http://dx.doi.org/10.2106/JBJS.19.00695

The following content was supplied by the authors as supporting material and has not been copy-edited or verified by JBJS.

SUPPLEMENT TO THE VERITAS TRIAL MANUSCRIPT

CONTENTS

Methods

Tables

METHODS

Below are additional details as indicated in the manuscript.

Blinding

Patients: Intervention type did not allow patients to be blinded.

Outcome Data Collectors: Although it was originally intended that data collectors conducting outcome assessments at 6- and 12-weeks be blinded to group assignment, this proved impractical because patients were required to differentiate the type of physical therapy follow-up visit by day on their diary. However, we selected outcome measures based on validated multi-item patient reported instruments with standardized response options that did not require interviewer interpretation or observation, thus minimizing potential measurement bias.

Study Team: Report data remained blinded to all until the database was locked.

Outcome Assessment

Timing: It was anticipated that both the 6- and 12-week follow-up calls may not occur exactly at 6 and 12 weeks, respectively, for every patient. However, the call center contacted enrolled patients as close as possible to the appropriate time since postoperative discharge date allowing a 2-week window for contact to be made. All patients were reached within the specified window.

Burden: Patients were asked to participate in the entire 6- and 12-week assessment by phone, lasting 20-30 minutes. Call center staff had a protocol to prioritize data needed for the primary endpoint if patients agreed to spend only a limited time on the follow-up call.

Primary Cost Endpoint:
The primary aim was to examine the hypothesis that patients who received the virtual physical therapy exercise rehabilitation program would have lower total costs in the 12-weeks following hospital discharge compared with patients in the usual care group who received traditional physical therapy. Total health service use cost at 12-weeks post-operative was the primary endpoint for this study. This was calculated using a Medicare fee-for-service model (2015 rates from when the study was designed) and assigned costs for the virtual program. Tele-health for rehabilitation services is not a reimbursable service, and thus we assigned a total intervention cost, including direct and indirect time with physical therapy (PT) and any in-person visits.
Costs per unit were as follows:

Healthcare Encounter	Unit	Cost
Intervention	Total (all interactions)	$600
Home health PT	<5 visits (cost per visit) ≥5 visits (single cost per 60-day episode)	$133 $2,325
Outpatient clinic PT	Single visit	$90
PT call/email	Single interaction	n/a
Doctor's office	Single visit	$150
Doctor's office call/email	Single interaction	n/a
Urgent care or ER visit	Single visit	$250
Re-hospitalization	Full length of one inpatient stay	$7,825
Inpatient rehab facility	Full length of stay	$10,720
Skilled nursing facility	Full length of stay	$6,510

Intervention Group Patients: We calculated total costs as the assigned cost of the intervention plus assigned costs for any reported doctor's office visits, urgent care or emergency room (ER) visits, re-hospitalizations, and inpatient rehabilitation or skilled nursing facility stays in the 12 weeks following discharge from the surgical hospital stay. The formula is as follows:

> Cost = intervention cost + (# of doctors office visits * $150) + (# of ER/UC visits * $250) + (# of re-hospitalizations * $7,825) + (# of skilled nursing facility stays * $6,510) + (# of inpatient rehabilitation facility stays * $10,720)

The cost formula for the intervention group was computed under the assumption that intervention patients do not require home health or outpatient clinic PT visits and that the costs of virtual PT are negligible. Based on the diary data collected, we cannot distinguish the costs between in-person or virtual PT without additional data collected from PT therapist reports or external data sources.

Control Group Patients: Total costs will be computed using data obtained from the 6-week and 3-month patient diaries reported to the call center based on PT visits, doctor's office visits, urgent care or ER visits, re-hospitalizations, and inpatient rehabilitation or skilled nursing facility stays. The formula is as follows:

> Cost = (confirmed home health and dates of service and then (1) # PT visits within those dates * $210, if # PT visits <5 or (2) Single cost per 60-day episode of $2,325, if # PT visits ≥5) + (confirmed outpatient clinic and dates of service and then # of PT visits within those dates * $90) + (# of doctors office visits * $150) + (# of ER/UC visits * $250) +(# of re-hospitalizations * $7,825) + (# of skilled nursing facility stays * $6,510) + (# of inpatient rehabilitation facility stays * $10,720)

Additional “cost formula rule” when assigning cost were as follows:

1) Home health visits within one week of the 60-day episode window were counted as within the 60-day episode of care to account for errors in self-reporting.

The null hypothesis for the primary endpoint is that there is no treatment difference between patients who receive virtual PT versus traditional home and/or clinic-based PT. The alternative hypothesis is that a treatment difference exists between patients who receive tele-rehab-supported PT versus traditional home and/or clinic-based PT.

Let μ_T and μ_C be the average total health care costs for the virtual and control PT groups, respectively. The null hypothesis and the alternative hypothesis were as follows:

$$H_0: \mu_T = \mu_C$$
$$H_A: \mu_T \neq \mu_C$$

The primary statistical method planned for the hypothesis test was t-test, and the mean difference between groups was presented with a 95% confidence interval (CI). The test was two-sided even though we were more interested in determining that the intervention group is superior to the control group to allow for a possible negative significant difference.

Let $\bar{X}_T$ and $\bar{X}_C$ be the sample mean costs for the virtual and control groups, respectively, and let S_T^2 and S_C^2 be the sample variance for the virtual and control samples, respectively. The equality of the variances of the two samples were tested using the Folded *F*-test (i.e., F=Max(S_T^2, S_C^2)/min (S_T^2, S_C^2)). If there was not strong statistical evidence to say that the variances of the two samples are different (insignificant *F*-test and 4-fold variance difference), then the alternative hypothesis for total cost would be concluded when the associated *t*-test statistic assuming equal variance is less than the 2.5th percentile of the Student’s *t* distribution with $n_T + n_C - 2$ degrees of freedom, where n_T is the number of subjects in the virtual group and n_C is the number of subjects in the control group. Otherwise, the *t*-test would be computed assuming the variances were unequal.

If a parametric method was determined not to be possible through normality checks (Shapiro-Wilks test) or transformations, a Wilcoxon rank-sum test would be performed for the primary effectiveness endpoint and a 95% CI for the median difference presented.

Secondary Endpoints

Secondary effectiveness outcomes evaluated non-inferiority (NI) of virtual PT versus traditional PT. Below each outcome measure is described with the NI margin used for the study.[7,12-18] Additional secondary endpoints were collected at 6 and/or 12 weeks post-operatively that were not part of NI testing for effectiveness or safety, mainly due to lack of clinically relevant NI margins for this population in the literature.

Outcome	Description	Non-Inferiority Margin	Timing (Mode) of Measurement
Knee extension	Knee range of motion measured in degrees by goniometry	6.3 degrees (MDC_{90})	6 weeks (measured in clinic)
Knee flexion		9.6 degrees (MDC_{90})	
Gait speed	10 meter walk test	0.10 m/s (MCID)	
(Knee Injury and Osteoarthritis Outcome Score) KOOS	42 items to measure 5 domains of difficulty with physical function with each item on a Likert of 0 (none / never) to 4 (extreme / constantly / always)	10 points (MPCI)	6- and 12-weeks (patient-reported to call center)
fall	Report of a fall in 12 weeks after hospital discharge	10% incidence	12-weeks (patient-reported to call center)
pain	Average pain rated from 0 (no pain) to 10 (worst imaginable)	1.7 points (MCID)	
rehospitalizations	Number of rehospitalizations in the 12 weeks after discharge	1 rehospitalization	

Abbreviations:
MDC90 = the amount of change in scores required to be 90% confident that it is beyond measurement error. MCID after TKA was not found.
MCID = Minimal clinically important difference
MPCI = minimal perceptible clinical improvement

SUPPLEMENTAL TABLES

eTable 1. Outcomes at Hospital Discharge Overall and By Study Group

		Randomized Treatment		
	Overall (N=290)	**Virtual PT (N=145)**	**Traditional PT (N=145)**	**P-Value**
Length of TKR surgery stay (days)				0.429
N	290	145	145	
Mean (SD)	1.7 (1.0)	1.6 (0.9)	1.7 (1.1)	
Median	2.0	1.0	2.0	
Interquartile range (IQR Q1,Q3)	1.0,2.0	1.0,2.0	1.0,2.0	
Range	(0.0-11.0)	(0.0-7.0)	(0.0-11.0)	
Pain score at discharge				0.460
N	254	127	127	
Mean (SD)	3.9 (2.1)	3.8 (2.2)	4.0 (2.0)	
Median	4.0	4.0	4.0	
IQR	3.0,5.0	2.0,5.0	3.0,5.0	
Range	(0.0-10.0)	(0.0-10.0)	(0.0-10.0)	
10-meter gait speed in m/sec				0.778
N	209	104	105	
Mean (SD)	0.3 (0.2)	0.3 (0.2)	0.3 (0.2)	
Median	0.3	0.3	0.3	
IQR	0.2,0.4	0.2,0.4	0.2,0.4	
Range	(0.0-1.7)	(0.0-1.7)	(0.0-1.5)	
Did the patient fall during their hospital stay?				1.000
Yes	1/290 (0.3%)	1/145 (0.7%)	0/145 (0.0%)	
No	289/290 (99.7%)	144/145 (99.3%)	145/145 (100.0%)	

eTable 2. Treatment Comparison for Exploratory Endpoints Examining Change Over Time by Study Group

	N. Obs	Virtual PT Mean (SD)	Traditional PT Mean (SD)	P Value
Baseline to 6-weeks				
KOOS	284	24.2 (14.4)	25.7 (15.6)	0.790
Pain	285	-1.5 (2.5)	-2.5 (2.5)	0.010
10m Gait Speed	245	0.1 (0.3)	0.0 (0.2)	0.101
Discharge to 6-weeks				
10m Gait Speed	204	0.7 (0.3)	0.7 (0.3)	0.319
Pain	249	-0.3 (2.4)	-0.9 (2.2)	0.105
Discharge to 12-weeks				
Pain	239	-1.2 (2.6)	-1.0 (2.9)	0.985
Baseline to 12-weeks				
KOOS	272	32.4 (15.6)	31.0 (15.7)	0.828
PROMIS Physical Health	270	2.7 (2.4)	2.5 (2.7)	0.459
PROMIS Mental Health	268	1.5 (2.2)	1.0 (2.5)	0.171
Satisfaction with Physical Function	272	3.6 (1.8)	3.6 (1.6)	0.465
Physical Activity, minutes per week, [median (IQR)]	263	21.8 (208.6) [10.0 (-20.0,90.0)]	46.0 (223.7) [20.0 (-20.0,90.0)]	0.758
Recovery Goal	286	4.7 (2.9)	4.7 (2.9)	0.887
Pain	271	-2.4 (2.6)	-2.6 (2.7)	0.941
6- to 12-weeks				
KOOS	270	8.2 (11.1)	5.4 (12.8)	0.153
Pain	270	-0.8 (2.2)	-0.2 (2.9)	0.254

Notes:
All continuous variables are presented as mean (SD) unless noted otherwise. IQR = interquartile range

The change for each outcome is defined as the later time point minus the earlier time point. For example, baseline to 6-weeks is the six week measurement minus baseline measurement.

Sidak p-values adjusting for multiple comparisons are presented for KOOS, gait speed and pain endpoints.

Gait speed and pain score at discharge are missing for patients from site 01. Change in gait speed and pain score from discharge to 6 weeks excludes patients from this one site.

http://dx.doi.org/10.2106/JBJS.19.00695

eTable 3. Treatment Comparisons for Fall Incidence

	Unadjusted Randomized Treatment		Adjusted Randomized Treatment	
	Virtual PT	**Traditional PT**	**Virtual PT**	**Traditional PT**
Any fall in 12 weeks, %	19.4 (13.7,26.8)	14.6 (9.6,21.5)	25.8 (17.7,35.9)	19.1 (12.2,28.7)
Any fall in 6 weeks, %	11.3 (7.0,17.6)	10.6 (6.5,16.8)	16.5 (10.2,25.7)	15.9 (9.7,25.0)
Any fall between 6-12 weeks, %	9.3 (5.5,15.3)	8.0 (4.5,13.8)	10.2 (5.4,18.3)	8.1 (4.0,15.7)

Fall incidence rates are presented as percentage and 95% confidence intervals.
Fall rates are adjusted for any fall reported at baseline in the 3 months prior to surgery (yes/no).