Telemedicine Applied to Kinesiotherapy for Hand Dysfunction in Patients with Systemic Sclerosis and Rheumatoid Arthritis: Recovery of Movement and Telemonitoring Technology

Matteo Piga, Iosto Tradori, Danilo Pani, Gianluca Barabino, Alessia Dessì, Luigi Raffo, and Alessandro Mathieu

ABSTRACT. ***Objective.*** To describe a feasibility study focused on a telemonitoring approach to self-managed kinesiotherapy sessions for the rehabilitation of hand function in patients with systemic sclerosis (SSc) and rheumatoid arthritis (RA).

Methods. Ten patients with SSc and 10 with RA were enrolled in a 3-month controlled trial (approval no. 9751/2012 – Italian Department of Health) to perform a home kinesiotherapy protocol, consisting of strengthening and mobility exercises, using a newly developed telemedicine system (a portable device and the related telemonitoring infrastructure). A further 10 patients with SSc and 10 with RA were enrolled as controls to perform a similar home kinesiotherapy protocol with the aid of common daily-life objects. Both groups were evaluated at baseline and at followup, after 6 and 12 weeks. The primary outcome of the trial was hand function measured by Dreiser's index (Functional Index for Hand OA, FIHOA), Health Assessment Questionnaire (HAQ), and the Hand Mobility in Scleroderma (HAMIS) test (only for SSc).

Results. Patients with SSc showed an improvement of FIHOA in both arms ($p < 0.01$) but the HAQ ($p = 0.016$) and the HAMIS test (right hand $p = 0.016$, left hand $p = 0.075$) improved significantly only in the experimental arm. Patients with RA showed a statistically significant improvement of FIHOA ($p = 0.013$) and HAQ ($p = 0.015$) in the experimental arm, while patients in the control arm did not significantly improve. However, no statistically significant differences in outcome measures between treatment methods were observed. Withdrawals were higher in control arms (SSc 20%; RA 30%) than in experimental arms (SSc 10%; RA 10%).

Conclusion. Telemonitoring of self-administered kinesiotherapy programs is a promising approach to the rehabilitation of hand functions in patients with rheumatic disease. (First Release June 1 2014; J Rheumatol 2014;41:1324–33; doi:10.3899/jrheum.130912)

Key Indexing Terms:
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Systemic sclerosis (SSc) and rheumatoid arthritis (RA) are chronic rheumatic diseases with different pathogenetic mechanisms and outcomes that affect hand disability, which in turn strongly influences the activities of daily living[1,2,3].

SSc is an autoimmune disease that targets the vasculature ultimately leading to fibrosis in the skin, the musculoskeletal system, and internal organs. Although SSc may affect various joints, the metacarpophalangeal (MCP) and the proximal interphalangeal (PIP) joints of the hands are primarily involved[4]. Thickening of the skin, tendon, and muscle can result in contractures of the fingers and hand impairment[5]. RA is a systemic chronic inflammatory disease primarily affecting synovial joints, mostly the wrist, and the MCP and PIP of the hands. Patients with RA often experience joint and tendon restrictions and adhesions due to fibrosis. These patients are prone to muscle atrophy as well as erosion of cartilage and bone, which can lead to substantial loss of function and, in the later stage, deformities[6].

Recovering hand function in patients with SSc and RA requires pharmacological treatment together with rehabilitative and kinesiotherapy interventions[7,8,9]. Rehabilitation provided by occupational therapists and/or physiotherapists, also called physical therapy, includes joint protection advice, heat, and manual mobilization techniques[9,10]. Kinesiotherapy consists of adapted physical exercises actively performed by patients. It is aimed at improving or maintaining functional abilities and usually follows an early rehabilitative intervention[11,12]. Few studies have specifically investigated the effect of physical exercise on the recovery of hand function in SSc and RA; therefore established guidelines for intervention are lacking[11,12]. Kinesiotherapy requires constant monitoring by health professionals, but closely assisting every patient can be difficult, because of the reduced availability of specialized facilities and qualified staff, especially in remote, usually rural, communities. Patients might be able to self-manage the exercises at home.

The Recovery of Movement and Telemonitoring (Re.Mo.Te.) project was undertaken to develop a telemedicine system to be used at home by patients with hand impairment for telemonitoring of self-administered kinesiotherapy (Appendix 1). This project originated the Re.Mo.Te. system, which consists of a portable standalone electronic device and the related telemonitoring infrastructure[13]. The system was then tested in the Re.Mo.Te. clinical trial in which patients with SSc and RA with hand impairment were enrolled. This article describes the Re.Mo.Te. clinical trial.

MATERIALS AND METHODS

The Re.Mo.Te. trial intervention. The Re.Mo.Te. clinical trial was set up as a pilot study to investigate the effectiveness of and the adherence to a self-managed hand kinesiotherapy protocol assisted by telemonitoring in patients with SSc and RA. Adherence to protocol was defined as the percentage of complete workout sessions over those scheduled.

The intervention protocol was defined starting from the exercises patients can perform at home, some derived from the literature[9,10,11] and others conceived *ex novo*, using common daily-life objects (Appendix 2). Such exercises were engineered with sensor tools subsequently embedded in the Re.Mo.Te. portable device (Figure 1A and Appendix 2). The exercises were adapted to avoid joint stress and overload and to improve strength and mobility. Strength exercises require isometric muscle contraction, whereas mobility exercises are low resistance or without resistance, and both should be performed by the patients at the maximum pain-free intensity. To standardize the treatment provided, all patients attended an individual training session, including a practical section, where they were taught how to perform the kinesiotherapy exercises according to the trial protocol. To make sure that the effort was performed only with fingers, patients were trained to keep the wrist in a neutral position during the exercises, resting on a flat surface when possible. To avoid threatening the validity of the comparison between cases and controls, we defined the working variables at the beginning and did not change them over the duration of the trial.

The Re.Mo.Te. telemonitoring system. Re.Mo.Te. is a newly developed system[13] designed through close cooperation between rheumatologists and bioengineers. It leads the patient in the execution of home rehabilitation exercises for the hand and allows health professionals to remotely oversee the results of workouts. Re.Mo.Te. consists of a portable device and the related telemonitoring infrastructure and exploits the store-and-forward approach: acquisition and storing of clinical information (e.g., data, image, sound, video) that is then forwarded to (or retrieved by) another site for clinical evaluation. The standalone device is integrated in a portable briefcase and includes a set of sensor tools to quantitatively analyze the execution of the exercises by measuring the physical variables of interest (Appendix 2). It is installation-free and neither a computer nor an Internet connection is required at the patient's home. For safety reasons, it is battery-powered and its use is disabled when charging. The tools were designed to reduce the risk of mechanical injuries, with moving elements covered in soft-touch material. The device provides 2 operating modes: real-time and store-and-forward. The first mode was designed for use in a clinical setting, under the supervision of a health professional who controls the device through a Bluetooth connection and a dedicated user interface on his/her computer, analyzing in real time the signals coming from the sensor tools to assess the quality of the execution. This operating mode is useful for training patients and for delivering the exercises at outpatient therapeutic clinic. The store-and-forward mode is used when the device is entrusted to the patients for autonomous home use.

The device guides the patient in the execution of the exercises, providing both visual (through LED and small character display) and audio (buzzer) feedback. The device manages the wireless transmission of the main statistics, summarizing the rehabilitation session, through an embedded GSM/GPRS module. A monitoring software interface is also provided for the doctors to supervise the patients' progress throughout the rehabilitation period in a deferred way. The telemonitoring software interface allows recognizing (1) the kinesiotherapic sessions performed by the patient (Figure 1B); (2) the number of sets and repetitions performed for each exercise; and (3) how the patient performed the exercises, providing adequate statistics (i.e., maximum, minimum, average, and SD of the relevant physical characteristics: time, speed, force, torque, etc.). The statistics are presented in graphs to the physician (Figure 1C), but can also be downloaded as spreadsheet files. The system offers a fast remote analysis of the home sessions, enabling identification of low adherence to the protocol or poor performance.

Preliminary evaluation, eligibility, and consent. Fifty patients with RA and 40 patients with SSc, diagnosed according to the American College of Rheumatology classification criteria, and referred to our rheumatology outpatient clinic, were screened with the aim of identifying 20 patients per disease homogeneous for demographic, clinical, and functional characteristics. The presence of tender and swollen joints, deformities, functional deficit, or impairment in the hands and wrists was evaluated. Participants were eligible if they had a Dreiser's index score ≥ 6 and had been receiving stable medications for 3 months. Exclusion criteria were irreversible anatomical damage such as bony ankylosis, tendon rupture, joint dislocation and subluxation, active arthritis, and digital ulcers. A 28-joint Disease Activity Score (DAS28) higher than 2.6 was an exclusion criterion for patients with RA. Changes of therapy were not allowed during the trial and were a reason for withdrawal from the study. Twenty patients per disease, matched for sex, age, disease duration, Health Assessment Questionnaire (HAQ) and Dreiser's Algo-Functional index (Functional Index of Hand OA, FIHOA) scores, were enrolled from February 2012 to June 2012. Informed consent was obtained from all participants. The protocol of the clinical trial, with a medical device not assessed for compliance with European safety standard for commercial use, was reviewed by the Ethics Committee (Azienda Ospedaliero Universitaria of Cagliari, no. 245/2011), and the trial was authorized by the Italian Department of Health (approval no. 9751/2012).

The experimental arm. Once matched in pairs, patients were assigned to the experimental or the control arm by permuted block randomization. Ten patients with SSc and 10 with RA were trained on the autonomous use of the experimental device by investigators. Every patient received individual 1-h training on the proper and safe use of the device, along with a user manual comprehensively describing the functioning and maintenance of

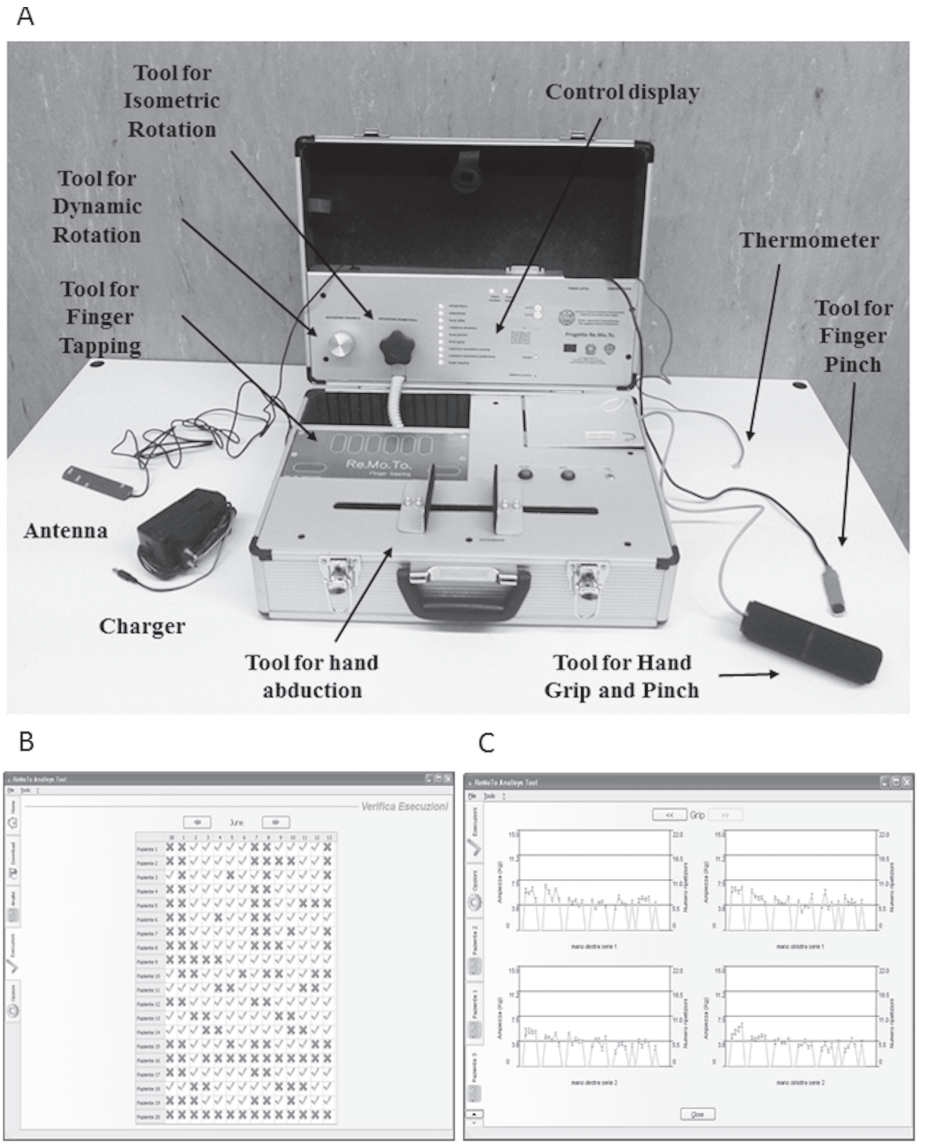

Figure 1. (A) The Re.Mo.Te. device. Two examples of the monitoring software interface: (B) the execution window of kinesiotherapic sessions, showing sessions performed (✓) and those missed (X); (C) an example of the hand grip exercise window showing the average trend of the sessions performed with the right hand (on the right) and those performed with the left hand (on the left); the panels at the top of the window show the average results of the first set of repetitions; those below refer to the second set of repetitions.

the device. Moreover, they received an illustrated booklet describing the exercises. The kinesiotherapy protocol of the experimental arm consisted of 4 strengthening and 3 mobility exercises (Appendix 2), to be repeated 5 days per week for 12 weeks, each session lasting a maximum of 50 min. Every workout was conducted at home by patients using the Re.Mo.Te. device and remotely monitored by physicians through the Re.Mo.Te. telemonitoring interface. Telemonitoring data were checked twice per week, allowing physicians to report on the adherence to protocol. To be aware of possible complications and minimize nonadherence and withdrawals, the investigators contacted patients by telephone if the following warning flags were detected: (1) loss of 1 or more workout sessions, or (2) a worsening trend in exercise statistics during the week.

The control arm. The remaining patients received individual training for 30 min to perform a kinesiotherapy protocol at home consisting of 3 strengthening and 3 mobility exercises (Appendix 2) using common objects, to be repeated 5 days per week for 12 weeks, each session lasting a maximum of 45 min. Patients received a booklet with pictures describing the exercises. This protocol is based on 1 exercise fewer, because of the difficulty in standardizing exercise number 6 (Appendix 2) using common household items. For patients enrolled in the control arm, no additional contact other than followup was scheduled, unless an adverse event occurred. At each visit they were asked to report on their weekly adherence to protocol.

Baseline and followup assessments. At baseline and at followup, after 6 and 12 weeks, every patient was assessed by a rheumatologist using HAQ, FIHOA, Medical Outcomes Study Short Form-36 (SF-36), pain visual analog scale (VAS), and VAS Global Health (GH). Hand disability in patients with SSc was also bilaterally evaluated by the Hand Mobility in Scleroderma (HAMIS) test. The DAS28 was calculated for patients with

RA, not as an outcome measure but to highlight any increase in inflammatory activity. Likewise, patients with SSc were evaluated for active joint inflammation, defined by the presence of synovitis and tendon friction rubs at clinical assessment. Afterward, a kinesiotherapist quantitatively assessed the hand strength (grip and pinch) measured through a sphygmomanometer[14]. The maximum hand abduction and the range of movement (ROM) of MCP joints for both hands was measured through a goniometer.

At the end of the followup, the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0) was administered to the patients enrolled in the experimental arms[15]. The purpose of the QUEST 2.0 was to evaluate patient satisfaction with the assistive device and the related services. It consists of 12 items rated on a 5-point Likert scale where 1 stands for "completely unsatisfied" and 5 for "completely satisfied". The patients also pinpointed the 3 items they considered the most important for the device evaluation.

Outcomes. The Re.Mo.Te. trial was primarily designed to determine the effectiveness of the kinesiotherapy experimental protocol in improving hand function, as mediated by increases in strength, dexterity, and range of motion (ROM), in patients with SSc and RA[16,17,18]. The secondary goal of this trial was to compare the experimental protocol versus a similar workout to highlight differences in hand function improvement and in patient compliance. Accordingly, the primary outcome of the trial was hand function measured by HAQ, FIHOA, and the HAMIS test for patients with SSc. Maximum hand abduction, joint ROM, grip strength, and pinch strength were secondary outcomes. The SF-36, VAS pain (0–100), and VAS-GH (0–100) were outcomes for quality of life (QoL) assessment. Compliance to protocol was defined by the number of patients who completed the 3-month trial. If a major violation to protocol occurred, the patient was withdrawn from the study. Major violations were defined as (1) a whole week without performing the workout sessions, or (2) more than 2 missed workout sessions per week, every week. Compliance for patients in the experimental arm was derived from the telemedicine system, while for those in the control arm it could only be indirectly inferred.

Statistical analysis. Data processing and statistical analyses were performed using MedCalc package for Windows, version 12.7.0.0 (MedCalc Software). The Kolmogorov-Smirnov test was used to test the normality of variable distribution between groups. The only variables with abnormal distribution between groups at baseline were the results of HAMIS test for both hands in patients with SSc. Repeated measures ANOVA and pairwise comparison between each visit and the immediately preceding one were used to address within-subject effect and compare quantitative variables throughout followup. Only data from patients who completed the clinical trial were included in this statistical analysis. A mixed model ANOVA providing a grouping variable (experimental arm/control arm) was used to address the between-subject and interaction effects. P values less than 0.05 were considered statistically significant. Bonferroni correction was applied to pairwise comparison results.

RESULTS

Patients with SSc. Patients in each arm showed improvement in primary outcomes, but no statistically significant difference between subjects was highlighted when findings from the 2 arms were compared. Table 1 summarizes results (mean, SD) from patients with SSc. The FIHAO significantly improved in both arms ($p = 0.006$), whereas the HAQ ($p = 0.016$) and the HAMIS (right hand $p = 0.016$; left hand $p = 0.075$) improved only in the experimental arm. Regarding secondary outcomes, patients in both arms achieved statistically significant results over time on pinch strength and MCP ROM measures for the dominant (right) hand, but grip and pinch strength measures for nondominant (left) hand significantly improved only in patients treated experimentally. Nevertheless, no statistically significant differences in secondary outcome measures between treatment methods were demonstrated. No QoL outcomes improved during followup in both arms.

Two patients from the control arm reported discontinuing the protocol for more than 1 week for no specific reason and were withdrawn from the study. One patient from the experimental arm discontinued the exercise protocol because of major abdominal surgery and was withdrawn from the trial. Patients in the experimental arm performed 93.4% ± 8.7% of the scheduled workout sessions (range from 71.4% to 98.8%; Figure 2); all of them were contacted by phone at least once during the study period following the telemonitoring detection of a warning flag. No adverse event related to the use of the device was recorded.

Patients with RA. Table 2 summarizes results (mean, SD) from patients with RA. Patients in the experimental arm experienced a progressive improvement of the variables under study, pointing out that the positive effect of the telemedicine-assisted exercise protocol was sustained during followup. In particular, FIHAO ($p = 0.013$) and HAQ ($p = 0.015$) showed a statistically significant improvement over time but, although patients included in the control arm did not significantly improve, no statistically significant differences between subjects were highlighted when primary outcome findings from the 2 arms were compared.

Patients in the experimental arm achieved statistically significant results in secondary outcomes over time on both grip and pinch strength, the latter showing a significant improvement when compared to results from patients enrolled in the control arm. Patients in experimental and control arms obtained good results on MCP ROM for both hands, but the validity of comparison between groups was threatened by an interaction effect.

According to DAS28, no disease relapse was recorded during the trial in either group. The reduction of DAS28 experienced by patients in the experimental arm is mainly due to the lowering of VAS-GH, a patient-reported component of the DAS28 composite index, rather than an effect of the kinesiotherapy treatment on inflammatory activity.

Three patients in the control arm reported major violations to the protocol and were withdrawn from the study. One patient from the experimental arm received intra-articular steroid for rhizarthrosis and was withdrawn from the trial. Patients in the experimental arm performed 89.1% ± 6.2% of the scheduled workout sessions (range from 77.9% to 97.6%; Figure 2); all were contacted by phone at least once during the study period because of the telemonitoring detection of a warning flag. No adverse event related to the use of the device was recorded.

Satisfaction interview. The QUEST 2.0 results are shown in Figure 3. The total QUEST score was 4.47 ± 0.30 (min 3.83; max 4.83), while the services subscale scored 4.79 ± 0.32

Table 1. Results of patients with systemic sclerosis (SSc) enrolled in the 2 arms of the Re.Mo.Te. clinical trial. Data are mean (± SD) unless otherwise indicated.

Variables	Experimental Arm				Control Arm					
	Baseline (T0)	Week 6 (T1)	Week 12 (T2)	Change Over Time, p[a]	Baseline (T0)	Week 6 (T1)	Week 12 (T2)	Change Over Time, p[a]	Cases vs Controls, p[b]	Interaction Effect, p
General data										
Age, yrs	57.0 (± 10.0)	—	—		57.4 (± 11.7)	—	—			
Sex	10 F	—	—		10 F	—	—			
Disease duration, yrs	6.9 (± 4.1)	—	—		6.7 (± 4.2)	—	—			
Limited/diffuse	8 L:2 D	—	—		8 L:2D	—	—			
Dominant hand	10 right				10 right					
Primary outcomes										
Dreiser's Index	13.9 (± 6.0)	9.9 (± 6.8)	7.7 (± 5.2)[§]	0.006	14.0 (± 6.4)	12.0 (± 6.5)	9.50 (± 5.2)[§]	0.006	0.496	0.984
HAQ	1.49 (± 0.4)°	0.76 (± 0.6)	0.81 (± 0.6)	0.016	1.56 (± 0.7)°°	1.06 (± 0.6)	1.09 (± 0.5)	0.063	0.287	0.988
HAMIS R hand	5.2 (± 6.2)	3.8 (± 6.6)	3.3 (± 6.0)	0.016	4.7 (±3.0)	3.2 (± 2.4)	3.2 (± 2.4)	0.104	0.832	0.246
HAMIS L hand	4.7 (± 4.1)	3.1 (± 4.3)	2.2 (± 3.2)	0.075	2.2 (± 2.0)	1.6 (± 2.0)	1.7 (± 2.1)	0.529	0.401	0.124
Secondary outcomes										
Hand abduction R, cm	6.6 (± 1.9)	7.5 (± 1.6)	7.3 (± 1.9)	0.175	6.7 (± 1.8)	7.3 (± 1.3)	7.3 (± 1.0)	0.321	0.948	0.848
Hand abduction L, cm	7.8 (± 1.5)	7.8 (± 1.9)	8.0 (± 1.6)	0.889	7.6 (± 2.1)	8.0 (± 1.8)	8.0 (± 1.6)	0.390	0.985	0.723
Hand Grip R, mmHg	55.8 (± 21.9)	64.4 (± 25.7)	71.7 (± 29.6)	0.080	48.1 (± 30.9)	60.0 (± 24.1)	63.1 (± 35.8)	0.078	0.598	0.884
Hand Grip L, mmHg	60.8 (± 29.6)	67.0 (± 31.2)	76.1 (± 32.6)[§]	0.007	62.5 (± 30.7)	70.0 (± 23.5)	74.1 (± 30.5)	0.376	0.947	0.830
Hand Pinch R, mmHg	43.6 (± 25.3)	54.4 (± 28.8)	63.3 (± 28.0)[§§]	0.002	28.1 (± 15.8)	40.6 (± 24.8)	49.4 (± 5.7)[§]	0.002	0.236	0.963
Hand Pinch L, mmHg	45.0 (± 27.5)	52.2 (± 32.5)	64.4 (± 26.3)[§§]	0.001	36.9 (± 17.5)°°	51.3 (± 18.3)	50.0 (± 22.7)	0.226	0.487	0.312
ROM MP joint R, degrees	77.4 (± 8.3)°	88.4 (± 11.4)	90.4 (± 12.0)[§]	0.011	80.6 (± 10.5)	87.5 (± 5.3)	91.1 (± 6.0)[§]	0.017	0.850	0.581
ROM MP joint L, degrees	91.7 (± 8.7)	97.1 (± 14.7)	97.2 (± 7.5)	0.118	83.1 (± 13.6)°	93.1 (± 8.8)	87.6 (± 21.2)	0.393	0.124	0.658
Quality of life outcomes										
VAS pain, mm	47.9 (± 26.5)	38.6 (± 26.2)	41.7 (± 34.3)	0.676	42.4 (± 42.1)	42.9 (± 36.4)	65.4 (± 38.7)	0.134	0.498	0.200
VAS-GH, mm	55.0 (± 28.3)	44.6 (± 17.8)	45.9 (± 29.6)	0.611	52.2 (± 35.4)	45.9 (± 40.4)	62.7 (± 34.7)	0.256	0.648	0.290
SF-36 PCS	32.4 (± 7.9)	31.7 (± 9.8)	33.1 (± 12.5)	0.699	31.4 (± 13.9)	34.7 (± 11.3)	34.9 (± 8.7)	0.251	0.821	0.389
SF-36 MCS	43.2 (± 16.1)	41.8 (± 13.1)	44.4 (± 11.0)	0.686	50.9 (± 13.8)	53.8 (± 12.2)	46.3 (± 16.0)	0.264	0.279	0.218

[a] Within subject effect. [b] Between subject effect. P values for [a] and [b] are corrected upon the estimates of sphericity by Greenhouse and Geisser (1958) and Huynh and Feldt (1976). [o] $p < 0.05$ baseline vs Week 6 by pairwise comparison; [oo] $p < 0.01$ baseline vs Week 6 by pairwise comparison. [§] $p < 0.05$ baseline vs Week 12 by pairwise comparison. [§§] $p < 0.01$ baseline vs Week 12 by pairwise comparison. P values for pairwise comparison are Bonferroni corrected. P values in boldface are statistically significant. HAQ: Health Assessment Questionnaire; HAMIS: Hand Mobility in Scleroderma; VAS: visual analog scale; GH: global health; SF-36: Medical Outcomes Study Short Form-36; PCS: physical component summary; MCS: mental component summary; ROM MP: ROM flexo-extension at metacarpophalangeal joints.

(min 4.00; max 5.00), and the device subscale scored 4.31 ± 0.38 (min 3.50; max 4.87). The lower score reached by the device subscale can be attributed to the size and weight of the prototype.

DISCUSSION

The novelty of Re.Mo.Te. consists in the application of telemedicine to hand rehabilitation in patients with disabling rheumatic diseases. The kinesiotherapy workout proposed in the trial includes strengthening, mobility, and dexterity exercises for rehabilitation of the hand in SSc and RA. The findings from both arms of the Re.Mo.Te. trial are consistent with those of previous studies, which found that kinesiotherapy in patients with SSc and RA improves hand function by increasing muscular strength and endurance, improving ROM and dexterity[9,10,11,12,16,17,18,19,20,21,22]. Although we were not able to demonstrate statistically significant differences in outcome measures between treatment methods, probably because of the small sample, patients enrolled in the experimental SSc and RA groups showed a significant change over time on a higher number of both primary and secondary outcomes when compared to controls. However, it remains to be proved whether such effectiveness is exclusively related to telemedicine.

Adherence to any exercise program is necessary to ensure its effectiveness in increasing strength and improving mobility, but patient compliance to home treatment programs is typically low and declines over time[23,24]. Low compliance with home kinesiotherapy is confirmed by the rate of withdrawals due to lack of adherence to treatment, recorded in the control arm of our study for both SSc (20%) and RA (30%). Conversely, no withdrawal secondary to lack of adherence was recorded in the experimental arms. The measured adherence to the protocol for patients enrolled in the experimental arms was continuous over time and reached about 90% for both diseases. Therefore, the better results achieved in the experimental arms could be attributed to the rehabilitation treatment implemented by

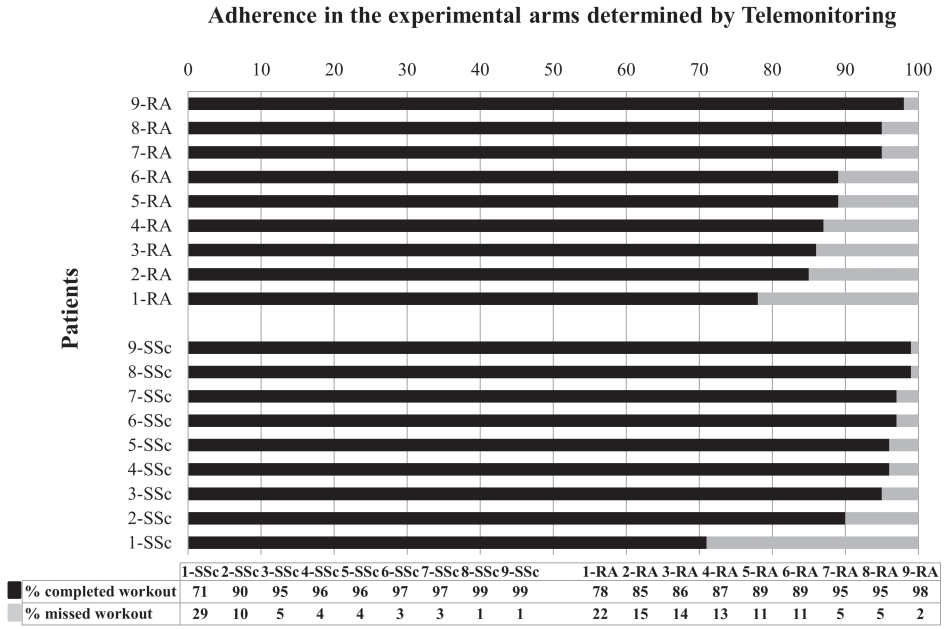

Figure 2. Percentage of completed (black) and missed (gray) workout, extracted from the telemonitoring system, for patients with systemic sclerosis and rheumatoid arthritis enrolled in the experimental arms.

Table 2. Results of patients with rheumatoid arthritis enrolled in the 2 arms of the Re.Mo.To. clinical trial. Data are mean (± SD) unless otherwise indicated.

Variables	Experimental Arm				Control Arm					
	Baseline (T0)	Week 6 (T1)	Week 12 (T2)	Change Over Time, p[a]	Baseline (T0)	Week 6 (T1)	Week 12 (T2)	Change Over Time, p[a]	Cases vs Controls, p[b]	Interaction Effect, p[b]
General data										
Age, yrs	56.3 (± 10.3)	—	—		56.8 (± 12.3)	—	—			
Sex	9F:1M	—	—		9F:1M	—	—			
Disease duration, yrs	13.1 (± 10.0)	—	—		12.8 (± 10.5)	—	—			
Dominant hand	10 right				10 right					
DAS28	1.8 (± 0.9)	1.4 (± 0.81)	1.4 (± 0.74)	0.018	2.0 (± 1.0)	2.0 (± 1.0)	2.0 (± 1.1)	0.875	0.270	0.247
Primary outcomes										
HAQ	1.22 (± 0.72)	0.89 (± 0.72)	0.68 (± 0.72)[§]	0.015	1.39 (± 0.74)	1.38 (± 0.88)	1.27 (± 1.01)	0.085	0.178	0.881
Dreiser's Index	16.3 (± 6.2)	11.0 (± 4.4)	9.9 (± 5.1)[§]	0.013	15.7 (± 6.0)	10.7 (± 6.9)°	13.1 (± 10.1)	0.143	0.560	0.454
Secondary outcomes										
Hand abduction R, cm	6.5 (± 2.2)	7.0 (± 1.5)	7.1 (± 1.1)	0.374	6.5 (± 2.13)	7.7 (± 1.4)	7.7 (± 1.1)	0.079	0.521	0.611
Hand abduction L, cm	7.5 (± 1.5)	7.9 (± 0.9)	8.5 (± 1.2)	0.108	7.1 (± 2.22)	7.7 (± 1.7)	8.1 (± 1.4)	0.309	0.603	0.820
Hand grip R, mmHg	59.1 (± 29.4)	77.2 (± 31.8)	92.0 (± 36.6)[§]	0.005	41.9 (± 26.8)°	63.6 (± 34.2)	66.1 (± 37.3)	0.005	0.235	0.532
Hand grip L, mmHg	56.7 (± 32.2)°	74.8 (± 25.2)	87.4 (± 34.3)[§§]	< 0.001	44.3 (± 30.9)°	62.9 (± 32.5)	54.3 (± 20.9)	0.240	0.197	0.133
Hand pinch R, mmHg	47.8 (± 21.4)	55.0 (± 13.1)*	68.3 (± 18.5)[§]	0.005	25.0 (± 13.7)	39.3 (± 21.1)	45.7 (± 16.9)	0.112	0.013	0.628
Hand pinch L, mmHg	46.1 (± 23.6)	53.9 (± 14.3)*	67.8 (± 19.2)[§§]	< 0.001	25.0 (± 17.6)	37.9 (± 17.3)	39.9 (± 16.7)	0.256	0.009	0.438
ROM MP joint R, degrees	85.9 (± 11.9)	89.7 (± 11.0)*	95.0 (± 8.9)[§§]	< 0 .001	71.4 (± 24.7)	93.6 (± 27.3)	89.9 (± 16.7)	0.044	0.524	0.063
ROM MP joint L, degrees	93.7 (± 9.5)	95.8 (± 3.7)*	98.9 (± 4.2)	0.083	77.1 (± 16.3)°	95.7 (± 14.0)	95.7 (± 14.8)[§]	0.008	0.193	0.008
Quality of life outcomes										
VAS pain, mm	41.5 (± 23.5)	25.4 (± 23.4)	24.0 (± 18.9)	0.247	42.1 (± 21.5)	39.0 (± 28.0)	40.3 (± 17.4)	0.891	0.256	0.596
VAS-GH, mm	60.5 (± 16.9)	42.4 (± 11.9)	38.8 (± 16.5)	0.056	59.7 (± 17.5)	55.7 (± 24.5)	57.0 (± 24.1)	0.820	0.152	0.383
SF-36 PCS	33.9 (± 9.0)	37.4 (± 7.6)	39.1 (± 5.6)[§]	0.018	29.6 (± 6.2)	38.0 (± 9.8)	36.2 (± 10.6)	0.039	0.559	0.258
SF-36 MCS	45.5 (± 10.9)	46.6 (± 14.0)	48.2 (± 14.5)	0.532	50.9 (± 14.9)	51.9 (± 10.7)	52.5 (± 17.0)	0.901	0.456	0.953

[a] Within subjects effect. [b] Between subjects effect. P values for [a] and [b] are corrected upon the estimates of sphericity by Greenhouse and Geisser (1958) and Huynh and Feldt (1976). P values in boldface are statistically significant. ° $p < 0.05$ baseline vs Week 6 by pairwise comparison; [§] $p < 0.05$ baseline vs Week 12 by pairwise comparison. [§§] $p < 0.01$ baseline vs Week 12 by pairwise comparison. *$p < 0.05$ Week 6 vs Week 12 by pairwise comparison. P values for pairwise comparison are Bonferroni corrected. HAQ: Health Assessment Questionnaire; DAS28: 28-joint Disease Activity Score; VAS: visual analog scale; GH: global health; SF-36: Medical Outcomes Study Short Form-36; PCS: physical component summary; MCS: mental component summary; ROM MP: ROM flexo-extension at metacarpophalangeal joints.

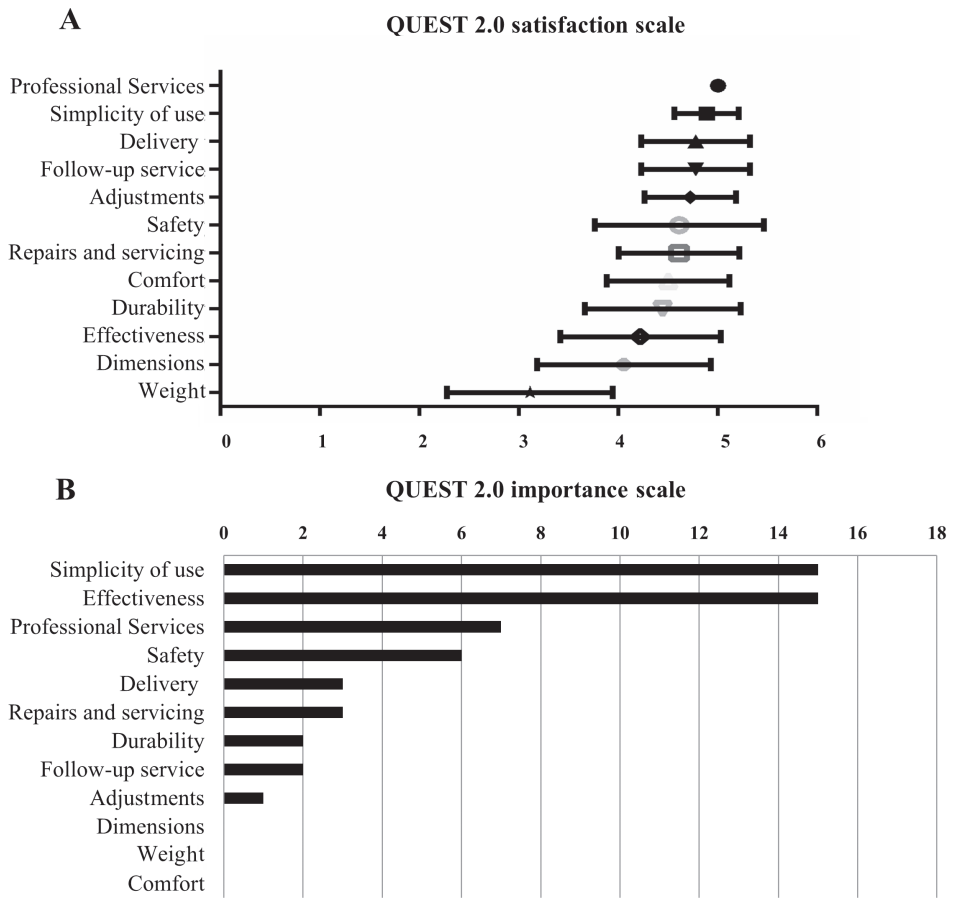

Figure 3. A. Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST) satisfaction results (mean ± SD). B. QUEST importance scale results.

Re.Mo.Te. technology, allowing health professionals to remotely monitor the workout and to intervene, minimizing protocol violations and maximizing patient compliance and adherence to treatment. There are, however, other possible explanations. The awareness of being monitored by health professionals may have promoted a change in the behavior of patients by increasing the intention to adhere to the exercise regime. Moreover, a better performance might have been ensured by the ergonomic tools embedded in the experimental device and the sensorial feedbacks. Finally, although the experimental and the control interventions were almost equal in terms of duration, intensity, and specificity of the exercises, the difference between the 2 arms in number of exercises may have weakened the validity of the comparison.

Telemedicine is rapidly becoming a promising option in many branches of medicine[25,26,27,28,29,30] and in rehabilitation as well[31]. Few patients with rheumatic disease who have hand impairment are referred to rehabilitative therapy and even fewer use this service[32]. Re.Mo.Te. may offer improved access to healthcare over distance and the opportunity to increase the intensity and duration of the rehabilitation program, satisfying both the need to exercise at home and the need for continuous supervision of kinesiotherapy. Moreover, the Re.Mo.Te. technology was appreciated and welcomed by patients. Indeed, according to the results obtained by QUEST 2.0, patients were satisfied with the services and the device in general and with the ease of use (4.9 ± 0.32) and effectiveness (4.2 ± 0.80) in particular, which the larger majority of them considered the most important aspects of Re.Mo.Te.

Notwithstanding some limitations, our preliminary study suggests how promising and effective the approach of telemonitoring self-directed kinesiotherapy sessions could be for the rehabilitation of hand function in patients with rheumatic disease. However, further larger studies will need to be undertaken to evaluate the telemonitoring effect on rehabilitation. Ongoing research will investigate the cost-effectiveness of a personalized program of kinesiotherapy driven by Re.Mo.Te. and specifically designed for the needs of the individual patient, as well as the technical support and organizational setup necessary to provide this new approach as a standard of care.

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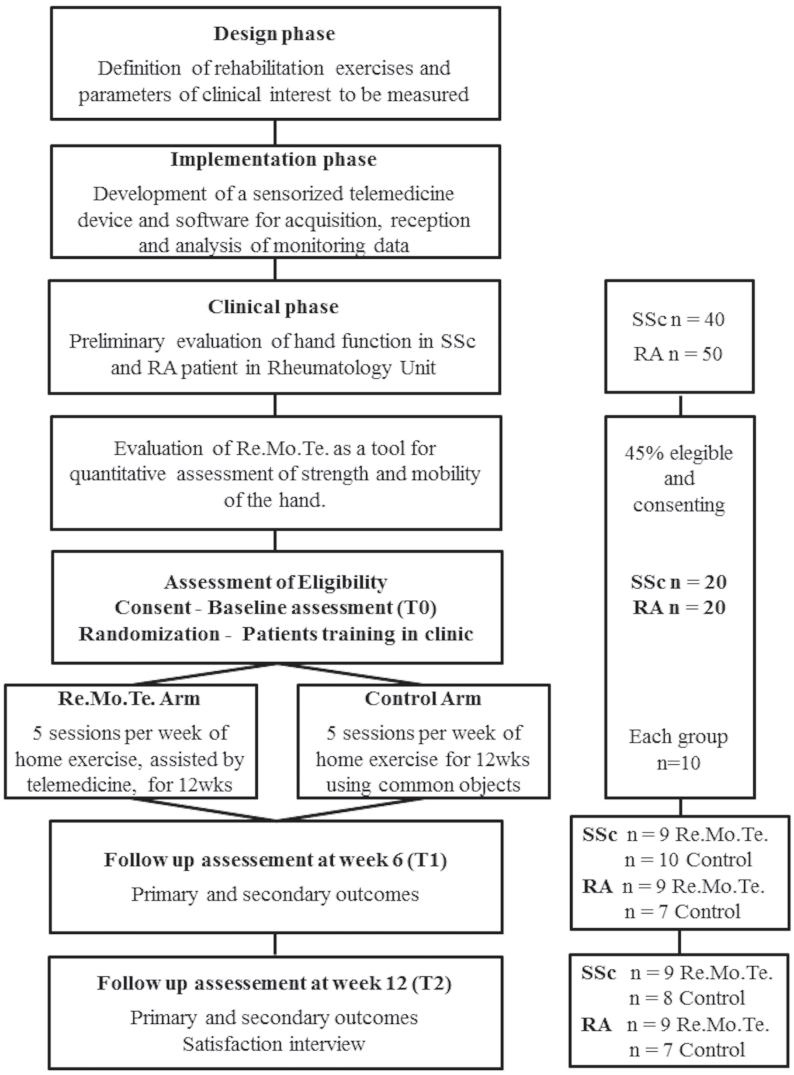
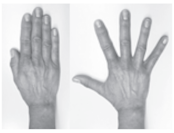
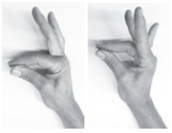
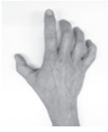
APPENDIX 1. Overview of the Re.Mo.Te. project and Re.Mo.Te. trial design. Re.Mo.Te.: Recovery of Movement and Telemonitoring Technology; SSc: systemic sclerosis; RA: rheumatoid arthritis.



REFERENCES

1. Sandqvist G, Hesselstrand R, Eberhardt K. A longitudinal follow-up of hand involvement and activities of daily living in early systemic sclerosis. Scand J Rheumatol 2009;38:304-10.
2. Björk MA, Thyberg IS, Skogh T, Gerdle BU. Hand function and activity limitation according to health assessment questionnaire in patients with rheumatoid arthritis and healthy referents: 5-year followup of predictors of activity limitation (The Swedish TIRA Project). J Rheumatol 2007;34:296-302.
3. Poole JL, Santhanam DD, Latham AL. Hand impairment and activity limitations in four chronic diseases. J Hand Ther 2013;26:232-6.
4. Avouac J, Walker U, Tyndall A, Kahan A, Matucci-Cerinic M, Allanore Y, et al. Characteristics of joint involvement and relationships with systemic inflammation in systemic sclerosis: results from the EULAR Scleroderma Trial and Research Group (EUSTAR) database. J Rheumatol 2010;37:1488-501.
5. Sandqvist G, Eklund M, Akesson A, Nordenskiold U. Daily activities and hand function in women with scleroderma. Scand J Rheumatol 2004;33:102-7.
6. Hallert E, Björk M, Dahlström O, Skogh T, Thyberg I. Disease activity and disability in women and men with early rheumatoid arthritis (RA): an 8-year followup of a Swedish early RA project. Arthritis Care Res 2012;64:1101-7.
7. Combe B, Landewe R, Lukas C, Bolosiu HD, Breedveld F, Dougados M, et al. EULAR recommendations for the management of early arthritis: report of a task force of the European Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Ann Rheum Dis 2007;66:34-45.
8. Li LC. What else can I do but take drugs? The future of research in nonpharmacological treatment in early inflammatory arthritis. J Rheumatol Suppl 2005;72:21-4.
9. Poole JL. Musculoskeletal rehabilitation in the person with scleroderma. Curr Opin Rheumatol 2010;22:205-12.
10. Hammond A. Rehabilitation in rheumatoid arthritis: a critical review. Musculoskeletal Care 2004;2:135-51.

APPENDIX 2. In the first column is the description of each exercise (E) together with the number of sets and repetitions. The pictures representative of each exercise for control arm (second column) and experimental arm (third column) are shown. The fourth column describes the tools (A) embedded in the Re.Mo.Te device and the main physical variables monitored in each exercise. Extracted variables included number of repetitions, exercise duration, and maximum and minimum amplitude, together with mean and SD of the physical quantities.

Exercise description	Control Arm	Experimental arm	Tool Description
E1. Hand abduction (mobility). Starting from the position of max adduction, spread the fingers as possible and narrow them up to the max abduction, repeating the exercise rhythmically and fluently (bilaterally 2 sets, 20 repetitions).			**A1**. The tool for the abduction of the hand; to assess the max abduction of the hand (against constant resistance). **EP:** extension
E2. Finger pinch (strength). Press, for at least 1 sec, the sensor (coin) between the thumb and other fingers alternating thumb-index, thumb-middle finger etc.. (bilaterally 1 sets, 10 repetitions)			**A2**. The tool for finger pinch; to assess the strength of the fingers in opposition to the thumb. **EP**: force
E3. Dynamic rotation (mobility). Turn the knob (cap) clockwise (10 laps) and counterclockwise (10 laps) without rotating the wrist. Objective: attempt in a quick and precise movement (bilaterally 2 sets, 10 repetitions)			**A3.** The tool for dynamic rotation, to evaluate the manipulative ability of the patient (against low-resistance). **EP**: Rotation angle and speed
E4. Hand grip (strength). Grab the instrument (cylinder) between the thumb and the other fingers, as it would hold a nutcracker, then try to tighten into a fist, for at least 1 sec. (bilaterally 2 sets, 20 repetitions).			**A4.** The tool for hand grip, to assess the strength of the hand grip. **EP**: force
E5. Hand pinch (strength). Grab the instrument (cylinder) between the thumb and the other fingers holding them lie flat, as shown in figure, then try to tighten it for at least 1 sec. (bilaterally 2 sets, 20 repetitions)			**A5**. The same tool, to assess the strength of the hand pinch. **EP**: force
E6. Isometric rotation (strength). Try to turn the knob, for at least 1 sec, clockwise (E6a) and then counterclockwise (E6b) acting only with the fingers (bilaterally 2 sets, 5 repetitions).	Not required for control arm		**A6**. The tool for isometric rotation, to evaluate the torque applied in a isometric rotation imparted with the fingers. **EP**: torque
E7. Piano-like (mobility). To perform the exercise correctly touch, as fast as possible, the sensitive areas (table) in sequence pinky-ring-middle-index-thumb, like playing a piano (bilaterally 2 sets, 20 repetitions).			**A7**. Finger tapping tool, to evaluate the hand dexterity in a movement piano-like (without counter-resistance). **EP:** touches per second, correct touches

11. Heine PJ, Williams MA, Williamson E, Bridle C, Adams J, O'Brien A, et al; SARAH Team. Development and delivery of an exercise intervention for rheumatoid arthritis: strengthening and stretching for rheumatoid arthritis of the hand (SARAH) trial. Physiotherapy 2012;98:121-30.
12. Mugii N, Hasegawa M, Matsushita T, Kondo M, Orito H, Yanaba K, et al. The efficacy of self-administered stretching for finger joint motion in Japanese patients with systemic sclerosis. J Rheumatol 2006;33:1586-92.
13. Pani D, Barabino G, Dessì A, Mathieu A, Raffo L. Apparatus, a system and a relating method for local or remote rehabilitation and functional evaluation of the hands. [Internet. Accessed May 1, 2014.] Available from: www.google.com/patents/US20130143718
14. Hamilton GF, McDonald C, Chenier TC. Measurement of grip strength: validity and reliability of the sphygmomanometer and jamar grip dynamometer. J Orthop Sports Phys Ther 1992; 16:215-9.
15. Demers L, Weiss-Lambrou R, Ska B. The Quebec user evaluation of satisfaction with assistive technology (QUEST 2.0): An overview and recent progress. Technol Disabil 2002;14:101-5.
16. Poole JL. Grasp pattern variations seen in the scleroderma hand. Am J Occup Ther 1994;48:46-54.
17. Badley EM, Wagstaff S, Wood PH. Measures of functional ability (disability) in arthritis in relation to impairment of range of joint

movement. Ann Rheum Dis 1984;43:563-9.
18. Dellhag B, Burckhardt CS. Predictors of hand function in patients with rheumatoid arthritis. Arthritis Care Res 1995;8:16-20.
19. Bongi SM, Del Rosso A, Galluccio F, Sigismondi F, Miniati I, Conforti ML, et al. Efficacy of connective tissue massage and McMennell joint manipulation in the rehabilitative treatment of the hands in systemic sclerosis. Clin Rheumatol 2009;28:1167-73.
20. Flint-Wagner HG, Lisse J, Lohman TG, Going SB, Guido T, Cussler E, et al. Assessment of a sixteen-week training program on strength, pain, and function in rheumatoid arthritis patients. J Clin Rheumatol 2009;15:165-71.
21. Baillet A, Payraud E, Niderprim VA, Nissen MJ, Allenet B, François P, et al. A dynamic exercise programme to improve patients' disability in rheumatoid arthritis: a prospective randomized controlled trial. Rheumatology 2009;48:410-5.
22. Rønningen A, Kjeken I. Effect of an intensive hand exercise programme in patients with rheumatoid arthritis. Scand J Occup Ther 2008;15:173-83.
23. Meichenbaum D, Turk D. Facilitating treatment adherence: a practitioner's guidebook. New York: Plenum Press; 1987.
24. Michie S, Rumsey N, Fussell A, Hardeman W, Johnston M, Newman S, et al. Improving health: changing behaviour. NHS health trainer handbook. 2008. [Internet. Accessed May 1, 2014.] Available from: www.ideals.illinois.edu/bitstream/handle/2142/46248/NHS%20Health%20Trainer%20Workbook%20-Susan%20Michie,%20et%20al%20-%20%20England.pdf?sequence=2
25. Davis P, Howard R, Brockway P. An evaluation of telehealth in the provision of rheumatologic consults to a remote area. J Rheumatol 2001;28:1910-3.
26. Lewtas J. Telemedicine in rheumatology. J Rheumatol 2001;28:1745-6.
27. Palaniswamy C, Mishkin A, Aronow WS, Kalra A, Frishman WH. Remote patient monitoring in chronic heart failure. Cardiol Rev 2013;21:141-50.
28. Levin K, Madsen JR, Petersen I, Wanscher CE, Hangaard J. Telemedicine diabetes consultations are cost-effective, and effects on essential diabetes treatment parameters are similar to conventional treatment: 7-year results from the Svendborg telemedicine diabetes project. J Diabetes Sci Technol 2013;7:587-95.
29. Yozbatiran N, Harness ET, Le V, Luu D, Lopes CV, Cramer SC. A tele-assessment system for monitoring treatment effects in subjects with spinal cord injury. J Telemed Telecare 2010;16:152-7.
30. Angius G, Pani D, Raffo L, Randaccio P, Seruis S. A tele-home care system exploiting the DVB-T technology and MHP. Methods Inf Med 2008;47:223-8.
31. Rogante M, Grigioni M, Cordella D, Giacomozzi C. Ten years of telerehabilitation: a literature overview of technologies and clinical applications. NeuroRehabilitation 2010;27:287-304.
32. Bassel M, Hudson M, Baron M, Taillefer SS, Mouthon L, Poiraudeau S, et al. Physical and occupational therapy referral and use among systemic sclerosis patients with impaired hand function: results from a Canadian national survey. Clin Exp Rheumatol 2012;30:574-7.