ORIGINAL ARTICLE

Functional and Clinical Outcomes of Telemedicine in Patients With Spinal Cord Injury

Laura Dallolio, MD, Mauro Menarini, MD, Sandra China, MD, Manfredi Ventura, MD, Andy Stainthorpe, PhD, Anba Soopramanien, MD, Paola Rucci, DStat, Maria Pia Fantini, MD, on behalf of the THRIVE Project

ABSTRACT. Dallolio L, Menarini M, China S, Ventura M, Stainthorpe A, Soopramanien A, Rucci P, Fantini MP, on behalf of the THRIVE Project. Functional and clinical outcomes of telemedicine in patients with spinal cord injury. Arch Phys Med Rehabil 2008;89:2332-41.

Objective: To compare the 6-month outcomes of telerehabilitation intervention with those of standard care for spinal cord injury (SCI).

Design: Multicenter randomized controlled trial.

Setting: Home, nursing, or unspecialized hospital care provided after discharge from a spinal cord unit.

Participants: Adult patients with nonprogressive, complete, or incomplete SCI discharged for the first time from the spinal cord unit to their homes (Belgium and Italy) or to their homes or another facility (England).

Interventions: All patients received the standard care they would have normally received after discharge from the spinal cord unit. In addition, patients in the telemedicine group received 8 telemedicine weekly sessions in the first 2 months, followed by biweekly telemedicine sessions for 4 months.

Main Outcome Measures: Functional status at 6 months, clinical complications during the postdischarge period, and patient satisfaction.

Results: No significant differences in the occurrence of clinical complications were found between the study groups. A higher improvement of functional scores in the telemedicine group was found only at the Italian site: FIM total score 3.38±4.43 (controls) versus 7.69±6.88 (telemedicine group), FIM motor score 3.24±4.38 (controls) versus 7.55±7.00 (telemedicine group; $P<.05$). Items contributing to this difference were grooming, dressing upper body, dressing lower body, and bed/chair/wheelchair transfer. Higher satisfaction with care was reported by patients in the telemedicine group across all sites.

Conclusions: Our study provides some of the first quantitative evidence, based on results from 1 site, that telerehabilitation may offer benefits to patients discharged from a spinal cord unit compared with standard care in terms of functional improvement. Further research is warranted to confirm or disprove this finding.

Key Words: Patient satisfaction; Rehabilitation; Spinal cord injuries; Telemedicine.

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SPINAL CORD INJURY can cause severe disability and a variety of serious medical complications with a high personal and economical burden of care.[1] The incidence of SCI in both Northern America and Europe has increased over the past 30 years, whereas the prevalence has remained more or less the same.[2] In Europe, there is an increasing incidence of more severe injuries, with a higher percentage of injuries being complete and causing tetraplegia.[2]

The rehabilitation of persons with these more severe injuries is usually provided in specialized spinal cord units, which is typically expensive, and the LOS can extend to several months.[3] Because the availability of space in these spinal cord units is limited, interventions to reduce LOS may increase the availability of beds and prevent delay of admission to spinal cord unit. Reducing LOS may also allow more persons to benefit from the specialized rehabilitation that these spinal cord units can provide to newly injured patients. Although there have been improvements in the clinical treatment of patients with SCI, medical complications after discharge from acute rehabilitation remains high.[4] One potential way to reduce LOS without compromising quality of care and increasing complications is to extend the support from the inpatient spinal cord unit to the home of patients with SCI in the form of telemedicine, which may improve the quality of care after discharge and further reduce complications after discharge.

List of Abbreviations

ANOVA	analysis of variance
CI	confidence interval
IRT	item response theory
LOS	length of stay
SCI	spinal cord injury
SCIM	Spinal Cord Independence Measure
SCIM II	Spinal Cord Independence Measure II
THRIVE	Telerehabilitation Through Interactive Video Endorsement

From the Dipartimento di Medicina e Sanità Pubblica, Bologna, Italy (Dallolio, Stainthorpe, Rucci, Fantini); Spinal Cord Unit—Montecatone Rehabilitation Institute, Imola (Bologna, Italy), (Menarini, China); Centre de Traumatologie et de Réadaptation, Brussels, Belgium (Ventura); Salisbury Health Care National Health Service Trust, Salisbury, UK (Soopramanien).

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Reprint requests to Laura Dallolio, MD, Dipartimento di Medicina e Sanità Pubblica, Via San Giacomo 12, Bologna, Italy, e-mail: *laura.dallolio@unibo.it.*

The THRIVE project includes the following investigators: Telemedicina Rizzoli, Bologna: Roberto Ongaro, David Menasci. Dipartimento di Medicina e Sanità Pubblica, Università di Bologna: Maria Pia Fantini, Laura Dallolio, Paola Rucci, Andy Stainthorpe. Spinal Cord Unit—Montecatone Rehabilitation Institute, Imola (Bologna): Mauro Menarini, Sandra China, Mario Loffredo, Francesco Gambino, Anna Maria Cresciulli, Daniela Monducci, Giovanna Ferrara, Elisabetta Cardelli. Health Information Management, Bruxelles: Marco D'Angelantonio, Reinhard Prior, John Oates. Centre de Traumatologie et de Réadaptation, Bruxelles: Manfredi Ventura. Salisbury Health Care National Health Service Trust, Salisbury: Helen Pain, Anba Soopramanien.

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The use of telemedicine plays an important role in improving the continuity of health care from specialized units to patients' homes.[5]

Since the 1960s, telemedicine has been used in a variety of health care settings, and its efficacy has been demonstrated in certain patient populations.[6-10] For example, telemedicine has been shown to confer benefits in terms of decreasing hospitalizations, improving glycemic control, blood pressure, and cholesterol in persons with diabetes mellitus.[11,12] Telemedicine has also been shown to improve cognitive status, treatment compliance, and stability of chronic disease for homebound elderly persons with common complex comorbidities.[13] Other studies have demonstrated improved outcomes with telemedicine in persons with depression, hypertension, and heart failure.[14-16] Telemedicine also has potential psychologic advantages and may assist in reducing the isolation of patients and their caregivers.[17] While useful data are emerging on some home-based telemedicine applications, good quality studies are still scarce, and generalizability of most recent assessments may be limited. Few studies have specifically evaluated the efficacy of telerehabilitation in patients with SCI or its potential limitations. The first study is based on 8 patients and demonstrated that pressure ulcers can be successfully managed via telerehabilitation.[18] Another study has emphasized the need for standardized electronic protocols to assist telehealth providers in the recognition and management of autonomic dysreflexia, a complication of SCI that may put patients at risk of serious morbidity and even death.[19] The largest study conducted to date[5] is based on 111 subjects who were randomized to video-based intervention for 9 weeks, telephone-based intervention for 9 weeks, or standard care, and followed for at least 1 year to monitor hospitalization days, depressive symptoms, and health-related quality of life. The authors indicated that telephone or video-based support was associated with a lower number of mean annual hospitalization days than standard care, but no clear evidence was found on differential functional improvement in the 3 treatment groups. Moreover, no data on clinical outcomes were collected.

To provide a quantitative assessment of the efficacy of telemedicine in the rehabilitation of patients with SCI, THRIVE was established and funded through the Fifth Framework Programme of the European Commission in 2003. This randomized controlled trial was conducted at 4 spinal cord units, 1 located in Belgium (Centre de Traumatologie et Réadaptation, Brussels), 1 in Northern Italy (Montecatone Rehabilitation Institute, Bologna), and 2 in the UK (Duke of Cornwall Spinal Treatment Centre, Salisbury, and the London Spinal Injuries Unit of Royal National Orthopaedic Hospital, Stanmore). The study evaluated the efficacy of a defined spinal cord unit–delivered telemedicine protocol compared with the standard care provided to patients discharged to their homes or to nonspecialized institutions (hospitals or nursing homes) in terms of functional improvement, clinical outcomes, and satisfaction with care. Preliminary data on 12 patients participating in the THRIVE project suggest several potential benefits of telemedicine intervention.[20] These potential benefits include providing advice that patients may not have otherwise received, a better understanding of family interaction, and improved ability in determining whether face-to-face practitioner intervention is required for medical problems.

The aim of this study is to compare the outcomes of standard care at 6 months postdischarge with those of telemedicine in patients with SCI participating in the THRIVE, in terms of functioning, disability, number and type of complications, and satisfaction with care.

METHODS

Study Participants

Study participants included adult patients with SCI discharged for the first time from the spinal cord unit to their homes (Belgium and Italy) or to their homes or another facility (UK).

Inclusion criteria were (1) having nonprogressive, complete, or incomplete SCI with lesion level at C4-L2, (2) living within the catchment area of the spinal cord unit (UK, Belgium) or being willing to travel to the spinal cord unit with their caregiver for 2 ambulatory follow-up visits (Italy) at months 2 and 6 after discharge, (3) age 18 years or older and willingness to participate with their caregivers (informed consent signed by the patient and the principal caregiver), and (4) having suitable home (nursing home, hospital) facilities to install broadband lines and videoconference equipment.

Enrolled participants were excluded from the study in the following circumstances: (1) the patient withdrew from the trial for any reason before the end of the trial period either by declaring voluntary withdrawal or by not participating in more than 2 consecutive scheduled telemedicine sessions, or (2) the patient was readmitted to the spinal cord unit or another hospital for a period lasting more than 2 weeks.

The protocol for the THRIVE study was subject to review by the appropriate ethics review group in the 4 participating centers. Eligible subjects provided written informed consent after receiving a complete description of the study and having an opportunity to ask questions.

Study Design and Interventions

The study was a multicenter randomized controlled trial. A computerized randomization sequence was generated for each research center. The randomization list was kept by the scientific coordinator of the project.

Eligible patients were randomized to treatment 8 days before their discharge from the spinal cord unit to facilitate installation of telemedicine equipment in their accommodation. Telerehabilitation was performed by use of a dedicated videoconferencing platform. The platform was composed of the following items: 1 central unit (set-top box), 1 webcam, 1 microphone with noise and echo cancellation, 1 remote controller, 1 universal serial bus electronic security key, 1 audio/video television connection cable and the related Syndicat des Constructeurs d'Appareils Radiorécepteurs et Téléviseurs (SCART) adapter, 1 power cable, 2 audio interconnection cables, 1 untwisted cable to connect to the integrated services digital network socket or to the asymmetric digital subscriber line modem, and 1 system reference manual. The videoconferencing platform was powered by software specifically designed to allow operation by people with limited manual skills and to allow the sending and storage of video messages.

Prior to discharge, baseline functional measurements were completed.

Disability was assessed at the follow-up visits by independent evaluators not involved in treatment of the patient. All patients received the standard home, nursing, or unspecialized hospital care they would normally have received after discharge from the spinal cord unit. In addition, patients in telemedicine group received 1 telemedicine session every week during the first 2 months (for a total of 8 sessions) followed by 9 telemedicine bimonthly sessions. Sessions lasted approximately 45 minutes and were of 2 types: type 1 sessions involved at least 1 medical doctor and 1 nurse, and type 2

sessions involved a physiotherapist and/or 1 occupational therapist.

Type 1 session consisted of a structured interview to collect signs and symptoms usually assessed in the clinical routine. The following items were investigated: any type of acute complaint, signs of new pressure ulcers, episodes of fever, bladder and bowel function, signs of urinary tract infections, pulmonary complications and autonomic dysreflexia, and symptoms of depression or anxiety. During the telemedicine videoconference, patients and their caregivers also had the opportunity to share views and concerns as well as to receive professional advice. At the end of the telemedicine session, physicians and nurses formulated specific recommendations to address medical and psychologic problems to be passed by caregivers on to the therapists or the general practitioners responsible for the care of the patients. In some cases, general practitioners attended the telemedicine sessions to be updated on the patient's progress.

Examples of items in the structured interview during type 1 sessions include, "Have there been requests to any personnel outside the spinal unit (eg, general practitioner, social workers, therapists)?" and "Have you had episodes of fever?" During type 2 sessions, therapists assessed a number of functional parameters related to mobility (ie, sitting up, sitting in bed) and other skills (ie, handwriting, use telephone) by means of a structured interview. Specific recommendations were given to address issues related to patient mobility such as transfer from bed to wheelchair, use of aids, prostheses, and use of remote controls for electronic devices in the immediate surroundings (ie, to turn on/off lights, to open doors).

Outcomes

Functional status was assessed using the FIM and by SCIM II.

Patients were assessed by trained clinicians 10 days before discharge (before randomization) and 6 months after discharge. The increase in FIM and SCIM II score from discharge to 6 months was used as an indicator of improvement.

In addition, clinical outcomes were monitored to ascertain whether the use of telemedicine was associated with lower incidence of complications. More effective monitoring permitted prompt intervention where necessary. The complications monitored during the first 6 months postdischarge included skin ulcers (pressure ulcers), urinary tract infections, problems associated with the use of urinary catheters, pulmonary infections, fever, pain, autonomic dysreflexia, and deep vein thrombosis. The medications prescribed to patients, the number and length of any readmissions to the spinal cord unit, and the number and length of emergency admissions to other hospitals were also monitored. Complications were assessed by spinal cord unit physicians who were not involved in the clinical care of those patients at months 2 and 6 ($\pm$1 week) on the occasion of a scheduled follow-up visit to the spinal cord unit or during an outpatient visit of spinal cord unit personnel to a patient's home or nursing home or general hospital. Patient and caregiver diaries were also used to record any type of complication and the associated treatment. Satisfaction with care was assessed using a specific questionnaire developed for this trial by 1 of the authors (A. Stainthorpe). Questions were rated on an ordinal scale (0–10), where 0 denotes the least satisfaction and 10 the most satisfaction.

Instruments

The FIM scale is a widely used standardized functional outcome measure consisting of 13 motor and 5 cognitive items rated on an ordinal scale.[21] The FIM scale has a minimum score of 18, indicating complete dependence, and a maximum score of 126, indicating total functional independence. Cross-cultural validity of the FIM scale was investigated by Lawton et al.[22] These authors emphasized that data from FIM motor scale for patients with SCI should not be pooled in their raw form or compared between countries. In fact, the FIM items need to be recalibrated using IRT analysis in order to ensure that their performance is the same across countries. However, IRT calibration procedures require large sample sizes. Because our study is not adequately powered for this purpose, we analyzed the FIM scores separately by site.

The SCIM is a disability scale developed by Catz et al[23] to assess the ability of the individual patient with a spinal cord lesion to perform daily tasks. SCIM II covers 18 tasks, all activities of daily living, grouped into 4 areas: Self-Care (scored 0–20), Respiration and Sphincter Management (0–40), Mobility in Room and Toilet (0–10), and Mobility Indoors and Outdoors (0–30). The total score ranges between 0 and 100. Patients are evaluated by observation. The validity and reliability of SCIM II were confirmed by Itzkovich et al.[24] The use of SCIM in cross-cultural trials is justified only for Spinal Cord Independence Measure, version III[25]; therefore, also for this scale, we analyzed the data separately by site.

Power Analysis

A sample size of 90 subjects a treatment group (ie, 30 telemedicine and 30 controls a site [Salisbury and Stanmore were combined to form 1 site] for a total of 180 subjects) was determined by setting the α level at .05 and the power at 80%. The software used was Power and Sample Size Calculations,[26] a free software program that can be downloaded at *http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize*.

Our computation assumes that the mean difference is .42 (corresponding to means of .87 vs .45 on the standardized FIM score in the telemedicine and control groups), and the common within-group SD is 1. This effect size was selected as the smallest effect that would be important to detect.

Statistical Analyses

The demographic and clinical characteristics of patients were compared among sites using the chi-square test for categorical variables and the 1-way ANOVA for continuous variables (such as age). The clinical outcomes were compared among groups using the chi-square test for categorical variables (occurrence of complications) and the 1-way ANOVA for continuous variables (FIM score, SCIM score). A paired-sample t test was used to analyze the gain in function at 6 months postdischarge. Because of the exploratory nature of the study, no adjustment of the probability level was performed for multiple comparisons. SPSS version 14.0[a] was used to conduct all the analyses.

RESULTS

The 137 study participants were recruited at 4 spinal cord units between November 2003 and February 2006. The patient flow is detailed in figure 1. Sixty-nine patients were randomly assigned to the telemedicine group (telemedicine group) and 68 to the control group; 62 patients in the telemedicine group and 65 patients in the control group received the intervention. The demographic and clinical characteristics of patients are provided in table 1. The mean age of the patients recruited was 40 years (range, 18–85y), and 107 (84.2%) were men. Comparison between sites revealed no differences on mean age, sex, status, occupational level, financial status, SCIM, and FIM scores at discharge or median LOS in the spinal cord unit (Kruskal-Wallis test=2.01, P=.366).

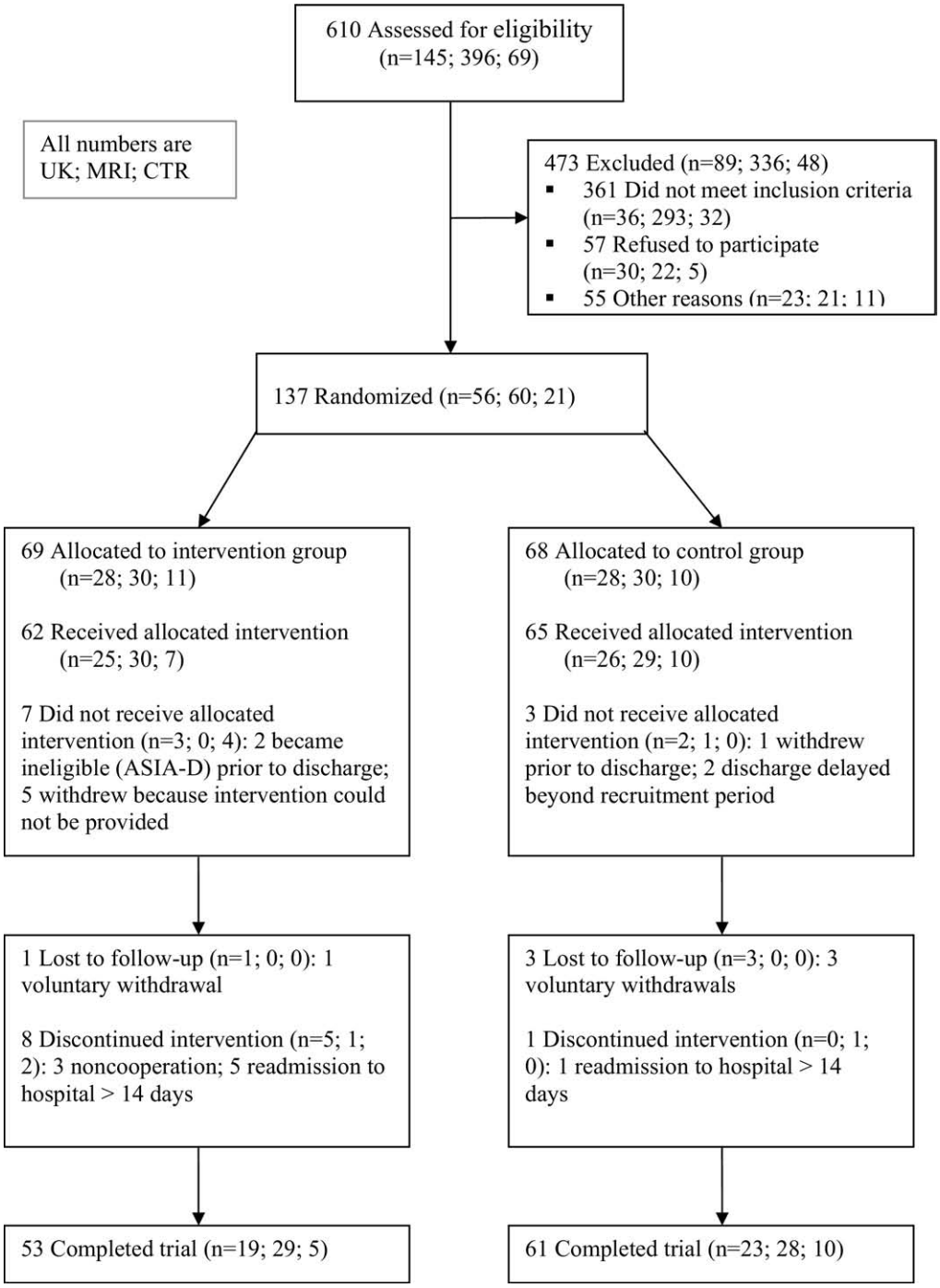

Fig 1. Patient flow. Abbreviations: ASIA-D, American Spinal Injury Association-D; CTR, Belgian site; MRI, Italian site; UK, English sites.

However, patients from the Italian site were more likely to be living with other people than patients from the other sites (χ^2=33.1, P<.001). Moreover, academic achievement was higher in the UK than in the other sites (χ^2=55.4, P<.001). The demographic characteristics and the disability levels at discharge of subjects in the telemedicine and control groups were comparable.

Clinical outcomes at 2 and 6 months were compared between telemedicine and standard care in patients for whom data were available (table 2). There were no significant differences in clinical complications between the 2 study groups. Readmissions of patients who entered the study and received the intervention numbered 17 in the control group and 9 in the telemedicine group (see table 2). Readmitted patients numbered 12 and 9, respectively. Three patients in the control group were admitted more than once. The percentage of readmitted patients did not differ between the 2 groups (18.5% vs 14.5%, χ^2=0.36, P=.550). The change in FIM and SCIM scores

Table 1: Demographic and Clinical Characteristics of Participants by Site

Characteristics	Bologna (n=59)	Brussels (n=17)	Salisbury and Stanmore (n=51)
Men, n (%)	53 (89.83)	12 (70.59)	42 (82.35)
Age (y)	37.34±13.64	37.88±15.41	43.90±15.75
Education (%)			
Up to 5 years	7 (11.9)	2 (11.8)	0 (0.00)
Secondary education	11 (18.6)	9 (52.9)	32 (62.7)
High school diploma	34 (57.6)	3 (17.6)	4 (7.8)
Further education	7 (11.9)	3 (17.6)	15 (29.4)
Status (%)			
Single	25 (42.4)	5 (29.4)	21 (41.2)
Living with partner	32 (54.2)	10 (58.8)	20 (39.2)
Separated	1 (1.7)	2 (11.8)	8 (15.7)
Widow	1 (1.7)	0 (0.00)	2 (3.9)
Live with (%)			
Alone	1 (1.7)	3 (17.6)	9 (17.6)
With 1 person	7 (11.9)	6 (35.3)	22 (43.1)
With 2 person	14 (23.7)	4 (23.5)	8 (15.7)
With 3 or more persons	37 (62.7)	4 (23.5)	12 (23.5)
Occupation level (%)			
Fixed job	31 (52.54)	10 (58.82)	9 (17.65)
Occasional job	4 (6.78)	3 (17.65)	0 (0.00)
Housewife	1 (1.69)	0 (0.0)	0 (0.00)
Retired	5 (8.47)	1 (5.88)	9 (17.65)
Student	10 (16.95)	2 (11.76)	1 (1.96)
Unemployed	7 (11.86)	1 (5.88)	27 (52.94)
Other	1 (1.69)	0 (0)	5 (8.9)
Financial status (%)			
Optimal	2 (3.39)	1 (5.88)	6 (11.76)
Good	24 (40.68)	14 (82.35)	15 (29.41)
Sufficient	32 (54.24)	1 (5.88)	15 (29.41)
Poor	1 (1.69)	1 (5.88)	10 (19.61)
Very poor	0 (0.00)	0 (0.00)	4 (7.84)
Missing	0	0	1 (1.96)
Tetraplegia (%)	24 (40.68)	3 (17.65)	20 (39.22)
Paraplegia (%)	35 (59.32)	14 (83.35)	28 (54.90)
Missing (%)	0	0	3 (5.88)
SCIM at discharge	52.59±17.96	63.11±23.96	46.9±23.34
FIM at discharge	88.28±24.77	94.76±34.50	87.19±26.40
Median LOS in the spinal cord unit (d)	186.5	224.5	230

NOTE. Values are means ± SDs unless otherwise noted.

at 6 months was compared between telemedicine and standard care in patients for whom data were available at each site (table 3). A significantly higher gain in FIM scores in the telemedicine group was found at the Italian site: the difference in mean total FIM gain was 4.31 (95% CI, 1.27–7.35; t test=–2.84, df=56, $P<.05$), and the difference in mean FIM motor gain was 4.31 (95% CI, 1.24–7.38; t test=2.81, df=56, $P<.05$). The individual items significantly ($P\leq.05$) contributing to the observed difference between groups in the FIM scores were grooming (0.483; 95% CI, 0–0.971), dressing upper body (0.552; 95% CI, 0.018–1.086), dressing lower body (0.517; 95% CI, 0.017–1.017), and bed/chair/wheelchair transfer (0.483; 95% CI, 0.044–0.922). The improvements in the motor FIM items in Bologna are graphically represented in figure 2. We did not find any differences in the SCIM total score gain between telemedicine and control groups, but significant ($P<.05$) improvements were found in 2 items: bed-wheelchair transfers (.207; 95% CI, .031–.383) and wheelchair-car transfers (.379; 95% CI, .080–.678; fig 3). We also carried out intention-to-treat analyses for FIM and SCIM data (using a last-observation carried forward approach) and for clinical outcomes. Because results were virtually overlapping with those based on the as-treated approach, we did not report them here.

Table 4 shows the comparison of mean scores of satisfaction with care between the 2 treatment groups (as treated analysis). In the telemedicine as well as the control groups, satisfaction with care was generally positive. However, patients assigned to telemedicine reported significantly higher satisfaction with care compared with those assigned to usual care on items exploring the relationship with medical and nursing staff, information, and treatment received.

DISCUSSION

To date, THRIVE is the largest clinical trial conducted with patients with SCI after their discharge from a spinal cord unit. The results of the study indicate that home-based telerehabilitation is viable for both patients with SCI and for the specialist within the spinal unit. In general, telerehabilitation sessions proved to be an effective way of monitoring and effecting therapy. During sessions, medical and nursing staff, physiotherapists, and occupational therapists had the opportunity to evaluate the living conditions of patients after discharge from the spinal unit. They were also able to comment on the suitability of the prescribed aids and to give advice about changes that might assist the welfare and autonomy of patient after the acute phase of SCI support. The caregivers also reported benefit through support from the spinal cord unit as they felt more confident in the daily management of the patient.

No substantial differences between the 2 treatment groups were found in terms of number and type of complications. Readmissions to the spinal cord unit numbered 5 in the control group and 1 in the telemedicine group, and the present study may not be sufficiently powered to provide evidence that telemedicine is more efficacious in preventing readmissions in the first 6 months after discharge. A larger study may be needed to investigate this aspect further.

Improvement in function, related to mobility and self-care, was significantly higher in the telemedicine group at the Italian site. The change in the motor FIM scale exceeded 4.4 points, denoting a real change beyond measurement error.[27] Although we did not find significant changes in SCIM total score between the 2 treatments, changes on specific items assessing wheelchair/bed and wheelchair/car transfers are significantly better for telemedicine. In general, changes on the FIM and SCIM areas measuring self-care, mobility in room and toilet/transfers, and mobility indoors and outdoors/locomotion would seem to favor telemedicine over standard care.

Functional improvement in the telemedicine group was found only in the Italian site and not the other 2 sites. There may be several explanations for the difference in outcomes between sites. Function at discharge (baseline) was not different between the 3 sites; however, the median LOS at the Italian site was shorter than the other 2 sites (although not statistically different). Due to the shorter LOS at the Italian site, there may have been more potential for further functional improvement that was facilitated by telemedicine. The lack of differences found in the Belgian site may have been a result of the small number of participants and the high variability of the scores on the functional measures. In the English sites, neither group improved in functional status at 2 and 6 months. Because the underlying mechanisms that lead to the success of home-based treatments have never been explored in the literature, we can only put forward some hypotheses. The Montecatone Rehabil-

Table 2: Clinical Outcomes

Clinical Outcomes*	2 Months (n=127)			6 Months (n=127)		
	Control (n=65)	TM (n=62)	*P*	Control (n=65)	TM (n=62)	*P*
Pressure ulcers after discharge						
Yes	7 (13.5)	9 (18.0)	.53	6 (14.3)	8 (16.7)	.76
No	45 (86.5)	41 (82)		36 (85.7)	40 (83.3)	
Missing	13	12		23	14	
Urinary tract infections treated by oral antibiotics						
Yes	24 (40.7)	26 (46.4)	.53	31 (59.6)	26 (50.0)	.32
No	35 (59.3)	30 (53.6)		21 (40.4)	26 (41.9)	
Missing	6	6		13	10	
Urinary tract infections treated by intravenous antibiotics						
Yes	0 (0.0)	2 (4.5)	.14	2 (5.9)	0 (0.0)	.11
No	48 (100)	42 (95.5)		32 (94.1)	43 (100)	
Missing	17	18		31	19	
Catheter blockages						
Yes	5 (10.6)	7 (16.7)	.41	6 (17.1)	7 (15.9)	.88
No	42 (89.4)	35 (83.3)		29 (82.9)	37 (84.9)	
Missing	18	20		30	18	
Catheter loss						
Yes	8 (17.0)	13 (30.2)	.14	7 (20.0)	7 (16.7)	.71
No	39 (83)	30 (69.8)		28 (80)	35 (83.3)	
Missing	18	19		30	20	
Catheter complication						
Yes	5 (11.6)	4 (10.3)	.84	3 (9.1)	1 (2.7)	.25
No	38 (88.4)	35 (89.7)		30 (90.9)	36 (97.3)	
Missing	22	23		32	25	
Pulmonary infections treated with oral antibiotics						
Yes	3 (4.9)	1 (1.8)	.36	2 (4.0)	5 (10.0)	.24
No	58 (95.1)	54 (98.2)		48 (96)	45 (90)	
Missing	4	7		15	12	
Number of days of fever (temperature >37.5°C)						
0	12 (48.0)	9 (36.0)	.64	10 (34.5)	8 (28.6)	.88
1	4 (16.0)	6 (24.0)		7 (24.1)	7 (25.0)	
2 or more	9 (36.0)	10 (40.0)		12 (41.4)	13 (46.4)	
Missing	40	37		37	34	
Number of days with pain treated with analgesics						
0	24 (45.3)	23 (50.0)	.37	20 (50.0)	18 (39.1)	.58
1–30	16 (30.2)	16 (34.8)		10 (25.0)	15 (32.6)	
>30	13 (24.5)	7 (15.2)		10 (25.0)	13 (28.3)	
Missing	12	16		25	16	
Episodes of autonomic dysreflexia						
Yes	6 (10.3)	10 (18.5)	.22	2 (4.0)	7 (14.3)	.07
No	52 (89.7)	44 (81.5)		48 (96)	42 (85.7)	
Missing	7	8		15	13	
Occurrence of help-seeking						
Yes	49 (80.3)	44 (81.5)	.87	48 (92.3)	43 (82.7)	.14
No	12 (19.7)	10 (18.5)		4 (7.7)	9 (17.3)	
Missing	4	8		13	10	
Readmissions to the spinal cord unit						
Yes	1 (1.6)	0 (0.0)	.33	4 (7.7)	1 (2.0)	.18
No	61 (98.4)	57 (100)		48 (92.3)	50 (98)	
Missing	3	5		13	11	
Readmissions to other hospitals						
Yes	4 (6.6)	2 (3.6)	.48	8 (15.1)	6 (12.0)	.65
No	58 (93.6)	54 (96.4)		45 (84.9)	44 (88)	
Missing	3	6		12	12	

NOTE. Numbers are frequencies and (percentages).
Abbreviation: TM, telemedicine.
*Percentages and *P* values are calculated over available data.

itation Institute is located in northern Italy and is the largest Italian spinal cord unit. It provides hospitalization services for patients from all the Italian regions. Most participants at the Italian site (61.7%) come from central and southern Italy, where there are few spinal cord units and less organized medical care in general for persons with SCI.

Table 3: FIM and SCIM Scores of Patients by Site at 6 Months From Discharge

Bologna							
Outcome Variables	Controls (Discharge n=29; 6mo n=28)	95% CI	TM (Discharge n=30; 6mo n=29)	95% CI	Difference (TM)–(Control)	95% CI	*P**
FIM							
Mean discharge total FIM	92.83±26.02	82.93–102.72	83.90±23.09	75.28–92.52	−8.93	−21.74–3.89	.17
Mean increase in total FIM at 6mo	3.38±4.43	1.69–5.06	7.69±6.88	5.07–10.31	4.31	1.27–7.35	<.01
Mean discharge motor FIM	58.03±25.94	48.17–67.90	49.13±22.94	40.57–57.70	−8.90	−21.65–3.85	.17
Mean increase in motor FIM at 6mo	3.24±4.38	1.57–4.91	7.55±7.00	4.89–10.21	4.31	1.24–7.38	<.01
Mean discharge cognitive FIM	34.79±0.41	34.64–34.95	34.77±0.63	34.53–35.00	−0.03	−0.30–0.25	.85
Mean increase in cognitive FIM at 6mo	0.14±0.35	0.00–0.27	0.14±0.52	−0.58–0.33	0	−0.23–0.23	1.0
SCIM							
Mean discharge SCIM	54.48±19.46	47.08–61.88	50.76±16.51	44.60–56.93	−3.72	−13.11–5.68	.43
Mean increase in SCIM	3.38±4.69	1.59–5.16	3.38±4.66	1.61–5.15	0	−2.46–2.46	1.0
Brussels							
Outcome Variables	Controls (Discharge n=10; 6mo n=10)	95% CI	TM (Discharge n=7; 6mo n=5)	95% CI	Difference (TM)–(Control)	95% CI	*P**
FIM							
Mean discharge total FIM	97.30±33.29	73.48–121.12	87.86±34.70	55.76–119.95	−9.44	−45.01–26.13	.58
Mean increase in total FIM at 6mo	21.10±31.07	−1.13–43.33	6.40±8.14	−3.71–16.51	−14.7	−45.75–16.35	.33
Mean discharge motor FIM	62.60±27.28	43.08–82.11	48.71±30.83	20.21–77.22	−13.89	−44.09–16.31	.35
Mean increase in motor FIM at 6mo	19.10±27.42	−0.52–38.72	4.80±4.87	−1.24–10.84	−14.3	−41.49–12.89	.28
Mean discharge cognitive FIM	32.60±5.54	28.63–36.56	33.14±2.12	31.19–35.1	0.54	−4.18–5.27	.81
Mean increase in cognitive FIM at 6mo	2.00±5.64	−2.03–6.03	0.20±0.45	−0.35–0.75	−1.8	−7.36–3.76	.50
SCIM							
Mean discharge SCIM	64.90±22.90	48.52–81.28	60.57±27.05	35.55–85.59	−4.33	−30.22–21.56	.72
Mean increase in SCIM	7.30±19.78	−6.85–21.45	1.40±1.95	−1.02–3.82	−5.9	−25.41–13.62	.53
Salisbury and Stanmore							
Outcome Variables	Controls (Discharge n=26; 6mo n=21)	95% CI	TM (Discharge n=25; 6mo n=18)	95% CI	Difference (TM)–(Control)	95% CI	*P**
FIM							
Mean discharge total FIM	81.88±27.45	70.55–93.21	93.70±24.32	83.18–104.21	11.82	−3.31–26.94	.12
Mean increase in total FIM at 6mo	−0.14±6.31	−3.02–2.73	−1.83±6.91	−5.21–1.60	−1.69	−5.98–2.60	.43
Mean discharge motor FIM	46.96±27.35	35.67–58.25	58.70±24.32	48.18–69.21	11.74	−3.36–26.83	.12
Mean increase in motor FIM at 6mo	−0.19±6.31	−3.06–2.68	−1.83±6.91	−5.27–1.60	−1.64	−5.93–2.65	.44
Mean discharge cognitive FIM	34.92±0.28	34.81–35.0	35.00±0.00	35–35	0.08	−0.04–0.20	.17
Mean increase in cognitive FIM at 6mo	0.05±0.22	−0.05–0.15	0.00±0.00	0–0	−0.05	−0.15–0.06	.36
SCIM							
Mean discharge SCIM	40.68±22.63	31.34–50.02	52.17±21.67	42.80–61.55	11.49	−1.41–24.39	.08
Mean increase in SCIM	0.10±7.39	−3.27–3.46	−2.06±9.06	−6.56–2.45	−2.15	−7.49–3.18	.42

NOTE. Values are means ± SDs.
Abbreviation: TM, telemedicine.
*For paired-sample *t* test.

Because primary care physicians usually do not have the expertise and the skills to deal with the complex needs of patients with SCI,[28] patients living in these areas typically use physiatrists, orthopedists, neurologists, or rheumatologists as their first line of contact in the event of a new health problem. Therefore, telemedicine offers a unique opportunity to patients living far from a spinal cord unit to be in contact regularly with medical and nursing staff with SCI expertise who would otherwise be unavailable to these patients.

In general, satisfaction with care was positive in both groups. However, those in the telemedicine group reported higher

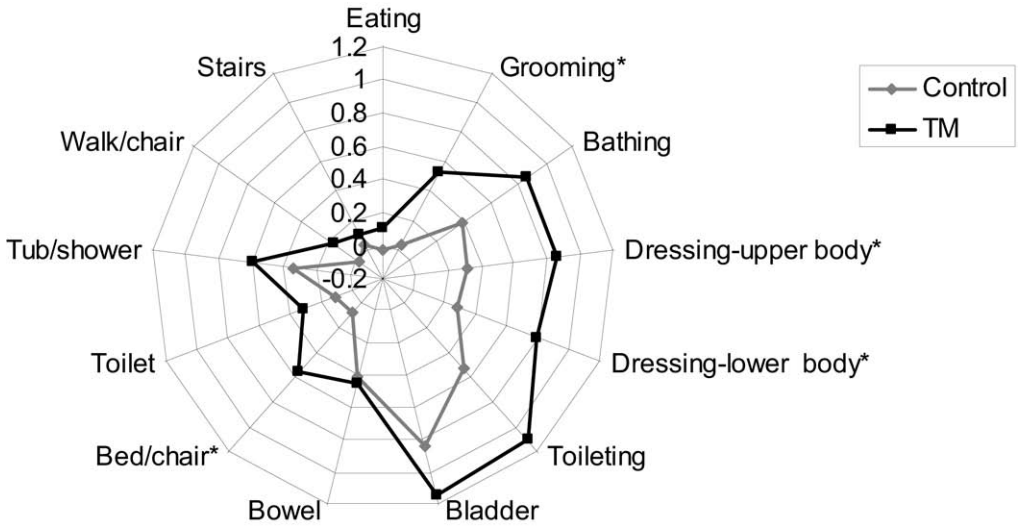

Fig 2. Radar chart: graphic representation of individual items (mean of the gain) in the motor component of the FIM in the 2 treatment groups (Italian site). *$P \leq .05$. Abbreviation: TM, telemedicine.

overall satisfaction of care than those receiving traditional care. The telemedicine group also reported improved satisfaction on virtually all individual measures of satisfaction of care. Our results are in line with those of Donnelly et al,[28] who assessed patients' satisfaction with long-term care for SCI provided by family doctors and spinal injury specialists in 3 countries. These authors reported an overall satisfaction rate of 74% for family doctors and 76% for SCI specialists.

Further research is needed to confirm whether or not telemedicine is a valuable alternative method to standard care in the first year postdischarge and whether home-based treatment is sufficiently safe to shorten the duration of hospitalization during the acute phase. Telemedicine interventions may be cost-saving if program costs are more than offset by a decrease in hospitalization costs; however, to date no information is available on the cost-effectiveness of telemedicine compared with usual care for SCI.[5] Galea et al[29] suggested that the selection of the candidate represents the first step toward the success of the program. The small sample size in this study limits the ability to determine the characteristics of the ideal patient for telemedicine. However, our clinical experience suggests that certain characteristics may facilitate treatment compliance, such as being open to new technologies and well educated. Therefore, the benefit of telemedicine might be seen only in subgroups of patients with specific characteristics that maximize the efficacy of the intervention.

Study Limitations

Our study results should be interpreted in light of several limitations. First, 2 of the 3 sites did not reach the target for

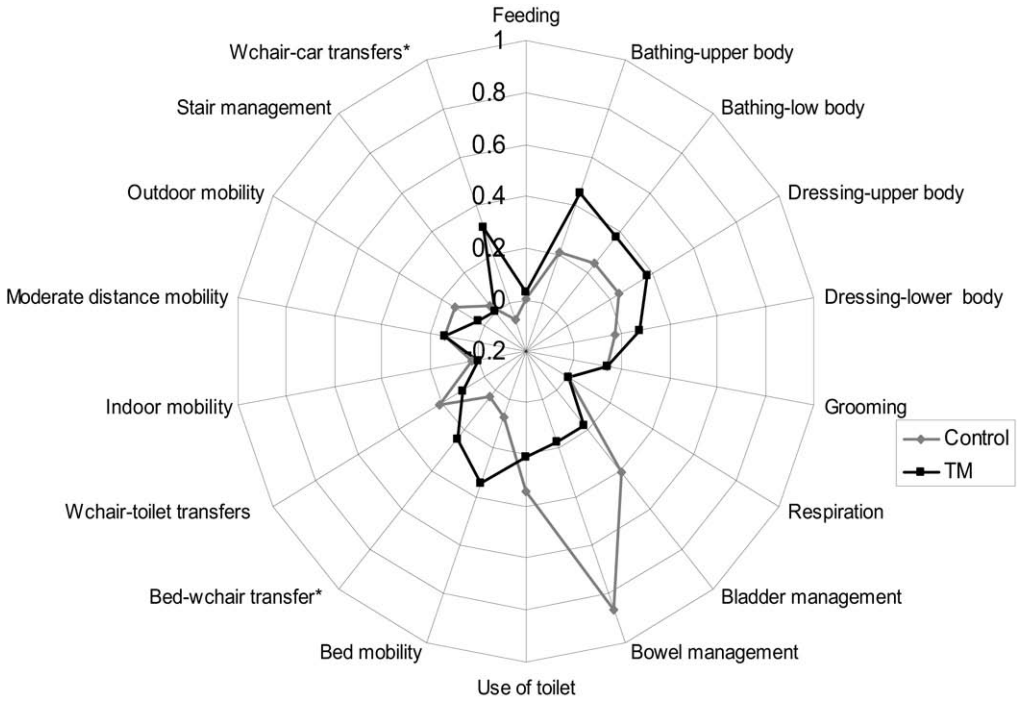

Fig 3. Radar chart: graphic representation of individual items (mean of the gain) of SCIM in the 2 treatment groups (Italian site). *$P < .05$. Abbreviation: TM, telemedicine.

Table 4: Satisfaction With Treatment

Item	TM (n=52)	Controls (n=59)	*P**
Relationship with medical care staff (very poor–excellent)	8.85±1.26	7.17±1.95	<.001
Relationship with nursing staff (very poor–excellent)	8.98±1.26	7.00±2.24	<.001
Relationship with the community and social care staff (very poor–excellent)	6.25±2.92	6.27±2.61	.80
Information provided concerning the support I have received (confusing–very helpful)	7.63±2.21	6.71±1.94	<.01
Information provided concerning the support I have received (incomplete–comprehensive)	7.59±2.47	6.44±2.11	<.01
Treatments received for my spinal injury and related issues (excellent–unsatisfactory)	8.04±2.03	6.76±2.03	<.01
Alternative approaches to the treatment I have received (consider alternatives–retain current approach)	7.94±2.38	6.52±2.59	<.01
If you considered alternative approaches, would you prefer links to the spinal unit to be (less close–closer)	7.66±2.11	8.12±5.94	.55
Are there specific areas of your treatment you would like to change? (N, %)	Yes 9 (16.36%)	Yes 22 (35.48)	<.02
With respect to your transition out of the spinal unit, do you consider that using THRIVE support has been (great help–great hindrance)	8.76±1.31	—	
Confident about future support at the end of the THRIVE project (not very confident–very confident)	7.18±2.53	—	
I have found using THRIVE telemedicine equipment (very easy–very problematic)	7.9±2.48	—	
Composite measure of satisfaction (mean of items 1–8)	7.9±1.24	6.9±1.55	<.001

NOTE. Values are means ± SDs unless otherwise noted. Items are scored 0 to 10. The meaning of 0 and 10 is in parentheses.
Abbreviation: TM, telemedicine.
*For Mann-Whitney *U* test (as treated analysis).

recruitment; therefore, the study is underpowered to detect differences in treatment efficacy among sites. Our findings on functional outcomes can be generalized only to Italian patients.

Second, the amount of missing data on clinical outcomes affects the external validity of our study and makes it difficult to draw a valid conclusion about the difference between the 2 treatments. Thus, our results, suggesting no significant differences in clinical complications between the 2 treatment groups, warrant replication in further studies.

CONCLUSIONS

The THRIVE study provides some of the first quantitative evidence, based on results from 1 site, that telerehabilitation may offer benefits to patients discharged from a spinal cord unit compared with standard care in terms of functional improvement. Given that these findings were seen in only 1 site, it may be possible that the context in which telemedicine is delivered plays an important part in its success. This study also demonstrated that telemedicine was associated with significantly improved satisfaction with care. Because the follow-up for this study was limited to 6 months, further research with larger sample sizes and longer follow-up may provide additional information regarding the utility of telemedicine for patients with SCI.

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Supplier

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