula, resulting in an actual power of 91.2%.

Participants

Participants were recruited from a single tertiary center and treated by fellowship-trained shoulder arthroplasty surgeons. Eligible participants were aged 60-85 years, diagnosed with primary rotator cuff tear arthropathy, and scheduled for unilateral rTSA. Exclusion criteria included previous ipsilateral shoulder arthroplasty, shoulder infection, need for discharge to a rehabilitation or long-term care facility, and conditions such as autoimmune or neuromuscular diseases. Additionally, participants had to be able to follow written directions in English. Patients with an indication other than cuff tear arthropathy were excluded from the study.

Randomization and blinding

After obtaining informed consent, participants were randomized in a 1:1 ratio to either the SPT group or the self-directed UHT group. Randomization was performed by an independent party using an Excel random number generator. Sequentially numbered sealed envelopes containing group assignments were opened just before surgical intervention. Separate individuals handled random allocation, patient enrollment, and outcome assessment to ensure blinding of clinical evaluators.

Interventions

Formal outpatient or supervised physical therapy group

Participants began SPT within 5 days postoperatively, with sessions 2-3 times per week for a total of 12 weeks. Initial therapy included elbow, wrist, and hand ROM exercises for the first 2 weeks, followed by the use of home pulleys starting at the 2-week postoperative mark. Arm use for activities of daily living commenced at 4 weeks, and internal rotation (IR) exercises started at 10 weeks postoperatively. Participants also received a list of suggested home exercises to complete 2-3 times per day at home that correlated to their progress through the therapy protocol. Patients were discharged from formal outpatient SPT at 12 weeks postoperatively or after passing an independent standard assessment by a physical therapist.

Unsupervised home therapy group

Participants followed a 12-week unsupervised home exercise program based on a detailed physical therapy manual provided before discharge. The manual included images and written explanations of exercises to be performed three times daily, with a graduated progression similar to the SPT group (Supplementary Materials). Exercises were demonstrated to patients before hospital discharge. In weeks 1-2 patients, performed passive elbow, wrist, and finger ROM exercises only and wore a sling at all times. In weeks 3-5 patients, received a pulley and performed passive pulley ROM and table slide ROM exercises. In weeks 6-11 patients, advanced to the early strengthening phase with passive external rotation exercises with a dowel rod, wall walk exercises, and active assist shoulder ROM. At 12 weeks, patients were given moderate strengthening exercises including active shoulder elevation, resistance band shoulder external rotation, active shoulder abduction, and towel-assisted IR exercises.

Compliance with both arms of the study was assessed on a binary basis during routine postoperative evaluations at 2 weeks, 6 weeks, 3 months, and 1 year postoperatively.

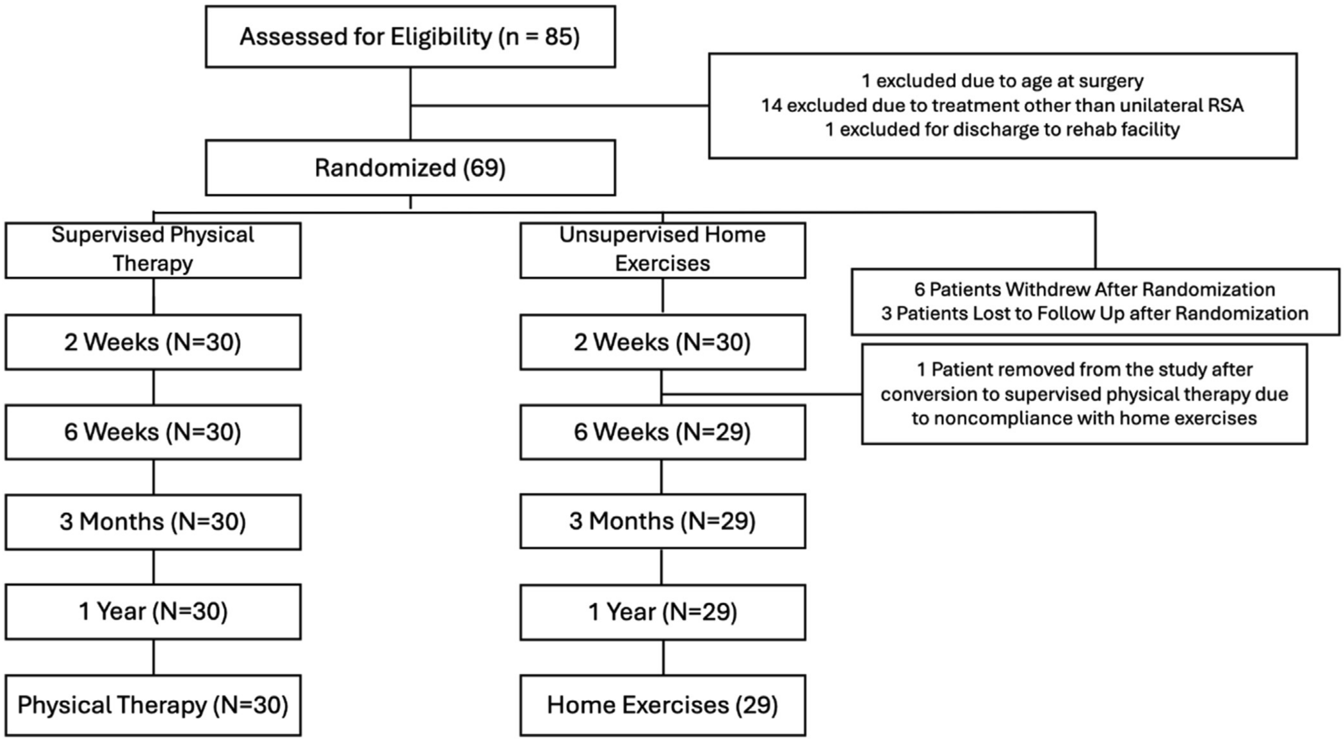

Figure 1 Consolidated Standards of Reporting Trials diagram. Eighty-five patients were initially assessed for eligibility. Sixty-nine patients were selected for randomization. The final cohort includes 30 patients in the supervised physical therapy (SPT) group and 29 patients in the unsupervised home therapy (UHT) group.

Outcome measures

The primary outcome was the change in the ASES score from baseline to 1 year postoperatively. Secondary outcomes included the Constant score, patient satisfaction, visual analog scale (VAS) for pain, and ROM measurements at 6 weeks, 3 months, and 1 year postoperatively. A Minimal Clinically Important Difference for the ASES score, Simple Shoulder Test score, and VAS pain score of 20.9 ($P < .001$), 2.4 ($P < .0001$), and 1.4 ($P = .0158$), respectively, were utilized as described by Tashjian et al.[13] An independent examiner blinded to group assignments assessed shoulder function and active ROM. Patients were reviewed for postoperative complications during the study period.

Data collection and management

Data were collected using REDCap (Vanderbilt University, Nashville, TN, USA), a secure web application for managing online surveys and databases. Standard descriptive statistics, chi-square tests, and *t*-tests were used for data analysis. The study's sample size was calculated to ensure 90% power to detect a 10-point difference in ASES scores, accounting for a 30% attrition rate, with 30 participants per group. ROM was evaluated by a single-blinded observer with a goniometer at routine clinic visits.

Data safety monitoring

Serious adverse events related to the study procedure were reported to the Data Safety Monitoring Board via email as they occurred. The Data Safety Monitoring Board met bimonthly to review adverse events and the study's feasibility. Participants who were unable or unwilling to attend follow-up visits completed patient-reported outcomes questionnaires via phone, email, or mail with verbal consent obtained using an IRB-approved script.

Table I
Demographics of study participants.

	UHT	SPT	*P* value
Patients, n	29	30	
Sex			
Female	14	18	
Male	15	12	.366
Age			
Mean (SD)	70.9 [6]	70 [5.5]	
Body mass index			
Mean (SD)	29.6 [6.4]	30.6 [6.5]	
Race			
Black/African American	8	6	
White	21	24	
Charlson comorbidity index			
Mean (SD)	4.1 [1.7]	3.9 [1.3]	
Smoking			
Never	13	12	
Former	9	13	
Current	6	5	

UHT, unsupervised home therapy; *SPT*, supervised physical therapy; *SD*, standard deviation.

Results

A total of 85 patients were assessed for eligibility. Of these, 69 met criteria for inclusion and were randomized. During follow-up, 10 additional patients either withdrew, were lost to follow-up, or were converted from home exercises to formal physical therapy (Fig. 1). Data from patients who withdrew from the study or crossed over from one treatment arm to another were removed from the final analysis. A total of 59 patients were randomized and included

Table II
Patient-reported outcomes at 1 year postoperatively.

PRO	UHT		SPT		*P* value
	n	Mean [SD]	n	Mean [SD]	
ASES score	23	77.6 [20.5]	26	81.1 [15.5]	.501
Simple Shoulder Score	22	20.3 [17.7]	24	21.9 [19.8]	.764
Constant score	7	76.1 [8.3]	9	67.5 [11.7]	.077
VAS	10	1.78 [23.1]	7	1.84 [22.1]	.952
Patient satisfaction (with procedure)	22		28		.298
Very satisfied		13		21	
Satisfied		6		4	
Neither		0		2	
Dissatisfied		2		0	
Very dissatisfied		1		1	
Patient satisfaction (with therapy protocol)	22		28		.629
Very satisfied		10		17	
Satisfied		11		8	
Neither		1		1	
Dissatisfied		0		1	
Very dissatisfied		0		1	

UHT, unsupervised home therapy; *SPT*, supervised physical therapy; *VAS*, visual analog scale; *PRO*, patient-reported outcome; *ASES*, American Shoulder and Elbow surgeons; *SD*, standard deviation.
This table included ASES score, Constant score, VAS score, and patient satisfaction.

through study completion. Patients underwent surgery by one of 3 shoulder and elbow fellowship-trained surgeons.

Demographics

Analysis of demographic characteristics, including sex, age, medical comorbidities, and smoking status yielded no significant differences between the two randomized groups (Table I).

Patient-reported outcomes

ASES scores averaged 77.6 for the UHT group and 81.1 for the SPT group at 1 year postoperatively with 23 and 26 patients completing 1-year ASES scores, respectively. There were no differences in the ASES ($P = .501$), Simple Shoulder Score ($P = .764$), Constant score ($P = .077$), or VAS score ($P = .952$) at 1 year postoperatively. In the UHT group, 86% of respondents were satisfied or very satisfied with their procedure and 95% were satisfied or very satisfied with their therapy protocol. In the SPT group, 89% were satisfied or very satisfied with their procedure and 89% were satisfied or very satisfied with their therapy protocol. The difference in neither of the means of these Likert scales was statistically significant between groups (Table II).

Range of motion

There were no statistically significant differences between the SPT and UHT groups at 3 months in forward flexion (UHT mean: 144.8; SPT mean: 140; $P = .489$), IR (UHT mean: 17; SPT mean: 17.1; $P = .497$), or external rotation with the arm adducted (UHT mean: 47.8; SPT mean: 52.7; $P = .319$) (Table III). No statistically significant difference developed at 1-year follow-up. There was marked attrition in follow-up for ROM measures with only 41 patients completing 3-month evaluation and 23 patients completing 1-year evaluation.

Complications and reoperation

No patients in either treatment arm developed a reported complication, and no patients underwent reoperation during the study period.

Table III
Postoperative range of motion at 3 months and 1 year.

	Postoperative	
	3-mo	1-yr
Unsupervised home therapy (n = 29)	n = 18	n = 9
Active range of motion		
Forward flexion	144.8 [20.9]	156.7 [22.5]
External rotation (adducted)	47.8 [17.7]	67.4 [29.3]
Internal rotation	17 [2.7]	13.1 [3.3]
Standard physical therapy (n = 30)		
Active range of motion	n = 23	n = 14
Forward flexion	140 [24.5]	153.2 [21.1]
External rotation (adducted)	52.7 [13]	56.4 [28.1]
Internal rotation	17.1 [3.1]	15 [3.6]
P values (UHT vs. SPT)		
Forward flexion	0.489	0.696
External rotation (adducted)	0.319	0.345
Internal rotation	0.497	0.314

UHT, unsupervised home therapy; *SPT*, supervised physical therapy.
This table included forward flexion, external rotation in adduction, and internal rotation.

Discussion

This randomized controlled trial found no difference between an UHT program compared to formal SPT in patients undergoing rTSA in terms of ROM and patient-reported outcomes at 3 months and 1 year postoperatively. These results provide external validation of previous randomized control trials (RCTs), reinforcing the potential of UHT programs as a viable alternative to traditional SPT.

Furthermore, not only were the ROM and patient reported outcome measures equivalent between the UHT and SPT groups, but our results showed no significant differences observed at the 3-month postoperative mark. This early convergence in ROM outcomes suggests that UHT can facilitate recovery at a pace comparable to SPT, potentially alleviating concerns about delayed rehabilitation progress in unsupervised settings. The ability of UHT programs to match the short-term gains achieved through SPT highlights the efficacy of these programs and suggests that early rehabilitation milestones can be met in addition to those assessed at the conclusion of the full recovery period.

This study's validation of previous RCTs is significant in supporting a paradigm shift toward more flexible and accessible rehabilitation methods. The COVID-19 pandemic highlighted the necessity for alternative rehabilitation strategies, as access to traditional SPT was severely restricted. This period underscored the practicality and effectiveness of UHT programs, especially when SPT sessions are inaccessible. Furthermore, the variability in insurance coverage for SPT services has accentuated the importance of viable, cost-effective alternatives. Patients undergoing rTSA, who often face financial and logistical barriers, stand to benefit significantly from validated UHT programs.

SPT, while potentially beneficial, imposes substantial costs on the healthcare system and patients. Beyond the direct financial burden of therapy sessions, patients often face logistical challenges including time commitments and associated loss of productivity at work, transportation barriers, and copayments. By demonstrating that UHT programs can achieve comparable short- and long-term outcomes to SPT, our study highlights the potential for UHT to mitigate these burdens without compromising clinical outcomes. Given the validation from now multiple RCTs, there is a strong case for reevaluating the necessity and frequency of SPT sessions in rTSA rehabilitation protocols.

Future research should focus on a cost-benefit analysis of UHT programs vs. SPT to provide a clearer picture of the economic advantages. This research should account for direct medical costs of therapy sessions and healthcare utilization as well as indirect costs to the patient, such as travel expenses and lost productivity. Understanding the economic implications will be critical for healthcare providers aiming to optimize resource allocation without compromising patient care and outcomes.

Despite the strengths of our study, several limitations must be acknowledged. The primary limitation is the reliance on patient reported outcome measures which showed relatively poor responsiveness. This study was conducted during the COVID-19 pandemic, and we encountered difficulty with getting patients to return physically to clinic for their 3-month and 1-year follow-up visits. Our primary outcome, ASES score, as well as patient satisfaction were collected over the phone and were completed at a relatively high rate with 1-year follow-up. However, our secondary outcome measures, including the Constant, Simple Shoulder Test, and VAS scores, as well as the ROM exam were part of the in-person visit workflow and were completed at a comparatively lower rate at the 1-year mark. As such, these results should be interpreted with substantial caution, given that these measures did not approach the number needed as determined by the a priori power analysis. Additionally, compliance with the UHT program was self-reported, introducing potential bias. However, this does reflect real-world conditions where patients' compliance to prescribed exercise regiments varies. Future studies could incorporate more objective measures of compliance, such as wearable activity trackers, to monitor compliance more accurately and provide a clearer picture of adherence and its impact on outcomes. Another limitation of the study is the practice setting, where all patients were treated by one of four fellowship-trained shoulder and elbow surgeons who perform rTSA at a high volume—which may not reflect all practice settings.

Conclusion

This single-blind RCT provides further evidence that an UHT program may be noninferior to outpatient SPT in patients undergoing rTSA. Though limited by poor follow-up, the study showed equivalent patient reported outcomes. There may be potential for reducing healthcare costs and patient burden with integration of UHT programs. Future research should focus on evaluating the cost-effectiveness of UHT in rTSA and should include objective measures of compliance with these regimens.

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Supplementary Data

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