A commentary by Mark J. Spangehl, MD, FRCS(C), is linked to the online version of this article at jbjs.org.

In-Home Telerehabilitation Compared with Face-to-Face Rehabilitation After Total Knee Arthroplasty

A Noninferiority Randomized Controlled Trial

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Background: The availability of less resource-intensive alternatives to home visits for rehabilitation following orthopaedic surgeries is important, given the increasing need for home care services and the shortage of health resources. The goal of this trial was to determine whether an in-home telerehabilitation program is not clinically inferior to a face-to-face home visit approach (standard care) after hospital discharge of patients following a total knee arthroplasty.

Methods: Two hundred and five patients who had a total knee arthroplasty were randomized before hospital discharge to the telerehabilitation group or the face-to-face home visit group. Both groups received the same rehabilitation intervention for two months after hospital discharge. Patients were evaluated at baseline (before total knee arthroplasty), immediately after the rehabilitation intervention (two months after discharge), and two months later (four months after discharge). The primary outcome measure was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire at the last follow-up evaluation. Secondary outcome measures included the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire, functional and strength tests, and knee range of motion. The noninferiority margin was set at 9% for the WOMAC.

Results: The demographic and clinical characteristics of the two groups of patients were similar at baseline. At the last follow-up evaluation, the mean differences between the groups with regard to the WOMAC gains, adjusted for baseline values, were near zero (for 182 patients in the per-protocol analysis): −1.6% (95% confidence interval [CI]: –5.6%, 2.3%) for the total score, –1.6% (95% CI: –5.9%, 2.8%) for pain, –0.7% (95% CI: –6.8%, 5.4%) for stiffness, and –1.8% (95% CI: –5.9%, 2.3%) for function. The confidence intervals were all within the predetermined zone of noninferiority. The secondary outcomes had similar results, as did the intention-to-treat analysis, which was conducted afterward for 198 patients.

Conclusions: Our results demonstrated the noninferiority of in-home telerehabilitation and support its use as an effective alternative to face-to-face service delivery after hospital discharge of patients following a total knee arthroplasty.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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Physical rehabilitation following total knee arthroplasty is an essential component of treatment[1-3] as it helps to improve functional outcomes and promotes the patient's return to his or her important activities[4,5]. Due in part to the aging population and the high prevalence of obesity and knee osteoarthritis, there has been a steady increase in the number of total knee arthroplasties performed over the last several years along with a decrease in the length of hospital stay and an earlier return home[6,7]. Consequently, providing rehabilitation services to this patient group has become a more important component of the workload of community physical therapists. In some communities in Quebec, Canada, this group represents approximately 20% of their caseload and >33% of home visits. Since community rehabilitation resources often have difficulty meeting this ever-increasing demand[2,3], the search for new effective approaches to ensure appropriate and accessible care delivery is important.

Telerehabilitation is an innovative way to deliver rehabilitation services remotely using information and telecommunication technologies. It may substitute for, or complement, face-to-face approaches (outpatient clinic or home visits), especially when access to health-care professionals is limited or difficult. In the past decade, there has been a growing body of scientific literature supporting telerehabilitation after a total knee arthroplasty[8-10]. However, a recent systematic review concluded that there is a pressing need for large-scale controlled studies evaluating the clinical benefits of telerehabilitation[11].

In 2011, Russell et al. reported the results of a randomized clinical trial on the effectiveness of outpatient telerehabilitation following total knee arthroplasty in sixty-five participants. The intervention was offered in an adjoining hospital room that simulated a home environment[12]. Although their results supported the clinical benefits of telerehabilitation, their trial did not fully address the challenges of in-home telerehabilitation, especially those related to the quality of service of the telecommunication network used in the community, technical difficulties with in-home installation of equipment, patient safety, and treatment adherence issues. The goal of the present noninferiority clinical trial was to determine whether in-home telerehabilitation, conducted from a service center to the patient's home and offered after hospital discharge to patients in the community following a total knee arthroplasty, is clinically equivalent to a face-to-face home visit approach.

Materials and Methods

Participants

Patients were recruited from the surgical waiting lists of orthopaedic surgeons in eight hospitals in three Quebec regions. Patients were eligible for inclusion criteria if they were (1) waiting for a primary total knee arthroplasty after a diagnosis of osteoarthritis, (2) returning home after hospital discharge, (3) living in an area served by high-speed Internet services (at least 512 kb/s in upload), and (4) living within a one-hour driving distance from the treating hospital. Patients were excluded if they (1) had health conditions that could interfere with tests or the rehabilitation program, including other lower-limb surgery in the last nine months; (2) were planning a second lower-limb surgery within four months; (3) had cognitive or collaboration problems; (4) had major postoperative complications; or (5) had weight-bearing restrictions for a period longer than two weeks after surgery.

The study protocol was approved by the research ethics committees of the hospitals and research centers involved. All patients participated voluntarily in the study and gave informed written consent. This trial was registered at www.controlled-trials.com. Its International Standard Randomized Controlled Trial Number is ISRCTN66285945.

Study Design

This study is a multicenter noninferiority randomized clinical trial. Just before hospital discharge, participants who underwent a primary total knee arthroplasty were randomly assigned to two groups: the telerehabilitation (TELE) group and the standard rehabilitation (STD) group. Both groups received the same rehabilitation intervention using two different approaches to service delivery, in-home telerehabilitation or face-to-face home visits (the STD approach) over the first two months after hospital discharge. Participants were evaluated at baseline (E1: before total knee arthroplasty), at hospital discharge (E2), after intervention (E3: two months after discharge), and two months later (E4: four months after discharge) by independent evaluators blinded to the group assignment.

Intervention

The rehabilitation intervention included sixteen sessions of forty-five to sixty minutes, supervised by a trained physical therapist. Each physical therapist was limited to intervention delivery in one group only. The intervention's intensity and duration were standardized and based on the recommendations of a group of experts[13]. The components of the intervention were an assessment before and after exercise (a structured interview and observation), supervised exercises during a period of approximately thirty minutes (mobility, strengthening, function, and balance), prescription of home exercises to perform on days without supervised sessions, and advice concerning pain control, walking aids, and the return to activities. The intensity and difficulty level of the exercises were increased according to each patient's tolerance and needs.

Modes of Service Delivery

In-Home Telerehabilitation (TELE Group)

The technological platform was based on h264 videoconference codecs (Tandberg 550 MXP; Cisco Systems, San Jose, California) with clinician-controlled PTZ (pan, tilt, zoom) cameras and dedicated software that allowed real-time two-way video and audio interaction over the Internet between the clinician at a rehabilitation center and a patient at home. The platform had been tested in previous studies[9,10]. It was installed in the home by a technician within a week of hospital discharge. The physiotherapist initiated the session at the time scheduled with the patient, and the patient had only to push a button to accept the communication and start the session.

Face-to-Face Home Visits (STD Group)

The physiotherapist visited the patients at home, traveling by car.

Outcome Measures

The primary outcome was the gain from baseline (E1) to the last follow-up (E4) in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC version 5, LK3.1). This questionnaire is widely used to evaluate the effect of intervention after total knee arthroplasty[14-16], and its metrological properties are well recognized[17-19], with a minimal clinically important difference established at 12%[20].

Secondary outcomes were changes from baseline to E4 in the Knee injury and Osteoarthritis Outcome Score (KOOS), a validated questionnaire[21] evaluating function, symptoms, and quality of life of patients with knee disorders[22,23], and the results at E4 on the six-minute-walk test[17,18,24], the timed stair test[25,26], range of motion[5,27,28], and maximal static and pain-free strength of the knee extensor and flexor muscles[29].

The demographic and clinical characteristics of the patients, including their comorbidities[30], were documented at baseline. Cointerventions, health

TABLE I Baseline Characteristics of the Patients

Characteristic*	STD Group (N = 101)	TELE Group (N = 104)	P Value†
Age† *(yr)*	67 ± 8	65 ± 8	0.13
Male patients *(no. [%])*	56 (55)	44 (42)	0.06
Body mass index† *(kg/m^2)*	33 ± 6	34 ± 7	0.13
Right knee involved *(no. [%])*	52 (51)	50 (48)	0.63
Time in yr since the onset of knee pain§ *(no. [%])*			0.99
≤1	2 (2)	3 (3)	
>1 and ≤5	30 (30)	32 (31)	
>5 and <10	26 (26)	26 (25)	
≥10	41 (41)	41 (40)	
Living alone *(no. [%])*	10 (10)	22 (21)	0.03
Occupation *(no. [%])*			0.71
Paid worker	27 (27)	28 (27)	
Retired	69 (68)	68 (65)	
Other	5 (5)	8 (8)	
Internet connection at home *(no. [%])*	82 (81)	74 (71)	0.09
Stratification by WOMAC score *(no. [%])*			0.85
<50%	54 (53)	57 (55)	
≥50%	47 (47)	47 (45)	
Previous lower limb surgery# *(no. [%])*	48 (48)	46 (46)	0.73
Comorbidity *(no. [%])*			
Arthritis	97 (96)	99 (95)	1.00
Osteoporosis	10 (10)	12 (11)	0.70
Asthma	8 (8)	19 (18)	0.03
COPD, ARDS, or emphysema	8 (8)	6 (6)	0.54
Angina	8 (8)	9 (9)	0.85
Congestive heart failure	6 (6)	7 (7)	0.82
Myocardial infarction	3 (3)	7 (7)	0.33
Neurological disorder	0 (0)	0 (0)	—
Stroke or transient ischemic attack	2 (2)	6 (6)	0.28
Peripheral vascular disorder	5 (5)	6 (6)	0.79
Diabetes	17 (17)	26 (25)	0.15
Gastrointestinal disorder	32 (32)	36 (35)	0.66
Depression	7 (7)	17 (16)	0.04
Anxiety or panic attack	10 (10)	17 (16)	0.17
Visual impairment	33 (33)	26 (25)	0.23
Hearing impairment	8 (8)	8 (8)	0.95
Disc degeneration	23 (23)	22 (21)	0.78
Obesity, BMI > 30 kg/m^2	70 (69)	72 (69)	0.99
Cancer**	15 (17)	16 (18)	0.87
Others††	51 (57)	56 (63)	0.44
No. of comorbidities per patient†	4.1 ± 1.8	4.5 ± 2.4	0.15
Functional status and quality of life†			
WOMAC score *(%)*			
Pain	53 ± 17	53 ± 20	0.96
Stiffness	47 ± 24	49 ± 22	0.56
Function	55 ± 18	54 ± 20	0.60
Total	54 ± 17	53 ± 19	0.73

continued

TABLE I (*continued*)

Characteristic*	STD Group (N = 101)	TELE Group (N = 104)	P Value†
KOOS score *(%)*			
Symptoms	54 ± 19	53 ± 18	0.64
Pain	47 ± 16	47 ± 19	0.87
Activities of daily living	55 ± 18	54 ± 20	0.65
Sports and recreational activities††	11 ± 12	16 ± 19	0.08
Quality of life	29 ± 18	28 ± 20	0.55
Six-minute walk test† *(m)*	348 ± 110	324 ± 123	0.15
Timed stair test† *(s)*	37 ± 18	44 ± 33	0.04
Range of motion† *(deg)*			
Involved knee			
Flexion	115 ± 13	114 ± 15	0.56
Extension	−6 ± 6	−5 ± 5	0.34
Contralateral knee			
Flexion	120 ± 14	122 ± 12	0.28
Extension	−3 ± 5	−1 ± 4	0.01
Isometric strength† *(Nm)*			
Involved knee			
In flexion			
At 60° of flexion	53 ± 29	49 ± 24	0.26
At 30° of flexion	61 ± 34	56 ± 28	0.27
In extension			
At 60° of flexion	108 ± 58	103 ± 52	0.59
At 30° of flexion	73 ± 37	70 ± 33	0.51
Contralateral knee			
In flexion			
At 60° of flexion	61 ± 30	58 ± 26	0.36
At 30° of flexion	72 ± 34	67 ± 29	0.21
In extension			
At 60° of flexion	136 ± 64	136 ± 66	0.99
At 30° of flexion	88 ± 40	88 ± 37	0.94

*COPD = chronic obstructive pulmonary disease, ARDS = acute respiratory distress syndrome, and BMI = body mass index. †P values were derived from Student t tests (two-sided tests) for continuous variables and from chi-square tests, or Fisher exact tests when needed, for categorical variables. ‡The values are given as the mean and the standard deviation. §Data were available for ninety-nine patients in the STD group and 102 patients in the TELE group. #Data were available for ninety-nine patients in the STD group and 100 patients in the TELE group. **Data were available for ninety patients in the STD group and nine-one patients in the TELE group. ††Data were available for eighty-nine patients in the STD group and eighty-nine patients in the TELE group. ‡‡Data were available for sixty-nine patients in the STD group and sixty-eight patients in the TELE group.

complications, adverse events, and level of physical activity[31] were documented at each follow-up visit.

Sample Size

It was estimated that a sample size of 102 per group would be necessary to test our research hypothesis on the primary outcome. The sample size calculation was based on the CONSORT (Consolidated Standards of Reporting Trials)[32] recommendations with the use of the confidence interval method proposed by Jones et al. in 1996[33]. The parameters used included an intergroup variability in the WOMAC gain (σ) of 21% (estimated from data in a previous trial[5]); a noninferiority margin (Δ) of 9%, which was fixed at 25% less (as recommended by previous work[32-34]) than the minimal clinically important difference for the WOMAC; a type-I error of 5% ($\alpha = 0.05$); a power of 80% as used in similar trials[33,35,36]; and a dropout rate of 15%.

Randomization

Stratification by hospital and according to functional status at baseline using the WOMAC score at E1 (a total score of ≥50% and <50%), with blocking within strata (a block size of 4 or 2, randomly distributed), was used to ensure a balanced distribution of participants in each group. A computer-generated randomization list (SAS Proc Plan, SAS/STAT 9.3; SAS Institute, Cary, North Carolina) was prepared by the statistician and given to the study's clinical coordinator of each site in a series of sealed envelopes. After E2, the study coordinator proceeded to randomization in the presence of the patient.

Blinding

All evaluators and investigators were blinded to group assignment for the entire duration of the study. Decisions related to data analyses were taken while investigators were still unaware of group assignment. However, blinding

TABLE II Results of the Per-Protocol Analysis for Change in Functional Status and Quality of Life of 182 Patients at Four Months After Hospital Discharge (E4)

Variables*	Mean (and Standard Error) at E4 Adjusted for E1		Mean Gain from Baseline at E4		
	STD Group (N = 98)	TELE Group (N = 84)	STD Group (N = 98)	TELE Group (N = 84)	Difference Between Groups*
WOMAC score *(%)*					
Pain	82.6 ± 1.4	84.4 ± 1.5	29.7	31.3	−1.6 (–5.9, 2.8)
Stiffness	71.9 ± 1.9	72.1 ± 2.1	23.7	24.3	−0.7 (–6.8, 5.4)
Function	83.9 ± 1.3	86.0 ± 1.4	29.4	31.2	−1.8 (–5.9, 2.3)
Total	82.6 ± 1.3	84.5 ± 1.4	29.0	30.6	−1.6 (–5.6, 2.3)
KOOS score *(%)*					
Symptoms	71.9 ± 1.5	75.7 ± 1.6	18.3	21.9	−3.6 (–8.3, 1.0)
Pain	78.1 ± 1.4	80.6 ± 1.5	31.1	33.6	−2.5 (–7.1, 2.1)
Activities of daily living	84.3 ± 1.3	86.9 ± 1.4	29.6	31.9	−2.3 (–6.3, 1.7)
Sports and recreational activities	30.1 ± 1.9	30.8 ± 2.1	17.6	19.6	−2.0 (–9.3, 5.4)
Quality of life	69.2 ± 1.9	70.3 ± 2.0	41.6	42.5	−0.9 (–7.5, 5.7)
Six-minute walk test *(m)*	398.3 ± 6.0	415.7 ± 6.4	58.7	74.3	−15.6 (–37.0, 5.9)
Timed stair test *(s)*	29.6 ± 1.2	25.6 ± 1.3	−12.9	−10.5	−2.4 (–5.5, 0.8)
Range of motion *(deg)*					
Involved knee					
Flexion	112.6 ± 1.0	112.4 ± 1.1	−2.0	−2.3	0.3 (–2.9, 3.5)
Extension	−3.5 ± 0.4	−3.6 ± 0.4	1.8	1.9	−0.1 (–1.2, 1.0)
Contralateral knee					
Flexion	123.1 ± 0.4	122.3 ± 0.5	1.8	1.2	0.7 (–0.9, 2.3)
Extension	−1.6 ± 0.2	−1.9 ± 0.2	0.5	0.4	0.2 (–0.6, 0.9)
Isometric strength† *(Nm)*					
Involved knee					
In flexion					
At 60° of flexion	54.9 ± 1.3	52.7 ± 1.4	4.6	1.8	2.9 (–2.1, 7.8)
At 30° of flexion	69.1 ± 1.6	67.8 ± 1.8	11.3	9.4	1.9 (–4.8, 8.6)
In extension					
At 60° of flexion	105.6 ± 2.8	107.2 ± 3.1	−0.1	0.5	−0.6 (–11.2, 9.9)
At 30° of flexion	74.7 ± 1.8	77.7 ± 2.0	3.3	5.6	−2.3 (–9.4, 4.8)
Contralateral knee					
In flexion					
At 60° of flexion	61.3 ± 0.9	60.2 ± 1.0	1.2	0.0	1.2 (–2.3, 4.7)
At 30° of flexion	71.1 ± 1.0	71.7 ± 1.1	1.1	1.5	−0.4 (–4.5, 3.7)
In extension					
At 60° of flexion	143.4 ± 2.4	145.3 ± 2.6	5.8	8.1	−2.3 (–12.0, 7.4)
At 30° of flexion	94.9 ± 1.5	94.3 ± 1.7	6.5	5.9	0.6 (–5.7, 6.9)

*Intergroup mean differences (STD – TELE), adjusted for the baseline score (E1), and 95% confidence intervals were obtained using the LSMEANS statement of the GLM procedure with the CL option. †Mean of two maximal and pain-free isometric strength trials measured using a Biodex System 3 dynamometer (Biodex Medical Systems, Shirley, New York).

of subjects and clinicians was not possible, considering the nature of the intervention.

Analysis and Statistical Methods

All statistical analyses were performed using SAS 9.3 software. The groups were first compared on baseline characteristics. For the continuous variables, Student t tests were conducted using the TTEST procedure. For the categorical variables, the FREQ (frequency and contingency) procedure was used to perform chi-square tests, or Fisher exact tests when chi-square testing was not valid. The main research hypothesis verified that the mean WOMAC score gain from baseline (E1) to the last follow-up (E4) in the TELE group would not be inferior compared with that in the STD group. The

TABLE III Results of the Intention-to-Treat Analysis for Change in Functional Status and Quality of Life of 198 Patients at Four Months After Hospital Discharge (E4)

Variables*	Mean (and Standard Error) at E4 Adjusted for E1		Mean Gain from Baseline at E4		
	STD Group (N = 100)	TELE Group (N = 98)	STD Group (N = 100)	TELE Group (N = 98)	Difference Between Groups*
WOMAC score *(%)*					
Pain	82.8 ± 1.4	84.0 ± 1.4	29.9	30.6	−0.7 (–4.8, 3.4)
Stiffness	72.1 ± 1.9	71.0 ± 2.0	23.9	23.2	0.7 (–5.2, 6.5)
Function	83.9 ± 1.3	84.9 ± 1.3	29.7	30.2	−0.4 (–4.3, 3.4)
Total	82.6 ± 1.3	83.5 ± 1.3	29.4	29.5	−0.1 (–3.9, 3.7)
KOOS score *(%)*					
Symptoms	71.9 ± 1.5	74.8 ± 1.5	18.6	21.2	−2.6 (–7.0, 1.8)
Pain	78.1 ± 1.4	80.1 ± 1.4	31.2	33.0	−1.8 (–6.2, 2.5)
Activities of daily living	84.2 ± 1.3	85.7 ± 1.3	30.0	30.8	−0.8 (–4.7, 3.0)
Sports and recreational activities	29.8 ± 1.9	30.9 ± 2.0	17.6	19.6	−1.9 (–8.8, 5.0)
Quality of life	69.0 ± 1.9	69.5 ± 1.9	41.6	41.9	−0.4 (–6.8, 6.1)
Six-minute walk test *(m)*	396.3 ± 5.9	407.5 ± 6.0	59.9	67.3	−7.4 (–27.8, 13.1)
Timed stair test *(s)*	29.9 ± 1.3	26.6 ± 1.4	−11.6	−12.7	−1.2 (–4.8, 2.4)
Range of motion *(deg)*					
Involved knee					
Flexion	112.4 ± 1.0	111.5 ± 1.0	−1.9	−3.0	1.1 (–2.1, 4.3)
Extension	−3.4 ± 0.4	−3.6 ± 0.4	1.8	1.8	0.01 (–1.0, 1.0)
Contralateral knee					
Flexion	122.9 ± 0.5	122.4 ± 0.5	1.8	1.5	0.3 (–1.3, 1.9)
Extension	−1.5 ± 0.2	−1.8 ± 0.2	0.5	0.3	0.1 (–0.6, 0.8)
Isometric strength† *(Nm)*					
Involved knee					
In flexion					
At 60° of flexion	54.9 ± 1.2	52.1 ± 1.3	4.5	1.1	3.4 (–1.3, 8.1)
At 30° of flexion	69.4 ± 1.6	67.1 ± 1.7	11.3	8.5	2.8 (–3.7, 9.2)
In extension					
At 60° of flexion	105.4 ± 2.7	105.7 ± 2.8	−0.3	−0.7	0.4 (–9.7, 10.4)
At 30° of flexion	74.6 ± 1.8	76.4 ± 1.9	3.3	4.4	−1.1 (–7.9, 5.7)
Contralateral knee					
In flexion					
At 60° of flexion	60.4 ± 0.9	59.9 ± 0.9	1.0	0.2	0.9 (–2.5, 4.2)
At 30° of flexion	70.2 ± 1.0	71.7 ± 1.0	0.9	2.1	−1.2 (–5.1, 2.7)
In extension					
At 60° of flexion	141.4 ± 2.4	143.9 ± 2.4	5.5	8.0	−2.5 (–11.7, 6.8)
At 30° of flexion	94.3 ± 1.5	93.9 ± 1.6	6.5	6.1	0.5 (–5.5, 6.4)

*Intergroup mean differences (STD – TELE), adjusted for the baseline score (E1), and 95% confidence intervals were obtained using the LSMEANS statement of the GLM procedure with the CL option. †Mean of two maximal and pain-free isometric strength trials measured using a Biodex System 3 dynamometer (Biodex Medical Systems, Shirley, New York).

gain in the TELE group was evaluated as noninferior only if the intergroup mean difference and its one-sided 95% confidence interval (CI) were <9% at E4. On the basis of the methodology of a noninferiority randomized trial, we tested the null hypothesis (H_0) of a group difference against the alternative that the two treatments are equivalent (H_1) according to our noninferiority margin of 9%. (Thus, for H_0, μSTD – μTELE ≥ 9%, and for H_1, μSTD – μTELE < 9%.) Intergroup mean differences, adjusted for the baseline score, and CIs were obtained using the LSMEANS (least squares means) statement of the GLM (general linear model) procedure with the CL (confidence limits) option.

In the primary analysis, only the subjects who participated in all evaluations and attended at least 75% of the intervention sessions were considered

TABLE IV Results of the Per-Protocol Analysis for Change in Functional Status and Quality of Life of 182 Patients at Two Months After Hospital Discharge (E3)

Variables*	Mean (and Standard Error) at E3 Adjusted for E1		Mean Gain from Baseline at E3		
	STD Group (N = 98)	TELE Group (N = 84)	STD Group (N = 98)	TELE Group (N = 84)	Difference Between Groups*
WOMAC score *(%)*					
Pain	76.5 ± 1.4	78.5 ± 1.5	23.6	25.3	−1.7 (–6.2, 2.7)
Stiffness	67.2 ± 1.9	68.6 ± 2.1	18.9	21.0	−2.1 (–7.8, 3.6)
Function	80.1 ± 1.3	82.0 ± 1.4	25.6	27.2	−1.6 (–5.8, 2.5)
Total	78.3 ± 1.3	80.2 ± 1.4	24.7	26.2	−1.5 (–5.5, 2.5)
KOOS score *(%)*					
Symptoms	67.8 ± 1.5	70.5 ± 1.6	14.3	16.8	−2.6 (–7.3, 2.1)
Pain	70.4 ± 1.4	73.5 ± 1.5	23.5	26.7	−3.2 (–8.1, 1.7)
Activities of daily living	80.7 ± 1.3	82.4 ± 1.4	26.0	27.2	−1.3 (–5.4, 2.9)
Sports and recreational activities	26.0 ± 2.0	26.1 ± 2.2	13.3	14.3	−1.1 (–8.3, 6.1)
Quality of life	61.6 ± 1.9	63.6 ± 2.1	33.9	35.6	−1.8 (–8.7, 5.2)
Six-minute walk test *(m)*	363.6 ± 5.9	382.1 ± 6.4	25.0	40.5	−15.5 (–35.6, 4.5)
Timed stair test *(s)*	33.9 ± 1.2	29.5 ± 1.3	−6.1	−9.2	3.1 (–0.7, 6.9)
Range of motion of involved knee *(deg)*					
Flexion	109.8 ± 1.0	109.5 ± 1.1	−4.8	−5.2	0.4 (–3.1, 3.9)
Extension	−4.7 ± 0.4	−4.7 ± 0.4	0.7	0.8	−0.1 (–1.2, 1.1)

*Intergroup mean differences (STD – TELE), adjusted for the baseline score (E1), and 95% confidence intervals were obtained using the LSMEANS statement of the GLM procedure with the CL option.

in the per-protocol analysis. The intention-to-treat analysis was also conducted secondarily[32,34] with all subjects who participated in at least one follow-up evaluation (E3 or E4). For subjects with missing data at E4, the observations at E3 were used according to the last-observation-carried-forward procedure[37]. The same analyses were repeated for all variables collected at E3 when the noninferiority of telerehabilitation treatment was confirmed at E4 (a null treatment difference [i.e., H_0] was excluded).

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Results

We evaluated 258 patients before surgery, and 206 were randomized after surgery. The reasons for exclusion are specified in Figure 1. Patients of both groups had similar baseline characteristics, except that more patients in the TELE group had asthma or a previous episode of depression or were living alone (Table I). Both groups had comparable levels of functional ability and quality of life at the baseline examination, except for the slightly longer time to climb stairs and slightly greater or better extension in the contralateral knee in the TELE group (Table I).

Compliance with the intervention was very high as demonstrated by the number of supervised sessions received by the participants (mean and standard deviation, 15.4 ± 1.9 for the TELE group and 16.0 ± 0.2 for the STD group, with a target value of sixteen sessions) and the timing of the first and last intervention sessions (mean, 6.1 ± 4.2 and 56.9 ± 7.4 days, respectively, for the TELE group and 3.7 ± 2.1 and 57.0 ± 5.2 days for the STD group, with target values of zero to seven days and 60 ± 7 days after discharge). Eighty-eight subjects (85%) in the TELE group and 100 subjects (99%) in the STD group received at least 75% of the sixteen allocated intervention sessions. Approximately 20% (twenty-two) of the participants in the TELE group received, in addition to the telerehabilitation sessions, one or more face-to-face home visits (mean, 2.3 ± 2.2 visits). The documented reasons for visiting TELE group participants at home were a poor Internet connection or persisting technical problems (six visits), delayed technology installation (twelve visits), an abnormal profile of knee recovery (three visits), unavailability of clinicians (two visits), and anxiety of the participant (one visit). In addition, six participants did not receive the allocated intervention because of dissatisfaction with the result of randomization, a poor Internet connection, and a perception of a complete recovery (Fig. 1).

Evaluations in both groups were performed according to the planned time line and with similar time intervals for the groups ($p > 0.05$). E1 occurred less than thirty days before surgery (mean, 9.4 ± 8.2 days for the TELE group and 8.7 ± 7.4 days for the STD group); E3, approximately two months (mean, 61.1 ± 3.8 days and 61.4 ± 5.2 days,

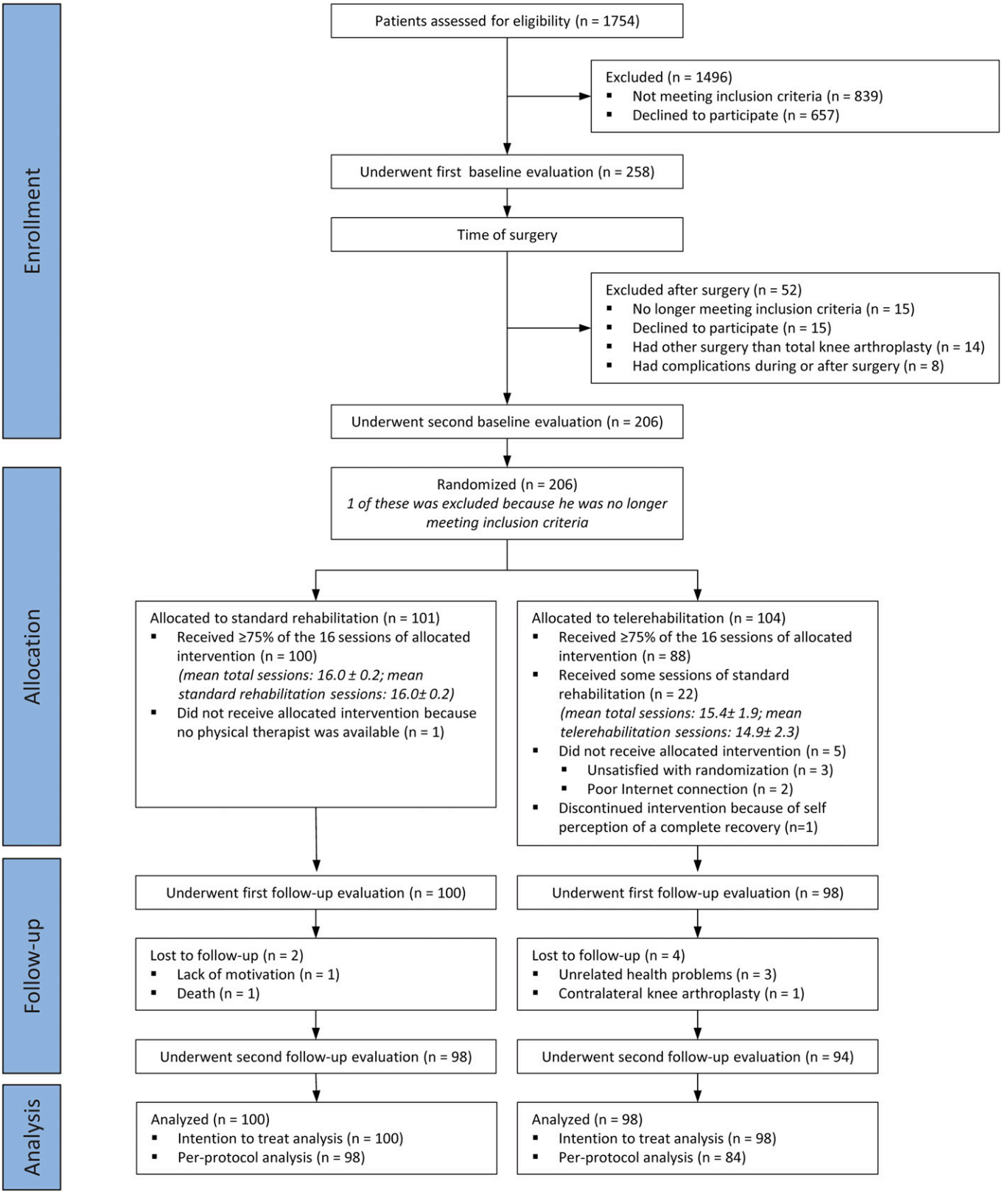

Fig. 1

Flowchart of the noninferiority randomized trial comparing the telerehabilitation with standard rehabilitation after hospital discharge of patients who had a total knee arthroplasty. The numbers of sessions are given as the mean and the standard deviation.

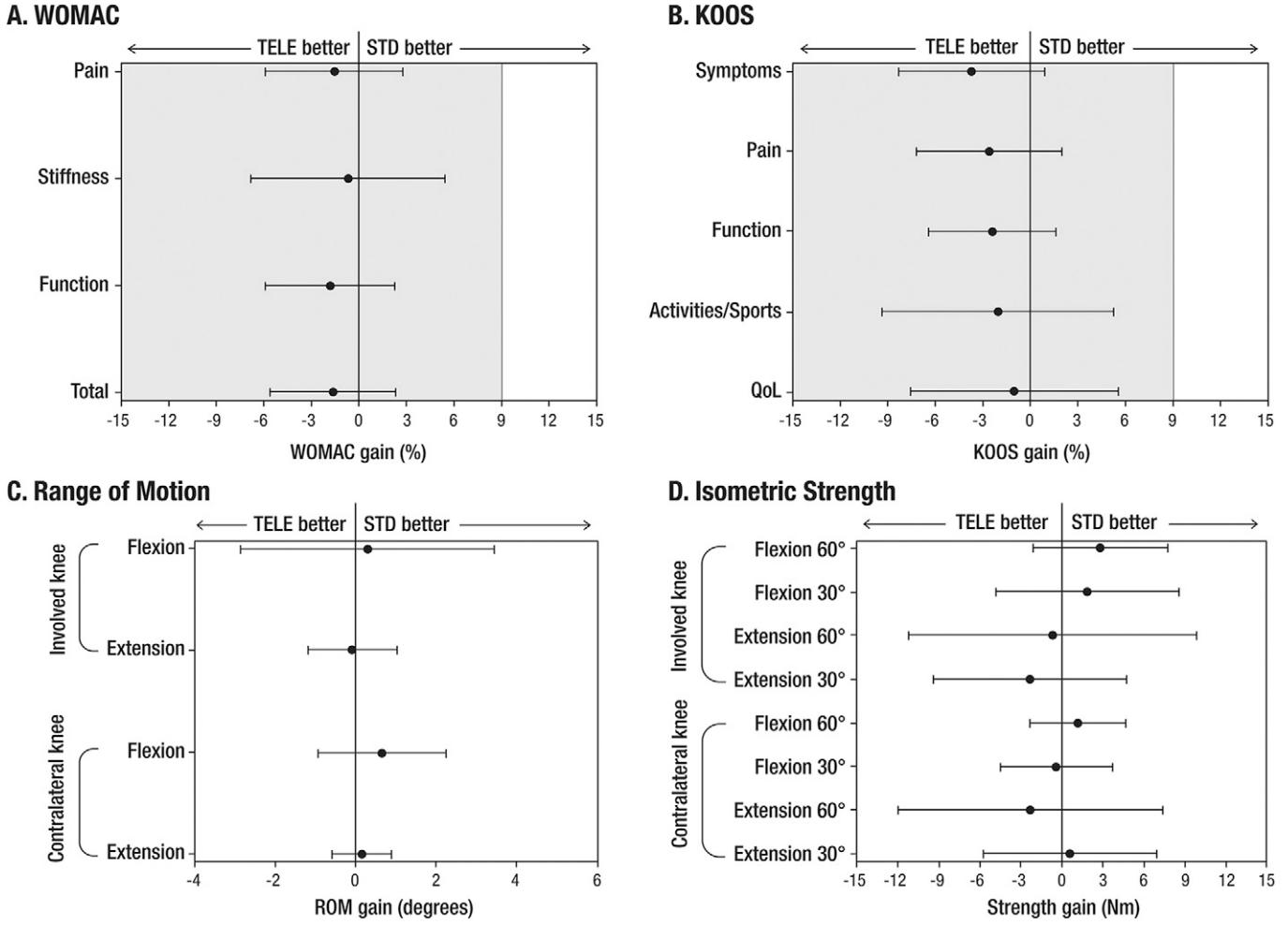

Fig. 2

Figs. 2-A through 2-D Differences between the standard (STD) and telerehabilitation (TELE) groups (STD – TELE) with regard to the gain from baseline (E1) at the last follow-up (E4) for functional ability and quality-of-life (QoL) outcomes. Error bars indicate two-sided 95% confidence intervals. The tinted area indicates the zone of noninferiority (**Figs. 2-A and 2-B**). All mean values for the WOMAC (**Fig. 2-A**), which is the main outcome, and the KOOS (**Fig. 2-B**) are close to zero, and all confidence intervals remain within the zone of noninferiority. All mean values for the range of motion (ROM) (**Fig. 2-C**) and isometric strength (**Fig. 2-D**) are close to zero.

respectively) after hospital discharge; and E4, approximately four months (mean, 116.1 ± 9.7 days and 117.3 ± 11.3 days) after hospital discharge. Data on assessments at E2 are not presented in this report.

Outcomes

At the last follow-up, the mean differences between the groups with respect to the WOMAC gains adjusted for baseline values were close to zero and slightly in favor of the TELE group (Table II; 182 subjects in the per-protocol analysis); in addition, confidence intervals all fell within the predetermined zone of noninferiority, with similar results for the functional status and quality-of-life secondary outcomes (Table II, Fig. 2). The intention-to-treat analysis performed secondarily for 198 subjects had similar results for all outcomes at E4 (Table III). Lastly, the noninferiority of the telerehabilitation treatment was also confirmed at E3 (Tables IV and V).

Adverse Events, Loss to Follow-up, and Cointerventions

During the follow-up period, a similar proportion of participants in both groups reported adverse events. No serious event was related to the telerehabilitation intervention, while two minor events were possibly related to the standard intervention (Table VI). The proportions lost to follow-up were equivalent in both groups. Most occurred at the last follow-up evaluation (Fig. 1).

Fifteen patients (six in the STD group and nine in TELE group) received additional physical therapy treatments after the completion of the planned intervention, with no significant difference between the groups. Two patients (both in the TELE group) consulted a professional chiropractor; one (in the STD group), an osteopath; and one (in the TELE group), a massage therapist. In addition, two (one in each group) had infiltration in the contralateral knee during the follow-up period. In the period between E3 and E4, the same proportion of patients per group

TABLE V Results of the Intention-to-Treat Analysis for Change in Functional Status and Quality of Life of 198 Patients at Two Months After Hospital Discharge (E3)

Variables*	Mean (and Standard Error) at E3 Adjusted for E1		Mean Gain from Baseline at E3		
	STD Group (N = 100)	TELE Group (N = 98)	STD Group (N = 100)	TELE Group (N = 98)	Difference Between Groups*
WOMAC score *(%)*					
Pain	76.9 ± 1.4	77.2 ± 1.4	23.9	24.1	−0.3 (–4.6, 4.0)
Stiffness	67.6 ± 1.9	67.4 ± 1.9	19.2	19.8	−0.6 (–6.1, 4.9)
Function	80.3 ± 1.3	80.5 ± 1.3	26.0	26.0	0.0 (–4.0, 4.0)
Total	78.5 ± 1.3	78.5 ± 1.3	25.2	24.9	0.3 (–3.6, 4.2)
KOOS score *(%)*					
Symptoms	68.0 ± 1.5	69.7 ± 1.5	14.7	16.2	−1.5 (–6.1, 3.0)
Pain	70.7 ± 1.4	72.1 ± 1.4	23.7	25.3	−1.7 (–6.4, 3.0)
Activities of daily living	80.9 ± 1.3	80.8 ± 1.3	26.5	26.0	0.5 (–3.5, 4.4)
Sports and recreational activities	25.6 ± 1.9	25.2 ± 2.1	13.4	13.4	0.0 (–6.8, 6.8)
Quality of life	61.3 ± 1.9	63.9 ± 1.9	33.9	36.0	−2.1 (–8.8, 4.5)
Six-minute walk test *(m)*	362.0 ± 5.9	373.2 ± 5.9	27.0	34.5	−7.6 (–27.0, 11.9)
Timed stair test *(s)*	34.2 ± 1.3	30.6 ± 1.3	−7.2	−8.7	1.5 (–2.7, 5.7)
Range of motion of involved knee *(deg)*					
Flexion	109.6 ± 1.0	108.9 ± 1.0	−4.6	−5.6	1.0 (–2.4, 4.3)
Extension	−4.5 ± 0.3	−4.8 ± 0.4	0.7	0.6	0.1 (–1.0, 1.2)

*Intergroup mean differences (STD – TELE), adjusted for the baseline score (E1), and 95% confidence intervals were obtained using the LSMEANS statement of the GLM procedure with the CL option.

visited their orthopaedic surgeon and general practitioner. Patients in both groups reported similar levels of physical activity[31] during the intervention period and in the interval between E3 and E4.

Discussion

The present clinical trial is the first we are aware of to demonstrate in real community conditions the noninferiority of a telerehabilitation approach in comparison with a standard face-to-face service delivery approach. The uniformly small intergroup differences, as well as the narrow confidence intervals, provide strong scientific evidence for clinical noninferiority of telerehabilitation and the relevance of its utilization in patient follow-up after total knee arthroplasty. Indeed, these differences are <2% for all WOMAC sections and <1° for the range of knee motion, meeting expected recuperation levels after four months[5,9,27].

A recent North American expert consensus panel on best practices for post-acute rehabilitation after total knee arthroplasty recommended that supervised rehabilitation interventions be provided by trained health professionals shortly after discharge from the acute care setting[38]. More than 75% of the panelists also recommended individual therapy, instead of group therapy, in an outpatient setting or at home, acknowledging at the same time the major variation in rehabilitation practices and program delivery models worldwide[1,2,38]. In Canada, Australia, and the United States, at least one-third of the patients receive some rehabilitation through face-to-face home-care services[3,38-40]. As the speed and sophistication of communication technologies improve, remote supervision becomes a serious alternative for health professionals, as long as equivalent outcomes are reached. To date, we are aware of only two randomized controlled trials on the effectiveness of in-home telerehabilitation after total knee arthroplasty that have been published. The first is a pilot trial of forty-eight patients followed at home in the initial four months after hospital discharge that was reported by our team and showed no difference in the clinical effectiveness of an eight-week telerehabilitation program compared with the usual physiotherapy care[9]. The second is a randomized noninferiority trial reported by Russell et al., which compared physical and functional outcomes in sixty-five patients who received the same six-week physiotherapy program delivered either face-to-face (in outpatient clinics) or via telerehabilitation but in a simulated home environment recreated in a hospital room[12]. Our study added evidence to these previous studies and confirmed the clinical equivalence of telerehabilitation for a large cohort of patients after total knee arthroplasty and in real community conditions. However, caution should be exercised in generalizing our results to other settings, intervention regimes, and populations.

Various measures were taken to ensure the internal and external validity of our results. Subjects were selected on the basis of precise, although not excessively restrictive, criteria so that they would be representative of the target population.

TABLE VI Adverse Events and Serious Adverse Events*

	STD Group (N = 101)	TELE Group (N = 104)
Adverse events		
Patients with adverse events *(no. [%])*	16 (16)	14 (13)
Events related to study therapy *(no.)*	2†	0
Events unrelated to study therapy *(no.)*	18	18
Type of event *(no.)*		
Involved knee		
Pain	5	2
Bruising	1	0
Swelling	1	0
Signs of infection (swelling, redness, heat, or pus)	2	2
Problems with wound-healing	2	2
Mobilization under anesthesia	1†	3†§
Other		
Fall with minor symptoms	4	3
Nausea and dizziness	1	0
Oxygen desaturation	1	0
Gastroenteritis	0	1
Urinary tract infection	1	2
Back pain	1	2
Anxiety about knee recovery	0	1
Serious adverse events		
Patients with serious adverse events *(no. [%])*	9 (9)	12 (12)
Events related to study therapy *(no.)*	0	0
Events unrelated to study therapy *(no.)*	12	16
Type of event *(no.)*		
Death	1	0
Hospitalization	5	7
Degradation of the general condition	0	1†
Hip fracture due to fall	0	1†
Gastrointestinal disorder	2†	0
Rheumatologic disorder	1†	0
Cardiac arrhythmia	0	1†
Thrombophlebitis	2	2†#
Spinal surgery	0	1
Inguinal hernia surgery	1	0
Cystocele surgery	0	1
Retinal detachment surgery	0	1
Total knee arthroplasty on contralateral side	0	1

*The principal investigator at each clinical site determined whether an adverse event or serious adverse event was related to a study therapy. †One patient fell during intervention with minor consequent symptoms; the second patient had wound bleeding during knee flexion exercises at the first treatment session. †Events related to hospitalization. Note that in each group, one patient was hospitalized for an unknown reason. §Two of the three patients were hospitalized because of this event. #One of the two patients was hospitalized because of this event.

Thus, there were no restrictions related to symptoms for other lower limb joints and previous lower limb operations, provided that these operations had occurred at least nine months earlier. This time delay was chosen because a plateau in functional recovery was observed from six months after joint replacements[41,42]. Moreover, the initial functional status stratification, determined by the WOMAC baseline score, allowed us to effectively distribute the patients with various surgical histories and personal or health characteristics (comorbidities) among the two groups. Furthermore, to ensure a good representation of hospital practices, recruitment took place over a broad territory, both rural and urban, and in eight hospitals serving patients

in both official languages (English and French). Standardized procedures ensured the respect of the study protocol and the quality of the data collected throughout the study. Finally, a large proportion of the participants completed the study (97%; n = 198) and were compliant with the intervention (89%; n = 182), and our sample exhibited few negative effects.

The demonstration that telerehabilitation is not clinically inferior to face-to-face rehabilitation in the promotion of functional recovery and quality of life during the first four months after total knee arthroplasty has many implications for future rehabilitation service delivery and overall clinical pathways. Although face-to-face treatment may be necessary in a few occasions and for some patients, our results strongly suggest that in-home telerehabilitation should be used to improve accessibility of rehabilitation services in rural and remote communities and in dense urban regions where volume, time, and cost of services are also major issues. The applicability of such an alternative service-delivery approach should, however, be carefully analyzed by surgeons, health professionals, and health-policy decision makers, weighing personal and environmental factors affecting their patients having total knee arthroplasty and the organizational context.

A comparison of the costs of in-home telerehabilitation and face-to-face approaches in our related study demonstrated the contexts in which in-home telerehabilitation is cost-effective[43]. In addition to the evidence about efficacy, the cost analysis will inform the decisions of stakeholders, surgeons, and health professionals regarding the introduction of telerehabilitation to their clinical pathways. ■

NOTE: Recruitment took place at Centre hospitalier universitaire de Québec (CHU-Q; L'Hôtel-Dieu de Québec, Hôpital Saint-François d'Assise) and Centre Hospitalier affilié de l'Enfant-Jésus, Québec; Centre hospitalier universitaire de Sherbrooke (CHUS; Hôpital Fleurimont, Hôtel-Dieu), Sherbrooke; Hôpital Jean-Talon and St. Mary's Hospital Center, Montréal; and Hôpital Hôtel-Dieu, Arthabaska, Québec, Canada. The authors thank all participants, the physical therapists, and the orthopaedic surgeons of the participating centers for their contributions to the study. The authors are also grateful to the research personnel for their assistance in the study coordination, data management, and analysis.

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