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Effect of Inpatient Rehabilitation vs a Monitored Home-Based Program on Mobility in Patients With Total Knee Arthroplasty
The HIHO Randomized Clinical Trial

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IMPORTANCE Formal rehabilitation programs, including inpatient programs, are often assumed to optimize recovery among patients after undergoing total knee arthroplasty. However, these programs have not been compared with any outpatient or home-based programs.

OBJECTIVE To determine whether 10 days of inpatient rehabilitation followed by a monitored home-based program after total knee arthroplasty provided greater improvements than a monitored home-based program alone in mobility, function, and quality of life.

DESIGN, SETTING, AND PARTICIPANTS In this 2-group, parallel, randomized clinical trial, including a nonrandomized observational group, conducted at 2 public, high-volume arthroplasty hospitals in Sydney, Australia (July 2012-December 2015), 940 patients with osteoarthritis undergoing primary total knee arthroplasty were screened for eligibility. Of the 525 eligible patients consecutively invited to participate, 165 were randomized either to receive inpatient hospital rehabilitation and home-based rehabilitation or to receive home-based rehabilitation alone, and 87 patients enrolled in the observation group.

INTERVENTIONS Eighty-one patients were randomized to receive 10 days of hospital inpatient rehabilitation followed by an 8-week clinician-monitored home-based program, 84 were randomized to receive the home-based program alone, and 87 agreed to be in the observational group, which included only the home-based program.

MAIN OUTCOMES AND MEASURES Mobility at 26 weeks after surgery, measured with the 6-minute walk test. Secondary outcomes included the Oxford Knee Score, which ranges from 0 (worst) to 48 (best) and has a minimal clinically important difference of 5 points; and EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D) visual analog scale, which ranges from 0 (worst) to 100 (best), and has a minimal clinically important difference of 23 points.

RESULTS Among the 165 randomized participants, 68% were women, and the cohort had a mean age, 66.9 years (SD, 8.4 years). There was no significant difference in the 6-minute walk test between the inpatient rehabilitation and either of the 2 home program groups (mean difference, −1.01; 95% CI, −25.56 to 23.55), nor in patient-reported pain and function (knee score mean difference, 2.06; 95% CI, −0.59 to 4.71), or quality of life (EQ-5D visual analog scale mean difference, 1.41; 95% CI, −6.42 to 3.60). The number of postdischarge complications for the inpatient group was 12 vs 9 among the home group, and there were no adverse events reported that were a result of trial participation.

CONCLUSIONS AND RELEVANCE Among adults undergoing uncomplicated total knee arthroplasty, the use of inpatient rehabilitation compared with a monitored home-based program did not improve mobility at 26 weeks after surgery. These findings do not support inpatient rehabilitation for this group of patients.

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Supplemental content

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In 2015 more than 49 000 total knee arthroplasties were performed in Australia, with the incidence per 100 000 population increasing from 115 to 207.3 since 2005.[1] From 1980 to 2010, the prevalence of total knee arthroplasty in the United States increased 11-fold.[2] Formalized rehabilitation is often provided after surgery, yet the modes of provision vary greatly.[3] Inpatient rehabilitation is one commonly used treatment option in Australia. Recent estimates indicate that a median 40% of privately insured patients per surgeon were transferred to inpatient rehabilitation in 2014, although this figure ranges from 0% to 100%.[4] This contrasts with the public sector utilization rate of 21%,[5] suggesting that factors other than need drive the high utilization rate in the private sector.

Use of inpatient rehabilitation after surgery also varies internationally. Both Switzerland and the United States have a high uptake,[6,7] the latter including less intensive rehabilitation in skilled nursing facilities.[8,9] In Canada and the United Kingdom, inpatient rehabilitation is uncommon after total knee arthroplasty.[7,10] This variability in use suggests either overuse or underuse, and given the added costs associated with its provision, it is important to determine its efficacy compared with other options.

Because the majority of procedures are performed in the private sector in Australia[11] and because their number is expected to increase worldwide as the population ages, the question of whether inpatient rehabilitation yields superior outcomes to less costly alternatives is of considerable interest.

Except, to our knowledge, for a randomized clinical trial (RCT)[12] involving Canadian patients who underwent either hip or knee arthroplasty, no published RCT has compared inpatient rehabilitation to any clinic-based program or to a monitored (clinician-supervised) or unmonitored (unsupervised) home program.

This RCT was conducted to determine if 10 days of inpatient rehabilitation followed by a monitored home program provided greater improvements than a monitored home program alone in mobility, function, and quality of life.

Key Points

Question Does inpatient rehabilitation result in better mobility following total knee arthroplasty than a monitored home-based program?

Findings This clinical trial randomized 165 adults free of significant complication after arthroplasty to 10 days of hospital inpatient rehabilitation followed by an 8-week, clinician-monitored, home-based program or home-based program only and were compared with an observation group of 87 patients who also participated in the home-based program. There was no significant difference in the 6-minute walk test between any of the groups at the primary end point of 26 weeks.

Meaning For adults undergoing uncomplicated total knee arthroplasty, inpatient rehabilitation did not improve mobility compared with a monitored home program.

Trial Design and Methods

Study Oversight

An independent data and safety monitoring board was established to monitor safety and provide advice on issues regarding scientific aspects of the trial. This board comprised a rehabilitation physician, physical therapist, and statistician. Only one initial board meeting was held because there were no adverse events reported.

Trial Design and Ethical Approval

The trial was a multicenter, 2-group parallel RCT with a third observational group (**Figure**). Ethical approval was granted by St Vincent's Hospital human research ethics committee. Written, informed consent was obtained from those willing to participate as well as provide baseline measures. The study design has been published elsewhere[13]; the study protocol is detailed in Supplement 1. Protocol changes are summarized in eMethods 1 in Supplement 2, but important changes included change in primary outcome from the proportion of participants attaining a minimum walk speed to distance walked in the 6-minute walk test; addition of a second recruiting hospital; and inclusion of an observational group.

Recruitment and Consent

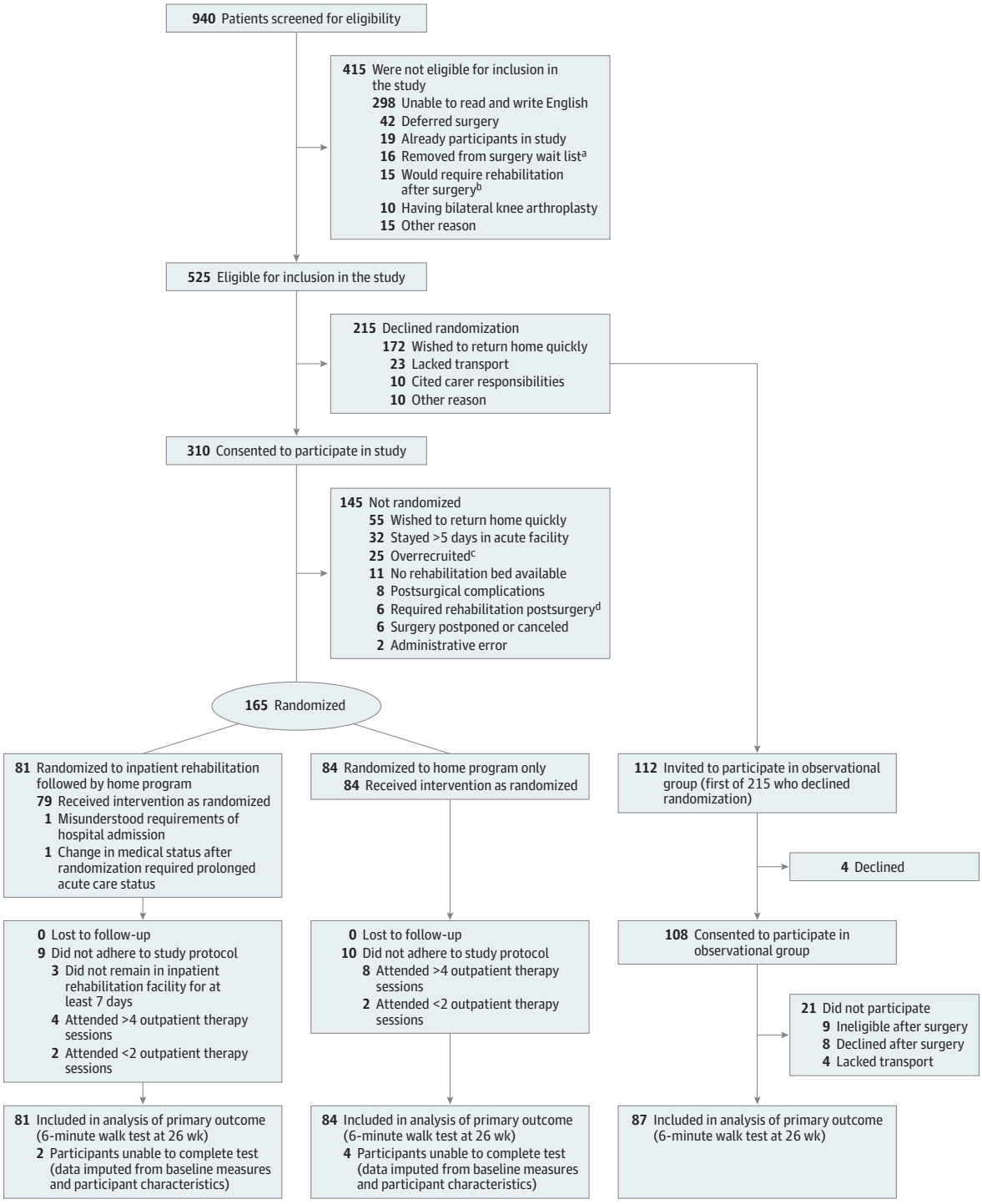
Participants were recruited from 2 high-volume arthroplasty hospitals in Sydney, Australia. Recruitment started at the second site halfway through the study, after further funding was secured. Consecutive patients presenting for primary unilateral total knee arthroplasty were screened for eligibility.

To be eligible, participants had to be older than 40 years with a primary diagnosis of osteoarthritis and to undergo a primary, unilateral total knee arthroplasty.

Major exclusion criteria were having a predisposition to be discharged to an inpatient rehabilitation facility due to lack of social support (lack of an able caregiver); having other major coexisting physical impairments such as hemiplegia or amputation; not being able to read English; and being unable to perform a home exercise program without support from another person.[14] After surgery, an inability to participate in the planned programs due to a complication was also an exclusion criterion.

Patients presenting at each site's preadmission clinic—typically within 6 weeks of surgery—were identified and screened by research personnel through chart review and direct questioning. Screening logs recorded the reasons invited patients were ineligible and detailed why otherwise eligible patients declined participation. Eligible persons who preferred to receive the home program, rather than be randomized, were invited to participate in an observational group and were followed up for 6 months after surgery. A selection bias toward inpatient rehabilitation was noted on commencement of the study. An observational group was followed up for analysis of a possible preference effect between those randomized to receive the home program and those who received this voluntarily.

Figure. Cohort Ascertainment, Randomization, and Study Timeline



[a] These patients did not proceed with surgical intervention.

[b] These patients had a predisposition to be discharged to an inpatient rehabilitation facility due to lack of social support (lack of an able caregiver) or other major coexisting physical impairments such as hemiplegia or amputation.

[c] To ensure sufficient participants were available for inclusion in the study, recruitment continued until the final participant was randomized. This strategy resulted in an overrecruitment of potential participants.

[d] These patients required inpatient rehabilitation after surgery due to either a significant complication or that their social supports had changed, so could not be randomized.

Randomization and Allocation Concealment

Randomization took place once it had been confirmed that participants were cleared for discharge by the fifth day after surgery. Clearance for discharge was determined by patients' ability to mobilize independently and negotiate stairs, with or without an aid. If it was determined that there was a need for inpatient rehabilitation, such patients were no longer eligible.

A centralized, telephone-based randomization service was used by the coordinating investigator for allocating participants in a 1:1 ratio. Participants were randomized by site to 1 of the 2 intervention groups using the method of minimization (adaptive stratified sampling).[15] This approach aims to reduce imbalance between groups on various prognostic factors that can occur despite random allocation. Age (≤68 y, >68 y), height (≤163 cm, >163 cm), and sex (man, woman) were used as stratifying variables because they are known to affect the primary outcome.[16]

Blinding

Outcome assessors were blind to group allocation and not involved in providing interventions. Because physical therapists delivering the intervention could not be blind to intervention, they did not play a part in the collection or analysis of outcomes and only provided 1 of the treatment options.

Interventions

Hospital Inpatient Rehabilitation

In accordance with Australian rehabilitation standards,[17] participants admitted to a rehabilitation unit each received twice-daily supervised sessions comprising an hour to an hour and a half of one-to-one physical therapy and an hour to an hour and a half of class-based exercises. These sessions comprised general aerobic components as well as general functional and muscle-specific exercises focused on restoring knee mobility, lower limb strength, and normal neuromuscular coordination, and gait patterns (eMethods 2 in Supplement 2). Regardless of performance level, participants were required to stay for 10 days so that variation in treatment received (in this case, duration of care) was not a confounder. Prior to discharge, participants were familiarized with the home program as described below.

Home Program

The home program, which was the usual care provided at the sites, was broadly based on the home program used in a recent RCT.[18] It was informed by exercise guidelines developed for older patients[19] and patients with osteoarthritis.[20] Approximately 2 weeks after surgery, participants allocated to the home program attended 1 group-based outpatient exercise session in the physical therapy department. The home program was rehearsed and exercises individualized as required due to comorbidities. As with the inpatient program, this home program comprised general aerobic components as well as general functional and muscle-specific exercises (eMethods 3 in Supplement 2). Participants were encouraged to attend 1 to 2 classes from the third to 10th week after surgery, to assist exercise progression and permit discussion of ongoing issues with therapists. Participants received a booklet detailing the home program and were permitted to contact the therapist by telephone in this period. They were also required to complete a diary detailing program adherence, health care utilization, and return-to-work data. To ensure that variation in attendance in the outpatient visits was not a confounder, all participants (regardless of group) were prescribed the same number of sessions.

Follow-up Assessments

Follow-up assessments took place at 10, 26, and 52 weeks after surgery and were performed by trained assessors blinded to group allocation. Research personnel called each participant within the week preceding their follow-up appointments to promote participant retention and completion of follow-up.

Primary Outcome

The primary outcome was the walking distance at 26 weeks measured using the 6-minute walk test,[16] for which participants were asked to walk fast laps of a 30-m flat track for 6 minutes, with verbal encouragement provided by the assessor at the end of each lap. The 6-minute walk test is a valid, reliable, responsive measure of functional mobility for knee osteoarthritis and following total knee arthroplasty.[21] A functional outcome based on a physical test was considered an appropriate choice because improvement in mobility is a primary goal of physical rehabilitation programs.[3,22] In order to aid interpretation of the relevance of any between-group differences in the 6-minute walk test observed and in the absence of data describing the minimum clinically important distance for this test after total knee arthroplasty, we incorporated a nested study to evaluate the minimal important improvement for this test.[23]

Secondary outcomes comprised both patient-reported and observer-measured outcomes including the Knee Injury and Osteoarthritis Outcome Score (subscales range, 0 [worst]-100 [best]; minimal clinically important difference, 8-10),[24] knee flexion (end) range of motion (<100°, ≥100°),[25] the EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D) descriptive index[26] (range, 1 [best possible health] through 0 [death] to −0.59 [worse than death]; minimal clinically important improvement, 0.31),[27] EQ-5D visual analog scale[26] (range, 0 [worst] to 100 [best]; minimal clinically important improvement, 23),[27] Oxford Knee Score[28] (range, 0 [worst] to 48 [best]; minimal clinically important difference, 5),[29] and a 15-m walk test. Direct and indirect health care costs, including visits to health professionals, were also captured using data recorded in diaries and face-to-face interviews.[30] A cost-benefit analysis was planned if inpatient therapy was shown to be superior.

Post Hoc Outcomes

Patient satisfaction with rehabilitation was collected at 10 weeks using a 20-cm visual analog scale anchored with "no satisfaction" (0 cm) and "complete satisfaction" (20 cm). Time off work was also captured.

Comorbid, sociodemographic, and anthropometric data were collected at baseline. Postdischarge complication (presentation to emergency department, readmission, reoperation, knee manipulation, death) and adverse event data (eg, falls) were collected until 52 weeks after surgery by self-report at follow-up visits and by a review of hospital electronic medical records. Preference for rehabilitation mode (monitored home-based rehabilitation program, inpatient rehabilitation program, or either) was ascertained prior to surgery. As per routine practice, Functional Independence Measure scores were collected on admission and discharge for participants who received inpatient rehabilitation.

Statistical Analysis

A detailed statistical analysis plan is included in the trial protocol in Supplement 1. The statistician who conducted the data analyses was blinded to group allocation.

The primary end point was functional mobility at 26 weeks after surgery. In the absence of a known minimal important difference for this test following total knee arthroplasty, we used a conventional estimate of a moderate effect size. Based on an SD of 120 m[18] and using the 0.5-SD criterion for identifying a moderate effect size, 140 participants were required to provide 80% power at a significance level of 5% to detect a 60-m between-group difference in walking distance at 26 weeks, assuming a dropout rate of less than 10%. The inclusion of a second recruitment site opportunistically allowed us to increase the sample to 165, which increased the power to 90%.

An intention-to-treat analysis[31] was the primary prespecified analysis in which all randomized participants were included. A mixed-effect model was implemented to analyze the primary outcome, incorporating site as a random effect. The treatment group was the main study factor and the 6-minute walk test distance at baseline, weight, comorbidities, and patient preference[32] were included as covariates. For participants with a missing outcome measure at 26 weeks, a single imputation method was used.[33]

For the continuous secondary outcome variables measured repeatedly at 10, 26, and 52 weeks, a multilevel hierarchical model was used to estimate the treatment by time interaction with site as 1 level of random effect and within-patient repeated measurements as another level of random effect. Baseline measurements of the outcome variables, together with weight, comorbidities, site, and participant preference, were included as covariates. For the binary outcome variables measured at 10, 26, and 52 weeks (knee flexion >100° or ≤100°), the similarly multilevel hierarchical model with logit link function was implemented with site and within-patient measurements as random effects and with the adjustment of the covariates as above.

The age, sex, and height of participants were used as stratification variables in the randomization procedure via a minimization algorithm. These 3 variables were included as additional covariates for the primary outcome analysis to incorporate the possible within-treatment group correlation associated with stratification.[34] The mixed-model analysis indicated above also included these 3 variables as additional covariates.

For the sensitivity analysis, the above analysis used for the primary outcome variables was also performed using the per-protocol sample. Adherence for both groups was defined as attendance at no less than 2 and no more than 4 outpatient sessions. This was because our operational definition of a monitored home program (as per other arthroplasty studies)[18,35,36] was attendance at up to 3 outpatient sessions. If participants regularly exceeded 4 sessions, we could reasonably be criticized for providing usual outpatient-based care, yet our comparison was intended to be a program of minimal intervention vs 1 far more intensive (inpatient) program (rehabilitation + monitored home program). Adherence for the inpatient rehabilitation group was further defined as having had a minimum 7 days of inpatient rehabilitation. Nonadherent participants were excluded from the per-protocol analysis.

For analyses involving the observational group, the mean values of the 6-minute walk test and other secondary outcomes were compared between the observational group and those in the home program at 26 weeks, adjusting for the aforementioned covariates.

For all analyses, a significance level of .05 was used, and tests were 2-sided. SAS version 9.4 software was used for statistical analysis (SAS Institute Inc).

Results

Sixty-nine percent of the trial participants were women (mean age of the randomized cohort, 66.9 years [SD, 8.4 years]; mean body mass index [BMI], 34.7 [SD, 7]; BMI is calculated as weight in kilograms divided by height in meters squared). Characteristics of the cohorts are summarized in **Table 1** (further details of characteristics and baseline outcomes are provided in eTable 1 and eTable 2, while a summary of those eligible who did not participate is provided eTable 3 in Supplement 2). A total of 165 patients underwent randomization (Figure). The primary outcome was collected for 79 participants (98%) in the inpatient rehabilitation group and for 80 (95%) in the home program. All 165 participants were included in the intention-to-treat analysis. Because only 6 participants had missing data at the primary end point, no statistical comparisons between them and those without missing data were made. The age (range, 51-70 years), sex (women, 5), and BMI (range, 25.0-45.96) profiles of the 6 participants with missing data were similar to the other 159 participants. In the per-protocol analysis, 72 participants (89%) receiving inpatient rehabilitation and 74 participants (88%) in the home program were included. Nineteen participants were excluded, 12 for receiving additional therapy outside of the study treatment and 7 for other protocol violations (Figure).

Outcomes

In the intention-to-treat analysis, there was no difference in the primary outcome of the 6-minute walk test among the 2 randomized groups (adjusted mean difference with imputation, −1.01; 95% CI, −25.56 to 23.55; **Table 2**). The per-

Table 1. Baseline Characteristics of Participants[a]

Characteristic	Inpatient Rehabilitation (n = 81)	Home Program (n = 84)	Observational (n = 87)	Not Randomized (n = 212)[b]
Women, No. (%)	56 (69)	57 (68)	38 (43)	123 (58)
Age, mean (SD), y	66.9 (8)	66.9 (9)	66.8 (9)	68.4 (9.3)
Height, mean (SD), m	1.62 (0.09)	1.63 (0.09)	1.66 (0.10)	1.64 (0.08)
Weight, mean (SD), kg	90.0 (18.8)	93.1 (21.8)	91.8 (22.8)	89.5 (20.8)
Body mass index[c]	34.7 (7)	34.8 (7)	32.9 (7)	33.0 (7.3)
Significant comorbidity, No. (%)[d]	61 (75)	67 (80)	63 (72)	Not collected
Education above secondary school, No. (%)	18 (22)	19 (23)	17 (20)	Not collected
Preference for inpatient rehabilitation, No. (%)	46 (57)	52 (62)		
Working at time of surgery, No. (%)	11 (14)	14 (17)	14 (16)	Not collected
Right knee arthroplasty, No. (%)	40 (49)	48 (57)	42 (48)	Not collected
6-Minute walk test, mean (SD), m	316.8 (107.7)	318.8 (108.0)	329.5 (115.3)	307 (109)
15-Meter walk test, mean (SD), sec	17.7 (11.9)	15.9 (7.2)	15.3 (6.4)	Not collected
Oxford Knee Score[e]	17.4 (7.0)	16.7 (7.2)	17.5 (8.1)	17.7 (7.4)
EQ-5D descriptive index[f]	0.39 (0.26)	0.36 (0.28)	0.37 (0.29)	0.39 (0.3)
EQ-5D visual analog scale[g]	66.3 (19.4)	64.0 (19.0)	64.1 (20.8)	66.4 (21.4)
KOOS scores, median (IQR)[h]				
$KOOS_4$	32.0 (19.0-44.0)	31.0 (19.0-43.0)	36.0 (22.0-44.0)	30.8 (20.0-39.0)
Pain	33.0 (22.0-44.0)	36.0 (24.0-46.0)	27.0 (10.0-60.0)	31.3 (22.0-42.0)
Symptoms	32.0 (21.0-46.0)	35.5 (21.0-53.0)	39.0 (19.0-66.0)	34.9 (21.0-46.0)
Activities of daily living	35.0 (26.0-47.0)	38.0 (26.5-47.0)	31.0 (17.0-44.0)	35.4 (24.0-47.0)
Quality of life	19.0 (6.0-31.0)	18.0 (0-31.0)	29.0 (14.0-43.0)	18.9 (6.0-31.0)
Sports and recreation	5.0 (0-15.0)	0 (0-15.0)	22.0 (12.0-35.0)	13.4 (0.0-20.0)
Knee flexion (end) ROM ≥100°, No. (%)	53 (65)	55 (65)	47 (54)	58/93 (62)

Abbreviations: IQR, interquartile range; ROM, range of motion.

[a] Percentages are rounded.

[b] Sample size for data presented for this group ranges from 61 to 212.

[c] Body mass index is the weight in kilograms divided by the square of the height in meters.

[d] A significant comorbidity is defined as a coexisting medical condition requiring medication.

[e] Scores on the Oxford Knee Score range from 0 (worst) to 48 (best).

[f] Scores on the EuroQol Group 5-Dimension Self-Report Questionnaire (EQ-5D) descriptive index range from 1 (best possible health), through 0 (death) to −0.59 (worse than death).

[g] Scores on the EQ-5D visual-analog scale range from 0 to 100; higher scores indicate better quality of life.

[h] Scores on the Knee Injury and Osteoarthritis Outcome Score (KOOS) subscales range from 0 (worst) to 100 (best). $KOOS_4$ is the mean score on the pain, symptoms, activities of daily living, and quality of life subscales.

protocol analysis of the primary outcome yielded similar results. Unadjusted results are provided in eTables 4 through 6 and eFigure 1 in Supplement 2.

The unadjusted and adjusted group effects were nonsignificant for all of the secondary outcomes across time. Per-protocol analyses yielded the same results across all time points.

There were also no between-group differences in the primary outcome when the home program and observational (those choosing the home program) groups were compared, with an adjusted 6-minute walk test mean difference at 26 weeks of −17.00 (95% CI, −41.27 to 7.28).

There were no significant between-group differences in complication data (**Table 3**). In the randomized groups the most common adverse event was stiffness requiring manipulation while patients were under anesthetic.

Beyond postoperative complications listed in Table 3, no other adverse events were reported.

Post Hoc Outcomes

There was a significant between-group difference for participant-rated satisfaction with rehabilitation (8.9%; 95% CI, 3.0%-14.9%; Table 3), but there were no significant between-group differences in return to work data (−0.23; 95% CI, −3.76 to 3.30).

Discussion

In this RCT, inpatient rehabilitation followed by a monitored home program did not provide superior mobility than did a monitored home program alone at 26 weeks after surgery for patients with uncomplicated arthroplasty who were deemed appropriate for discharge directly home. As per the study protocol,[13] cost-effectiveness analysis was not undertaken in light of the nonsuperior findings. Nevertheless, recent evidence suggested cost-effectiveness is reduced if total knee arthroplasty is associated with a stay in an inpatient rehabilitation facility.[37] Given the increasing numbers of people undergoing the procedure worldwide[38,39] and given the concerns about its sustainability,[40] clinicians and policy makers need to consider the cost implications and sustainability of the rehabilitation options available for adults undergoing total knee arthroplasty. These considerations have motivated new models of care delivery and reimbursement such as the Comprehensive Care for Joint Replacement model in the United States,[41] whereby noninpatient therapies are encouraged. Given that the amount of inpatient therapy provided daily in the current study is comparable with that provided in inpatient rehabilitation

Table 2. Outcomes at 10, 26, and 52 Weeks—Adjusted Values[a]

Outcome	Total No. of Participants[b]		Inpatient Rehabilitation	Home Program	Mean Difference Between Inpatient Rehabilitation and Home Program	Observational[c]	Mean Difference Between Observational and Home Program
	Inpatient Rehabilitation	Home Program					
Primary Outcome (With Imputation)							
6-Minute walk test at wk 26, m							
Intention to treat	81	84	402.7 (370.9 to 434.5)	403.7 (372.0 to 435.4)	−1.01 (−25.56 to 23.55)	389.0 (372.3 to 405.6)	−17.00 (−41.27 to 7.28)
Per protocol	72	74	390.4 (366.3 to 414.5)	392.1 (368.0 to 416.2)	−1.68 (−27.53 to 24.18)	389.9 (372.5 to 407.1)	6.01 (−17.62 to 31.64)
Secondary Outcomes by Study Week							
6-Minute walk test, m							
10	79	79	386.8 (353.7 to 419.8)	383.2 (350.2 to 416.1)	3.60 (−23.17 to 30.38)		
52	77	73	391.2 (358.1 to 424.4)	404.8 (371.6 to 438.0)	−13.54 (−40.69 to 13.61)		
15-m walk test, m							
10	74	74	13.0 (11.9 to 14.0)	13.2 (12.1 to 14.3)	−0.26 (−1.80 to 1.27)		
26	79	80	12.5 (11.4 to 13.6)	12.0 (10.9 to 13.1)	0.50 (−1.01 to 2.01)	12.2 (11.4 to 13.0)	0.62 (−0.61,1.85)
52	79	77	12.3 (11.2 to 13.4)	12.7 (11.6 to 13.8)	−0.42 (−1.94 to 1.10)		
Oxford Knee Score							
10	79	78	33.3 (31.4 to 35.2)	32.1 (30.2 to 34.0)	1.21 (−1.45 to 3.88)		
26	80	80	36.9 (35.0 to 38.7)	34.8 (32.9 to 36.7)	2.06 (−0.59 to 4.71)	35.8 (33.9 to 37.7)	0.54 (−2.26 to 3.33)
52	80	80	36.5 (34.6 to 38.4)	37.0 (35.2 to 38.9)	−0.55 (−3.21 to 2.10)		
EQ-5D descriptive index							
10	79	78	0.74 (0.69 to 0.78)	0.69 (0.65 to 0.74)	0.04 (−0.02 to 0.10)		
26	80	80	0.74 (0.70 to 0.78)	0.72 (0.68 to 0.77)	0.02 (−0.04 to 0.08)	0.72 (0.68,0.77)	−0.01 (−0.07 to 0.05)
52	80	80	0.70 (0.66 to 0.75)	0.73 (0.69 to 0.78)	−0.03 (−0.09 to 0.03)		
EQ-5D visual-analog scale							
10	79	78	80.4 (76.9 to 83.9)	79.7 (76.1 to 83.3)	0.68 (−4.38 to 5.74		
26	80	80	78.8 (75.3 to 82.3)	80.2 (76.7 to 83.8)	−1.41 (−6.42 to 3.60)	75.4 (71.6 to 79.3)	−5.47 (−11.22 to 0.28)
52	80	80	76.9 (73.4 to 80.4)	77.4 (73.8 to 81.0)	−0.50 (−5.53 to 4.52)		
$KOOS_4$ scores							
10	78	75	66.9 (62.9 to 70.9)	66.7 (62.6 to 70.8)	0.15 (−5.58 to 5.88)		
26	80	79	75.7 (71.7 to 79.7)	73.7 (69.7 to 77.7)	1.99 (−3.68 to 767)	74.8 (70.9 to 78.8)	-2.95 (-8.74 to 2.84)
52	80	80	76.4 (72.4 to 80.4)	77.0 (73.0 to 81.0)	−0.55 (−6.21 to 5.11)		
Knee flexion (end) range of motion ≥100°, No. (%)							
10	78	80	55 (70.5)	56 (70.0)			
(95% CI)			(60.4 to 80.6)	(60.0 to 80.0)			
26	80	80	66 (82.5)	62 (77.5)		77 (88.5)	
(95% CI)			(74.2 to 90.8)	(68.4 to 86.7)		(81.8 to 95.2)	
52	80	79	67 (83.8)	69 (87.3)			
(95% CI)			(75.7 to 91.8)	(80.0 to 94.7)			

Abbreviations: EQ-5D, EuroQol Group 5-Dimension Self-Report Questionnaire; $KOOS_4$, Knee Injury and Osteoarthritis Outcome Score.

[a] Values are presented as mean (95% CI) using intention-to-treat data unless otherwise indicated. See Table 1 for definitions of score ranges. Values are adjusted, and with imputation for primary outcome. Baseline measurements of the outcome variables, together with weight, comorbidities, and participant preference, were included as covariates. Site was included as a random effect. The crude and adjusted group effect was nonsignificant for all secondary outcomes at 10, 26, and 52 weeks.

[b] There were a maximum of 81 and 84 participants for the inpatient and home groups, respectively, at each time point. All outcomes were collected for all 87 observational participants, 11 in this group were excluded from per-protocol analysis.

[c] The observational group was only followed up at 26 weeks, hence the gaps in the Table.

Table 3. Postoperative and Post Hoc Outcomes for Participants[a]

Characteristic	Inpatient Rehabilitation (n = 81)	Home Program (n = 84)	Mean Difference Between Inpatient Rehabilitation and Home Program	Observational (n = 87)	Mean Difference Between Observational and Home Program
Outpatient physical therapy sessions, mean (95% CI), No.	3.02 (2.75 to 3.30)	3.07 (2.81 to 3.34)	−0.05 (−0.43 to 0.33)	2.62 (2.37 to 2.88)	−0.45 (−0.82 to −0.09)
Days in inpatient rehabilitation, mean (95% CI), No.[b]	9.51 (9.10 to 9.92)	NA		NA	
FIM, mean (95% CI)[c]					
On admission to inpatient rehabilitation	111.5 (110.2 to 112.7)	NA		NA	
Discharge from inpatient rehabilitation	116.5 (115.3 to 117.7)	NA		NA	
Protocol violations, No. (%)	9 (11.1)	10 (11.9)		11 (12.6)	
(95% CI)	(4.3 to 18.0)	(5.0 to 18.8)		(5.7 to 19.6)	
Total knee arthroplasty					
Emergency department visits, No. (%)	4 (4.9)	4 (4.8)		5 (5.8)	
(95% CI)	(0.2 to 9.7)	(0.2 to 9.3)		(0.9 to 10.6)	
Readmissions, No. (%)	4 (4.9)	2 (2.4)		2 (2.3)	
(95% CI)	(0.2 to 9.7)	(0.0 to 5.6)		(0.0 to 5.5)	
Manipulations under anesthetic, No. (%)	4 (4.9)	3 (3.6)		1 (1.2)	
(95% CI)	(0.2 to 9.7)	(0.0 to 7.5)		(0.0 to 3.4)	
Time to return to work, mean (95% CI), wk	7.57 (4.86 to 10.28)	7.80 (5.54 to 10.06)	−0.23 (−3.76 to 3.30)	8.43 (5.87 to 10.99)	0.63 (−2.71 to 3.96)
Satisfaction with rehabilitation, mean (95% CI), %[d]	91.9 (87.6 to 96.1)	82.9 (78.7 to 87.2)	8.9 (3.0 to 14.9)	NA	

[a] No significant differences were found between groups in the reported outcomes except for the number of outpatient physical therapy sessions for the observational group compared with the group receiving the home program (*P* value = .02).

[b] Sixty-nine of the 81 participants randomized to inpatient rehabilitation (ie, 85%) stayed in the hospital for 10 days. Two of the 81 participants did not attend inpatient rehabilitation. Of the 79 who did, 1 was discharged prior to 7 days due to illness of his father.

[c] Scores on the Functional Independence Measure (FIM) range from 18 to 126; higher scores indicate better and more independent function.

[d] The score for satisfaction with rehabilitation was a visual analog scale that ranged from 0 to 100; higher scores indicate higher satisfaction. There was a significant between-group difference for participant-rated satisfaction (*P* = .004).

facilities in the United States,[9] the findings of this study suggest that patients who have undergone arthroplasty are not being disadvantaged by these initiatives in terms of physical recovery. Considering that the home-based program resulted in the same outcomes as the highest-intensity rehabilitation model, any other rehabilitation model providing less intensive rehabilitation therapy than the US model, including skilled nursing facilities, would be expected to yield similar results. The findings should also inform rehabilitation models elsewhere, encouraging clinicians to focus on the most cost-effective options. Understanding why inpatient rehabilitation may be associated with higher-level satisfaction (as was the case for our study) would also be useful for informing alternative models.

This study has several strengths. The baseline characteristics of the randomized sample appear comparable with those of other related RCTs,[18,35] as is the magnitude of the change over time of the primary outcome,[35,42] conferring generalizability of study results to other cohorts. The between-group difference observed in the primary analysis (1 m) was far less than what was found to be the minimal important difference (improvement) in the associated nested study (26-55 m).[23] Thus, the difference observed was neither statistically nor clinically relevant. The large sample size, with very little loss to follow-up, ensured that the statistical power of the study remained high. Therapeutic validity was also high given that the 2 treatment groups were markedly different, with the inpatient group based on mandated daily hours of prescribed therapy.[17] The inclusion of the observational group allowed comparison between those who received the home program because they preferred it and those who received it because they were allocated to it. It could account for a possible preference effect that can be present in trials in which the intervention cannot be blinded.[32] Both the observational group and inclusion of preference in the analysis clearly showed that preference did not affect study outcomes.

Limitations

This study has limitations. The generalizability of the results to the private health care setting within Australia is unclear. However, patients who undergo total knee arthroplasty at public and private institutions have been observed to report similar outcomes for up to a year.[43] Thus, insurance status or the public or private sector may not be an important consideration. The results apply only to patients deemed appropriate for discharge directly home. No comment can be made on the comparative efficacy of inpatient therapy for the minority of patients—5% to 10% excluded in our study—who are deemed to require admission to an inpa-

tient facility based on presenting characteristics such as significant comorbidity or poor progress after surgery. Although the assessors were blinded to allocation group, the participants were not. Considering that the study end points were either subjective or, for the primary end point, under volitional control, it is acknowledged that they were potentially subject to bias. In addition, it is not known if inpatient therapy produced greater gains prior to 10 weeks. However, early gains that are no longer apparent at 10 weeks, or do not translate into earlier return to work or less health resource use, are arguably not meaningful nor would they justify the cost differential that exists between inpatient and home programs.

Conclusions

Among adults undergoing uncomplicated total knee arthroplasty, the use of inpatient rehabilitation compared with a monitored home-based program did not improve mobility at 26 weeks after surgery. This study finding does not support inpatient rehabilitation for this group of patients.

ARTICLE INFORMATION

Author Contributions: Mr Buhagiar had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Buhagiar, Naylor, Harris, Kohler, Wright.
Acquisition, analysis, or interpretation of data: Buhagiar, Naylor, Harris, Xuan, Fortunato, Wright.
Drafting of the manuscript: Buhagiar, Naylor, Harris, Xuan, Fortunato.
Critical revision of the manuscript for important intellectual content: Buhagiar, Naylor, Harris, Xuan, Kohler, Wright.
Statistical analysis: Buhagiar, Xuan.
Obtained funding: Buhagiar, Naylor, Harris, Kohler.
Administrative, technical, or material support: Buhagiar, Kohler, Wright, Fortunato.
Supervision: Naylor, Harris, Xuan, Kohler.

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REFERENCES

1. Australian Orthopaedic Association National Joint Replacement Registry. *Analysis of State and Territory Health Data—All Arthroplasty*. South Australia, Australia: Australian Orthopaedic Association; 2016.

2. Maradit Kremers H, Larson DR, Crowson CS, et al. Prevalence of total hip and knee replacement in the United States. *J Bone Joint Surg Am*. 2015;97(17):1386-1397.

3. Naylor J, Harmer A, Fransen M, Crosbie J, Innes L. Status of physiotherapy rehabilitation after total knee replacement in Australia. *Physiother Res Int*. 2006;11(1):35-47.

4. Royal Australian College of Surgeons. Surgical practice variation report—orthopaedic procedures. RACS website. http://www.surgeons.org/policies-publications/publications/surgical-variance-reports. 2015. Accessed January 5, 2017.

5. Arthroplasty Clinical Outcomes Registry. Arthroplasty clinical outcomes registry annual report 2015. ACORN website. http://acornregistry.org/images/ACORN_AnnualReport_2015.pdf. 2016. Accessed January 5, 2017.

6. Benz T, Angst F, Oesch P, et al. Comparison of patients in three different rehabilitation settings after knee or hip arthroplasty: a natural observational, prospective study. *BMC Musculoskelet Disord*. 2015;16:317.

7. Hart A, Bergeron SG, Epure L, Huk O, Zukor D, Antoniou J. Comparison of US and Canadian perioperative outcomes and hospital efficiency after total hip and knee arthroplasty. *JAMA Surg*. 2015;150(10):990-998.

8. DeJong G, Hsieh CH, Gassaway J, et al. Characterizing rehabilitation services for patients with knee and hip replacement in skilled nursing facilities and inpatient rehabilitation facilities. *Arch Phys Med Rehabil*. 2009;90(8):1269-1283.

9. Pezzin LE, Roberts BA, Miao H, Dillingham TR. Regulatory policies, the "75% rule," and post-acute care discharge setting. *Am J Phys Med Rehabil*. 2011;90(11):954-958.

10. Artz N, Dixon S, Wylde V, Beswick A, Blom A, Gooberman-Hill R. Physiotherapy provision following discharge after total hip and total knee replacement: a survey of current practice at high-volume NHS hospitals in England and Wales. *Musculoskeletal Care*. 2013;11(1):31-38.

11. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Annual Report. AOANJRR website. https://aoanjrr.sahmri.com/documents/10180/275066/Hip%2C%20Knee%20%26%20Shoulder%20Arthroplasty. 2016. Accessed January 5, 2017.

12. Mahomed NN, Davis AM, Hawker G, et al. Inpatient compared with home-based rehabilitation following primary unilateral total hip or knee replacement: a randomized controlled trial. *J Bone Joint Surg Am*. 2008;90(8):1673-1680.

13. Buhagiar MA, Naylor JM, Harris IA, et al. Hospital Inpatient versus Home-based rehabilitation after knee arthroplasty (The HIHO study): study protocol for a randomized controlled trial. *Trials*. 2013;14:432.

14. Consultative Committee on Private Rehabilitation. Guidelines for recognition of private hospital-based rehabilitation services. Australian Government Department of Health website. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-phicirculars2013-32a. Accessed January 5, 2017.

15. Pocock SJ, Simon R. Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. *Biometrics*. 1975;31(1):103-115.

16. Troosters T, Gosselink R, Decramer M. Six-minute walk test: a valuable test, when properly standardized. *Phys Ther*. 2002;82(8):826-827.

17. Australasian Faculty of Rehabilitation Medicine. *Standards for the Provision of Inpatient Adult Rehabilitation Medicine Services in Public and Private Hospitals 2011*. New South Wales, Australia: Royal Australian College of Surgeons; 2012.

18. Ko V, Naylor J, Harris I, Crosbie J, Yeo A, Mittal R. One-to-one therapy is not superior to group or home-based therapy after total knee arthroplasty: a randomized, superiority trial. *J Bone Joint Surg Am*. 2013;95(21):1942-1949.

19. Nelson ME, Rejeski WJ, Blair SN, et al. Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. *Med Sci Sports Exerc*. 2007;39(8):1435-1445.

20. American Geriatrics Society Panel on Exercise and Osteoarthritis. Exercise prescription for older adults with osteoarthritis pain: consensus practice recommendations. A supplement to the AGS Clinical Practice Guidelines on the management of chronic pain in older adults. *J Am Geriatr Soc*. 2001;49(6):808-823.

21. Ko V, Naylor JM, Harris IA, Crosbie J, Yeo AET. The six-minute walk test is an excellent predictor of

functional ambulation after total knee arthroplasty. *BMC Musculoskelet Disord*. 2013;14:145.

22. Artz N, Elvers KT, Lowe CM, Sackley C, Jepson P, Beswick AD. Effectiveness of physiotherapy exercise following total knee replacement: systematic review and meta-analysis. *BMC Musculoskelet Disord*. 2015;16:15.

23. Naylor JM, Mills K, Buhagiar M, Fortunato R, Wright R. Minimal important improvement thresholds for the six-minute walk test in a knee arthroplasty cohort: triangulation of anchor- and distribution-based methods. *BMC Musculoskelet Disord*. 2016;17(1):390.

24. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes*. 2003;1(1):64.

25. Naylor JM, Yeo AET, Mittal R, Ko VW, Harris IA. Improvements in knee T and symptomatic and functional behavior after knee arthroplasty based on preoperative restriction in T. *J Arthroplasty*. 2012;27(6):1100-1105.

26. Xie F, Pullenayegum EM, Li SC, Hopkins R, Thumboo J, Lo NN. Use of a disease-specific instrument in economic evaluations: mapping WOMAC onto the EQ-5D utility index. *Value Health*. 2010;13(8):873-878.

27. Paulsen A, Roos EM, Pedersen AB, Overgaard S. Minimal clinically important improvement (MCII) and patient-acceptable symptom state (PASS) in total hip arthroplasty (THA) patients 1 year postoperatively. *Acta Orthop*. 2014;85(1):39-48.

28. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg Br*. 1998;80(1):63-69.

29. Clement ND, MacDonald D, Simpson AH. The minimal clinically important difference in the Oxford knee score and Short Form 12 score after total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc*. 2014;22(8):1933-1939.

30. Lavernia CJ, D'Apuzzo MR, Hernandez VH, Lee DJ, Rossi MD. Postdischarge costs in arthroplasty surgery. *J Arthroplasty*. 2006;21(6)(suppl 2):144-150.

31. Intention-to-treat analysis. CONSORT website. http://www.consort-statement.org/checklists/view/32-consort/96-statistical-methods. Accessed January 5, 2017.

32. Preference Collaborative Review Group. Patients' preferences within randomised trials: systematic review and patient level meta-analysis. *BMJ*. 2008;337:a1864.

33. Donders AR, van der Heijden GJ, Stijnen T, Moons KG. Review: a gentle introduction to imputation of missing values. *J Clin Epidemiol*. 2006;59(10):1087-1091.

34. Additional analyses. CONSORT website. http://www.consort-statement.org/checklists/view/32-consort/97-additional-analyses. Accessed January 5, 2017.

35. Kramer JF, Speechley M, Bourne R, Rorabeck C, Vaz M. Comparison of clinic- and home-based rehabilitation programs after total knee arthroplasty. *Clin Orthop Relat Res*. 2003;(410):225-234.

36. Madsen M, Larsen K, Madsen IK, Søe H, Hansen TB. Late group-based rehabilitation has no advantages compared with supervised home-exercises after total knee arthroplasty. *Dan Med J*. 2013;60(4):A4607.

37. Losina E, Walensky RP, Kessler CL, et al. Cost-effectiveness of total knee arthroplasty in the United States: patient risk and hospital volume. *Arch Intern Med*. 2009;169(12):1113-1121.

38. Kurtz SM, Lau E, Ong K, Zhao K, Kelly M, Bozic KJ. Future young patient demand for primary and revision joint replacement: national projections from 2010 to 2030. *Clin Orthop Relat Res*. 2009;467(10):2606-2612.

39. National Joint Registry for England and Wales. *12th Annual Report*. Hertfordshire, UK: National Joint Registry; 2015.

40. Wilson NA, Schneller ES, Montgomery K, Bozic KJ. Hip and knee implants: current trends and policy considerations. *Health Aff (Millwood)*. 2008;27(6):1587-1598.

41. Centers for Medicare & Medicaid Services (CMS), HHS. Medicare program; comprehensive care for joint replacement payment model for acute care hospitals furnishing lower extremity joint replacement services. *Fed Regist*. 2015;80(226):73273-73554.

42. Bade M, Struessel T, Dayton M, et al. Early high-intensity versus low intensity rehabilitation after total knee arthroplasty: a randomized controlled trial [published online November 3, 2016]. *Arth Care Res (Hoboken)*. doi:10.1002/acr.23139

43. Adie S, Dao A, Harris IA, Naylor JM, Mittal R. Satisfaction with joint replacement in public versus private hospitals: a cohort study. *ANZ J Surg*. 2012;82(9):616-624.