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Effectiveness of tele-rehabilitation in patients with knee osteoarthritis: A randomized controlled trial

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Abstract

Objective: The primary objective of this randomized controlled trial was to evaluate the effectiveness of tele-rehabilitation (TR) compared to conventional rehabilitation (CT) in reducing pain (as measured by the Numeric Pain Rating Scale [NPRS]) in patients with knee osteoarthritis (OA). Secondary objectives included assessing changes in physical function and quality of life, as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Short Form-36 (SF-36) health survey, respectively.

Methods: Fifty-five patients diagnosed with knee OA were randomly allocated to either the TR group ($n = 29$), receiving remote physiotherapy sessions three times a week for four weeks, or the CT group ($n = 26$), undergoing traditional outpatient rehabilitation with the same exercise regimen. Outcomes were measured at baseline and after a three-month follow-up period.

Results: At baseline, there were no significant differences between groups in terms of NPRS and WOMAC scores. After three months, both the CT and the TR groups showed significant improvements in pain reduction (NPRS, $p < 0.001$), WOMAC score ($p < 0.001$), and in some subscales of the SF-36 (i.e., physical functioning, role limitation attributable to physical problems, energy, and pain).

Conclusion: Tele-rehabilitation is an effective alternative to CT for reducing pain and improving quality of life in patients with knee OA. These findings suggest that TR can be incorporated alongside conventional approaches to provide a comprehensive treatment strategy for managing knee OA, enhancing patient outcomes in various dimensions of well-being.

Trial registration NCT05719350; Telerehabilitation in Patients With Osteoarthritis (TABLET).

Keywords

Knee osteoarthritis, tele-rehabilitation, pain management, physical functioning, physical therapy

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Introduction and background

Osteoarthritis (OA) poses a significant public health challenge, being one of the primary causes of disability among the elderly population in developed countries and adversely affecting patients' quality of life. During the COVID-19 pandemic, the need for safe and effective alternatives for OA management has become even more evident.[1] Knee OA, in particular, afflicts over

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32.5 million adults in the United States alone, making it the second most costly health condition treated in American hospitals.[2] In Italy, the prevalence of symptomatic knee OA was estimated to be around 29.8% among the elderly aged over 65.[3]

The latest guidelines from the American College of Rheumatology/Arthritis Foundation (ACR)[3] and the Osteoarthritis Research Society International (OARSI)[4,5] have highlighted a range of therapeutic options, including specific exercise programs that have proven effective in reducing pain and slowing OA progression.[6–10] Traditionally, these treatments are delivered in outpatient clinical settings with the support of rehabilitation professionals.[6]

The emergence of tele-rehabilitation (TR) programs has responded to the growing demand for treatment methods that ensure safety and therapeutic continuity.[11] Tele-rehabilitation allows the remote delivery of rehabilitation programs, in accordance with the Individual Rehabilitation Project (IRP) guidelines, proving especially useful in both post-acute and chronic phases of patient neuromuscular recover.[12–15] In this context, TR emerges as a promising solution, offering patients with chronic diseases the opportunity to follow personalized rehabilitation programs from their own home, as an alternative or in addition to traditional treatment.[16]

The aim of this study is to assess whether an evidence-based exercise program, targeted at elderly individuals with knee OA and delivered through TR, can be as effective, if not more, compared to conventional rehabilitation (CT) in terms of pain reduction and quality of life improvement. Furthermore, the study seeks to explore the impact of TR on treatment adherence and patient satisfaction, potentially offering a more accessible and flexible solution for OA management.

Methods

Study design and population

The study is as a randomized controlled trial. It was registered on ClinicalTrials.gov (code NCT05719350). The study population was composed of individuals diagnosed with knee OA, identified according to the ACR and NICE criteria,[3,17,18] and with Kellgren–Lawrence grade ≥ 2. Eligibility criteria included individuals aged over 18 years, able to provide informed consent for participation in the study, and capable of using electronic devices such as PCs, tablets, or smartphones. Subjects with a Numeric Pain Rating Scale (NPRS) value >3[19–22] indicating moderate to severe knee pain were included. Subjects who have participated in any rehabilitation exercise programs, whether in an outpatient setting or via remote care, within the last 6 months prior to enrollment in the study were excluded. Subjects were randomized assigned to either TR or CT group using a 1:1 allocation ratio. Subject allocation to treatments occurred sequentially as each participant entered the study. Both the TR group and the CT group received the same protocol of land-based therapeutic exercises. Tele-rehabilitation group received the rehabilitation program through video-call (WhatsApp, FaceTime applications) and communicated with healthcare providers throughout the duration of the exercise session.

The research protocol received approval from the Ethics Committee AVEC (Comitato Etico Area Vasta Emilia Centro) under protocol code CE AVEC: /Sper/IOR806/2022. Written informed consent was obtained from all participants. No devices were provided to the participants, which used their own equipment for the TR sessions.

Recruitment and allocation

Patient recruitment took place in February 2023 and lasted one month. Patients were contacted by phone call and invited to participate in the study by physiotherapists who were affiliated with the institution.

In the Sport Activities section, different levels of physical activity are listed: “Absent” (0 physical activity sessions per week), “Low” (1 physical activity session per week), “Moderate” (2–3 physical activity sessions per week), and “High” (more than 3 physical activity sessions per week).

Randomization procedure

To ensure a fair and unbiased allocation of participants to the TR group and the CT group, our study utilized the online tool available at www.randomizer.org. This website is known for providing simple yet effective randomization services, suitable for various research settings.

Implementation. An independent member of our research team, who was not involved in participant recruitment, treatment, or assessment, used www.randomizer.org to generate the randomization sequence. This process was conducted by entering the total number of participants and specifying two equal groups, which facilitated a balanced distribution between the TR and CT groups.

Allocation concealment. The use of www.randomizer.org contributed to allocation concealment by ensuring that the sequence was immediately applied without revealing future allocations. This procedure was strictly followed to prevent any potential bias, with group assignments being disclosed to the research team only after each participant’s enrolment and initial assessment were complete.

Blinding. Given the nature of the interventions, it was not possible to blind participants or therapists to group assignments. However, to mitigate any risk of bias in outcome assessment, the researchers responsible for evaluating the study outcomes were kept blind to group allocations. This was achieved by keeping the randomization sequence and resulting group

assignments confidential, accessible only to the independent team member who performed the randomization.

Data collection was carried out by a team of physiotherapists, who underwent prior training for the assessments. This approach aimed to minimize bias in data collection and analysis.

Intervention

In both the experimental (TR) and conventional (CT) groups, the rehabilitation sessions were systematically supervised by a physiotherapist who attended small groups with a maximum of five subjects. The sessions took place three days a week, with the schedule set on Mondays, Wednesdays, and Fridays, spanning a period of four weeks for a total 12 sessions.

The decision to measure pain intensity four weeks after intervention is based on expected therapeutic effects, literature evidence, and practical research considerations. This time frame aligns with when noticeable improvements from rehabilitation exercises are typically observed, allowing for an assessment of immediate post-treatment outcomes.[23] It balances the need to detect changes due to the intervention against the potential for external factors to influence results over longer periods.[19] Furthermore, a four-week assessment provides timely feedback on treatment efficacy, supporting informed decisions about future therapeutic directions. This approach is underpinned by both the cumulative nature of the interventions and existing research findings on pain management and rehabilitation effectiveness within a similar period.[24]

The knee joint exercises comprised four land-based exercises, lasting approximately 20–25 min in total. Each exercise targeted specific muscle strengthening and joint mobility, with intervals of approximately 1–2 min between exercises.

The knee exercises for the experimental group included the following:

1. Knee flexion/extension in a seated position.
2. Quadriceps strengthening with isometric contraction in a seated position.
3. Sit-to-Stand (squat) from a chair.
4. Squat isometric exercise in an upright standing position.

Conventional group (CT): subjects received the same rehabilitation (exercise) program described above, but they were supervised by a physiotherapist, as outpatient setting at the Istituto Ortopedico Rizzoli (IOR), Bologna, Italy.

Outcomes

The primary outcome measure was the change in pain levels as measured by the NPRS. Numeric Pain Rating Scale is a commonly used pain assessment tool in both clinical and research settings. The scale ranges from 0 (no pain) to 10 (worst imaginable pain). It provides a simple and effective method to measure the intensity of pain perceived by an individual at a specific moment.[20] All subjects' pain level was assessed by NPRS at three different time points: baseline (T0, i.e., before the start of the treatment), at the end of the treatment (T1, i.e., after four weeks of intervention), and at three-month follow-up (T2). In addition to the primary outcome, secondary outcomes were evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Short Form 36 Health Survey (SF-36) survey. The WOMAC is a validated questionnaire that assesses pain, stiffness, and physical functioning designed to assess the health status and functional limitations of individuals with OA, particularly affecting the knee and hip joints. The score range 0–96, with higher values indicating worse function.[25,26] The SF-36 is a widely used health-related quality of life questionnaire that measures various aspects of physical and mental health. It consists of 36 items that cover eight distinct health domains, providing a comprehensive assessment of the individual's health status and functional outcomes. The score range 0–100, with higher values indicating better quality of life.[27,28] Outcome data regarding NPRS, WOMAC index, and SF-36 were reported at different time points: T0 (baseline), T1 (post-intervention), and T2 (follow-up).

Neither serious medical conditions nor side effects were reported during the study. Minor issues included fatigue, transient articular and muscular discomfort, and initial difficulties with certain exercises, highlighting the safety and feasibility of both rehabilitation methods.

Sample size

The power analysis for sample size definition was performed, considering the NPRS score as the primary endpoint in the follow-up. Assuming the scores are normally distributed, the comparison between the two groups was based on an unpaired *t*-test. Based on the literature,[29] the standard deviation was estimated to be 1.7. Assuming that the minimum clinically significant difference between the two groups is 2 points (effect size = 1.178) and considering a two-sided *t*-test for noninferiority design, the minimum sample size required, with an alpha error of 0.05 (Z $1\text{-}\alpha = 1.645$) and a power of at least 0.9 (Z $1\text{-}\beta = 1.282$), $\delta 0 = 1$, and $\sigma = 1.7$, the minimum number of participants needed in each group was 25, for a total sample size of 50 cases. Accounting for a 5% dropout rate, the sample size was set to maintain statistical power with at least 48 completing participants, that is, 24 per group, thereby ensuring the validity of the statistical analyses relative to the study's objectives.

Statistical analyses

To address the primary research question, an independent two-sample *t*-test was employed to compare the mean

NPRS scores between the experimental and control groups at the conclusion of the treatment phase and the follow-up assessment. Additionally, paired *t*-tests were conducted to investigate within-group changes in pain scores from baseline to the respective time points. To answer the primary research question, a two-sample independent *t*-test was used to compare the mean NPRS scores between the experimental and control group at baseline, at the end of the treatment phase and at the follow-up assessment. In addition, paired *t*-tests were conducted to examine within-group variations in pain scores from baseline to the respective time points. At baseline, we conducted a frequency distribution analysis to examine the relationships between the qualitative variables in our study. This allowed us to assess the initial distribution of participant characteristics, such as gender, age, work activity, school education, and sporting activity performed in the two study groups. These data were used to ensure the initial comparability of the groups. Secondary outcome measures, encompassing functional status and quality of life, were assessed using the WOMAC and the SF-36, respectively. Independent *t*-tests were conducted to determine differences in mean scores between the two groups at the different time points, and paired *t*-tests to assess within-group changes from baseline. Post hoc pair-wise comparison was assessed with ANOVA repeated measures with Šidák correction. Prior to statistical analysis, data were tested for normality as per the assumptions of parametric statistics. The statistical significance level for all analyses was set at $\alpha = 0.05$, ensuring robust and accurate inference. For minimal clinical important difference (MCID) evaluation, the total WOMAC scores were normalized as a percentage and converted in a reverse format ranging from 0 (worst) to 100 (best).[25]

The Shapiro–Wilk test results indicate that the NPRS scores for both the TR and CT groups, at baseline (T0) and after intervention (T1), follow a normal distribution. This is because the *p*-values for all tests are above 0.05, suggesting no significant deviation from normality. Tele-rehabilitation group at T0: Statistic = 0.944, $p = 0.131$; TR group at T1: Statistic = 0.966, $p = 0.460$; CT group at T0: Statistic = 0.984, $p = 0.918$; CT group at T1: Statistic = 0.970, $p = 0.548$. Advanced statistical software packages (SPSS Statistics, version 24, IBM Corp., Armonk, NY, USA) were used.

Results

Patient recruitment flowchart is shown in Figure 1.

Demographics and characteristics of the studied subjects are reported in Table 1.

Regarding the Kellgren–Lawrence classification, subjects were graded as follows: 16 scored 2 ($n = 9$ CT; $n = 7$ RT), 34 scored 3 ($n = 16$ CT; $n = 18$ RT), and 6 subjects scores 4 ($n = 2$ CT; $n = 4$ RT).

Outcome data regarding NRS, WOMAC index, and SF-36 are reported in Table 2 at different time points: T0 (baseline), T1 (postintervention), and T2 (follow-up).

Numeric Pain Rating Scale

Patients in both groups (TR and CT) reported a significant reduction in pain value after the exercise program (T1), and the reduction was maintained in the follow up ($p = 0.0005$) (Table 2). The post hoc pairwise comparison with Šidák correction showed significant differences of NPRS values between T0 and T1 ($p < 0.001$), and between T0 and T2 ($p < 0.001$) in TR. Similarly, in the CT, NPRS value was statistically lower in T1 versus T0 ($p < 0.001$), and T2 versus T0 ($p \leq 0.001$). No differences were found in NRS values when comparing TR versus standard protocol at the tested time points.

Western Ontario and McMaster Universities Osteoarthritis Index

A significantly lower WOMAC score was found for both experimental TR and CT at T1 and T2 ($p = 0.0005$) (Table 2). The post hoc pairwise comparison with Šidák correction showed significant differences of WOMAC index between T0 and T1 ($p < 0.001$), and between T0 and T2 ($p \leq 0.001$) in the TR. Similarly, in the CT group, WOMAC score was statistically lower in T1 versus T0 ($p < 0.001$), and T2 versus T0 ($p < 0.001$).

The analysis of differences of WOMAC score among groups showed that TR subjects had significant lower values both at T1 ($p = 0.019$) and T2 ($p = 0.008$).

The statistical analysis performed for each subscale of WOMAC (pain, stiffness, and function) did not found significant differences between groups at the baseline (data not shown).

The between-group analysis at the baseline showed significantly higher sports activities in the TR group than in the conventional group, and therefore we performed further analysis to evaluate a possible role of individuals' sport activity on outcomes. Patients were divided according to their level of sports activities (none, level 1, and level ≥2); because the sport activity of level 3 was reached only by one individual, it was included in the group of level 2. Since the subgroup analysis with very few cases is not highly reliable, we performed a multivariate analysis with sport activity correction on the improvements of the scores of the two outcomes. The multivariate analysis adjusted for sport activity showed that the intervention has a significant influence on outcomes when considered across the levels, while its effect alone was only tendential ($p < 0.1$) for NPRS (data not shown). The post hoc pairwise analysis spread by sport level showed non difference in the improvement of 0 level of sport, but a better improvement in the level 1 of sport in the TR group. No comparisons can be made for the higher level.

Short Form 36 Health Survey

Short Form 36 – Physical functioning. As shown in Table 2, the score of Physical Functioning significantly increased in

Table 1. Baseline characteristics of the sample, tele-rehabilitation, and conventional rehabilitation group.

	All sample ($n = 55$)	TR ($n = 29$)	CT ($n = 26$)	p
Age (years)	61.0 ± 14.8	58.6 ± 17.4	63.6 ± 11.0	0.248
Body mass index (kg/m^2)	26.2 ± 4.0	27.1 ± 3.9	25.5 ± 4.1	0.111
Gender				
Men	21 (38%)	12 (41%)	9 (35%)	
Women	34 (62%)	17 (59%)	17 (65%)	
Education				0.285
Primary school	3 (5.5%)	2 (6.9%)	1 (3.8%)	
Secondary school	9 (16.4%)	2 (6.9%)	7 (26.9%)	
High school	26 (47.3%)	15 (51.7%)	11 (42.3%)	
Degree	17 (30.9%)	10 (34.5%)	7 (26.9%)	
Work activities				0.688
Employee	22 (40.0%)	11 (37.9%)	11 (42.3%)	
Professional	9 (16.4%)	5 (17.2%)	4 (15.4%)	
Retiree	22 (40.0%)	11 (37.9%)	11 (42.3%)	
Student	2 (3.6%)	2 (6.9%)	0 (0.0%)	
Sport activities				**0.002**
Absent	29 (52.7%)	13 (44.8%)	16 (61.5%)	
Low	15 (27.3%)	5 (17.2%)	10 (38.5%)	
Moderate	10 (18.2%)	10 (34.5%)	0 (0.0%)	
High	1 (1.8%)	1 (3.4%)	0 (0.0%)	

*$p < 0.05$.

both TR and CT subjects after the exercise program ($p = 0.0005$). The post hoc pairwise comparison with Sidak test showed a significant difference of the score between T0 and T1 ($p < 0.05$), and between T0 and T2 ($p < 0.01$) in the CT. In TR group, we found statistical difference of the score in the comparison between T0 and T2 ($p < 0.05$).

Short Form 36 – Role limitation attributable to physical problems. After the exercise program, the score significantly increased in both TR ($p < 0.05$) and CT ($p < 0.05$). The post hoc pairwise comparison with Sidak test showed a significant difference of the score between T0 and T1 ($p < 0.05$), and between T0 and T2 ($p = 0.01$) in the CT. In TR subjects, we found statistical difference of the score in the comparison between T0 and T1 ($p < 0.05$), and between T0 and T2 ($p < 0.05$).

Short Form 36 – Role limitation attributable to emotional problems. In the domain of Role Emotional, the exercise protocol did not cause modification in reported value during the follow up both for TR and CT patients. Comparing the different protocols (TR vs standard care), we found statistically higher values in the subject who follow the TR protocol versus the standard care at all the time points T0 ($p < 0.05$), T1 ($p < 0.05$), and T2 ($p < 0.05$).

Short Form 36 – Energy. After the exercise program, the score of Energy significantly increased in both TR ($p < 0.05$) and CT groups ($p = 0.001$). The post hoc pairwise comparison with Sidak test showed a significant difference of the score between T0 and T1 ($p = 0.05$), and between T0 and T2 ($p = 0.01$) in the CT. In TR group, we found statistical difference of the score in the comparison between T0 and T1 ($p < 0.05$) and between T0 and T2 ($p < 0.05$).

Short Form 36 – Emotional well-being. There was no significant difference of this item score along with the follow-up, for both experimental groups. No significant differences were found between TR and CT, either.

Short Form 36 – Social functioning. There was no significant difference of Social Functioning score along the follow-up, for both experimental groups.

Comparing the different protocols (TR vs standard care), we found statistically higher values in the subject who follow the TR protocol versus the standard care at all the time points T0 ($p < 0.05$), T1 ($p < 0.05$), and T2 ($p < 0.05$).

Short Form 36 – Pain. After the exercise program, the score of Pain significantly ameliorated in both TR ($p = 0.0005$) and CT subjects ($p = 0.0005$). The post hoc pairwise comparison with Sidak test showed a significant difference between T0 and T1 ($p < 0.001$), and T0 and T2 ($p < 0.001$) in both groups.

Short Form 36 – General health. A significant increase in GH value after the exercise program and in the follow up was reported by subjects in both TR ($p < 0.05$) and CT ($p = 0.001$) groups. The post hoc pairwise comparison with Šidák test showed a significant difference between

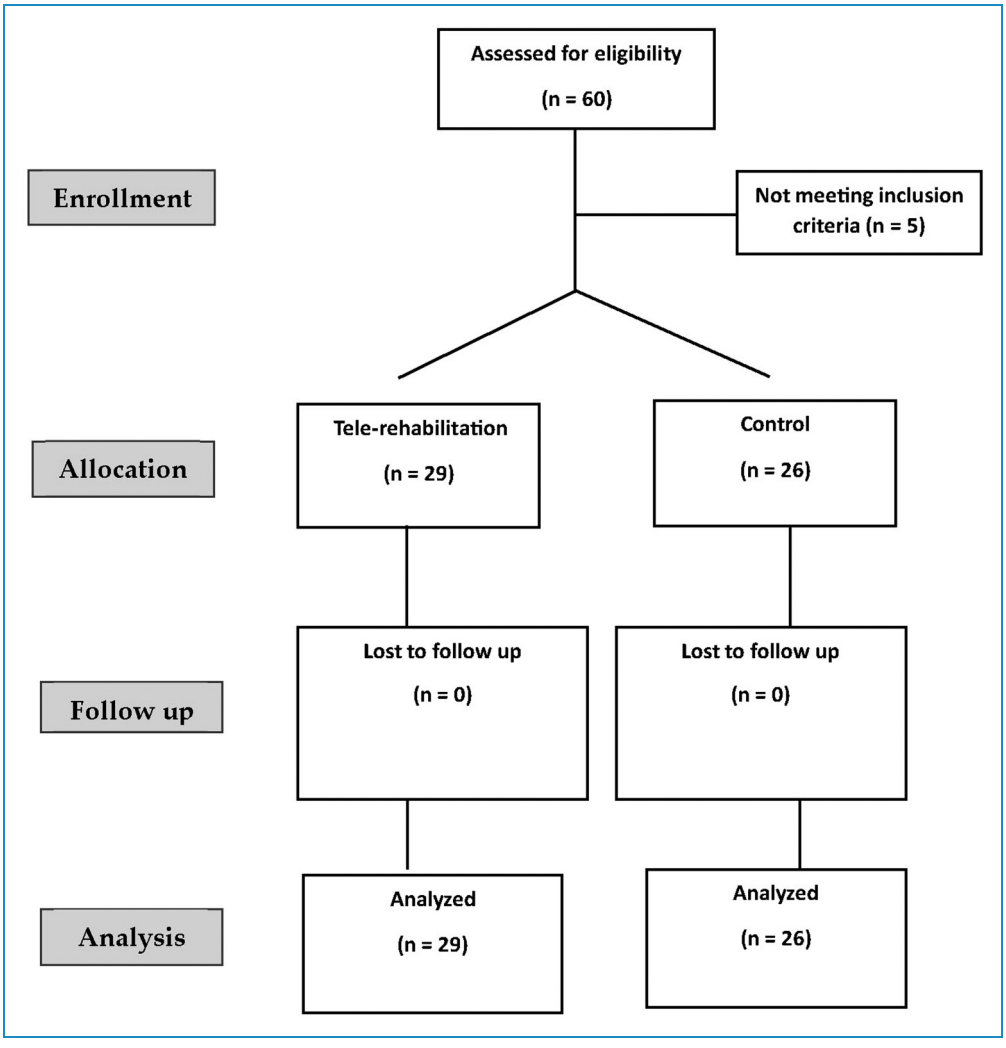

Figure 1. Flowchart of patients' recruitment.

Table 2. Differences among groups and during the follow up for the outcome variables.

					Post hoc analysis with Sidack multiple comparison		
	T0	T1	T2	ANOVA repeated measures (*p*)	T0 vs T1	T0 vsT2	T1 vsT2
NPRS (0–10)							
TR group	4.3 (1.6)	1.6 (1.9)	1.3 (2.1)	**<0.0005****	*<0.0001***	*<0.0001***	*ns*
CT group	4.4 (1.4)	1.4 (1.8)	1.5 (2.0)	**<0.0005****	*<0.0001***	*<0.0001***	*ns*
Difference among groups (*p*)	*0.703*	*0.735*	*0.553*				
WOMAC (0–96)							
TR group	27.4(17.8)	14.4(15.8)	8.9(15.2)	**<0.0005****	*<0.0001***	*<0.0001***	*<0.0001***
CT group	35.5(21.0)	23.0(15.9)	14.2 (14.5)	**<0.0005****	*<0.0001***	*<0.0001***	*<0.0001***
Difference among groups (*p*)	*0.157*	***0.019****	***0.008*****				
SF-36 (0–100)							
Physical Functioning							
TR group	71.2(20.1)	75.0(16.7)	76.0 (16.0)	**<0.0005****	*ns*	*0.024*	*ns*
CT group	59.8(27.7)	70.2(21.9)	71.9(21.4)	**<0.0005****	*<0.0001***	*<0.0001***	*ns*
Difference among groups (*p*)	*0.147*	*0.592*	*0.766*				
Role limitations attributable to physical problems							
TR group	69.8(34.6)	78.4(23.6)	79.2(22.9)	**0.046***	0.20	0.10	*ns*
CT group	66.0(29.2)	72.7(30.2)	73.5(29.9)	**0.014***	0.33	0.40	*ns*
Difference among groups (*p*)	*0.478*	*0.545*	*0.522*				
Role limitations attributable to emotional problems							
TR group	91.0(23.8)	94.9(12.1)	95.0(12.0)	0.174	–	–	–
CT group	79.4(28.1)	79.4(28.6)	78.6(30.8)	0.830	–	–	–
Difference among groups (*p*)	***0.031****	***0.017****	***0.017****				
Energy							
TR group	65.0(18.5)	70.2(13.5)	70.7(13.2)	**0.021***	*0.026**	*0.037**	*ns*
CT group	57.9(20.4)	67.0(15.0)	68.9(14.0)	**0.001***	*0.05*	*0.01**	*ns*
Difference among groups (*p*)	*0.134*	*0.460*	*0.747*				

(continued)

Table 2. Continued.

	T0	T1	T2	ANOVA repeated measures (*p*)	Post hoc analysis with Sidack multiple comparison		
					T0 vs T1	T0 vsT2	T1 vsT2
Emotional Well-Being							
TR group	79.0(17.5)	79.0(17.5)	79.0(17.5)	nv	–	–	–
CT group	73.7(16.9)	74.1(16.2)	73.9(16.0)	0.611	–	–	–
Difference among groups (*p*)	*0.149*	*0.189*	*0.159*				
Social Functioning							
TR group	83.2(15.4)	83.2(15.4)	83.2(15.4)	nv	–	–	–
CT group	66.7(26.6)	72.7(17.9)	72.8(18.0)	0.085	–	–	–
Difference among groups (*p*)	***0.012****	***0.035****	***0.040****				
Pain							
TR group	59.9(17.6)	88.0(17.2)	90.3(19.1)	**0.0005****	*<0.0001***	*<0.0001***	*ns*
CT group	49.4(18.3)	85.1(21.0)	89.7(16.1)	**0.0005****	*<0.0001***	*<0.0001***	*ns*
Difference among groups (*p*)	*0.123*	*0.768*	*0.673*				
General Health							
TR group	66.6(17.6)	70.0(15.5)	71.0(15.5)	**0.019***	*0.029**	*0.014**	*ns*
CT group	57.5(18.3)	61.0(15.0)	66.7(14.3)	**0.001***	*ns*	*<0.0001***	*0.025**
Difference among groups (*p*)	***0.038****	***0.010****	*0.117*				

Data collected at T0, T1, and T2 are represented as mean values ± SD. In the post hoc analysis, the significance of comparisons within groups (and between groups) is highlighted through *p*-values. Significant results are italicized (*$p < 0.05$; **$p < 0.01$). Nv: not evaluable.

T0 and T1 ($p < 0.001$) in the CT and between T0 and T1 ($p = 0.029$), and T0 and T2 ($p < 0.05$) in the TR group.

Comparing the different protocols (TR vs standard care), we found statistically higher values in the subject who follow the TR protocol versus the standard care one at T0 ($p < 0.05$), and T1 ($p = 0.010$).

The comparison between the TR and CT groups was actually conducted at the end of the 12th session, that is, four weeks from the beginning of the treatment. This timing was aimed to assess the immediate effects of the interventions directly after their completion.

The analysis of effect sizes is reported in Table 3.

The Cohen's *d* values show significant improvements within both groups for the NPRS and WOMAC measures, indicating effective pain management and functional improvement.

The negative signs for Cohen's *d* values in the SF-36 Physical Functioning measure are due to the direction of improvement (increase in scores), which does not align with the convention used in calculating Cohen's *d*. The SF-36 Physical Functioning scores also improved, with moderate effect sizes, suggesting enhanced physical functioning postintervention. The magnitude of these values still provides useful information about the size of the effect.

Discussion

The main finding of the present study is that a home physiotherapy exercise protocol that is supervised by a therapist via TR is not inferior to the same protocol delivered as outpatient treatment in improving pain levels and functional outcomes in patients with symptomatic knee OA.

Table 3. Analysis of effect sizes of tele-rehabilitation versus conventional therapy in knee osteoarthritis.

Outcome measure	Group	Pre-intervention mean (SD)	Post-intervention mean (SD)	Cohen's *d*
NPRS	TR	4.3 (1.6)	1.6 (1.9)	1.5
	CT	4.4 (1.4)	1.4 (1.8)	1.8
WOMAC	TR	27.4 (17.8)	14.4 (15.8)	0.8
	CT	35.5 (21.0)	23.0 (15.9)	0.7
SF-36 Physical Functioning	TR	71.2 (20.1)	76.0 (16.0)	−0.3
	CT	59.8 (27.7)	71.9 (21.4)	−0.5

Former research investigated the role and efficacy of remote care in managing chronic musculoskeletal pain and function. According to previous studies,[30,31] we observed a significant reduction in pain and an increase in patients' self-assessment of their general function, health status, and quality of life, after the physiotherapy program, and the beneficial effects were maintained at three-month follow up. Unlike other studies, however, we evaluated the bare effect of an exercise protocol supervised by a physiotherapist without confounding factors such as additional physical pharmacological therapies, different number of sessions, or the use of assistive devices. In the study by Azma et al. 2017[32] on pain and physical function of patients with knee OA, no differences were found between tele rehabilitation and office-based physiotherapy up to six months after treatment, but the outpatient group was subjected to additional passive physiotherapeutic interventions (i.e., transcutaneous electrical nerve stimulation, ultrasound, and thermotherapies). Similarly, Das et al.[31] reported no differences in pain and functional scores in early-knee OA patients who underwent teleconsultation (including remote examination) versus outpatient consultation, but the management protocol included heat therapy, calcium and vitamin D supplementation, and oral NSAIDs for 10 days, besides physiotherapy exercises.

Considering patient's education, a recommendation by OARSI guideline for OA management, the rehabilitation supervised by a physiotherapist (using video or phone calls) likely increase patient's participation and adherence to treatment and self-care. Remote physiotherapist interventions with digital tools commonly used for communication can help to improve home exercise adherence.[16] Compared to the home-based home exercise program, the supervision of a physiotherapist prevents the risks of adverse effects (wrong postures, excessive articular load, muscular stains) and ensures the accuracy of the exercise performance. In our study, patients were assisted by a physiotherapist throughout the sessions. In the case of standard rehabilitation protocols and following adequate education, caregiver may support TR as well. In a study by Ortiz-Piña et al.,[24] a 12-week TR program supervised by family caregivers had better outcomes in terms of functional independence and physical condition (self-assessment and performance-based) for elderly individuals with hip fractures compared to traditional home-based rehabilitation. These findings suggest that TR could be a valid option for managing the recovery process in older patients when perceived barriers limit the access to outpatient care.

At the baseline, no difference in the scores on pain and physical functioning evaluated by NPRS, WOMAC, and corresponding specific domains in the SF-36 questionnaire was found between CT and RT groups. The WOMAC index is a disease specific questionnaire accounting for the three cardinal clinical hallmarks of the osteoarthtritis (i.e., pain, stiffness and physical function) and therefore, it is the best tool to describe the study population. Indeed, we observed few significant differences among the groups at the baseline, specifically in the *role limitations attributable to emotional problems*, in the *social functioning* and in the reported *general health*, of the SF-36. The latter could represent a bias in the study, still we believe that they are likely the expression of individuals' psychologic rather than physical traits, and therefore should not influence the effects of a rehabilitation program. We have also found that TR subjects were more physically active, than controls. Specifically, the above features could impact the compliance with remote training and should be taken into account in programs of telerehabilitation that are not supervised by a physiotherapist, as in our study.

Rehabilitation (either RH or TR) improves outcomes across all groups and at all levels of sports activity, and, at a low level of sport activity, TR subjects showed a significantly better improvement (note that low level sport activity subgroup, level 1, comprised only five subjects in the TR group on a total of 15 subjects, i.e., 27.3%). Further studies with larger samples across different levels of sports activity could investigate whether active individuals might benefit the most from TR, but this was beyond the scope of this study.

In our study, pain levels decreased statistically in both the TR and traditional rehabilitation groups, after the four-week exercise protocol and at the three-month follow up; there was no statistical difference between the two experimental groups at all time points, confirming the comparable efficacy in pain improvement using the two approaches. Regarding self-reported function, both WOMAC index and SF-36 specific items (i.e., physical functioning, role limitations attributable to physical problems, energy) resulted statistically improved in both experimental groups. The total WOMAC score was statistically lower in the TR group after the treatment suggesting a better health status of this group. Interestingly, TR subjects reported significantly higher score in the subscale of general health, emotional problems, and social functioning at the baseline, and this may correlate with the incidental observation that they were also more physically active. Moreover, we found that the difference in the mean change of the normalized total WOMAC score improved of 22.2% in control and 19.2% in TR subjects, following the physiotherapy protocol. These values are far above the MCID required for knee OA (i.e., 17%, Clement at al.).[25] Minimal clinical important difference is an indicator of the perceived effect size, and in the case of WOMAC score, it is the smallest change in score perceived by patients about their general function following a treatment. These results also suggest that TR may have a positive impact on specific aspects of functionality, offering additional benefits compared to traditional rehabilitation. Although the TR program was indeed conducted under the supervision of a physical therapist, similar to traditional outpatient care, TR can significantly reduce operating costs of healthcare facilities keeping patients at their home. In this view, TR could reduce the burden on healthcare facilities and on patients, who could benefit from logistic opportunities and a reduction in travel and social efforts to reach rehabilitation centers.

In conclusion, our data indicate that TR is as effective as traditional physiotherapist-led rehabilitation in mitigating pain and ameliorating function in individuals with knee OA. These findings affirm TR not only as a noninferior but also as valid alternative to CT.

Limitations

Limitations of our study are crucial for contextualizing its findings. The short duration of the follow-up period limited our ability to assess the long-term sustainability of the improvements gained through TR. Additionally, the absence of a nontreated control group prevents a comprehensive understanding of the natural progression of knee OA without intervention, which could have provided valuable baseline data for comparison. The small sample size also poses constraints on the generalizability of our results, potentially limiting the statistical power to detect significant differences or subtle effects of the TR intervention. Future research should aim to include longer follow-up periods to better evaluate the lasting impact of TR, incorporate a nontreated control group for more in-depth comparisons, and increase sample sizes to enhance the robustness and applicability of findings.

Conclusions

The study concludes that TR is an effective and viable alternative to conventional physiotherapist-led rehabilitation for managing knee OA, demonstrating comparable outcomes in pain reduction and functional improvement. This underscores TR's strength not in surpassing conventional therapy in efficacy but in offering a flexible, accessible, and potentially resource-efficient option for knee OA care.

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References

1. Ragni E, Mangiavini L, Viganò M, et al. Management of osteoarthritis during the COVID-19 pandemic. *Clin Pharmacol Ther* 2020; 108: 719–729.
2. Yelin E, Weinstein S and King T. The burden of musculoskeletal diseases in the United States. *Semin Arthritis Rheum* 2016; 46: 259–260.
3. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for

the management of osteoarthritis of the hand, hip, and knee. *Arthritis Rheumatol* 2020; 72: 220–233.
4. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage* 2019; 27: 1578–1589.
5. Fitzgerald GK, Hinman RS, Zeni J, et al. OARSI clinical trials recommendations: design and conduct of clinical trials of rehabilitation interventions for osteoarthritis. *Osteoarthritis Cartilage* 2015; 23: 803–814.
6. Peat G and Thomas MJ. Osteoarthritis year in review 2020: epidemiology & therapy. *Osteoarthritis Cartilage* 2021; 29: 180–189.
7. Deyle GD, Allison SC, Matekel RL, et al. Physical therapy treatment effectiveness for osteoarthritis of the knee: a randomized comparison of supervised clinical exercise and manual therapy procedures versus a home exercise program. *Phys Ther* 2005; 85: 1301–1317.
8. Farr JN, Going SB, McKnight PE, et al. Progressive resistance training improves overall physical activity levels in patients with early osteoarthritis of the knee: a randomized controlled trial. *Phys Ther* 2010; 90: 356–366.
9. Richmond J, Hunter D, Irrgang J, et al. Treatment of osteoarthritis of the knee (nonarthroplasty). *J Am Acad Orthop Surg* 2009; 17: 591–600.
10. Shorter E, Sannicandro AJ, Poulet B, et al. Skeletal muscle wasting and its relationship with osteoarthritis: a mini-review of mechanisms and current interventions. *Curr Rheumatol Rep* 2019; 21: 40.
11. Graber J, Churchill L, Struessel T, et al. Expert consensus for the use of outpatient rehabilitation visits after total knee arthroplasty: a Delphi study. *J Orthop Sports Phys Ther* 2023: 1–9. doi:10.2519/jospt.2023.11840.
12. Lee AC, Davenport TE and Randall K. Telehealth physical therapy in musculoskeletal practice. *J Orthop Sports Phys Ther* 2018; 48: 736–739.
13. Turolla A, Rossettini G, Viceconti A, et al. Musculoskeletal physical therapy during the COVID-19 pandemic: is telerehabilitation the answer? *Phys Ther* 2020; 100: 1260–1264.
14. Wang CC, Chao JK, Chang YH, et al. Care for patients with musculoskeletal pain during the COVID-19 pandemic: physical therapy and rehabilitation suggestions for pain management. *J Chin Med Assoc* 2020; 83: 822–824.
15. Zhang ZY, Tian L, He K, et al. Digital rehabilitation programs improve therapeutic exercise adherence for patients with musculoskeletal conditions: a systematic review with meta-analysis. *J Orthop Sports Phys Ther* 2022; 52: 726–739.
16. Bennell K, Nelligan RK, Schwartz S, et al. Behavior change text messages for home exercise adherence in knee osteoarthritis: randomized trial. *J Med Internet Res* 2020; 22: e21749.
17. Altman R, Asch E, Bloch D, et al. Development of criteria for the classification and reporting of osteoarthritis. Classification of osteoarthritis of the knee. Diagnostic and Therapeutic Criteria Committee of the American Rheumatism Association. *Arthritis Rheum* 1986; 29: 1039–1049.
18. National Institute of Health Care Excellence. *Osteoarthritis: Care and Management in Adults*. London, UK: NICE, 2014.
19. Zhu B, Ba H, Kong L, et al. The effects of manual therapy in pain and safety of patients with knee osteoarthritis: a systematic review and meta-analysis. *Syst Rev* 2024; 13: 91.
20. Childs JD, Piva SR and Fritz JM. Responsiveness of the Numeric Pain Rating Scale in patients with low back pain. *Spine (Phila Pa 1976)* 2005; 30: 1331–1334.
21. Hawker GA, Mian S, Kendzerska T, et al. Measures of adult pain: Visual Analog Scale for Pain (VAS pain), Numeric Rating Scale for Pain (NRS pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care Res (Hoboken)* 2011; 63(Suppl 11): S240–S252.
22. Kapstad H, Hanestad BR, Langeland N, et al. Cutpoints for mild, moderate and severe pain in patients with osteoarthritis of the hip or knee ready for joint replacement surgery. *BMC Musculoskelet Disord* 2008; 9: 55. PMID: 18426591; PMCID: PMC2386464.
23. Bostan A and Kaya P. Effect of instrument-assisted soft tissue mobilization combined with exercise therapy on pain and muscle endurance in patients with chronic neck pain: a randomized controlled study. *J Man Manip Ther* 2024; 32: 131–140.
24. Ortiz-Piña M, Molina-Garcia P, Femia P, et al. Effects of telerehabilitation compared with home-based in-person rehabilitation for older adult's function after hip fracture. *Int J Environ Res Public Health* 2021; 18: 5493.
25. Clement ND, Bardgett M, Weir D, et al. What is the minimum clinically important difference for the WOMAC Index after TKA? *Clin Orthop Relat Res* 2018; 476: 2005–2014.
26. Salaffi F, Leardini G, Canesi B, et al. Reliability and validity of the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index in Italian patients with osteoarthritis of the knee. *Osteoarthritis Cartilage* 2003; 11: 551–560.
27. Bunevicius A. Reliability and validity of the SF-36 health survey questionnaire in patients with brain tumors: a cross-sectional study. *Health Qual Life Outcomes* 2017; 15: 92.
28. Apolone G and Mosconi P. The Italian SF-36 health survey: translation, validation and norming. *J Clin Epidemiol* 1998; 51: 1025–1036.
29. Michener LA, Snyder AR and Leggin BG. Responsiveness of the Numeric Pain Rating Scale in patients with shoulder pain and the effect of surgical status. *J Sport Rehabil* 2011; 20: 115–128.
30. Latif-Zade T, Tucci B, Verbovetskaya D, et al. Systematic review shows tele-rehabilitation might achieve comparable results to office-based rehabilitation for decreasing pain in patients with knee osteoarthritis. *Medicina (Kaunas)* 2021; 57: 64.
31. Das G, Sharma K, Das S, et al. Platelet-rich plasma in patients with symptomatic osteoarthritis knee: An evidence- and consensus-based 2023 International Society for Musculoskeletal Ultrasound in Pain Medicine Guidelines. *J Recent Adv Pain*. Published online January 1, 2023. doi:10.4103/jmupm.jmupm_3_23
32. Azma K, RezaSoltani Z, Rezaeimoghaddam F, et al. Efficacy of tele-rehabilitation compared with office-based physical therapy in patients with knee osteoarthritis: a randomized clinical trial. *J Telemed Telecare* 2018; 24: 560–565.