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Internet-Based Outpatient Telerehabilitation for Patients Following Total Knee Arthroplasty

A Randomized Controlled Trial

By Trevor G. Russell, PhD, Peter Buttrum, BPhty, Grad Cert (Health Management), Richard Wootton, DSc, PhD, and Gwendolen A. Jull, PhD

Investigation performed at the Queen Elizabeth II Jubilee Hospital, Brisbane, Australia

Background: Total knee arthroplasty is an effective means for relieving the symptoms associated with degenerative arthritis of the knee. Rehabilitation is a necessary adjunct to surgery and is important in regaining optimum function. Access to high-quality rehabilitation services is not always possible, especially for those who live in rural or remote areas. The aim of this study was to evaluate the equivalence of an Internet-based telerehabilitation program compared with conventional outpatient physical therapy for patients who have had a total knee arthroplasty.

Methods: This investigation was a single-blinded, prospective, randomized, controlled noninferiority trial. Sixty-five participants were randomized to receive a six-week program of outpatient physical therapy either in the conventional manner or by means of an Internet-based telerehabilitation program. The primary outcome measure was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) measured at baseline and six weeks by a blinded independent assessor. Secondary outcomes included the Patient-Specific Functional Scale, the timed up-and-go test, pain intensity, knee flexion and extension, quadriceps muscle strength, limb girth measurements, and an assessment of gait. Noninferiority was assessed through the comparison of group differences with a noninferiority margin and with linear mixed model statistics.

Results: Baseline characteristics between groups were similar, and all participants had significant improvement on all outcome measures with the intervention ($p < 0.01$ for all). After the six-week intervention, participants in the telerehabilitation group achieved outcomes comparable to those of the conventional rehabilitation group with regard to flexion and extension range of motion, muscle strength, limb girth, pain, timed up-and-go test, quality of life, and clinical gait and WOMAC scores. Better outcomes for the Patient-Specific Functional Scale and the stiffness subscale of the WOMAC were found in the telerehabilitation group ($p < 0.05$). The telerehabilitation intervention was well received by participants, who reported a high level of satisfaction with this novel technology.

Conclusions: The outcomes achieved via telerehabilitation at six weeks following total knee arthroplasty were comparable with those after conventional rehabilitation.

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

Total knee arthroplasty is performed to correct deformity, improve function, maintain motion, and alleviate knee pain. Following inpatient acute postoperative care, it is common practice in the United States, Australia, and the United Kingdom to refer patients who have had a total knee arthroplasty for ongoing outpatient or community-based rehabilitation[1,2]. There is substantial research to demonstrate that long-term rehabilitation is important to facilitate recovery in muscle strength[3-7], range of motion[4,8-13], gait[14,15], proprioception[16], and activities of daily living[17,18]. For these reasons, postoperative

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rehabilitation is considered a necessary adjunct to surgery and an essential component in returning patients who have had a total knee arthroplasty to optimal functional levels[2].

Access to this rehabilitation may be difficult for many patients who have had a total knee arthroplasty, especially those who live in rural or remote areas. The distance and associated costs of travel, funding limitations, and lack of health-care providers in these communities all limit health-service availability[19]. One possible solution is the use of telerehabilitation technology to enable rehabilitation service delivery from a distance[20]. Such services not only have the potential to improve access for patients in geographically isolated areas but also may alleviate transportation cost and time demands for both the health-care system and the client; improve the continuity of client care; improve the ability to control the timing, intensity, and sequencing of a rehabilitation intervention; and provide additional benefits associated with the rehabilitation of patients in their own social and vocational environment[20].

While this technology offers great potential, it is incumbent on evidence-based professions to demonstrate the efficacy of alternative interventions. The aim of this randomized controlled trial was to evaluate the efficacy of Internet-based telerehabilitation compared with conventional outpatient physical therapy for patients who have had a total knee arthroplasty. It was hypothesized that physical and functional outcomes achieved through telerehabilitation would not be inferior to those achieved with conventional therapy.

Materials and Methods

This trial was a single-blinded, prospective, randomized, controlled noninferiority trial. A noninferiority trial seeks to determine whether a new intervention is therapeutically equivalent, or not inferior, to an existing reference intervention[21]. In this study, the new intervention, telerehabilitation, was compared with the conventional standard of rehabilitation following total knee arthroplasty in Australia, which is a face-to-face rehabilitation program with a physiotherapist. The trial was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12606000346572) and was conducted according to the extension of the CONSORT (Consolidated Standards of Reporting Trials) guideline for noninferiority trials[21]. Ethical clearance for this study was granted by the relevant human research ethics committees, and all participants were required to provide informed consent prior to their involvement in the study.

Patients who were over eighteen years of age and who had received a unicompartmental or unilateral total knee arthroplasty at a city hospital in Brisbane, Australia, were considered for this study. The following exclusion criteria were applied: an inability to walk with use of a walking aid, concomitant medical conditions that may influence the rehabilitation process, an inability to attend a six-week rehabilitation intervention, an unwillingness to refrain from receiving any supplementary rehabilitation for the duration of the study, and an inability to speak English. Participants were recruited in the immediate postoperative phase, while they were inpatients at the hospital.

Sample size calculations for a noninferiority trial[22] were performed on the primary outcome measure (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]). The noninferiority margin (Δ) was set at 1.3 WOMAC (global) points in accordance with the minimal clinically important difference reported by Angst et al.[23]. Analysis of the first thirty participants revealed a standard deviation of 1.95 scale points for the change between WOMAC (global) scores before and after treatment. With use of an alpha level of 0.05 and a power of 0.8, the sample size was estimated at twenty-seven participants per intervention group. Allowing for a 25% loss to follow-up, while maintaining this level of statistical power for the primary analysis, a total of sixty-eight subjects (thirty-four per group) were recruited.

Randomization was performed with use of a computerized random-number generator. Randomization was restricted by a permuted block design of size four with stratification to one of two intervention physical therapists. Stratification to physical therapist was considered important to ensure that each physical therapist provided treatment to half of the participants in each group, thus minimizing any individual practitioner biases. Randomization codes were sealed in sequentially numbered opaque envelopes, which were assigned to participants in their order of recruitment by an independent administrative officer.

Participant assessments conducted before and after the intervention were performed by a single research assistant who had no other involvement in the study and who was blinded to participant group assignment. Participants were reminded prior to each assessment not to reveal details of their group allocation.

Participants were randomly allocated to receive a six-week rehabilitation program either in the conventional manner (the control group) or remotely by means of a video-linked telerehabilitation program (the telerehabilitation group). The intervention commenced approximately one week after hospital discharge for all participants and consisted of one treatment session with a duration of forty-five minutes per week. Integral to each treatment session was the development and review of a comprehensive home exercise program that participants were encouraged to complete twice daily at home. To standardize the treatment given in each group, a clinical pathway protocol was developed. This protocol provided a week-by-week guide on relevant assessment and treatment items and goals to address. For example, guidelines were presented on how to appropriately address items such as range of motion, muscle strength, mobility, swelling management, education, and the home exercise program. Within the bounds of the protocol, the physical therapist was at liberty to choose techniques and exercises most relevant to the participant. Prior to hospital discharge, all received a standardized inpatient rehabilitation program based on local postoperative guidelines.

Control Group

Rehabilitation for the control group was administered in an outpatient physical therapy department, according to standard clinical protocol. Intervention sessions were limited to forty-five minutes, during which the physical therapist administered an appropriate

assessment, treatment techniques, and exercise interventions within the bounds of the local postoperative guidelines.

Telerehabilitation Group

Participants in the telerehabilitation group received all rehabilitation through real-time interaction with a physical therapist across a low-bandwidth (18-kbit/sec) Internet-based telerehabilitation system (described below). Intervention sessions were limited to forty-five minutes, during which physical therapists administered a rehabilitation program that consisted of self-applied techniques under the guidance of the remote therapist, along with exercises and education in the postoperative management of the total knee replacement. For the purposes of this study, participants and physical therapists were located in isolated rooms of the hospital. The participant's room was arranged to resemble a home environment and contained only common household equipment such as towels, a chair, and a tape measure. Assessment and treatment was individualized for each participant within the bounds of the same local postoperative guidelines used for the control group.

The Telerehabilitation System

A computer-based telerehabilitation system specifically engineered for this study was used to enable the remote rehabilitation consultations. The system was designed to enable low-bandwidth (18-kbit/sec) videoconferencing between sites via dial-up Internet connections. In addition to real-time videoconferencing, the system included a battery of measurement tools that could be used to quantify the participant's physical performance across the Internet link. The system also enabled the physical therapist to capture high-quality (640 × 480-pixel resolution) video clips of participants at any time during a consultation by means of an integrated store-and-forward file mechanism to enable a more detailed observation of the participant. Previous work by the authors has demonstrated the validity and reliability of this system in enabling the accurate assessment of physical performance by means of the Internet[24-29].

Outcome Measures

Outcome measurements were performed on all participants at the commencement of the first treatment session and at the conclusion of the final treatment session in week 6.

Primary Outcome

The primary outcome measure was the WOMAC. The WOMAC fulfills the conventional criteria for validity, reliability, and sen-

TABLE I Baseline Comparison of Physical and Functional Outcome Measures in Control and Telerehabilitation Groups

Outcome	Control Group (N = 34)		Telerehabilitation Group (N = 31)		Statistical Analysis*	
	Mean	Standard Deviation	Mean	Standard Deviation	F Value	P Value
Age *(yr)*	69.6	7.2	66.2	8.4	3.03	0.09
Time from discharge to intervention *(days)*	10.2	4.1	9.3	3.7	0.78	0.38
Active flexion range *(deg)*	92.1	14.29	85.3	11.9	4.31	0.04†
Passive flexion range *(deg)*	95.4	15.7	91.9	11.5	1.04	0.31
Extension range *(deg)*	7.1‡	4.9	6.1‡	4.7	0.76	0.39
Muscle strength (quadriceps lag) *(deg)*	16.3	5.7	19.3	8.7	2.66	0.11
Limb girth (knee) *(cm)*	44.8	3.6	46.9	3.3	5.60	0.02†
Limb girth (calf) *(cm)*	39.4	3.8	40.3	3.4	1.03	0.31
Timed up-and-go *(sec)*	26.8	16.6	28.8	12.1	0.33	0.57
Patient-Specific Functional Scale *(points)*	4.6	1.8	4.2	1.2	1.25	0.27
WOMAC§ *(points)*						
Pain	3.7	1.8	4.3	2.7	1.28	0.26
Stiffness	4.4	2.3	5.3	2.3	2.77	0.10
Function	4.1	1.8	4.8	2.5	1.87	0.18
Global	4.0	1.7	4.8	2.2	2.54	0.12
Spitzer Quality-of-Life Uniscale *(points)*	3.8	2.8	3.1	2.1	1.19	0.28
Visual analog scale pain score *(points)*	5.2	1.5	4.4	1.4	4.11	0.06
Gait# *(points)*	12.5	6.8	13.2	5.8	0.20	0.66

*Statistical analysis was performed with a univariate general linear model with a fixed factor of group. †Denotes significance at the $p < 0.05$ level. ‡Positive numbers denote a lack of full extension. §WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index. #Assessed according to the Gait Assessment Rating Scale[39].

sitivity to change[23,30-34] and has been used extensively in total knee replacement and osteoarthritis clinical trials.

Secondary Outcomes

Secondary outcome measures included the Patient-Specific Functional Scale[35], the Spitzer Quality-of-Life Uniscale[36], the timed up-and-go test[37], and pain intensity rated on a visual analog scale (VAS)[38]. A series of physical measures that were recorded included active and passive knee flexion and knee extension, quadriceps muscle strength assessed by knee extension lag during a straight-leg raise, girth measurements at the knee, and an assessment of gait with use of the Gait Assessment Rating Scale[39].

In addition to these outcomes, all participants were asked to complete an exercise log at the end of each day, indicating the number, nature, and duration of exercise completed during that day. Participants allocated to the telerehabilitation group were also requested to complete a satisfaction questionnaire. The questionnaire consisted of seven items related to their experience with, and perception of, the telerehabilitation sessions. Participants responded to each question on a 10-cm VAS.

Data Analysis

An alpha level of 0.05 was used for all analyses. Baseline characteristics of the intervention group were compared with use of the Mann-Whitney U test (nominal-interval data) and univariate general linear model statistics (continuous data).

Noninferiority was evaluated by calculating the within-group differences from baseline on the primary outcome measure (WOMAC) and the 95% confidence interval of these differences and observing whether this confidence interval, centered on the observed difference between the groups, lay entirely between $-\Delta$ (1.3 WOMAC global points) and zero[22].

The clinical treatment effect of each intervention group was further analyzed with use of a linear mixed model statistic on both primary and secondary outcomes. The statistic was calculated with observed outcomes as the dependent variables and with fixed factors of treatment group (telerehabilitation and control) and assessment point (baseline and after the intervention). This analysis was conducted to assess the contribution of individual factors and their combined interactions on the dependent variable. The outcome of primary interest was the interaction effect between group and time. Fixed predicted values and residuals from these analyses were used for data inspection purposes.

Finally, compliance with the home exercise program in each intervention group was compared with the Mann-Whitney U statistic, and the participant satisfaction questionnaire was analyzed descriptively.

Source of Funding

This study did not receive any external funding.

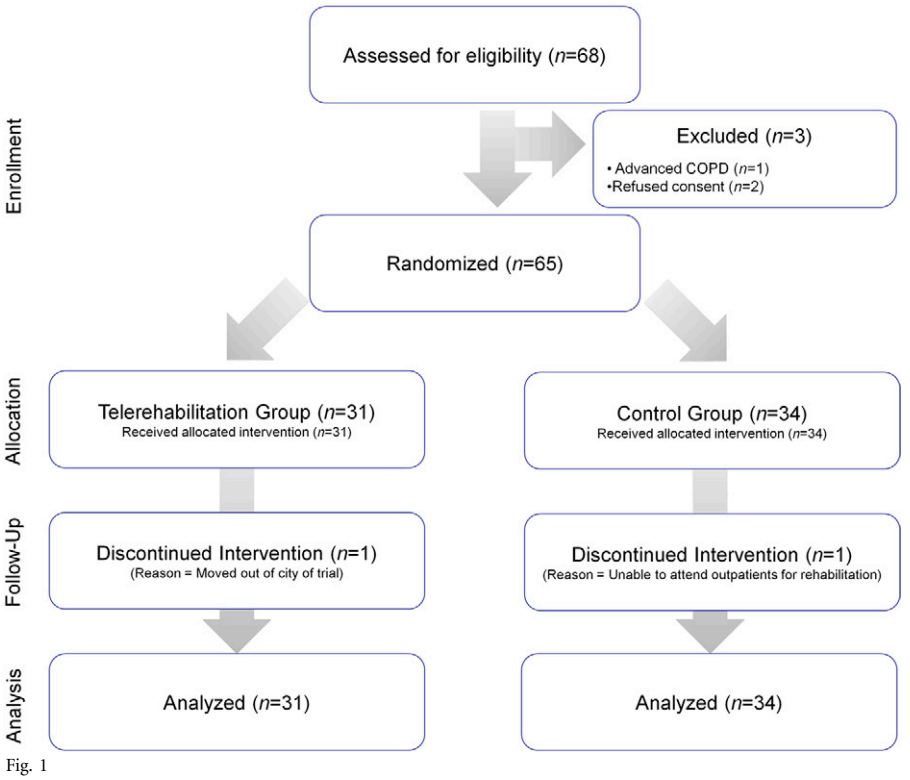

Fig. 1

Flow diagram of participant progress through the randomized controlled trial. COPD = chronic obstructive pulmonary disease.

Results

Sixty-five participants were recruited and randomized into the trial, with thirty-four and thirty-one allocated to the control and telerehabilitation groups, respectively (Fig. 1). One participant from each group dropped out in week 2 of the trial: one in the telerehabilitation group moved away from the study location and one in the control group cited transportation difficulties. Neither participant attended the assessment after the intervention so their data could not be used in the analysis.

Participant Characteristics

Of the sixty-five participants in the study, sixty (92%) had a primary semiconstrained total knee replacement, four (6%) had an unconstrained unicompartmental replacement, and one participant (2%) had a revision of a semiconstrained total knee replacement. The participants had a mean age (and standard deviation) of 68 ± 7.9 years. There was a nonsignificant difference ($Z = -1.61$, $p = 0.11$) with regard to sex between the control and telerehabilitation groups, with 41% and 61%, respectively, of the participants being female.

Of the twenty-four outcome measurements performed at baseline, two variables (8%) demonstrated significant differences between intervention groups: (1) the measurement of active knee flexion was found to be higher in the control group, and (2) the limb girth measurements at the knee joint line were larger in the telerehabilitation group (Table I).

Primary Outcome

The absolute mean change and percentage improvement from baseline for the primary outcome measure (WOMAC global) at the study end point were 2.16 and 52.7%, respectively, for the control group and 3.26 and 67.6% for the telerehabilitation group. The difference between the groups was not found to be significant ($F = 3.11$, $p = 0.08$).

Both groups had significant and clinically important improvements from baseline ($p < 0.01$ for all).

The one-sided 95% upper confidence interval for the treatment difference was 2.07 points, which is outside the predetermined noninferiority margin of 1.3 points. It is im-

TABLE II Change in Outcome Measures Before and After Treatment and Results of the Linear Mixed Model Analysis for Each Outcome Measure

Outcome	Control Group (N = 34)		Telerehabilitation Group (N = 31)		Difference Between Groups		Statistical Analysis	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	95% Confidence Interval	F Value	P Value
Primary outcome measures								
WOMAC† *(points)*								
Pain	2.19	1.76	2.97	2.31	0.78	–0.26 to 1.83	1.40	0.24
Stiffness	1.84	2.43	3.30	2.32	1.46	0.24 to 2.68	4.29	0.04*
Function	2.45	1.84	3.52	2.35	1.07	–0.01 to 2.14	1.83	0.18
Global	2.16	1.72	3.26	2.04	1.10	0.14 to 2.07	3.11	0.08
Secondary outcome measures								
Active flexion range *(deg)*	17.82	12.31	19.82	10.78	–2.00	–7.86 to 3.86	0.26	0.61
Passive flexion range *(deg)*	17.17	13.86	17.89	10.50	–0.72	–6.97 to 5.52	0.03	0.86
Extension range *(deg)*	3.62	3.94	3.45	3.45	–0.16	–2.05 to 1.73	0.02	0.89
Muscle strength (quadriceps lag) *(deg)*	5.70	5.18	9.24	7.25	3.54	0.36 to 6.71	1.46	0.23
Limb girth (knee) *(cm)*	2.36	1.93	2.22	1.83	–0.15	–1.10 to 0.80	0.00	0.95
Limb girth (calf) *(cm)*	2.12	2.90	1.04	1.48	–1.08	–2.26 to 0.10	0.76	0.39
Timed up-and-go *(sec)*	12.19	10.12	16.33	10.94	4.15	–1.21 to 9.50	1.61	0.21
Patient-Specific Functional Scale *(points)*	3.97	1.66	5.05	1.42	–1.08	–1.86 to –0.30	4.28	0.04*
Spitzer Quality-of-Life Uniscale *(points)*	1.61	1.78	1.53	2.67	–0.08	–1.24 to 1.07	0.58	0.45
Visual analog scale pain score *(points)*	3.29	1.31	3.07	1.55	–0.28	–0.94 to 0.49	0.22	0.95
Gait† *(points)*	6.94	6.00	7.67	4.35	0.73	–1.94 to 3.40	0.17	0.68

*Denotes significance at the $p < 0.05$ level. †WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index. †Assessed according to the Gait Assessment Rating Scale[39].

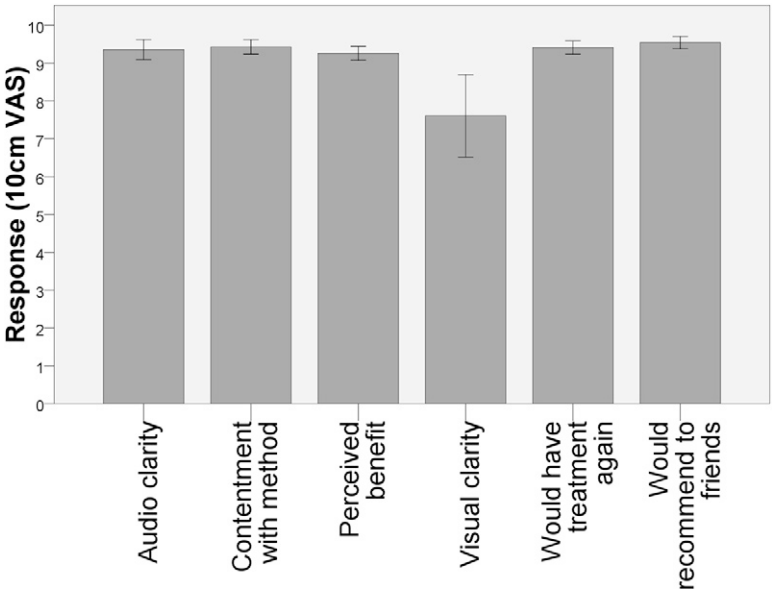

Fig. 2

The satisfaction of the participants in the telerehabilitation group with the new mode of delivery. The bars represent the mean and 95% confidence interval. VAS = visual analog scale.

portant to note that although the previously stated noninferiority margin was exceeded, the improvement in the telerehabilitation group exceeded that of the control group, thus conforming to the prospective criteria of noninferiority.

Secondary Outcomes

The mean change from baseline for each secondary outcome measure and the results of the linear mixed model statistic are presented in Table II. Nonsignificant differences between the telerehabilitation and control groups were found for all outcomes with the exception of the Patient-Specific Functional Scale ($F = 4.28$, $p = 0.04$) and the stiffness subscale of the WOMAC questionnaire ($F = 4.29$, $p = 0.04$). Close inspection of the data revealed that the significant difference was in favor of the telerehabilitation group in both cases.

Compliance with the home exercise program, evaluated through the completion of an exercise diary, revealed a mean compliance (and standard deviation) of 1.7 ± 0.8 exercise sessions per day in the control group compared with 2.2 ± 0.5 sessions per day in the telerehabilitation group. Differences were nonsignificant ($Z = -1.55$, $p = 0.12$). Responses to the satisfaction questionnaire completed by the telerehabilitation group are presented in Figure 2.

Discussion

Telerehabilitation is a new method of service delivery that has promised to revolutionize the delivery of rehabilitation services. To date, little evidence supports the efficacy of such clinical interventions. This study provides empirical evidence that such technology can be used to provide effective rehabilitation services after acute postoperative care for patients who have undergone total knee arthroplasty. The results were found to support the study hypothesis that participants with telerehabilitation intervention achieved physical and functional outcomes at six weeks that were not inferior to those achieved with traditional face-to-face therapy.

The success of the randomization procedure was confirmed by largely homogeneous groups at baseline, and the physical and functional measurements of the participants in this study at baseline are consistent with those reported elsewhere[40-43]. All physical and functional measures assessed in this randomized controlled trial were found to improve both clinically and significantly ($p < 0.01$) from baseline in both intervention groups and are consistent with those reported elsewhere[44-48]. This trial was designed and powered to test for noninferiority of the telerehabilitation intervention compared with the conventional care group on the primary outcome measure of the WOMAC (global) score. The prospective noninferiority criterion of 1.3 WOMAC points was exceeded in this study as the one-sided 95% upper confidence interval for the treatment difference was 2.07 points, with greater improvements achieved in the telerehabilitation group than in the conventional group. This result indicates that the telerehabilitation intervention was not inferior to the conventional intervention and actually produced some outcomes that were clinically superior. The linear mixed model statistic revealed that this clinical improvement did not reach significance for the global WOMAC score ($p = 0.08$); however, a significant difference in outcomes, in favor of the telerehabilitation intervention, was achieved for the stiffness subscale of the WOMAC scale ($p = 0.04$). Analysis of the secondary outcome measures revealed no difference in outcomes ($p > 0.05$ for all), with the exception of the

Patient-Specific Functional Scale, which was significantly better for the telerehabilitation group ($p = 0.04$).

A number of factors may have facilitated rehabilitation in the telerehabilitation group. The nature of the telerehabilitation intervention, which relied more on the education of patients in the self-application of mobilization techniques and had a greater emphasis on exercise, may have provided participants with a heightened opportunity for self-treatment outside the formal physical therapy treatment session. A higher reliance on education in the telerehabilitation group may have assisted in producing a higher technical proficiency in the home exercise program. Greater education has been demonstrated to facilitate a so-called internal locus of control, which is recognized as an important factor in patient compliance[49,50]. This observation is at least partially supported by exercise diary data, which revealed that the participants in the control group completed an average of 1.7 ± 0.8 exercise sessions per day compared with an average of 2.2 ± 0.5 in the telerehabilitation group.

In agreement with previous studies in telehealth[51], a high level of satisfaction (an average score of >9 on the 10-cm VAS) was observed for all satisfaction questionnaire items, with the exception of question 4, which related to the visual quality of the videoconference. Patients reported a high level of contentment with the service and indicated that they would have this method of rehabilitation again and recommend it to friends. The high rating for audio clarity was encouraging as this provides evidence that clear audio signals can be obtained by means of low-bandwidth, Internet-based communications. A lower mean satisfaction rating for visual clarity (7.6 ± 2.9) was reported for question 4. The image quality did not appear to affect the overall perceived benefit of the telemedicine intervention. The video images possible by means of high-speed broadband networks will improve the quality of video images in future applications.

A number of limitations in the current study are acknowledged. By requiring the participants to attend a simulated home environment in the hospital, their compliance with the telerehabilitation intervention may have been greater than if the intervention had been offered in the home, where they could simply have elected not to turn on the device. A limited follow-up period of six weeks has implications for the interpretation of the results as the long-term effects of this rehabilitation program are unknown. Therefore, future research must utilize extended follow-up periods to better characterize the long-term implications of this alternative mode of service delivery. Finally, the quality of the Internet connection between the telerehabilitation units was easily monitored in this controlled environment, a factor that may be variable when delivered in a patient's home. For these reasons, this investigation should be considered as a proof-of-principle study, and future research should be conducted in the communities and homes of isolated patients to explore the impact of these factors. Future research should also incorporate economic analyses to assess the fiscal impact of remotely delivered physical therapy. Such analyses are critical as health-care providers are unlikely to implement telerehabilitation without clear evidence of its financial viability and sustainability.

Managing the rehabilitation needs of a growing number of patients who have had total knee arthroplasty presents a major challenge to clinicians and health-policy decision makers. Alternate service-delivery models need to be considered to address these demands and to improve access to services. This trial provides evidence for the efficacy of low-bandwidth telerehabilitation in producing clinically relevant physical and functional results six weeks after patients have had a total knee replacement. ■

Trevor G. Russell, PhD
Gwendolen A. Jull, PhD
Division of Physiotherapy,
School of Health and Rehabilitation Sciences,
University of Queensland, Brisbane 4072, Australia.
E-mail address for T. Russell: t.russell@shrs.uq.edu.au

Peter Buttrum, BPhty, Grad Cert (Health Management)
Department of Physiotherapy, QEII Jubilee Hospital,
Kessels Road, Brisbane 4108, Australia

Richard Wootton, DSc, PhD
The Scottish Centre for Telehealth, Top Floor,
Foresterhill Lea,
Foresterhill, Aberdeen AB25 2ZY, Scotland

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