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Variation in patient requirement for post-discharge physical therapy following total hip and knee arthroplasty

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Keywords:	Total knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy, Treatment satisfaction
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Post-discharge physical therapy following TKA & THA

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Post-discharge physical therapy following TKA & THA

35 ABSTRACT

- **Objectives**: To determine the proportion of patients that partake in post-discharge physiotherapy
- 37 following hip and knee arthroplasty, assess the influence on post-operative outcomes, and model
- 38 which patient would benefit from post-operative physio therapy from pre-operative data.
- 39 Design: Prospective cohort study
- 40 Setting: Single NHS orthopaedic teaching hospital
- **Participants:** 1395 THAs and 1374 TKAs over a 2.5 year period.
- 42 Outcome measures: Access of post-discharge physiotherapy was reported at 6-months post-op. The
 43 Oxford Hip or Knee Score and EQ5D questionnaire and post-operative satisfaction metric.
- **Results**: 662 (48.2%) TKA and 493 (35.3%) THA patients accessed post-discharge physiotherapy.
- 45 THAs accessing physiotherapy were younger (64.9 vs 69.1y, p<0.001) and more likely to be female
- 46 (p<0.001). PROs (p<0.001) and satisfaction (p=0.001) were superior in THAs not accessing
- 47 physiotherapy. TKAs accessing physiotherapy were younger (68.2 vs 71.0y, p<0.001) and more likely
- 48 to live in a less deprived area (p=0.028). PROs (p<0.001) and satisfaction (p<0.001) were superior in
- TKA patients not accessing physiotherapy. Regression models using PRO and demographic data
 predicted post-discharge therapy access with an accuracy of only 17% greater than chance in THAs
- 51 and 7% in TKAs.
 - 52 Conclusions: Only a third of THA and half of TKA patients accessed post-discharge physiotherapy.
 53 The patients that did not access physiotherapy reported superior outcome scores and satisfaction,
 54 suggesting variation in need for post-arthroplasty physiotherapy, however it was not possible to
- reliably predict which patients would seek access to additional therapy from pre-operative symptom
 data.
- - 58 Keywords: Total knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy, Treatment satisfaction

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ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS

- • This is a relatively large patient cohort of 2769 total hip and knee replacements performed over a 2
- year period at a single orthopaedic unit evaluating a consistent specific delivery model of post-discharge rehabilitation provision.
 - A particular strength of this study design is the depth of linked demographic and outcomes data available with which to construct the predictive models.
 - • Data relating to access of post-surgical physiotherapy was reported by the patient at 6 months post-operation.
- • We are not able to determine the referral route by which the patient accessed post-discharge Jetc.. acific therapy www
- therapy, nor what specific therapy was received.

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Post-discharge physical therapy following TKA & THA

72 INTRODUCTION

Lower limb osteoarthritis is an extremely common and disabling condition, which may ultimately require surgical intervention. In excess of 90,000 total hip and 90,000 total knee arthroplasties are performed each year in the UK alone [1]. Projections suggest continued increases of surgical volume year on year [2, 3]. Though joint replacement is effective at reducing pain and improving physical function in patients with end stage osteoarthritis, a sub-group of patients continue to report dissatisfaction with their post-operative outcome [4, 5] highlighted by protracted physical impairment [6] and activity limitations [7-10].

Physical therapy is thought to be an important component in achieving optimal results following lower limb arthroplasty [11]. Immediately post-surgery, throughout the inpatient stay, physiotherapy is aimed at encouraging mobilisation and facilitating a safe discharge. Though subsequent post- discharge physiotherapy is often promoted there is considerable national and international variation in actual therapy provision. Specific rehabilitation protocols are strongly entrenched at individual units however the wider efficacy of post-operative physiotherapeutic intervention is poorly established [12-18]. This uncertainty as to effectiveness makes it difficult for commissioning organisations, healthcare providers, and patients to make decisions as to the role of post-discharge physiotherapy following total joint arthroplasty.

91 The purpose of this study was to assess what proportion of patients access post-discharge 92 physiotherapy following total hip and knee arthroplasty, whether therapy impacts upon post-93 operative patient reported outcomes and whether it is possible to predict which patients go on to 94 seek additional post-discharge physiotherapy.

12.

96 METHODS

97 Study design and participants

98 This was a prospective observational cohort study. Data collection was through questionnaires administered pre-operatively at hospital clinic appointment and then via postal review at 6 post-operatively. Ethical approval was obtained from the institutional review board (11/AL/0079).
101 Patients undergoing unilateral total hip or knee arthroplasty (THA or TKA) at a single NHS teaching hospital were prospectively assessed over a 32 month period between January 2013 and September 2015.
104 The study centre is the only hospital receiving adult referrals for a predominantly urban regional

104 The study centre is the only hospital receiving adult referrals for a predominantly urban regional
 105 population of approximately 850 000 people. Surgery was carried out by multiple consultant
 106 orthopaedic surgeons and their supervised trainees. Routine local protocols are followed for all
 107 aspects of inpatient post-operative care. Immediate post-operative therapy is also protocol driven
 108 focussing on knee range of movement, muscle re-education and mobilising with appropriate walking
 109 aids.

Post-discharge practice at the study centre is to provide outpatient physiotherapy as required. As
 such, patients are referred to out-patient physiotherapy based on clinically assessed need at time of
 discharge or at 6 week post-operative clinical review, with additional referral routes available to the
 patient through general practice services and a national patient self-referral telephone triage
 system.

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Outcome measures

Statistical analysis

SPSS version 21.0.

out-patient physiotherapy.

(p=0.438) between the groups (Table 1).

Total Hip Arthroplasty

RESULTS

outcome and 48 good joint function.

independently from the clinical teams.

descriptive profile and a single index value for health status.

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Post-discharge physical therapy following TKA & THA

Demographic data was obtained for patient health status and socioeconomic denominators. Physical

The Oxford Hip and Knee Scores (OHS and OKS) each consist of 12 questions assessing the patient's

The EQ-5D is a standardised instrument with five items for use as a measure of self-reported general

health [21]. Applicable to a wide range of health conditions and treatments, it provides a simple

Patient satisfaction was assessed using a 5 point Likert response format at 6 months post-surgery.

Self-report of physiotherapy attendance was recorded a 6 month assessment. Data was collected

Demographic indicators are given as frequencies or means with standard deviations as a measure of

dispersal. Differences between patients who accessed physiotherapy after total joint surgery and

those who did not were investigated with t-tests, chi-square tests and Mann-Whitney-U tests as

To identify predictors of physiotherapy access we used a binary logistic regression model with

physiotherapy access as dependent variable and patient characteristics and preoperative OKS/OHS

building technique (likelihood ratio) with an entry criterion of alpha=0.05. Model fit is described with

percentage of correct classifications and predictors are given as odds ratios with corresponding 95%

confidence intervals. Using this methodology the chance level of correct classifications is 50% and

the model-based classification is compared against this value. Analyses were performed with BMI

Data from 1395 THA patients (58.1% female, mean age 67.6 ± 11.8 years) and 1374 TKA patients

(56.6% female, mean age 69.7 \pm 9.3 years) was available for analysis. Of this total surgical cohort,

662 (48.2%) knee arthroplasty and 493 (35.3%) hip arthroplasty patients accessed post-operative

THA patients accessing physiotherapy were younger (64.9 vs 69.1 years, p<0.001) and more likely to

be female (p<0.001), however there were no differences in BMI (p=0.788) or social deprivation index

and EQ-5D as predictors. The predictors were included using a forward selection stepwise model

appropriate. Effect sizes for differences in metric variables are given as Cohen's d.

pain and function [19, 20]. Each item is answered on a 5-point response scale ranging from 0 to 4,

generating a summed total score ranging from 0 to 48, where 0 indicates the worst possible

outcomes were assessed with the Oxford Hip or Knee Score and EQ5D questionnaire.

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Post-discharge physical therapy following TKA & THA

 Patient outcomes scores at 6 months were superior in the 64.7% of THA patients that did not access post-operative physiotherapy in terms of absolute OHS (35.8 vs 39.4 points, p<0.001). Baseline scores were subtly, but statistically, worse in the group that accessed post-operative therapy (20.1 points vs 21.4 points, p=0.008), however the patients that did not access physiotherapy made a larger gain in pain and function scores (pre-to post-op change in OHS 15.6 points vs 18.0 points, p<0.001, Cohen's d=0.23) (Table 1 and Figure 1). EQ5D scores pre and post-surgery were lower in patients referring for physiotherapy both pre-surgery (0.35 vs 0.41, p=0.004,) and post-surgery (0.70 vs 0.80, p<0.001). Cohen's d for pre-postoperative improvement was 0.12 with mean changes in EQ5D score of 0.35 in those that accessed physiotherapy compared to 0.39 in those that did not (p=0.023) (Table 1 and Figure 2). The patients that did not access post-operative physiotherapy were more satisfied at 6 months (p<0.001, Z=-6.43), with approximately twice the number of patients dissatisfied and very dissatisfied in the group that accessed physiotherapy (Table 1).

Total Knee Arthroplasty

TKA patients accessing physiotherapy were modestly but significantly younger (68.2 vs 71.0 years,
 p<0.001). There was no difference in gender (p=0.099). Those that accessed physiotherapy were
 more likely to live in a less deprived area (p=0.028); there was no difference in BMI between groups
 (p=0.198) (Table 2).

- Patient outcomes were superior in the 51.8% of TKA patients that did not access post-operative
 physiotherapy in terms of absolute OKS (35.9 vs 32.3 points, p<0.001). There was no difference in
 pre-operative score between groups (20.9 points respectively, p = 0.965), reflected in a lesser
 change in OKS for the group that accessed physiotherapy post-operatively (11.4 points vs 15.0
- 177 points, p<0.001, Cohen's d=0.39) (Table 2 and Figure 3).
- There were also differences in improvement measured with the EQ-5D (Table 2). Patients accessing
 physiotherapy improved 0.25 points, compared to 0.35 points in those who did not (p<0.001,
 Cohen's d=0.32, Figure 4). Again there was no difference in pre-operative scores between groups
 (0.43 vs 0.41, p = 0.183), while postoperative scores differed significantly (0.68 vs 0.77, p<0.001).
- The patients that did not access post-operative physiotherapy were more satisfied (p<0.001, Z=-
 8.22), with approximately twice the number of patients dissatisfied and very dissatisfied in the group
 - 184 that accessed physiotherapy (Table 2).

186 Multivariate analysis

Binary logistic regression modelling was undertaken to determine if post-operative access to physiotherapy could be predicted by pre-operative patient variables. A regression model with three predictors (age, sex and pre-operative EQ-5D score) was able to correctly classify 66.9% of THA patients with regard to post-operative physiotherapy access (Table 3). This percentage of correct classifications was significantly (p<0.001) different from chance level (50% correct classifications). In TKA patients the regression model comprised only two significant predictors (age and sex) and provided a percentage of correct classifications of 57.4%, again significantly better than chance (p<0.001).

		Post-discharge physical therapy following TKA & THA
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2 3	195	
4 5	196	DISCUSSION
6	197	Only a third of patients that underwent total hip arthroplasty and half of those who underwent total
/ Q	198	knee arthroplasty accessed post-discharge outpatient physiotherapy to assist with their recovery.
0 9	199	The patients that did not access post-discharge physiotherapy do not seem to have been adversely
10	200	affected by this decision as this group reported superior outcome scores. Functional outcome and
11	201	satisfaction scores at 6 months in patients that did not access additional physiotherapy compare well
12	202	to national outcome figures for both hip and knee arthroplasty [22], suggesting that post-discharge
13	203	outpatient therapy is not necessarily required in all cases. Indeed it would appear that referral for
14	204	post-discharge therapy may be a marker of patients at risk of poor outcomes.
15	205	There is no consensus as to how best to rebabilitate patients following lower limb joint arthroplasty
17	205	Systematic reviews of post-operative rebabilitation interventions suggest that no one approach is
18	200	beneficial in improving outcomes [8, 16-18] and a recent Cochrane review stressed the general low
19	207	quality of the evidence hase [23]
20	200	quanty of the evidence base [25].
21	209	In this study, routine post-discharge out-patient physiotherapy was not provided following total hip
22	210	and knee replacement. Instead the local standard of care was for patients to undertake prescribed
24	211	home exercises, with all patients able to access additional out-patient physiotherapy services should
25	212	they require or wish to. Under this system, patients are referred to physiotherapy based on clinical
26	213	need. This 'need' for therapy was determined by clinical staff at time of discharge (either doctor or
27	214	physiotherapist), or at 6 week out-patient review (consultant team or allied health professional
28	215	arthroplasty practitioner), or at any point through the patient's GP service. Separately the patient
29 30	216	could refer themselves via a self-referral telephone triage system or access private therapy out with
31	217	the NHS.
32	218	We cannot, evaluate the effectiveness of post-discharge physiotherapy with this data. Those who
33	219	accessed additional therapy in this cohort reported lower scores, suggesting greater physical
34	220	dysfunction in the early post-operative phase. It may be that the additional therapy improved the
35	221	patient outcomes compared to having had no such intervention. Patients and clinicians expect a
36 27	222	rehabilitation component to be provided as part of the care pathway for joint arthroplasty. Though
38	223	there is a role for physiotherapy, it may be that differing levels of therapy provision should be
39	224	targeted to those that require additional input as opposed to blanket provision for all in the early
40	225	post-operative phase. Self-directed home exercises were sufficient for the majority of patients in
41	226	this study. From a health economic and service delivery perspective this is clearly attractive,
42	227	however relies on accurately targeting therapy provision to those that require the additional input.
43 44	220	We were able to construct statistically significant regression models using the energy data to
45	228	we were able to construct statistically significant regression models using pre-operative data to
46	229	poor in terms of accuracy. The bin replacement model was only 17% greater than change at
47	250	identifying the nation to that accessed physiotherapy. The THA nation to who accessed physiotherapy.
48	231	post on reported lower general boalth scores (EOED) but broadly equivalent joint specific boalth
49	232	scores (OHS). This drove the regression model and perhans suggests frailty may be related to the
50 51	233	requirement for additional therapy however it must be noted that these nations were on average 5
52	235	vears younger than the larger group that did not attend additional physiotherapy. Interestingly pre-
53	236	operative pain levels. BMI and deprivation status did not influence the models.
54		
55	237	Notably more knee arthroplasty patients required or wished to access additional physiotherapy than
56 57	238	hip arthroplasty, which is perhaps consistent with the reports of greater treatment success and
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patient outcomes following hip arthroplasty [5, 24]. Despite applying a range of pre-operative
demographic and symptom state indicators, we were only able to model the additional use of postdischarge physiotherapy to an accuracy of 7% greater than chance. Interestingly in the TKA cohort,
the model relied solely on small associations with age and sex. In this model, pre-operative pain /
function / health scores, social deprivation and BMI did not help determine which patient would go
on to require additional therapy.

Though various factors have been associated with poor clinical outcomes following TKA, currently, we cannot reliably predict pre-operatively who will struggle to recover post-operatively. Larger and more comprehensive predictor studies (for example incorporating psychological variables) are required to determine which patient factors lead to poorer post-operative outcomes and to see if particular patient groups benefit from post-discharge physiotherapy. Further insight may be

250 provided by the multicentre TRIO study which is currently evaluating this [25].

251 Strengths and Limitations

252 Strengths of this study are the relatively large consecutive patient cohort of approximately 1400 THA 253 and 1400 TKA operations performed over a 2.5 year period at a single orthopaedic unit, and the 254 depth of linked demographic and outcomes data available. Our data is in line with UK national 255 figures for patient demographics and pre and post-operative outcome scores. Limitations are that 256 the access to physiotherapy was documented and reported by the patient at 6 months and we are 257 not able to determine the route by which the patient accessed post-discharge therapy, nor what 258 specific therapy was received. The relatively short post-operative 6 month timeframe results that we 259 cannot comment on longitudinal changes in outcomes, nor whether those patients that access 260 physiotherapy 'caught-up' with those that did not in terms of clinical outcome scores at subsequent 261 later time points.

262

263 CONCLUSION

In a large single centre study, only a third of hip arthroplasty and half of knee arthroplasty patients
accessed post-discharge physiotherapy. Those who did not access additional therapy reported
greater post-operative outcome scores and satisfaction, suggesting variation in requirement for
post-arthroplasty physiotherapy. We were unable to predict pre-operatively (with demographics and
symptom report) which patients would subsequently access additional input. Future work should
explore additional factors with a view to targeting additional treatment to improve outcomes.

270

271 CONTRIBUTORS

272 DFH, conceived the study, interpreted the results, drafted and revised the manuscript. FCL 273 performed the statistical analysis, drafted the results and contributed to manuscript revisions. DJM 274 obtained the data, collated the data and contributed to manuscript drafting and revision. GMF 275 contributed to results interpretation, manuscript drafting and revision. DJB contributed to results 276 interpretation, manuscript drafting and revision. HRS contributed to results interpretation, 277 manuscript drafting and revision. JTP contributed to the study design, results interpretation, 278 manuscript drafting and revision. CRH contributed to the study design, results interpretation, 279 manuscript drafting and revision.

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287 CONFLICT OF INTEREST STATEMENT

interpretation of data nor writing of the maunscript.

DFH, DJB, GMF and HRS, are grant holders on the Arthritis Research UK funded TRIO study. Though
there is no financial or direct academic conflict, this work can be considered as relevant background
for the (currently) ongoing TRIO study.

292 ETHICAL APPROVAL

FUNDING

293 Ethical approval was obtained from the Scotland A Research Ethics Committee (11/AL/0079).

295 DATA SHARING STATEMENT

- 296 The raw data cannot be made publically available to protect patient confidentiality, however
- 297 restricted data may be made available if deemed reasonable by the data custodian. Such requests

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should be made to CRH via the corresponding author.

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Post-discharge physical therapy following TKA & THA

TABLES

358 Table 1 Descriptive and outcome data for THA by post-operative physiotherapy access

|--|

Referred for physiotherapy	Yes	No	Effect size		р
Sex					
female N (%)	324 (65.7)	486 (53.9)		$X^2 = 18.352$	p<0.001 [‡]
male N (%)	169 (34.3)	416 (46.1)			
Side					
left, N (%)	212 (43.5)	422 (47.6)		$X^2 = 2.123$	p=0.157 [‡]
right N (%)	275 (56.5)	464 (52.4)			
SIMD					
1 st quintile N (%)	37 (7.5)	76 (8.4)		Z = -0.78	p=0.438*
2 nd quintile N (%)	78 (15.8)	160 (17.7)			
3 rd quintile N (%)	85 (17.2)	166 (18.4)			
4 th quintile N (%)	129 (26.2)	193 (21.4)			
5 th quintile N (%)	164 (33.3)	307 (34.0)			
Age Mean (SD)	64.9 (13.2)	69.1 (10.6)	0.35^{\pm}	T = -6.08	p<0.001 ⁺
BMI Mean (SD)	28.3 (6.9)	28.2 (5.0)	0.02^{\pm}	T = 0.27	p=0.788 ⁺
OKS					
Pre-op	20.1 (8.6)	21.4 (8.6)	1.31 [±]	T = -2.67	¢=0.008 [†]
Post-op	35.8 (9.8)	39.4 (8.6)	0.39 [±]	T = -6.96	p<0.001 [†]
Improvement	15.6 (10.6)	18.0 (9.9)	0.23 [±]	T = -4.06	p<0.001 ⁺
EQ5D					
Pre-op	0.35 (0.3)	0.41 (0.3)	0.20 [±]	T = -2.92	p=0.004 ⁺
Post-op	0.70 (0.3)	0.80 (0.2)	0.39^{\pm}	T = -6.52	p<0.001 [†]
Improvement	0.35 (0.4)	0.39 (0.3)	0.12 [±]	T = -2.28	p=0.023 ⁺
Satisfaction					
Very satisfied	280 (57.4)	648 (73.3)		Z = -6.43	p<0.001*
Satisfied	122 (25.0)	165 (18.7)			
Neither satisfied nor dissat	44 (9.0)	43 (4.9)			
Dissatisfied	27 (5.5)	13 (1.5)			
Verv dissatisfied	15 (3.1)	15 (1.7)			

360 Mann-Whitney-U*, t-test⁺, Chi-square⁺, Cohen's d[±]

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Post-discharge physical therapy following TKA & THA

Table 2 Descriptive and outcomes data for TKA by postoperative physiotherapy access

Referred for physiotherapy	Yes	No	Effect size		Р
Sex					
female N (%)	390 (58.9)	388 (54.5)		$X^2 = 2.726$	p=0.099
male N (%)	272 (41.1)	324 (45.5)			
Side					
left N (%)	321 (49.5)	337 (47.7)		$X^2 = 0.404$	p=0.52
right N (%)	328 (50.5)	369 (52.3)			
SIMD					
1 st quintile N (%)	63 (9.5)	66 (9.3)		Z = -2.19	p=0.028
2 nd quintile N (%)	104 (15.7)	162 (22.8)			
3 rd quintile N (%)	122 (18.4)	136 (19.1)			
4 th quintile N (%)	164 (24.8)	138 (19.4)			
5 th quintile N (%)	209 (31.6)	210 (29.5)			
Age Mean (SD)	68.2 (9.7)	71.0 (8.6)	0.30^{\pm}	T = -5.73	p<0.00
BMI Mean (SD)	31.1 (6.0)	30.6 (5.9)	0.01^{\pm}	T = 1.29	p=0.19
OKS					
Pre-op	20.9 (7.8)	20.9 (7.9)	< 0.01 [±]	T = -0.04	p=0.96
Post-op	32.3 (9.8)	35.9 (9.1)	0.38^{\pm}	T = -6.99	p<0.00
Improvement	11.4 (9.4)	15.0 (8.9)	0.39^{\pm}	T = -7.16	p<0.00
EQ5D					
Pre-op	0.43 (0.3)	0.41 (0.3)	0.07 [±]	T = 1.33	p=0.18
Post-op	0.68 (0.3)	0.77 (0.2)	0.35 [±]	T = -6.34	p<0.00
Improvement	0.25 (0.3)	0.35 (0.3)	0.32 [±]	T = -6.15	p<0.00
Satisfaction, N (%)					
Very satisfied	271 (41.6)	427 (61.3)		Z = -8.22	p<0.00
Satisfied	214 (32.8)	198 (28.4)			
Neither satisfied nor dissat	98 (15.0)	43 (6.2)			
Dissatisfied	51 (7.8)	20 (2.9)			
Very dissatisfied	18 (2.8)	9 (1.3)			

364 Mann-Whitney-U*, t-test^{\dagger}, Chi-square^{\dagger}, Cohen's d^{\pm}

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Post-discharge physical therapy following TKA & THA

Table 3 Predictive accuracy of demographic and preoperative outcome-parameters for patients

referring for physiotherapy

		TH	Α				TKA	
	OR	95% confidence interval	p	Correct classifications	OR	95% confidence interval	p	Correct classifications
Age Sex	1.03 1.60	1.02-1.04	<0.001 <0.001	66.9 %	1.04 1.26	1.02-1.05 1.01-1.58	<0.001 0.038	57.4 %
2-5D	1.54	1.08-1.20	0.018		-	-	-	-

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Post-discharge physical therapy following TKA & THA

1		
2 3	372	FIGURES
4 5	373	Figure 1 - Change in Oxford Hip Scores by post-operative physiotherapy access in THA patients
6	374	Figure 2 - Change in EQ5D scores by post-operative physiotherapy access in THA patients
7 8	375	Figure 3 - Change in Oxford Knee Scores by post-operative physiotherapy access in TKA patients
9 10	376	Figure 4 - Change in EQ5D scores by post-operative physiotherapy access in TKA patients
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276x223mm (96 x 96 DPI)



No

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274x220mm (96 x 96 DPI)



	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment,
		exposure, follow-up, and data collection
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of
		selection of participants. Describe methods of follow-up
		Case-control study—Give the eligibility criteria, and the sources and methods of
		case ascertainment and control selection. Give the rationale for the choice of cases
		and controls
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of
		selection of participants
		(b) Cohort study-For matched studies, give matching criteria and number of
		exposed and unexposed
		Case-control study—For matched studies, give matching criteria and the number of
		controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect
		modifiers. Give diagnostic criteria, if applicable
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there
		is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) Cohort study-If applicable, explain how loss to follow-up was addressed
		Case-control study-If applicable, explain how matching of cases and controls was
		addressed
		Cross-sectional study-If applicable, describe analytical methods taking account of
		sampling strategy
		(<u>e</u>) Describe any sensitivity analyses
Continued on next page		

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and
		analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information
data		on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Cohort study-Report numbers of outcome events or summary measures over time
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their
		precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and
		why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful
		time period
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and sensitivity
		analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.
		Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity
		of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other informati	on	
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable,
		for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Exploring variation in patient access of post-discharge physiotherapy following total hip and knee arthroplasty under a choice based system in the UK: an observational cohort study.

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Primary Subject Heading :	Surgery
Secondary Subject Heading:	Rehabilitation medicine, Rheumatology
Keywords:	Total knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy

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Access of post-discharge physiotherapy following TKA & THA

Objectives: To assess a targeted 'therapy as required' model of post-discharge outpatient

physiotherapy provision. Specifically we investigated what proportion of patients accessed post-

discharge physiotherapy following THA and TKA, whether accessing therapy was associated with

ABSTRACT

post-arthroplasty patient reported outcomes and whether it was possible to predict which patients' would access post-discharge physiotherapy from pre-operative data. Design: Prospective cohort study Setting: Single National Health Service orthopaedic teaching hospital Participants: 1395 patients undergoing THA and 1374 patients undergoing TKA. Outcome measures: Self-reported access of post-discharge physiotherapy, the Oxford Hip or Knee Score and EQ5D questionnaire and post-operative satisfaction metric.

Results: 662 (48.2%) TKA and 493 (35.3%) THA patients accessed additional post-discharge

46 physiotherapy. Patient reported outcomes (p<0.001) and satisfaction (p=0.001) were higher in both

47 THA and TKA patients that did not access the post-discharge physiotherapy. Regression models using

pre-operative symptom burden and demographic data predicted post-discharge therapy access with
 an accuracy of only 17% greater than chance in THA and 7% in TKA.

50 Conclusions: In a choice based service model of targeted rehabilitation 'as required' following hip
 51 and knee arthroplasty only a third of THA and half of TKA patients accessed post-discharge

52 outpatient therapy. The patients that did not access additional outpatient physiotherapy reported

- 53 higher outcome scores and satisfaction, suggesting variation in the need for post-arthroplasty
- physiotherapy, and that targeting of rehabilitation may be a cost-effective model, however it was
 not possible to reliably predict which patients would access post-discharge physiotherapy pre-
- 56 operatively.

Keywords: Total knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy

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Access of post-discharge physiotherapy following TKA & THA

ARTICLE SUMMARY

STRENGTHS AND LIMITATIONS

- • This is a relatively large patient cohort of 2769 total hip and knee replacements performed over a 2 year period at a single orthopaedic unit evaluating a consistent and specific delivery model of post-discharge rehabilitation provision.
- A particular strength of this study design is the depth of linked demographic and outcomes data available with which to construct the predictive models.
- • Data relating to access of post-surgical physiotherapy was reported by the patient at 6 months post-operation.
- • We are not able to determine the referral route by which the patient accessed post-discharge Jerc. acific therapy w.
- therapy, nor what specific therapy was received.

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Access of post-discharge physiotherapy following TKA & THA

72 INTRODUCTION

Lower limb osteoarthritis is an extremely common and disabling condition, which may ultimately require surgical intervention. In excess of 90,000 total hip and 90,000 total knee arthroplasties (THA and TKA) are performed each year in the UK alone¹. Projections suggest continued increases of surgical volume year on year^{2 3}. Though joint replacement is effective at reducing pain and improving physical function in patients with end stage osteoarthritis, a sub-group of patients continue to report dissatisfaction with their post-operative outcome^{4 5} highlighted by protracted physical impairment ⁶ and activity limitations⁷⁻¹⁰.

Physiotherapy is thought to be an important component in achieving optimal results following THA or TKA¹¹. Immediately post-surgery, throughout the inpatient stay, physiotherapy is aimed at encouraging mobilisation and facilitating a safe discharge. Though subsequent post- discharge physiotherapy is often promoted there is considerable national and international variation in actual therapy provision. Specific rehabilitation protocols are strongly entrenched at individual physiotherapy departments however the wider efficacy of post-operative physiotherapeutic intervention is poorly established¹²⁻¹⁸. This uncertainty as to effectiveness of physiotherapy interventions makes it difficult for commissioning organisations, healthcare providers, and patients to make decisions as to the role of post-discharge physiotherapy following total joint arthroplasty, and in determining the correct level and mechanism of funding for such services. As a result there is substantial variety in the delivery and content of post-operative physiotherapy following joint arthroplasty across the UK.

The purpose of this study was to assess a targeted 'therapy as required' model of post-discharge physiotherapy provision. Under this service model, routine post-discharge out-patient physiotherapy is not provided following THA and TKA. Instead the local standard of care is for patients to undertake prescribed home exercises, with all patients able to access additional out-patient physiotherapy services should they require or wish to do so. Specifically, we investigated what proportion of patients accessed post-discharge physiotherapy following THA and TKA, whether accessing therapy was associated with post-arthroplasty patient reported outcomes and whether it was possible to predict which patients would access post-discharge physiotherapy from pre-operative data.

103 METHODS

104 Study design and participants

This was a prospective observational cohort study. All patients undergoing primary hip and knee arthroplasty were invited to participate in the study that ran alongside the department's routine outcomes data collection project. Data collection was through questionnaires administered preoperatively at hospital clinic appointment (2 weeks prior to surgery) and then via postal review at 6 months post-operatively. Patients were sent forms on the 6 month anniversary of the surgical episode, with a further follow-up sent 2 weeks later if no response was received.

Ethical approval was obtained from the Scotland A Research Ethics Committee (11/AL/0079).
Informed consent was obtained. Patients undergoing primary unilateral THA or TKA at a single
National Health Service teaching hospital were prospectively assessed over a 32 month period
between January 2013 and September 2015.

		Access of post-discharge physiotherapy following TKA & THA
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2		
3	115	The study centre is the only hospital receiving adult referrals for a predominantly urban regional
4	116	population of approximately 850 000 people. Surgery was carried out by 12 consultant orthopaedic
5	117	surgeons and their supervised trainees. Local protocols were followed for all aspects of pre-
0 7	118	operative, inpatient, and post-operative care.
8	119	Pre-operatively a booklet is provided to patients with information about the procedure (THA or TKA)
9	120	which includes detail on rehabilitation, advising as to activity and highlighting exercises to perform
10	120	Immediate nost-operative therapy (inpatient stay) is protocol driven focussing on knee range of
11	121	movement muscle re-education and mobilising with appropriate walking aids to facilitate a safe
12	172	discharge. Dost-discharge practice at the study centre is to promote continued performance of the
13	123	ascharge. Post-discharge practice at the study centre is to promote continued performance of the
14	124	referred to out patient physiotherapy based on clinically assessed pood at time of discharge or at 6
15	125	week pact operative clinical review, with additional referral revites available to the nations through
10	120	general practice convices and a national national referral tolenhouse triage system
18	127	general practice services and a national patient sen-referral telephone triage system.
19	128	Demographic data was obtained for the patient's age, sex, BMI, socioeconomic denominators using
20	129	the Scottish Index of Multiple Deprivation (SIMD). The SIMD is a national statistic based on postcode.
21	130	It combines data on 38 indicators across 7 domains, namely: income, employment, health,
22	131	education, skills and training, housing, geographic access and crime. We applied the 2012 SIMD
23	132	dataset. Physical outcomes were assessed with the Oxford Hip or Knee Score (OHS and OKS) and
24	133	EuroQol- 5 Dimension (EQ-5D-3L) questionnaire. Both questionnaires have been thoroughly
25	134	validated and are the national statistics of choice in the UK for measuring arthroplasty outcomes.
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27	135	
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30	130	
31	137	The Oxford Hip and Knee Scores each consist of 12 questions assessing the patient's pain and
32	138	function ^{19 20} . Each item is answered on a 5-point response scale ranging from 0 to 4, generating a
33	139	summed total score ranging from 0 to 48, where 0 indicates the worst possible outcome and 48
34	140	good joint function.
35 36	1 4 1	The FO FD is a standardized instrument with five items accurate whility call are used activities
37	141	The EQ-5D is a standardised instrument with five items covering mobility, self-care, usual activities,
38	142	pain and discomfort as well as anxiety and depression ⁻² . As a measure of self-reported general
39	143	health, it is applicable to a wide range of health conditions and treatments and provides a simple
40	144	descriptive profile and a single index value for health status. Lower scores represent a worse health
41	145	sate.
42	146	Patient satisfaction was assessed using a 5 point Likert response format at 6 months post-surgery.
43	147	Patients were asked to rate their overall satisfaction with their operated hip or knee (response
44 45	148	options: very satisfied, satisfied, unsure, dissatisfied or very dissatisfied). Self-report of
45	149	physiotherapy attendance was recorded at 6 month assessment.
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48	150	
49	151	Patient and Public Involvement
50	191	
51	152	There was no specific patient involvement in the design or conduct of the study methodology,
52	153	however the study question as to the role of physiotherapy in the post-operative period following
53 54	154	joint arthroplasty was highlighted as a priority area for research by a patient feedback project at the
54 55	155	study centre.
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Access of post-discharge physiotherapy following TKA & THA

Statistical analysis

Analyses were performed with SPSS V21.0²². Demographic indicators are presented as frequencies or means with standard deviations as a measure of dispersal. Differences between patients who accessed physiotherapy after total joint arthroplasty and those who did not were investigated with t-tests, chi-square tests and Mann-Whitney-U tests as appropriate. Effect sizes for differences in metric variables are given as Cohen's d.

To identify predictors of physiotherapy access we used a binary logistic regression model with physiotherapy access as dependent variable and patient characteristics and preoperative OKS/OHS and EQ-5D as predictors. The predictors were included using a forward selection stepwise model building technique (likelihood ratio) with an entry criterion of alpha=0.05. Model fit is described with percentage of correct classifications and predictors are given as odds ratios with corresponding 95% confidence intervals. Using this methodology, the chance level of correct classifications is 50% and the model-based classification is compared against this value.

RESULTS

1534 patients underwent primary THA and 1503 primary TKA in the study time window. 97% of cases were coded as being performed for a diagnosis of osteoarthritis. Survey data was available for 1395 (90.9%) THA patients and for 1374 (91.4%) TKA patients. All data was included in the analysis. THA patients had a mean age of 67.6 ± 11.8 years, 58.1% were female, TKA patients had a mean age 69.7 ± 9.3 years, 56.6% were female. Of this total surgical cohort, 493 (35.3%) THA and 662 (48.2%) TKA patients accessed post-operative out-patient physiotherapy.

Total Hip Arthroplasty

THA patients accessing physiotherapy were younger (64.9 vs 69.1 years, p<0.001) and more likely to be female (p<0.001), however there were no differences in BMI (p=0.788) or social deprivation index (p=0.438) between the groups (Table 1).

Patients that did not access post-operative physiotherapy had statistically higher scores (39.4±8.6) on the OHS than patients who accessed post-operative physiotherapy (35.8±9.8) at 6 months followup (p<0.001). At baseline, patients that accessed post-operative physiotherapy had statistically lower scores (20.1±8.6) than patients who accessed post-operative physiotherapy (21.4±8.6) on the OHS (p=0.008). However patients that did not access physiotherapy made a larger gain in pain and function scores measures with the OHS: improvement from baseline to 6 months follow-up was 15.6±10.6 points without post-surgery physiotherapy access and 18.0±9.9 points for such that did access physiotherapy, p<0.001, Cohen's d=0.23) (Table 1 and Figure 1). EQ5D scores pre and post-surgery were lower in patients referring for physiotherapy both pre-surgery (0.35 vs 0.41, p=0.004,) and post-surgery (0.70 vs 0.80, p<0.001). Cohen's d for pre-postoperative improvement was 0.12 with mean changes in EQ5D score of 0.35 in those that accessed physiotherapy compared to 0.39 in those that did not (p=0.023) (Table 1 and Figure 2).

The patients that did not access post-operative physiotherapy were more satisfied at 6 months (p<0.001, Z=-6.43), with approximately twice the number of patients dissatisfied and very

dissatisfied in the group that accessed physiotherapy (Table 1).

Access of post-discharge physiotherapy following TKA & THA

1		Access of post-discharge physiotherapy following TKA & THA
2		
3	198	
4 5	199	Total Knee Arthroplasty
6	200	TKA patients accessing physiotherapy were modestly but significantly younger (68.2 vs 71.0 years,
/	201	p<0.001). There was no difference in gender (p=0.099). Those that accessed physiotherapy were
0 0	202	more likely to live in a less deprived area (p=0.028); there was no difference in BMI between groups
10	203	(p=0.198) (Table 2).
11		
12	204	Patient outcomes were better in the 51.8% of TKA patients that did not access post-operative
13	205	physiotherapy in terms of absolute OKS (35.9 vs 32.3 points, p<0.001). There was no difference in
14	206	pre-operative score between groups (20.9 points respectively, p = 0.965), reflected in a lesser
15	207	change in OKS for the group that accessed physiotherapy post-operatively (11.4 points vs 15.0
16	208	points, p<0.001, Cohen's d=0.39) (Table 2 and Figure 3).
1/	209	There were also differences in improvement measured with the EO-5D (Table 2) Patients accessing
10	210	nhysiotherapy improved 0.25 points, compared to 0.35 points in those who did not ($p<0.001$
20	210	Cohen's $d=0.32$ Figure 4) Again there was no difference in pre-operative scores between groups
21	211	(0.43 ys 0.41 n = 0.183) while postonerative scores differed significantly $(0.68 ys 0.77 n < 0.001)$
22	212	$(0.43 \times 0.41, p = 0.103)$, while postoperative scores unreled significantly $(0.00 \times 0.77, p < 0.001)$.
23	213	The patients that did not access post-operative physiotherapy were more satisfied (p<0.001, Z=-
24	214	8.22), with approximately twice the number of patients dissatisfied and very dissatisfied in the group
25	215	that accessed physiotherapy (Table 2).
26 27	210	
27	210	
29	217	Multivariate analysis
30		
31	218	Binary logistic regression modelling was undertaken to determine if post-operative access to
32	219	physiotherapy could be predicted by pre-operative patient variables. A regression model with three
33	220	predictors (age, sex and pre-operative EQ-5D score) was able to correctly classify 66.9% of THA
34	221	patients with regard to post-operative physiotherapy access (Table 3). This percentage of correct
35	222	classifications was significantly (p<0.001) different from chance level (50% correct classifications). In
30 27	223	TKA patients the regression model comprised only two significant predictors (age and sex) and
38	224	provided a percentage of correct classifications of 57.4%, again significantly better than chance
39	225	(p<0.001).
40	226	
41	220	
42	227	DISCUSSION
43	110	There is no concensus as to how best to republikate national following TUA or TKA. Surfacestic
44 45	228	mere is no consensus as to now pest to renabilitate patients following THA or TKA. Systematic
45 46	229	reviews of post-operative renabilitation interventions suggest that no one approach is beneficial in
40 47	230	improving outcomes and a recent Cochrane review stressed the general low quality of the
48	231	evidence base . In this study we review an 'access physiotherapy as needed' model of post-
49	232	discharge service delivery. Routine post-discharge out-patient physiotherapy was not provided
50	233	following THA and TKA. Instead the local standard of care was for patients to undertake prescribed
51	234	nome exercises, with all patients able to access additional out-patient physiotherapy services should
52	235	they require or wish to do so. Under this system, patients can be referred to physiotherapy based on
53	236	clinical need as determined by clinical staff at time of discharge (either doctor or physiotherapist), or
54 55	237	at 6 week out-patient review (consultant team or allied health professional arthroplasty
55 56	238	practitioner), or at any point through the patient's GP service. Separately the patient could refer
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59 60

Access of post-discharge physiotherapy following TKA & THA

themselves via a self-referral telephone triage system or access private therapy out with the National Health Service.

Under this system, only a third of patients that underwent THA and half of those who underwent TKA accessed post-discharge outpatient physiotherapy to assist with their recovery. The patients that did not access post-discharge physiotherapy do not seem to have been adversely affected by this decision as this group reported better outcome scores. A difference in pre-to post-operative change in Oxford Score of approximately 3 points was observed between the THA patients, and approximately 4 points in the TKA patients that accessed physiotherapy compared to those that did not. The minimal clinically important difference in Oxford Scores has been estimated at 5 points²⁴, in THA and 4 points in TKA suggesting the statistical differences reported in the THA patients are unlikely to reflect a clinically meaningful difference, but that the TKA data may represent variation in clinical outcomes between groups.

The Oxford Scores, EQ—5D scores and satisfaction scores at 6 months reported by the patients that did not access additional post-discharge physiotherapy compare well to national outcome figures for both THA and TKA patients²⁵. This suggests that post-discharge outpatient physiotherapy is not necessarily required in all cases, and that (broadly) patients and clinicians are able to make a judgement as to whether they should attend such therapy. Indeed it would appear that referral for post-discharge therapy may be a marker of patients at risk of poor outcomes.

This is an observational cohort study and we do not attempt to evaluate the effectiveness of undertaking post-discharge physiotherapy with this data. Those who accessed additional therapy in this cohort reported lower scores, suggesting greater physical dysfunction in the early post-operative phase. It may be that the additional therapy improved the patient outcomes compared to having had no such intervention. Patients and clinicians expect a rehabilitation component to be provided as part of the care pathway for joint arthroplasty. Though there is a role for physiotherapy around total joint arthroplasty, it may be that post-discharge physiotherapy should be targeted to those that require additional input as opposed to blanket provision for all in the early post-operative phase. In this setting, self-directed home exercises appear to have been sufficient for the majority of patients to achieve a good outcome post-arthroplasty. From a health economic and service delivery perspective this is clearly attractive, however relies on accurately targeting physiotherapy to those that require the additional input.

We were able to construct statistically significant regression models using pre-operative data to correctly classify the patients that accessed post-operative therapy, however these models were poor in terms of accuracy. The hip replacement model was only 17% greater than chance at identifying the patients that accessed physiotherapy. The THA patients who accessed physiotherapy post-op reported lower general health scores (EQ5D) but broadly equivalent joint specific health scores (OHS). The EQ5D data essentially drove the regression model and perhaps suggests poorer health status or frailty may be related to the requirement for additional therapy; however it must be noted that these patients were on average 5 years younger than those that did not attend additional physiotherapy, suggesting health and not age is the pertinent factor here. Interestingly pre-operative pain levels, BMI and deprivation status did not influence the models.

Notably more TKA patients required or wished to access additional physiotherapy than THA, which is perhaps consistent with the reports of greater treatment success and patient outcomes following hip arthroplasty^{5 26}. Despite applying a range of pre-operative demographic and symptom state

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indicators, we were only able to model the additional use of post-discharge physiotherapy to an
accuracy of 7% greater than chance. Interestingly in the TKA cohort, the model relied solely on small
associations with age and sex. In this model, pre-operative pain / function / health scores, social
deprivation and BMI did not help determine which patient would go on to require additional
therapy.

Though various factors have been associated with poor clinical outcomes following TKA, currently, we cannot reliably predict pre-operatively who will struggle to recover post-operatively. Larger and more comprehensive predictor studies (for example incorporating psychological variables) are required to determine which patient factors lead to poorer post-operative outcomes and to see if particular patient groups benefit from post-discharge physiotherapy. Further insight may be provided by the multicentre TRIO and COASt studies that are currently evaluating this in the UK^{26, 27}. Alternatively, it may be that it is the patient's response to surgery as opposed to pre-operative characteristics is that determine the need for post-operative rehabilitation and that there is no reliable way to predict this pre-operatively.

298 Strengths and Limitations

A strength of this study is the relatively large patient cohort of 2769 arthroplasties and the depth of linked demographic and outcome data. Additionally, that our data is in line with UK national figures for patient demographics and pre and post-operative outcome scores lends wider credibility. Limitations are that the access of physiotherapy was documented and reported by the patient at 6 months post-arthroplasty and we are not able to determine the route by which the patient accessed this post-discharge therapy, nor what specific therapy was received. The relatively short post-operative 6 month timeframe results that we cannot comment on longitudinal changes in outcomes, nor whether those patients that access physiotherapy 'caught-up' with those that did not in terms of clinical outcome scores at subsequent later time points. The study was not designed to evaluate the effectiveness of the physiotherapy received, however future studies may be able to targeted therapy to patients deemed 'at need of intervention', and randomise to differing levels or modes of intervention.

312 CONCLUSION

In a choice based service model of targeted physiotherapy 'as required' following hip and knee arthroplasty only a third of THA and half of TKA patients accessed post-discharge physiotherapy. Those who did not access additional therapy reported greater post-operative outcome scores and satisfaction, suggesting a variation in requirement for post-arthroplasty physiotherapy. We were unable to predict pre-operatively (with demographic and symptom data) which patients would subsequently access additional input.

320 CONTRIBUTORS

321 DFH, conceived the study, interpreted the results, drafted and revised the manuscript. FCL
 322 performed the statistical analysis, drafted the results and contributed to manuscript revisions. DJM
 323 obtained the data, collated the data and contributed to manuscript drafting and revision. GMF
 324 contributed to results interpretation, manuscript drafting and revision. DJB contributed to results

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- interpretation, manuscript drafting and revision. HRS contributed to results interpretation,
 manuscript drafting and revision. JTP contributed to the study design, results interpretation,
 manuscript drafting and revision. CRH contributed to the study design, results interpretation,
 manuscript drafting and revision.

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 interpretation of data nor writing of the manuscript.

336 CONFLICT OF INTEREST STATEMENT

DFH, DJB, GMF and HRS, are grant holders on the Arthritis Research UK funded TRIO study. Though
 there is no financial or direct academic conflict, this work can be considered as relevant background
 for the (currently) ongoing TRIO study.

341 ETHICAL APPROVAL

- 342 Ethical approval was obtained from the Scotland A Research Ethics Committee (11/AL/0079).

344DATA SHARING STATEMENT

- 345 The raw data cannot be made publicly available to protect patient confidentiality, however
- 346 restricted data may be made available if deemed reasonable by the data custodian. Such requests
- 347 should be made to CRH via the corresponding author.

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Access of post-discharge physiotherapy following TKA & THA

TABLES

427 Table 1 Descriptive and outcome data for THA by post-operative physiotherapy access

Referred for physiotherapy	Yes	No	Effect size		р
Sex					
female N (%)	324 (65.7)	486 (53.9)		$X^2 = 18.352$	p<0.001
male N (%)	169 (34.3)	416 (46.1)			
Side					
left, N (%)	212 (43.5)	422 (47.6)		$X^2 = 2.123$	p=0.157
right N (%)	275 (56.5)	464 (52.4)			
SIMD					
1 st quintile N (%)	37 (7.5)	76 (8.4)		Z = -0.78	p=0.438
2 nd quintile N (%)	78 (15.8)	160 (17.7)			
3 rd quintile N (%)	85 (17.2)	166 (18.4)			
4 th quintile N (%)	129 (26.2)	193 (21.4)			
5 th quintile N (%)	164 (33.3)	207 (34.0)			
Age Mean (SD)	64.9 (13.2)	69.1 (10.6)	0.35^{\pm}	T = -6.08	p<0.001
BMI Mean (SD)	28.3 (6.9)	28.2 (5.0)	0.02^{\pm}	T = 0.27	p=0.788
OKS					
Pre-op	20.1 (8.6)	21.4 (8.6)	1.31 [±]	T = -2.67	p=0.008
Post-op	35.8 (9.8)	39.4 (8.6)	0.39 [±]	T = -6.96	p<0.001
Improvement	15.6 (10.6)	18.0 (9.9)	0.23 [±]	T = -4.06	p<0.001
EQ-5D					
Pre-op	0.35 (0.3)	0.41 (0.3)	0.20 [±]	T = -2.92	p=0.004
Post-op	0.70 (0.3)	0.80 (0.2)	0.39 [±]	T = -6.52	p<0.001
Improvement	0.35 (0.4)	0.39 (0.3)	0.12 [±]	T = -2.28	p=0.023
Satisfaction					
Very satisfied	280 (57.4)	648 (73.3)		Z = -6.43	p<0.001
Satisfied	122 (25.0)	165 (18.7)			
Neither satisfied nor	44 (9.0)	43 (4.9)			
dissatisfied	27 (5.5)	13 (1.5)			
Dissatisfied	15 (3.1)	15 (1.7)			
Very dissatisfied					

429 Mann-Whitney-U*, t-test⁺, Chi-square[∓], Cohen's d[±]

430 Scottish Index of Multiple Deprivation (SIMD); Body Mass Index (BMI); Oxford Knee Score (OKS); EuroQol 5-

431 Dimension (EQ-5D)

Access of post-discharge physiotherapy following TKA & THA

Table 2 Descriptive and outcomes data for TKA by postoperative physiotherapy access

Referred for physiotherapy	Yes	No	Effect size		Р
Sex					
female N (%)	390 (58.9)	388 (54.5)		<i>X</i> ² = 2.726	p=0.099 [‡]
male N (%)	272 (41.1)	324 (45.5)			
Side					
left N (%)	321 (49.5)	337 (47.7)		$X^2 = 0.404$	p=0.525 [‡]
right N (%)	328 (50.5)	369 (52.3)			
SIMD					
1 st quintile N (%)	63 (9.5)	66 (9.3)		Z = -2.19	p=0.028*
2 nd quintile N (%)	104 (15.7)	162 (22.8)			
3 rd quintile N (%)	122 (18.4)	136 (19.1)			
4 th guintile N (%)	164 (24.8)	138 (19.4)			
5 th quintile N (%)	209 (31.6)	210 (29.5)			
Age Mean (SD)	68.2 (9.7)	71.0 (8.6)	0.30^{\pm}	T = -5.73	p<0.001
BMI Mean (SD)	31.1 (6.0)	30.6 (5.9)	0.01^{\pm}	T = 1.29	p=0.198
OKS					·
Pre-op	20.9 (7.8)	20.9 (7.9)	<0.01 [±]	T = -0.04	p=0.965
Post-op	32.3 (9.8)	35.9 (9.1)	0.38^{\pm}	T = -6.99	p<0.001
Improvement	11.4 (9.4)	15.0 (8.9)	0.39^{\pm}	T = -7.16	p<0.001
FO-5D					
Pre-op	0.43 (0.3)	0.41 (0.3)	0.07 [±]	T = 1.33	$p=0.183^{1}$
Post-op	0.68 (0.3)	0.77 (0.2)	0.35 [±]	T = -6.34	p<0.001
Improvement	0.25 (0.3)	0.35 (0.3)	0.32 [±]	T = -6.15	p<0.001
Satisfaction, N (%)					
Very satisfied	271 (41.6)	427 (61.3)		Z = -8.22	p<0.001*
Satisfied	214 (32.8)	198 (28.4)			-
Neither satisfied nor dissat	98 (15.0)	43 (6.2)			
Dissatisfied	51 (7.8)	20 (2.9)			
Very dissatisfied	18 (2.8)	9 (1.3)			
• · · · · · · · ·	()	- ()			

435 Mann-Whitney-U*, t-test⁺, Chi-square[‡], Cohen's d[±]

436 Scottish Index of Multiple Deprivation (SIMD); Body Mass Index (BMI); Oxford Hip Score (OKS); EuroQol 5-

437 Dimension (EQ-5D)

Access of post-discharge physiotherapy following TKA & THA

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439	Table 3 Predictive accuracy of demographic and preoperative outcome-parameters for patients
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referring for physiotherapy

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			TH	A				ТКА	
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		OR	confidence interval	n	Correct classifications	OR	confidence interval	n	Correct classification
	Age	1.03	1.02-1.04	<0.001	66.9 %	1.04	1.02-1.05	<0.001	57.4 %
	Sex	1.60 1.54	1.27-2.03 1.08-1.20	<0.001 0.018		1.26	1.01-1.58	0.038	_
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Access of post-discharge physiotherapy following TKA & THA

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Figure 1 - Change in Oxford Hip Scores by post-operative physiotherapy access in THA patients

Figure 3 - Change in Oxford Knee Scores by post-operative physiotherapy access in TKA patients

Figure 2 - Change in EQ5D scores by post-operative physiotherapy access in THA patients

Figure 4 - Change in EQ5D scores by post-operative physiotherapy access in TKA patients

FIGURES

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112x90mm (300 x 300 DPI)



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Section/Topic	ltem #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	scribe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data 4,5	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4,5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	learly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if pplicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe 4,5 comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	4,5
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and 5,6 why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5,6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	4
		(d) If applicable, explain how loss to follow-up was addressed	4
		(e) Describe any sensitivity analyses	6

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	6
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	6,7
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	6,7
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	6,7
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	6,7
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	8,9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	8,9
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	8,9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Exploring variation in patient access of post-discharge physiotherapy following total hip and knee arthroplasty under a choice based system in the UK: an observational cohort study.

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-021614.R2
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Date Submitted by the Author:	22-Aug-2018
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Primary Subject Heading :	Surgery
Secondary Subject Heading:	Rehabilitation medicine, Rheumatology
Keywords:	Total knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy, Outcomes

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Access of post-discharge physiotherapy following TKA & THA

- **Objectives**: To assess a targeted 'therapy as required' model of post-discharge outpatient
- 36 physiotherapy provision. Specifically, we investigated what proportion of patients accessed post-
- 37 discharge physiotherapy following THA and TKA, whether accessing therapy was associated with
- 38 post-arthroplasty patient reported outcomes and whether it was possible to predict which patients
- 39 would access post-discharge physiotherapy from pre-operative data.
- **Design**: Prospective cohort study
- 41 Setting: Single National Health Service orthopaedic teaching hospital
- 42 Participants: 1395 patients undergoing THA and 1374 patients undergoing TKA.

Outcome measures: Self-reported access of post-discharge physiotherapy, the Oxford Hip or Knee
 44 Score and EQ-5D questionnaire and post-operative surgical episode satisfaction metric.

Results: 662 (48.2%) patients with TKA and 493 (35.3%) patients with THA accessed additional post-46 discharge physiotherapy. Patient reported outcomes (p<0.001) and surgical episode satisfaction 47 (p=0.001) scores were higher in both THA and TKA patients who did not participate in post-discharge 48 physiotherapy. Regression models using pre-operative symptom and demographic data predicted 49 post-discharge therapy access with an accuracy of only 17% greater than chance in patients with

- 50 THA and 7% greater than chance in patients with TKA.
- **Conclusions:** In a choice based service model of targeted 'therapy as required' following hip and 52 knee arthroplasty only a third of THA and half of TKA patients accessed post-discharge outpatient 53 physiotherapy. Patients who reported greater post-operative outcome scores and surgical episode 54 satisfaction did not access post-discharge physiotherapy, suggesting variation in the need for post-55 arthroplasty rehabilitation. As such, targeting rehabilitation may be a cost-effective model, however 56 it was not possible to reliably predict which patients would access post-discharge physiotherapy 57 from pre-operative data.
- 59 Keywords: Total Knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy, Outcomes

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Access of post-discharge physiotherapy following TKA & THA

61 ARTICLE SUMMARY

63 STRENGTHS AND LIMITATIONS

• This is a relatively large patient cohort of 2769 total hip and knee replacements performed over a 2
 year period at a single orthopaedic unit evaluating a consistent and specific delivery model of post discharge rehabilitation provision.

A particular strength of this study design is the depth of linked demographic and outcomes data
available with which to construct the predictive models.

• Data relating to access of post-surgical physiotherapy was reported by the patient at 6 months

post-operation via a survey tool and is open to potential responder biases, however the large sample
 size somewhat mitigates this issue.

• We are not able to determine the referral route by which the patient accessed post-discharge

73 therapy, nor the specific content of the physiotherapy received.

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Access of post-discharge physiotherapy following TKA & THA

INTRODUCTION

Lower limb osteoarthritis is an extremely common and disabling condition, which may ultimately require surgical intervention. In excess of 90,000 total hip and 90,000 total knee arthroplasties (THA and TKA) are performed each year in the UK alone¹. Projections suggest continued increases of surgical volume year on year²³. Though joint replacement is effective at reducing pain and improving physical function in patients with end stage osteoarthritis, a sub-group of patients continue to report dissatisfaction with their post-operative outcome^{4 5} highlighted by protracted physical impairment⁶ and activity limitations⁷⁻¹⁰.

Physiotherapy is thought to be an important component in achieving optimal results following THA or TKA¹¹. Immediately post-surgery and throughout the inpatient stay, physiotherapy is aimed at encouraging mobilisation and facilitating a safe discharge. Though subsequent further post-discharge physiotherapy is often promoted there is considerable national and international variation in actual therapy provision. Specific rehabilitation protocols are strongly entrenched at individual physiotherapy departments however the wider efficacy of post-operative physiotherapeutic intervention is poorly established¹²⁻¹⁸. This uncertainty as to effectiveness of physiotherapy interventions makes it difficult for commissioning organisations, healthcare providers, and patients to make decisions as to the role of post-discharge physiotherapy following total joint arthroplasty, and in determining the correct level and mechanism of funding for such services. As a result there is substantial variety in the delivery and content of post-operative physiotherapy following joint arthroplasty across the UK.

The purpose of this study was to explore variation in patient access of post-discharge physiotherapy following THA and TKA under a choice based system in the UK. Under this 'therapy as required' service model, post-discharge out-patient physiotherapy is not routinely provided following THA and TKA. Instead, the local standard of care is for patients to undertake prescribed home exercises, with all patients able to access additional out-patient physiotherapy should they require or wish to do so. Specifically, we investigated what proportion of patients accessed additional post-discharge physiotherapy following THA and TKA, whether accessing therapy was associated with post-arthroplasty patient reported outcomes and whether it was possible to predict which patients would access post-discharge physiotherapy from pre-operative data.

- - **METHODS**

Study design and participants

This was a prospective observational cohort study. All patients undergoing primary THA and TKA were invited to participate in the study that ran alongside the department's routine outcomes data collection project. Data collection was through questionnaires administered pre-operatively at hospital clinic appointment (2 weeks prior to surgery) and then via postal review at 6 months post-operatively. Patients were sent forms on the 6 month anniversary of the surgical episode, with a further follow-up sent 2 weeks later if no response was received. Ethical approval was obtained from the Scotland A Research Ethics Committee (11/AL/0079).

- Informed consent was obtained. Patients undergoing primary unilateral THA or TKA at a single
- National Health Service teaching hospital were prospectively assessed over a 32 month period
- between January 2013 and September 2015.

ing TKA & THA

		Access of post-discharge physiotherapy following TKA & THA
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2	110	The study centre is the only bespital receiving adult referrals for a prodominantly urban regional
3 1	110	ne study centre is the only hospital receiving addit referrais for a predominantly urban regional
4 5	119	population of approximately 850 000 people. Surgery was carried out by 12 consultant orthopaedic
5	120	surgeons and their supervised trainees. Local protocols were followed for all aspects of pre-
7	121	operative, inpatient, and post-operative care.
8	122	Pre-operatively a booklet was provided to patients with information about the procedure (THA or
9	123	TKA) which included detail on rehabilitation, advising as to activity and highlighting exercises to
10	124	perform. Immediate post-operative therapy (inpatient stay) was protocol driven focussing on knee
11	125	range of movement muscle re-education and mobilising with appropriate walking aids to facilitate a
12	126	safe discharge. Post-discharge practice at the study centre is to promote continued performance of
13	120	the exercises learned and only to provide outpatient physiotherapy as required. As such patients
14 15	128	were referred to out-natient physiotherapy based on clinically assessed need at time of discharge or
15	120	at 6 week nost-operative clinical review, with additional referral routes available to the national
10	120	through general practice services and a national national self-referral telephone triage system
18	150	through general practice services and a national patient sen referral telephone thage system.
19	131	Demographic data was obtained for the patient's age, sex, BMI and socioeconomic denominators
20	132	using the Scottish Index of Multiple Deprivation (SIMD). The SIMD is a national statistic based on
21	133	postcode. It combines data on 38 indicators across 7 domains, namely: income, employment, health,
22	134	education, skills and training, housing, geographic access and crime. We applied the 2012 SIMD
23	135	national dataset, and report quintiles (from least deprived to most deprived; the 5 th quintile
24 25	136	representing the most deprived patients). We employed the 'datazone' approach where quintile cut-
25	137	points are identified based on the potential scores in the national SIMD dataset as opposed to
27	138	reporting quintile distributions calculated from the population in question. Physical outcomes were
28	139	assessed with the Oxford Hip or Knee Score (OHS and OKS) and EuroQol- 5 Dimension (EQ-5D)
29	140	questionnaire. Both questionnaires have been thoroughly validated and are the national statistics of
30	141	choice in the UK for measuring arthroplasty outcomes.
31		
32	142	
33 24	143	Outcome measures
34	2.0	
36	144	The Oxford Hip and Knee Scores each consist of 12 questions assessing the patient's pain and
37	145	function ^{19 20} . Each item is answered on a 5-point response scale with scores ranging from 0 to 4,
38	146	generating a summed total score from 0 to 48, where 0 indicates the worst possible outcome and 48
39	147	the best possible score. The minimally important clinical difference (MCID) of the scores is generally
40	148	accepted as 5 points in THA, and 4 points in TKA.
41		
42	149	The EQ-5D is a standardised instrument with five items covering mobility, self-care, usual activities,
43 44	150	pain and discomfort as well as anxiety and depression ²¹ . As a measure of self-reported general
44 45	151	health, it is applicable to a wide range of health conditions and treatments and provides a simple
46	152	descriptive profile and a single index value for health status. Lower scores represent a worse health
47	153	state. We applied the most commonly used EQ-5D-3L version, with 3 possible responses to the 5
48	154	questions, and a summary index calculated by applying preference weights for the UK general

- h 3 possible responses to the 5 questions, and a summary index calculated by applying preference weights for the UK general 154 population²². The summary score is anchored at 0 signifying 'death' and 1 'perfect health', however 155 with score weighting negative value are possible and are interpreted as health states worse than 156 157 death.
 - 158 Patient surgical episode satisfaction was assessed using a 5 point Likert response format at 6 months 159 post-surgery. Patients were asked to rate their overall satisfaction with their operated hip or knee

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163 Patient and Public Involvement

There was no specific patient involvement in the design or conduct of the study methodology,
however the study question as to the role of physiotherapy in the post-operative period following
joint arthroplasty was highlighted as a priority area for research by a patient feedback project at the
study centre.

169 Statistical analysis

Analyses were performed with SPSS V21.²³. Demographic indicators are presented as frequencies or means with standard deviations as a measure of dispersal. Differences between patients who accessed physiotherapy after total joint arthroplasty and those who did not were investigated with ttests, chi-square tests, and Mann-Whitney-U tests as appropriate. Effect sizes for differences in continuous variables are given as Cohen's d

174 continuous variables are given as Cohen's d.

To identify predictors of physiotherapy access we used a binary logistic regression model with
physiotherapy access as dependent variable and patient characteristics and preoperative OKS/OHS
and EQ-5D as predictors. The predictors were included using a forward selection stepwise model
building technique (likelihood ratio) with an entry criterion of alpha=0.05. Model fit is described with
percentage of correct classifications and predictors are given as odds ratios with corresponding 95%
confidence intervals. Using this methodology, the chance level of correct classifications is 50% and

181 the model-based classification is compared against this value.

183 RESULTS

184 1534 patients underwent primary THA and 1503 primary TKA in the study time window. 97% of 185 cases were coded as being performed for a diagnosis of osteoarthritis (the remaining patients being 186 rheumatoid or psoriatic arthritis). Survey data was available for 1395 (90.9%) THA patients and for 187 1374 (91.4%) TKA patients. All data was included in the analysis. THA patients had a mean age of 188 67.6 ± 11.8 years, 58.1% were female, TKA patients had a mean age 69.7 ± 9.3 years, 56.6% were 189 female. Of this total surgical cohort, 493 (35.3%) THA and 662 (48.2%) TKA patients accessed post-190 operative out-patient physiotherapy.

192 Total Hip Arthroplasty

Patients with TKA accessing post-discharge physiotherapy were younger (64.9 vs 69.1 years,
 p<0.001) and more likely to be female (p<0.001), however there were no differences in BMI

195 (p=0.788) or social deprivation index (p=0.438) between the groups (Table 1).

Patients that did not access post-discharge physiotherapy reported statistically higher scores
(39.4±8.6) on the OHS than patients who accessed post-discharge physiotherapy (35.8±9.8) at 6
months follow-up (p<0.001). At baseline, patients who accessed post-discharge physiotherapy had
statistically lower scores (20.1±8.6) than patients who did not access post-discharge physiotherapy

Access of post-discharge physiotherapy following TKA & THA

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2 3	200	(21.4±8.6, p=0.008). However, patients who did not access post-discharge physiotherapy made a
4	201	larger gain. OHS improvement from baseline to 6 months follow-up was 15.6±10.6 points in those
5	202	who accessed post-discharge physiotherapy and 18.0 ± 9.9 points for those who did not (p<0.001.
б	203	Cohen's d=0.23) (Table 1 and Figure 1). These statistical differences observed in OHS between
7	204	grouns does not however reflect clinically meaningful variations in patient outcomes based on the
8	204	MCID of the score
9	205	
10	206	EQ-5D scores were lower in patients accessing post-discharge physiotherapy both pre-surgery (0.35
11	207	vs 0.41, p=0.004,) and post-surgery (0.70 vs 0.80, p<0.001). Cohen's d for pre-postoperative
12	208	improvement was 0.12 with mean changes in EQ-5D score of 0.35 in those that accessed
13 14	209	physiotherapy compared to 0.39 in those that did not ($p=0.023$) (Table 1 and Figure 2).
15		
16	210	The patients who did not access post-operative physiotherapy reported greater surgical episode
17	211	satisfaction at 6 months (p<0.001, Z=-6.43), with twice the number of patients reporting either
18	212	dissatisfied or very dissatisfied observed in the group that accessed physiotherapy (Table 1).
19	212	
20	213	
21	214	Total Knee Arthroplasty
22		
23	215	Patients with TKA accessing post-discharge physiotherapy were modestly but significantly younger
24 25	216	(68.2 vs 71.0 years, p<0.001). There was no difference in sex (p=0.099). Patients who accessed
25 26	217	physiotherapy were more likely to live in a less deprived area (p=0.028); there was no difference in
20 27	218	BMI between groups (p=0.198) (Table 2).
28	210	Patient outcomes were better in the 51.8% of TKA patients that did not access post discharge
29	219	physicathorany in terms of absolute OKS (25.0 vs. 22.2 noints, nz(0.001). There was no difference in
30	220	physiotherapy in terms of absolute OKS (33.9 vs 32.5 points, $p<0.001$). There was no difference in
31	221	pre-operative score between groups (20.9 points in each group, p=0.965), reflected in a lesser
32	222	change in OKS for the patients who accessed post-discharge physiotherapy (11.4 points vs 15.0
33	223	points, p<0.001, Conen's d=0.39) (Table 2 and Figure 3). These between group differences may
34	224	reflect clinically important variations in patient outcomes based on the MCID of the OKS.
35	225	There were also differences in improvement measured with the EQ-5D (Table 2). Patients accessing
30 27	226	post-discharge physiotherapy improved by 0.25 points, compared to 0.35 points in those who did
38	227	not ($p < 0.001$, Cohen's d=0.32. Figure 4). Again there was no difference in pre-operative scores
39	228	hetween groups (0.43 vs 0.41 $n = 0.183$) while post-operative scores differed significantly (0.68 vs
40	220	0.77 n < 0.001
41	225	0.77, p<0.001).
42	230	The patients who did not access post-operative physiotherapy reported greater surgical episode
43	231	satisfaction (p<0.001, Z=-8.22), with twice the number of dissatisfied and very dissatisfied patients in
44	232	the group that accessed post-discharge physiotherapy (Table 2).
45	• • • •	
46 47	233	
4/ 40	234	Multivariate analysis
40 49		
50	235	A regression model with three predictors (age, sex and pre-operative EQ-5D score) was able to
51	236	correctly classify 66.9% of patients with THA in regard to post-operative physiotherapy access (Table
52	237	3). This percentage of correct classifications was significantly (p<0.001) different from chance level
53	238	(50% correct classifications). In patients with TKA the regression model comprised only two
54	239	significant predictors (age and sex) and provided a percentage of correct classifications of 57.4%,
55	240	again significantly better than chance (p<0.001).
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Access of post-discharge physiotherapy following TKA & THA

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DISCUSSION



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- There is no consensus as to how best to rehabilitate patients following THA or TKA. Systematic reviews of post-operative rehabilitation interventions suggest that no one approach is beneficial in improving outcomes^{8 16 18} and a recent Cochrane review stressed the general low quality of the evidence base²⁴. In this study we review an 'therapy as required' model of service delivery, where routine post-discharge out-patient physiotherapy was not provided following THA and TKA. Instead
- the local standard of care was for patients to undertake prescribed home exercises, with all patients able to access additional out-patient physiotherapy should they require or wish to do so. Under this system, patients could be referred to physiotherapy by clinical staff at time of discharge (inpatient medical or therapy teams), or at 6 week post-surgical out-patient review (surgical team or specialist physiotherapist / nurse practitioner), or at any point through the patient's General Practitioner service. Separately the patient could refer themselves via a national self-referral telephone triage system or self-fund physiotherapy from a private provider, distinct to provision via the National Health Service.
- Under this 'therapy as required' system, only a third of patients who underwent THA and half of those who underwent TKA accessed post-discharge outpatient physiotherapy to assist with their recovery. The patients that did not access post-discharge physiotherapy do not seem to have been adversely affected by this decision as this group reported generally better outcome and surgical episode satisfaction scores. A difference in pre-to post-operative change in Oxford Score of approximately 3 points was observed between the THA patients, and approximately 4 points in the TKA patients that accessed physiotherapy compared to those that did not. The minimal clinically important difference in Oxford Scores has been estimated at 5 points, in THA and 4 points in TKA²⁵ suggesting the statistical differences reported in the THA patients are unlikely to reflect a clinically meaningful difference, but that the TKA data may represent variation in clinical outcomes between groups.
- The Oxford Scores, EQ-5D scores and satisfaction scores at 6 months reported by the patients that did not access additional post-discharge physiotherapy compare well to national outcome figures for both THA and TKA patients²⁶. This suggests that post-discharge outpatient physiotherapy is not necessarily required in all cases, and that (broadly) patients and clinicians are able to make a judgement as to whether they should attend such therapy.

This is an observational cohort study and we do not attempt to evaluate the effectiveness of post-discharge physiotherapy with this data. Those who accessed additional therapy in this cohort reported lower scores, suggesting greater pain and physical dysfunction in the early post-operative phase. It may be that the additional therapy improved the patient outcomes compared to having had no such intervention. Patients and clinicians expect a rehabilitation component to be provided as part of the care pathway for joint arthroplasty. Though there is a role for physiotherapy around total joint arthroplasty, it may be that post-discharge physiotherapy should be targeted to those that require additional rehabilitation to optimise outcomes as opposed to blanket provision for all in the early post-operative phase. In this setting, self-directed home exercises appear to have been sufficient for the majority of patients to achieve a good outcome post-arthroplasty. This finding could be explored for cost-effectiveness from the health economic and service delivery perspective, however relies on accurately targeting physiotherapy to those that require the additional input.

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Access of post-discharge physiotherapy following TKA & THA

We were able to construct statistically significant regression models using pre-operative data to correctly classify the patients that accessed post-operative therapy, however these models were poor in terms of accuracy. The model describing access of post-discharge physiotherapy following THA was only 17% greater than chance at identifying which patients accessed physiotherapy. The patients who accessed post-discharge physiotherapy reported lower general health scores (EQ-5D) but broadly equivalent joint specific pain and function scores (OHS). The EQ-5D data essentially drove the regression model and perhaps suggests poorer health status may be related to the requirement for additional therapy; however, it must be noted that these patients were on average 5 years younger than those that did not attend additional physiotherapy, suggesting health and not age is the pertinent factor here. Interestingly pre-operative pain and functional ability (Oxford Score), BMI and deprivation status did not influence the models.

Notably more TKA patients required or wished to access additional physiotherapy than THA, which is perhaps consistent with the reports of greater treatment success and patient outcomes following hip arthroplastv^{5 26}. Despite applying a range of pre-operative demographic and symptom state indicators, we were only able to model the additional use of post-discharge physiotherapy to an accuracy of 7% greater than chance. Interestingly in the TKA cohort, the model relied solely on small associations with age and sex. In this model, pre-operative pain / function / health scores, social deprivation and BMI did not help determine which patients would go on to require additional therapy.

Though various factors have been associated with poor clinical outcomes following TKA, currently, we cannot reliably predict pre-operatively who will struggle to recover post-operatively. Larger and more comprehensive predictor studies (for example incorporating psychological variables) are required to determine which patient factors lead to poorer post-operative outcomes and to see if particular patient groups benefit from post-discharge physiotherapy. Further insight may be provided by the multicentre TRIO and COASt studies that are currently evaluating this in the UK^{27, 28}. Alternatively, it may be that it is the patient's response to surgery as opposed to pre-operative characteristics that determine the need for post-operative rehabilitation and that there is no reliable way to predict this pre-operatively.

Strengths and Limitations

A strength of this study is the relatively large patient cohort of 2769 arthroplasties and the depth of linked demographic and outcome data. Additionally, that our data is in line with UK national figures for patient demographics and pre and post-operative outcome scores lends wider credibility. Limitations are that the access of post-discharge physiotherapy was documented and reported by the patient at 6 months post-arthroplasty, which open potential responder biases. Further, we are not able to determine the route by which the patient accessed this post-discharge therapy, nor the content of the specific physiotherapy received. The relatively short post-operative 6 month timeframe results that we cannot comment on longitudinal changes in outcomes, nor whether those patients that access physiotherapy 'caught-up' with those that did not in terms of clinical outcome scores at subsequent later time points. The study was not designed to evaluate the effectiveness of the physiotherapy received, however future studies may be able to target therapy to patients deemed 'at need of intervention', and randomise to differing levels or modes of intervention.

CONCLUSION

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Access of post-discharge physiotherapy following TKA & THA

In a choice based service model of targeted 'therapy as required' following hip and knee arthroplasty

only a third of THA and half of TKA patients accessed post-discharge physiotherapy. Patients who reported greater post-operative outcome scores and surgical episode satisfaction did not access additional therapy, suggesting a variation in requirement for post-arthroplasty physiotherapy. We were unable to predict pre-operatively (with demographic and symptom data) which patients would subsequently access additional input. CONTRIBUTORS DFH conceived the study, interpreted the results, drafted and revised the manuscript. FCL performed the statistical analysis, drafted the results and contributed to manuscript revisions. DJM collated the data and contributed to manuscript drafting and revision. GMF contributed to results interpretation, manuscript drafting and revision. DJB contributed to results interpretation, manuscript drafting and revision. HRS contributed to results interpretation, manuscript drafting and revision. JTP contributed to the study design, results interpretation, manuscript drafting and revision. CRH contributed to the study design, results interpretation, manuscript drafting and revision. FUNDING STATEMENT This work was indirectly supported by an institutional award from Stryker to the University of Edinburgh [RB0412] and an international scholarship for short-term scientific projects from the University of Innsbruck. The funders had no role in the study design, collation or analysis of data, interpretation of data nor writing of the manuscript. CONFLICT OF INTEREST STATEMENT DFH, DJB, GMF and HRS, are grant holders on the Arthritis Research UK funded TRIO study. Though there is no financial or direct academic conflict, this work can be considered as relevant background for the (currently) ongoing TRIO study. **ETHICAL APPROVAL** Ethical approval was obtained from the Scotland A Research Ethics Committee (11/AL/0079). DATA SHARING STATEMENT The raw data cannot be made publicly available to protect patient confidentiality; however restricted data may be made available if deemed reasonable by the data custodian. Such requests should be made to CRH via the corresponding author.

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Access of post-discharge physiotherapy following TKA & THA

444 TABLES

446 Table 1 Demographic and outcome data for patients with THA by post-discharge physiotherapy447 access

Referred for physiotherapy	Yes	No	Effect size	statistic	significance
Sex N (%)					
female	324 (65.7)	486 (53.9)		<i>X</i> ² = 18.352	p<0.001 [‡]
male	169 (34.3)	416 (46.1)			
Side N (%)					
left	212 (43.5)	422 (47.6)		<i>X</i> ² = 2.123	p=0.157 [‡]
right	275 (56.5)	464 (52.4)			
SIMD					
1 st quintile N (%)	37 (7.5)	76 (8.4)		Z = -0.78	p=0.438*
2 nd quintile N (%)	78 (15.8)	160 (17.7)			
3 rd quintile N (%)	85 (17.2)	166 (18.4)			
4 th quintile N (%)	129 (26.2)	193 (21.4)			
5 th guintile N (%)	164 (33.3)	307 (34.0)			
Age Mean (SD)	64.9 (13.2)	69.1 (10.6)	0.35^{\pm}	T = -6.08	p<0.001 ⁺
BMI Mean (SD)	28.3 (6.9)	28.2 (5.0)	0.02 [±]	T = 0.27	р=0.788 ⁺
OHS	() ()				·
Pre-on	20 1 (8 6)	21 4 (8 6)	1 21 [±]	T2 67	$n = 0.008^{\dagger}$
Post-op	35.8 (9.8)	21.4 (8.6) 39.4 (8.6)	0.39 [±]	T = -6.96	p=0.008
Change	15.6 (10.6)	18.0 (9.9)	0.23 [±]	T = -4.06	p<0.001 ⁺
FO-5D					
Pre-op	0.35 (0.3)	0.41 (0.3)	0.20^{\pm}	T = -2.92	p=0.004 ⁺
Post-op	0.70 (0.3)	0.80 (0.2)	0.39 [±]	T = -6.52	p<0.001 ⁺
Change	0.35 (0.4)	0.39 (0.3)	0.12^{\pm}	T = -2.28	p=0.023 ⁺
Satisfaction					
Very satisfied	280 (57.4)	648 (73.3)		Z = -6.43	p<0.001*
Satisfied	122 (25.0)	165 (18.7)			
Neither satisfied / dissatisfied	44 (9.0)	43 (4.9)			
Dissatisfied	27 (5.5)	13 (1.5)			
Very dissatisfied	15 (3 1)	15 (1.7)			

449 Mann-Whitney-U*, t-test⁺, Chi-square⁺, Cohen's d[±]

450 Scottish Index of Multiple Deprivation (SIMD); Body Mass Index (BMI); Oxford Hip Score (OKS); EuroQol 5451 Dimension (EQ-5D)

Access of post-discharge physiotherapy following TKA & THA

Table 2 Demographic and outcomes data for patients with TKA by post-discharge physiotherapy

454 access

Referred for physiotherapy	Yes	No	Effect size	statistic	significance
Sex N (%)					
female	390 (58.9)	388 (54.5)		$X^2 = 2.726$	p=0.099 [‡]
male	272 (41.1)	324 (45.5)			
Side N (%)					
left	321 (49.5)	337 (47.7)		$X^2 = 0.404$	p=0.525 [‡]
right	328 (50.5)	369 (52.3)			
SIMD					
1 st quintile N (%)	63 (9.5)	66 (9.3)		Z = -2.19	p=0.028*
2 nd quintile N (%)	104 (15.7)	162 (22.8)			
3 rd quintile N (%)	122 (18.4)	136 (19.1)			
4 th quintile N (%)	164 (24.8)	138 (19.4)			
5 th quintile N (%)	209 (31.6)	210 (29.5)			
Age Mean (SD)	68.2 (9.7)	71.0 (8.6)	0.30^{\pm}	T = -5.73	p<0.001 [†]
BMI Mean (SD)	31.1 (6.0)	30.6 (5.9)	0.01^{\pm}	T = 1.29	p=0.198 [†]
OKS					
Pre-op	20.9 (7.8)	20.9 (7.9)	< 0.01 [±]	T = -0.04	p=0.965
Post-op	32.3 (9.8)	35.9 (9.1)	0.38 [±]	T = -6.99	p<0.001 ⁺
Improvement	11.4 (9.4)	15.0 (8.9)	0.39 [±]	T = -7.16	p<0.001'
EQ-5D					
Pre-op	0.43 (0.3)	0.41 (0.3)	0.07 [±]	T = 1.33	p=0.183
Post-op	0.68 (0.3)	0.77 (0.2)	0.35 [±]	T = -6.34	p<0.001
Improvement	0.25 (0.3)	0.35 (0.3)	0.32 [±]	T = -6.15	p<0.001'
Satisfaction, N (%)					
Very satisfied	271 (41.6)	427 (61.3)		Z = -8.22	p<0.001*
Satisfied	214 (32.8)	198 (28.4)			
Neither satisfied / dissatisfied	98 (15.0)	43 (6.2)			
Dissatisfied	51 (7.8)	20 (2.9)			
Very dissatisfied	18 (2.8)	9 (1.3)			

456 Mann-Whitney-U*, t-test⁺, Chi-square⁺, Cohen's d[±]

457 Scottish Index of Multiple Deprivation (SIMD); Body Mass Index (BMI); Oxford Knee Score (OKS); EuroQol 5-

458 Dimension (EQ-5D)

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Access of post-discharge physiotherapy following TKA & THA

Table 3 Predictive accuracy of model parameters for patients accessing post-discharge physiotherapy

			TH	Α				ТКА	
		OR	95% confidence	n	Correct	OR	95% confidence interval	<u>n</u>	Correct
	Age Sex	1.03 1.60 1.54	1.02-1.04 1.27-2.03 1.08-1.20	<pre>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>></pre>	66.9 %	1.04 1.26	1.02-1.05 1.01-1.58	<0.001 0.038	57.4 %
463		1.04	1.00-1.20	0.010					
464									

Access of post-discharge physiotherapy following TKA & THA

FIGURES

- Figure 1 - Change in Oxford Hip Scores by THA post-discharge physiotherapy access
- Figure 2 - Change in EQ-5D scores by THA post-discharge physiotherapy access
- Figure 3 - Change in Oxford Knee Scores by TKA post-discharge physiotherapy access
- Figure 4 - Change in EQ-5D scores by TKA post-discharge physiotherapy access







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Section/Topic	ltem #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4,5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4,5
Bias	9	Describe any efforts to address potential sources of bias	4,5
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5,6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5,6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	4
		(d) If applicable, explain how loss to follow-up was addressed	4
		(e) Describe any sensitivity analyses	6

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	6
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	6,7
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	6,7
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	6,7
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	6,7
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	8,9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	8,9
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	8,9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Exploring variation in patient access of post-discharge physiotherapy following total hip and knee arthroplasty under a choice based system in the UK: an observational cohort study.

Journal:	BMJ Open
Manuscript ID	bmjopen-2018-021614.R3
Article Type:	Research
Date Submitted by the Author:	29-Nov-2018
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Primary Subject Heading :	Surgery
Secondary Subject Heading:	Rehabilitation medicine, Rheumatology
Keywords:	Total knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy, Outcomes

SCHOLARONE[™] Manuscripts

		Access of post-discharge physiotherapy following TKA & THA
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3	1	Exploring variation in patient access of post-discharge physiotherapy following total hip and knee
4 5	2	arthroplasty under a choice based system in the UK: an observational cohort study.
6 7	3	
8	4	David Hamilton[1], Fanny Loth[2], Deborah MacDonald[1], Gary MacFarlane[3], David Beard[4],
9 10	5	Hamish Simpson[1], James Patton[1], Colin Howie[1]
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Access of post-discharge physiotherapy following TKA & THA

34 ABSTRACT

- **Objectives**: To assess a targeted 'therapy as required' model of post-discharge outpatient
- 36 physiotherapy provision. Specifically, we investigated what proportion of patients accessed post-
- 37 discharge physiotherapy following total hip arthroplasty (THA) and total knee arthroplasty (TKA),
- 38 whether accessing therapy was associated with post-arthroplasty patient reported outcomes and
- 39 whether it was possible to predict which patients would access post-discharge physiotherapy from
 40 pre-operative data.
- 13 41 **Design**: Prospective, observational, longitudinal cohort study14
- 15 42 Setting: Single National Health Service orthopaedic teaching hospital in the United Kingdom
- Participants: 1395 patients undergoing total hip arthroplasty and 1374 patients undergoing total
 knee arthroplasty.
- Primary and Secondary Outcome measures: Self-reported access of post-discharge physiotherapy,
 the Oxford Hip or Knee Score, EuroQol 5-dimension questionnaire and post-operative surgical
 anisode satisfaction matrix
- 47 episode satisfaction metric.
- **Results**: 662 (48.2%) patients with TKA and 493 (35.3%) patients with THA accessed additional post-
- 49 discharge physiotherapy. Patient reported outcomes (p<0.001) and surgical episode satisfaction
- 50 (p=0.001) in both hip and knee arthroplasty were higher in patients that did not participate in post-
- discharge physiotherapy. Regression models using pre-operative symptom burden and demographic
 data predicted post-discharge therapy access with an accuracy of only 17% greater than chance in
- patients with THA and 7% greater than chance in patients with TKA.
- **Conclusions:** In a choice-based service model of targeted rehabilitation 'as required' following hip and knee arthroplasty only a third of hip arthroplasty and half of knee arthroplasty patients accessed post-discharge outpatient therapy. Patients who reported greater post-operative outcome scores and surgical episode satisfaction did not access post-discharge physiotherapy, suggesting variation in the need for post-arthroplasty outpatient physiotherapy. As such, targeting of rehabilitation may be a cost-effective model, however it was not possible to reliably predict which patients would access post-discharge physiotherapy from pre-operative data.
- 41 61
 - 62 Keywords: Total knee Arthroplasty, Total Hip Arthroplasty, Physiotherapy
Access of post-discharge physiotherapy following TKA & THA

64 ARTICLE SUMMARY

66 STRENGTHS AND LIMITATIONS

• This is a relatively large patient cohort of 2769 total hip and knee replacements performed over a 2
year period at a single orthopaedic unit evaluating a consistent and specific delivery model of postdischarge rehabilitation provision.

A particular strength of this study design is the depth of linked demographic and outcomes data
available with which to construct the predictive models.

Data relating to access of post-surgical physiotherapy was reported by the patient at 6 months
post-operation via a survey tool, and is open to responder biases, however the large sample size
somewhat mitigates this issue.

• We are not able to determine the referral route by which the patient accessed post-discharge

76 therapy, nor the specific content of the physiotherapy received.

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77 INTRODUCTION

Lower limb osteoarthritis is an extremely common and disabling condition, which may ultimately require surgical intervention. In excess of 90,000 total hip and 90,000 total knee arthroplasties (THA and TKA) are performed each year in the UK alone¹. Projections suggest continued increases of surgical volume year on year^{2 3}. Though joint replacement is effective at reducing pain and improving physical function in patients with end stage osteoarthritis, a sub-group of patients continue to report dissatisfaction with their post-operative outcome^{4 5} highlighted by protracted physical impairment ⁶ and activity limitations⁷⁻¹⁰.

Physiotherapy is thought to be an important component in achieving optimal results following THA or TKA¹¹. Immediately post-surgery, throughout the inpatient stay, physiotherapy is aimed at encouraging mobilisation and facilitating a safe discharge. Though subsequent post- discharge physiotherapy is often promoted there is considerable national and international variation in actual therapy provision. Specific rehabilitation protocols are strongly entrenched at individual physiotherapy departments however the wider efficacy of post-operative physiotherapeutic intervention is poorly established¹²⁻¹⁸. This uncertainty as to effectiveness of physiotherapy interventions makes it difficult for commissioning organisations, healthcare providers, and patients to make decisions as to the role of post-discharge physiotherapy following total joint arthroplasty, and in determining the correct level and mechanism of funding for such services. As a result there is substantial variety in the delivery and content of post-operative physiotherapy following joint arthroplasty across the UK.

The purpose of this study was to explore variation in patient access of post-discharge physiotherapy following THA and TKA under a choice based system in the UK. Under this service model, routine post-discharge out-patient physiotherapy is not provided following THA and TKA. Instead the local standard of care is for patients to undertake prescribed home exercises, with all patients able to access additional out-patient physiotherapy services should they require or wish to do so. Specifically, we investigated what proportion of patients accessed post-discharge physiotherapy following THA and TKA, whether accessing therapy was associated with post-arthroplasty patient reported outcomes and whether it was possible to predict which patients would access post-discharge physiotherapy from pre-operative data.

42 108

44 109 **METHODS**

4546 110 Study design and participants

This was a prospective observational cohort study. All patients undergoing primary THA and TKA were invited to participate in the study that ran alongside the department's routine outcomes data collection project. Data collection was through questionnaires administered pre-operatively at hospital clinic appointment (2 weeks prior to surgery) and then via postal review at 6 months post-operatively. Patients were sent forms on the 6 month anniversary of the surgical episode, with a further follow-up sent 2 weeks later if no response was received. Ethical approval was obtained from the Scotland A Research Ethics Committee (11/AL/0079). All study participants provided informed consent prior to inclusion in the cohort. Patients undergoing primary unilateral THA or TKA at a single National Health Service teaching hospital were

prospectively assessed over a 32 month period between January 2013 and September 2015.

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121 The study centre is the only hospital receiving adult referrals for a predominantly urban regional
 122 population of approximately 850 000 people. Surgery was carried out by 12 consultant orthopaedic

bobulation of approximately 850 000 people. Surgery was carried out by 12 consultant of thopa
 123 surgeons and their supervised trainees. Local protocols were followed for all aspects of pre-

7 124 operative, inpatient, and post-operative care.

Pre-operatively a booklet was provided to patients with information about the procedure (THA or TKA) which included detail on rehabilitation, advising as to activity and highlighting exercises to perform. Immediate post-operative therapy (inpatient stay) was protocol driven focussing on knee range of movement, muscle re-education and mobilising with appropriate walking aids to facilitate a safe discharge. Post-discharge practice at the study centre is to promote continued performance of the exercises learned and only to provide outpatient physiotherapy as required. As such, patients were referred to out-patient physiotherapy based on clinically assessed need at time of discharge or at 6 week post-operative clinical review, with additional referral routes available to the patient through general practice services and a national patient self-referral telephone triage system.

Demographic data was obtained for the patient's age, sex, BMI and socioeconomic denominators using the Scottish Index of Multiple Deprivation (SIMD). The SIMD is a national statistic based on postcode. It combines data on 38 indicators across 7 domains, namely: income, employment, health, education, skills and training, housing, geographic access and crime. We applied the 2012 SIMD national dataset, and report quintiles (from least deprived to most deprived; the 5th quintile representing the most deprived patients). We employed the 'datazone' approach where quintile cut-points are identified based on the potential scores in the national SIMD dataset as opposed to reporting quintile distributions calculated from the population in question Physical outcomes were assessed with the Oxford Hip or Knee Score (OHS and OKS) and EuroQol- 5 Dimension (EQ-5D) questionnaire. Both questionnaires have been thoroughly validated and are the national statistics of choice in the UK for measuring arthroplasty outcomes.

³⁴ 145

36 146 Outcome measures37

The Oxford Hip and Knee Scores each consist of 12 questions assessing the patient's pain and
 function^{19 20}. Each item is answered on a 5-point response scale ranging from 0 to 4, generating a
 summed total score ranging from 0 to 48, where 0 indicates the worst possible outcome and 48
 good joint function.

The EQ-5D is a standardised instrument with five items covering mobility, self-care, usual activities, pain and discomfort as well as anxiety and depression²¹. As a measure of self-reported general health, it is applicable to a wide range of health conditions and treatments and provides a simple descriptive profile and a single index value for health status. Lower scores represent a worse health state. We applied the most commonly used EQ-5D-3L version, where there are 3 possible responses to the 5 questions.

Patient surgical episode satisfaction was assessed using a 5 point Likert response format at 6 months
post-surgery. Patients were asked to rate their overall satisfaction with their operated hip or knee
(response options: very satisfied, satisfied, unsure, dissatisfied, or very dissatisfied). Self-report of
physiotherapy attendance was recorded at 6 month assessment.

- 5859 162 Patient and Public Involvement

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- There was no specific patient involvement in the design or conduct of the study methodology,
 163 There was no specific patient involvement in the design or conduct of the study methodology,
 164 however the study question as to the role of physiotherapy in the post-operative period following
 165 joint arthroplasty was highlighted as a priority area for research by a patient feedback project at the
 166 study centre.
- 9 167

11 168 Statistical analysis

Analyses were performed with SPSS V21.0²². Demographic indicators are presented as frequencies or means with standard deviations as a measure of dispersal. Differences between patients who accessed physiotherapy after total joint arthroplasty and those who did not were investigated with t-tests, chi-square tests, and Mann-Whitney-U tests as appropriate. Effect sizes for differences in continuous variables are given as Cohen's d.

To identify predictors of physiotherapy access we used a binary logistic regression model with physiotherapy access as dependent variable and patient characteristics and preoperative OKS/OHS and EQ-5D as predictors. The predictors were included using a forward selection stepwise model building technique (likelihood ratio) with an entry criterion of alpha=0.05. Model fit is described with percentage of correct classifications and predictors are given as odds ratios with corresponding 95% confidence intervals. Using this methodology, the chance level of correct classifications is 50% and the model-based classification is compared against this value.

29 181

30 182 **RESULTS** 31

1534 patients underwent primary THA and 1503 primary TKA in the study time window. 97% of cases were coded as being performed for a diagnosis of osteoarthritis (the remaining patients being coded as rheumatoid or psoriatic arthritis). Survey data was available for 1395 (90.9%) patients that underwent THA and for 1374 (91.4%) patients that underwent TKA. All data was included in the analysis. Patients with THA had a mean age of 67.6 ± 11.8 years, 58.1% were female, patients with TKA had a mean age 69.7 ± 9.3 years, 56.6% were female. Of this total surgical cohort, 493 (35.3%) THA and 662 (48.2%) TKA patients accessed post-operative out-patient physiotherapy.

41 190

43 191 Total Hip Arthroplasty 44

Patients with TKA accessing post-discharge physiotherapy were younger (64.9 vs 69.1 years,
 p<0.001) and more likely to be female (p<0.001), however there were no differences in BMI

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 494 (p=0.788) or social deprivation index (p=0.438) between the groups (Table 1).
- Patients that did not access post-discharge physiotherapy had statistically higher scores (39.4±8.6) on the OHS than patients who accessed post-discharge physiotherapy (35.8±9.8) at 6 months follow-up (p<0.001). At baseline, patients that accessed post-discharge physiotherapy had statistically lower scores (20.1±8.6) than patients who accessed post-discharge physiotherapy (21.4±8.6) on the OHS (p=0.008). However patients who accessed physiotherapy made a larger gain in pain and function scores with the OHS: improvement from baseline to 6 months follow-up was 15.6±10.6 points without post-discharge physiotherapy access and 18.0±9.9 points for such that did access physiotherapy (p<0.001, Cohen's d=0.23) (Table 1 and Figure 1).

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1		Access of post-discharge physiotherapy following TKA & THA
2 3 4 5 6 7	203 204 205 206	EQ-5D scores were lower in patients accessing post-discharge physiotherapy both pre-surgery (0.35 vs 0.41, p=0.004,) and post-surgery (0.70 vs 0.80, p<0.001). Cohen's d for pre-postoperative improvement was 0.12 with mean changes in EQ-5D score of 0.35 in those that accessed physiotherapy compared to 0.39 in those that did not (p=0.023) (Table 1 and Figure 2).
8 9 10 11 12 13	207 208 209 210	The patients who did not access post-operative physiotherapy reported greater surgical episode satisfaction at 6 months (p<0.001, Z=-6.43), twice the number of patients reporting either dissatisfied or very dissatisfied were observed in the group that accessed physiotherapy (Table 1).
14 15	211	Total Knee Arthroplasty
16 17 18 19 20 21	212 213 214 215	Patients with TKA accessing post-discharge physiotherapy were modestly but significantly younger (68.2 vs 71.0 years, p<0.001). There was no difference in sex (p=0.099). Patients who accessed physiotherapy were more likely to live in a less deprived area (p=0.028); there was no difference in BMI between groups (p=0.198) (Table 2).
22 23 24 25 26 27 28	216 217 218 219 220	Patient outcomes were superior in the 51.8% of TKA patients that did not access post-discharge physiotherapy in terms of absolute OKS (35.9 vs 32.3 points, p<0.001). There was no difference in pre-operative score between groups (20.9 points in each group p=0.965), reflected in a lesser change in OKS for the patients who accessed post-discharge physiotherapy (11.4 points vs 15.0 points, p<0.001, Cohen's d=0.39) (Table 2 and Figure 3).
29 30 31 32 33 34	221 222 223 224 225	There were also differences in improvement measured with the EQ-5D (Table 2). Patients accessing post-discharge physiotherapy improved 0.25 points, compared to 0.35 points in those who did not (p <0.001, Cohen's d=0.32, Figure 4). Again there was no difference in pre-operative scores between groups (0.43 vs 0.41, p = 0.183), while post-operative scores differed significantly (0.68 vs 0.77, p <0.001).
35 36 37 38 39 40	226 227 228 229	The patients who did not access post-operative physiotherapy reported greater surgical episode satisfaction (p<0.001, Z=-8.22), with twice the number of patients dissatisfied and very dissatisfied in the group that accessed post-discharge physiotherapy (Table 2).
40 41 42	230	Multivariate analysis
43 44 45 46 47 48 49 50 51 52 53 54 55 56	231 232 233 234 235 236 237 238 239 240	Binary logistic regression modelling was undertaken to determine if post-operative access to physiotherapy could be predicted by pre-operative patient variables. A regression model with three predictors (age, sex and pre-operative EQ-5D score) was able to correctly classify 66.9% of patients with THA in regard to post-operative physiotherapy access (Table 3). This percentage of correct classifications was significantly (p<0.001) different from chance level (50% correct classifications). In patients with TKA the regression model comprised only two significant predictors (age and sex) and provided a percentage of correct classifications of 57.4%, again significantly better than chance (p<0.001).
57 58	241	There is no consensus as to how best to rehabilitate patients following THA or TKA. Systematic
59 60	242 243	reviews of post-operative rehabilitation interventions suggest that no one approach is beneficial in improving outcomes ^{8 16 18} and a recent Cochrane review stressed the general low quality of the

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evidence base²³. In this study we review an 'access physiotherapy as needed' model of post-discharge service delivery. Routine post-discharge out-patient physiotherapy was not provided following THA and TKA. Instead the local standard of care was for patients to undertake prescribed home exercises, with all patients able to access additional out-patient physiotherapy services should they require or wish to do so. Under this system, patients can be referred to physiotherapy based on clinical need as determined by clinical staff at time of discharge (either inpatient medical or therapy teams), or at 6 week out-patient review (medical, nursing or therapy team performing these out-patient post-surgery reviews), or at any point through the patient's General Practitioner service. Separately the patient could refer themselves via a self-referral telephone triage system or access private physiotherapy self-funded and distinct to physiotherapy provision via the National Health Service.

Under this system, only a third of patients that underwent THA and half of those who underwent TKA accessed post-discharge outpatient physiotherapy to assist with their recovery. The patients that did not access post-discharge physiotherapy do not seem to have been adversely affected by this decision as this group reported better outcome scores. A difference in pre-to post-operative change in Oxford Score of approximately 3 points was observed between the THA patients, and approximately 4 points in the TKA patients that accessed physiotherapy compared to those that did not. The minimal clinically important difference in Oxford Scores has been estimated at 5 points²⁴, in THA and 4 points in TKA suggesting the statistical differences reported in the THA patients are unlikely to reflect a clinically meaningful difference, but that the TKA data may represent variation in clinical outcomes between groups.

The Oxford Scores, EQ-5D scores and satisfaction scores at 6 months reported by the patients that did not access additional post-discharge physiotherapy compare well to national outcome figures for both THA and TKA patients²⁵. This suggests that post-discharge outpatient physiotherapy is not necessarily required in all cases, and that (broadly) patients and clinicians are able to make a judgement as to whether they should attend such therapy.

This is an observational cohort study and we do not attempt to evaluate the effectiveness of undertaking post-discharge physiotherapy with this data. Those who accessed additional therapy in this cohort reported lower scores, suggesting greater physical dysfunction in the early post-operative phase. It may be that the additional therapy improved the patient outcomes compared to having had no such intervention. Patients and clinicians expect a rehabilitation component to be provided as part of the care pathway for joint arthroplasty. Though there is a role for physiotherapy around total joint arthroplasty, it may be that post-discharge physiotherapy should be targeted to those that require additional rehabilitation to optimise outcomes as opposed to blanket provision for all in the early post-operative phase. In this setting, self-directed home exercises appear to have been sufficient for the majority of patients to achieve a good outcome post-arthroplasty. This finding could be explored for cost-effectiveness from the health economic and service delivery perspective, however relies on accurately targeting physiotherapy to those that require the additional input.

We were able to construct statistically significant regression models using pre-operative data to correctly classify the patients that accessed post-operative therapy, however these models were poor in terms of accuracy. The model describing access of post-discharge physiotherapy following THA was only 17% greater than chance at identifying the patients that accessed physiotherapy. The patients that underwent THA who accessed physiotherapy post-discharge reported lower general health scores (EQ-5D) but broadly equivalent joint specific pain and function (OHS). The EQ-5D data essentially drove the regression model and perhaps suggests poorer health status may be related to the requirement for additional therapy; however it must be noted that these patients were on

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average 5 years younger than those that did not attend additional physiotherapy, suggesting health
 and not age is the pertinent factor here. Interestingly pre-operative pain and functional ability
 (Oxford Score), BMI and deprivation status did not influence the models.

Notably more TKA patients required or wished to access additional physiotherapy than THA, which is perhaps consistent with the reports of greater treatment success and patient outcomes following hip arthroplasty⁵²⁶. Despite applying a range of pre-operative demographic and symptom state indicators, we were only able to model the additional use of post-discharge physiotherapy to an accuracy of 7% greater than chance. Interestingly in the TKA cohort, the model relied solely on small associations with age and sex. In this model, pre-operative pain / function / health scores, social deprivation and BMI did not help determine which patient would go on to require additional therapy.

Though various factors have been associated with poor clinical outcomes following TKA, currently, we cannot reliably predict pre-operatively who will struggle to recover post-operatively. Larger and more comprehensive predictor studies (for example incorporating psychological variables) are required to determine which patient factors lead to poorer post-operative outcomes and to see if particular patient groups benefit from post-discharge physiotherapy. Further insight may be provided by the multicentre TRIO and COASt studies that are currently evaluating this in the UK^{26, 27}. Alternatively, it may be that it is the patient's response to surgery as opposed to pre-operative characteristics that determine the need for post-operative rehabilitation and that there is no reliable way to predict this pre-operatively.

30 310

31 311 Strengths and Limitations 32

A strength of this study is the relatively large patient cohort of 2769 arthroplasties and the depth of linked demographic and outcome data. Additionally, that our data is in line with UK national figures for patient demographics and pre and post-operative outcome scores lends wider credibility. Limitations are that the access of post-discharge physiotherapy was documented and reported by the patient at 6 months post-arthroplasty, which open potential responder biases. Further, we are not able to determine the route by which the patient accessed this post-discharge therapy, nor the content of the specific physiotherapy received. The relatively short post-operative 6 month timeframe results that we cannot comment on longitudinal changes in outcomes, nor whether those patients that access physiotherapy 'caught-up' with those that did not in terms of clinical outcome scores at subsequent later time points. The study was not designed to evaluate the effectiveness of the physiotherapy received, however future studies may be able to target therapy to patients deemed 'at need of intervention', and randomise to differing levels or modes of intervention.

50 325 **CONCLUSION** 51

In a choice based service model of targeted physiotherapy 'as required' following hip and knee arthroplasty only a third of THA and half of TKA patients accessed post-discharge physiotherapy. Patients who reported greater post-operative outcome scores and surgical episode satisfaction did not access additional therapy, suggesting a variation in requirement for post-arthroplasty physiotherapy. We were unable to predict pre-operatively (with demographic and symptom data) which patients would subsequently access additional input.

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3	333	CONTRIBUTORS
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5	334	DFH, conceived the study, interpreted the results, drafted and revised the manuscript. FCL
7	335	performed the statistical analysis, drafted the results and contributed to manuscript revisions. DJM
8	336	obtained the data, collated the data and contributed to manuscript drafting and revision. GMF
9	337	contributed to results interpretation, manuscript drafting and revision. DJB contributed to results
10	338	interpretation, manuscript drafting and revision. HRS contributed to results interpretation,
11	339	manuscript drafting and revision. JTP contributed to the study design, results interpretation,
12	340	manuscript drafting and revision. CRH contributed to the study design, results interpretation,
13 1/1	341	manuscript drafting and revision.
15 16	342	
17 18	343	FUNDING STATEMENT
19	344	This work was supported by Arthritis Research UK [ref 71000] and an institutional award from
20	345	Stryker to the University of Edinburgh [ref RB0412]. The funders had no role in the study design,
21 22	346	collation or analysis of data, interpretation of data nor writing of the manuscript.
23 24	347	
24 25 26	348	CONFLICT OF INTEREST STATEMENT
27	349	DFH, DJB, GMF and HRS, are grant holders on the Arthritis Research UK funded TRIO study. Though
28	350	there is no financial or direct academic conflict, this work can be considered as relevant background
29	351	for the (currently) ongoing TRIO study.
30 31		
32	352	
33	353	ETHICAL APPROVAL
34 25		
35 36	354	Ethical approval was obtained from the Scotland A Research Ethics Committee (11/AL/0079).
37	355	
38		
39 40	356	DATA SHARING STATEMENT
41	357	The raw data cannot be made publicly available to protect patient confidentiality, however
42	358	restricted data may be made available if deemed reasonable by the data custodian. Such requests
43	359	should be made to CRH via the corresponding author.
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³ 436 **TABLES**

Table 1 Demographic and outcome data for patients with THA by post-discharge physiotherapyaccess

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Referred for physiotherapy	Yes	No	Effect size	statistic	significance
Sex N (%)					
female	324 (65.7)	486 (53.9)		$X^2 = 18.352$	p<0.001 [‡]
male	169 (34.3)	416 (46.1)			
Side N (%)					
left	212 (43.5)	422 (47.6)		<i>X</i> ² = 2.123	p=0.157 [‡]
right	275 (56.5)	464 (52.4)			
SIMD					
1 st quintile N (%)	37 (7.5)	76 (8.4)		Z = -0.78	p=0.438*
2 nd quintile N (%)	78 (15.8)	160 (17.7)			
3 rd quintile N (%)	85 (17.2)	166 (18.4)			
4 th quintile N (%)	129 (26.2)	193 (21.4)			
5 th quintile N (%)	164 (33.3)	307 (34.0)			
Age Mean (SD)	64.9 (13.2)	69.1 (10.6)	0.35 [±]	T = -6.08	p<0.001 ⁺
BMI Mean (SD)	28.3 (6.9)	28.2 (5.0)	0.02 [±]	T = 0.27	p=0.788 ⁺
OHS					
Pre-op	20.1 (8.6)	21.4 (8.6)	1.31 [±]	T = -2.67	p=0.008 ⁺
Post-op	35.8 (9.8)	39.4 (8.6)	0.39 [±]	T = -6.96	p<0.001 ⁺
Change	15.6 (10.6)	18.0 (9.9)	0.23 [±]	T = -4.06	p<0.001 ⁺
EQ-5D					
Pre-op	0.35 (0.3)	0.41 (0.3)	0.20 [±]	T = -2.92	p=0.004 ⁺
Post-op	0.70 (0.3)	0.80 (0.2)	0.39 [±]	T = -6.52	p<0.001 ⁺
Change	0.35 (0.4)	0.39 (0.3)	0.12 [±]	T = -2.28	p=0.023 ⁺
Satisfaction					
Very satisfied	280 (57.4)	648 (73.3)		Z = -6.43	p<0.001*
Satisfied	122 (25.0)	165 (18.7)			
Neither satisfied nor	44 (9.0)	43 (4.9)			
dissatisfied	27 (5.5)	13 (1.5)			
Dissatisfied	15 (3.1)	15 (1.7)			
Very dissatisfied					

441 Mann-Whitney-U*, t-test[†], Chi-square[‡], Cohen's d[±]

442 Scottish Index of Multiple Deprivation (SIMD); Body Mass Index (BMI); Oxford Hip Score (OKS); EuroQol 5 443 Dimension (EQ-5D)

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Access of post-discharge physiotherapy following TKA & THA

Table 2 Demographic and outcomes data for patients with TKA by post-discharge physiotherapy446 access

Referred for physiotherapy	Yes	No	Effect size	statistic	significance
Sex N (%)					
female	390 (58.9)	388 (54.5)		$X^2 = 2.726$	p=0.099*
male	272 (41.1)	324 (45.5)			
Side N (%)					
left	321 (49.5)	337 (47.7)		$X^2 = 0.404$	p=0.525‡
right	328 (50.5)	369 (52.3)			
SIMD					
1 st quintile N (%)	63 (9.5)	66 (9.3)		Z = -2.19	p=0.028*
2 nd quintile N (%)	104 (15.7)	162 (22.8)			
3 rd quintile N (%)	122 (18.4)	136 (19.1)			
4 th quintile N (%)	164 (24.8)	138 (19.4)			
5 th quintile N (%)	209 (31.6)	210 (29.5)			
Age Mean (SD)	68.2 (9.7)	71.0 (8.6)	0.30 [±]	T = -5.73	p<0.001*
BMI Mean (SD)	31.1 (6.0)	30.6 (5.9)	0.01 [±]	T = 1.29	p=0.198*
ОКЅ					
Pre-op	20.9 (7.8)	20.9 (7.9)	<0.01 [±]	T = -0.04	p=0.965*
Post-op	32.3 (9.8)	35.9 (9.1)	0.38 [±]	T = -6.99	p<0.001*
Improvement	11.4 (9.4)	15.0 (8.9)	0.39 [±]	T = -7.16	p<0.001*
FO-5D					
Pre-op	0.43 (0.3)	0.41 (0.3)	0.07 [±]	T = 1.33	p=0.183 ⁺
Post-op	0.68 (0.3)	0.77 (0.2)	0.35 [±]	T = -6.34	p<0.001 ⁺
Improvement	0.25 (0.3)	0.35 (0.3)	0.32 [±]	T = -6.15	p<0.001 ⁺
Satisfaction, N (%)					
Very satisfied	271 (41.6)	427 (61.3)		Z = -8.22	p<0.001*
Satisfied	214 (32.8)	198 (28.4)			
Neither satisfied nor dissat	98 (15.0)	43 (6.2)			
Dissatisfied	51 (7.8)	20 (2.9)			
Very dissatisfied	18 (2.8)	9 (1.3)			
•	- (-)	- (-)			

448 Mann-Whitney-U*, t-test[†], Chi-square[‡], Cohen's d[±]

Scottish Index of Multiple Deprivation (SIMD); Body Mass Index (BMI); Oxford Knee Score (OKS); EuroQol 5Dimension (EQ-5D)

50 451

Access of post-discharge physiotherapy following TKA & THA

Table 3 Predictive accuracy of demographic and preoperative outcome-parameters for patients

- 453 accessing post-discharge physiotherapy

		TKA	
s OR	95% confidence interval	e p	Correct classification
1.04	1.02-1.05	<0.001	57.4 %
1.26	1.01-1.58	0.038	
1.04	1.01-1.58	0.038	57.4 /0
-	-	-	-
.20 0.018	.20 0.018 -	.20 0.018	.20 0.018

Access of post-discharge physiotherapy following TKA & THA

FIGURES

- Figure 1 Change in Oxford Hip Scores by post-operative physiotherapy access in THA patients
- Figure 2 - Change in EQ-5D scores by post-operative physiotherapy access in THA patients
- μ Locres L Les by post-op Figure 3 - Change in Oxford Knee Scores by post-operative physiotherapy access in TKA patients
- Figure 4 - Change in EQ-5D scores by post-operative physiotherapy access in TKA patients







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Section/Topic	ltem #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4,5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4,5
Bias	9	Describe any efforts to address potential sources of bias	4,5
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	Intitative variables 11 Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why		5,6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5,6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	4
		(d) If applicable, explain how loss to follow-up was addressed	4
		(e) Describe any sensitivity analyses	6

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed	6
		eligible, included in the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential	6,7
		confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	6,7
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence	6,7
		interval). Make clear which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were categorized	6,7
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	8,9
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	8,9
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	8,9
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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