

Functional capacity and quality of life after telerehabilitation in post-tuberculosis lung disease: a randomized controlled trial

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ABSTRACT

Objective: Despite advances in diagnosis and treatment, approximately 50% of individuals affected by tuberculosis develop post-tuberculosis lung disease (PTLD), leading to functional limitations and reduced quality of life (QoL). Pulmonary rehabilitation programs have demonstrated benefits in patients with PTLD; however, access remains limited, and telerehabilitation may offer a cost-effective solution. This study sought to compare physical capacity and QoL in patients with PTLD following an eight-week telerehabilitation program. Methods: This was a randomized controlled trial including 30 participants with confirmed PTLD. They were recruited and randomly assigned to an intervention group that received weekly telerehabilitation or a control group that received standard care. The interventions included aerobic training, breathing exercises, strength training, and stretching exercises. Physical capacity and QoL were assessed before and after the interventions by means of isokinetic dynamometry, the six-minute walk test, the five-repetition sit-to-stand test, spirometry, handgrip strength, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36), and the Saint George's Respiratory Questionnaire. Results: After eight weeks, the intervention group showed significant improvements in all physical capacity parameters and QoL. Quadriceps strength correlated significantly with the physical functioning and mental health domains of the SF-36. Conclusions: Our findings suggest that telerehabilitation is an effective approach for enhancing physical function and QoL in patients with PTLD.

Keywords: Tuberculosis, pulmonary; Physical Therapy Modalities; Telehealth; Physical Fitness: Exercise.

INTRODUCTION

Pulmonary tuberculosis remains the leading cause of death from infectious diseases, with approximately 8.2 million cases diagnosed in 2023. This is the highest recorded number of cases since 1997. However, a 5.4% reduction in mortality was observed in comparison with 2022, likely due to an increase in the number of individuals receiving treatment (76-78%), despite global funding remaining below the target set by the WHO.(1)

Despite advances in diagnostic methods and therapeutic medications, it is estimated that approximately 50% of affected individuals develop long-term sequelae, leading to some degree of functional limitation or impaired quality of life (QoL), which characterizes post-tuberculosis lung disease (PTLD).(2-4)

PTLD requires a multidisciplinary approach, including permanent preventive measures to avoid reinfection and participation in pulmonary rehabilitation programs in certain cases. This approach has demonstrated significant benefits in functional recovery and improved QoL, with positive effects on physical capacity, fatigue levels, social participation, and overall health status. (5-7)

The number of rehabilitation centers worldwide is insufficient to meet the demands of patients with various functional limitations caused by different diseases. One potential strategy to expand access to these services is the implementation of telerehabilitation programs, enabling patients to complete at least part of the rehabilitation protocol at home. This approach offers advantages such as enhanced mobility and reduced treatment costs.(8-16)

There have been no randomized controlled trials (RCTs) on telerehabilitation in patients with PTLD. Therefore, the objective of the present study was to evaluate the effects of a telerehabilitation program on the physical capacity and QoL of patients with PTLD.

METHODS

Study design, setting, and participants

This was a single-center RCT conducted at the Federal University of Rio de Janeiro—located in the city of Rio de Janeiro, Brazil-in collaboration with the Istituti Clinici Scientifici Maugeri—a referral center in the city of Tradate, Italy—which supported the study design and statistical

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analysis, following the guidelines established in the Consolidated Standards of Reporting Trials statement. (17)

Participants were recruited from among those followed at the Federal University of Rio de Janeiro Tuberculosis Outpatient Clinic and underwent an initial screening that included a clinical interview (with dyspnea being assessed by the modified Medical Research Council scale), imaging tests (chest X-rays or CT scans), complete blood count, and biochemical profile assessment. Selected individuals with confirmed PTLD underwent QoL and physical capacity assessment.

Eligible patients had a Mini-Mental State Examination score > 24 (range, 0-30) and confirmed PTLD, as evidenced by residual lesions detected through clinical examination (clinical history, symptom assessment, and physical examination), imaging tests (chest X-rays or CT scans), functional assessment (spirometry, SpO $_2$ measurement, or the six-minute walk test [6MWT]), and/or subjective evaluation (QoL questionnaire or frequent symptoms score). $^{(3,18)}$

Individuals with comorbidities that could interfere with the assessments or those unavailable for telemonitoring via videoconference were excluded. Participants were excluded if adverse events hindered their participation in weekly videoconferences or their ability to perform the prescribed exercises as outlined in the study protocol.

Control variables and outcome measures

The instruments, methods, and variables used in the present study included the following: a) general physical examination, including body weight and height, measured with a mechanical scale with a stadiometer (110 CH; Welmy, Santa Bárbara D'Oeste, Brazil); systemic blood pressure, measured with an aneroid sphygmomanometer (Premium®; Missouri Mikatos, Embu, Brazil); SpO₂ and HR, measured with a portable pulse oximeter (9500; Nonin Medical, Inc., Plymouth, MN, USA); and RR, measured with a digital stopwatch; b) standard spirometry, performed with a single-user spirometer (Koko Sx®, nSpire Health Inc., Longmont, CO, USA) and analyzed in accordance with Brazilian national guidelines for pulmonary function tests(19,20); c) body composition assessment via tetrapolar multifrequency bioelectrical impedance analysis, performed with a body composition analyzer (InBody 230®; InBody Co. Ltd., Seoul, Korea); d) QoL assessment with the Saint George's Respiratory Questionnaire (SGRQ)(21) and the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)(22); e) calf circumference measurement, muscle mass being considered reduced if < 33 cm in women and < 34 cm in men⁽²³⁾; f) the 6MWT, performed in accordance with the recommendations of the American Thoracic Society, the expected six-minute walk distance (6MWD) for the Brazilian population being taken into consideration for analysis $^{(24,25)}$; g) The five-repetition sit-to-stand test (5STS), leg strength being considered reduced if test duration > $14 s^{(26,27)}$; h) handgrip strength, measured with a Jamar hydraulic hand dynamometer (Sammons Preston, Bolingbrook, IL, USA), with results being expressed in kg/f and being compared with reference values for the Brazilian population⁽²⁸⁾; and i) isokinetic dynamometry of the leg muscles, a Biodex[®] isokinetic dynamometer (Lumex Inc., Ronkonkoma, NY, USA) being used in order to evaluate muscle strength and fatigue of the dominant leg on the basis of peak torque of the quadriceps and hamstring muscles, 75°/s (5 repetitions) and 240°/s (15 repetitions) being performed with 2 min resting time.⁽²⁹⁾

Randomization and masking

Consecutive participants completing antituberculosis treatment and meeting the inclusion criteria were randomly assigned to either the intervention or control group using a block randomization method, with a block size of four. An independent statistician who was not involved in participant recruitment, treatment, or assessment prepared a computer-generated randomization sequence. Treatment assignments were concealed in opaque, sealed envelopes, which were opened sequentially after participants provided written informed consent and completed the baseline assessments.

Intervention and reevaluation

The intervention and control groups received general guidance on pulmonary tuberculosis symptoms and prevention during the initial face-to-face consultation and weekly videoconferences.

The intervention group received physiotherapy care via telemonitoring (telerehabilitation) once a week. This included an initial face-to-face consultation, in which a personalized exercise program was prescribed and demonstrated. The participants were instructed to perform the exercises for 45 min per day, five days per week (> 200 min/week) for eight weeks. During the videoconferences, adherence to the exercise program was evaluated, questions were addressed, and modifications (e.g., adjustments in repetitions, sets, or duration) were made as needed. (30)

Information on the program was provided via an illustrated booklet, with a tracking page for exercise completion. The exercises were divided into four parts: aerobic training, breathing exercises, strength training, and stretching. Exercise volume was prescribed on the basis of individual functional capacity, with a 20-s rest between sets (Chart 1).^(3,5,30)

After eight weeks, reevaluation of the intervention and control groups was performed by blinded examiners, who used the same research instruments to measure QoL and physical capacity in both groups. After data collection and analysis, all of the individuals in the control group were provided with full guidance to perform the same intervention protocol as that performed by the intervention group.

Sample size and data analysis

A sample size calculation indicated that 40 participants would be ideal on the basis of a pilot study



Chart 1. Steps, components, and exercises in the intervention group.

Steps	Components	Exercise/Activity
Aerobic training	Walk	A 20-min uninterrupted walk, once a day, on flat ground, with perceived exertion of 4-6 on the modified Borg scale.
Breathing exercise	Respiratory	Deep diaphragmatic breathing through the nose followed by exhaling with pursed lips and abdominal contraction. Three series of 8 repetitions.
Strength training	Arms*	Push-ups with a trunk inclination of 60 degrees. Two series of 10 repetitions.
	Legs*	Squats, with knee flexion until a 90-degree angle, trunk erect, feet parallel and apart at shoulder width, supported by a fixed chair, without using the upper limbs. Two series of 10 repetitions. Unilateral plantar flexion in the upright position. Two series of 10 repetitions.
Stretching exercises**	Arms	Horizontal abduction and bilateral extension in the standing position, while supported (e.g., a doorframe).
	Legs	Trunk flexion in a seated position, with knees in extension and feet apart at shoulder width. Unilateral dorsiflexion and extension of the ipsilateral thigh, supported on the flexed contralateral leg and leaning against a wall (pushing position).

^{*}The volume of strength training was individualized at the initial consultation, when exercise was prescribed.
**Stretching exercises were maintained for 20 s in each position, considering the individual range of motion and pain threshold. The recommended time interval between each exercise was 20 s.

assessing the 6MWD. With the use of the Student's t-test (a=5%; power = 80%), a minimum of 30 participants were found to be required for statistical significance.

Statistical analysis was performed with SigmaStat, version 3.1 (Grafiti LLC, Palo Alto, CA, USA). Data distribution was assessed with the Kolmogorov-Smirnov test. Associations between variables were analyzed with Spearman's or Pearson's correlation coefficient, as appropriate. Comparisons were performed with Fisher's exact test, ANOVA, the Student's t-test, or their nonparametric equivalents. Differences and correlations were considered significant at p < 0.05.

The local research ethics committee approved the study protocol (CAAE 10481219.9.0000.5257), and the study was registered at ClinicalTrials.gov (NCT04844502). All participants provided written informed consent. The study protocol was published elsewhere, (31) detailing the design, methodology, and planned analyses of the present RCT.

RESULTS

Eighty individuals were recruited. After the eligibility criteria were applied, 30 participants (11 females and 19 males) were randomized (Figure 1). Notably, all enrolled participants fully adhered to the study, and no adverse events occurred during the eight-week protocol.

Participant characteristics obtained through medical history taking, medical record review, physical examination, and spirometry are presented in Table 1. Comparisons between the control and intervention groups showed no significant differences at the initial assessment. The results for physical capacity and QoL, obtained from initial and follow-up assessments of the intervention (rehabilitation) and control

(nonrehabilitation) groups, were compared, with the differences and confidence intervals presented in Table 2. Comparisons between the post-rehabilitation group and the initial control group were made, and no clinically significant differences were observed.

After eight weeks of intervention, significant improvements were observed in all physical capacity parameters within the intervention group, including comparisons with predicted values for the 6MWD: predicted value for the total sample, 622.6 ± 54.4 m vs. pre-intervention value, 503.6 ± 120.5 m, corresponding to $80.9 \pm 19.0\%$; predicted value for the intervention group, 601.5 ± 46.9 m vs. post-rehabilitation value, 571.2 ± 134.4 m, corresponding to $95.0 \pm 21.4\%$. Additionally, overall QoL as assessed by the SGRQ improved, along with notable gains in the physical functioning and mental health domains of the SF-36. Quadriceps muscle strength was positively associated with SF-36 physical functioning and mental health domains (Figure 2).

DISCUSSION

This was the first RCT on telerehabilitation in patients with PTLD. Our results show that, in a cohort of patients with PTLD and functional limitations, an eight-week pulmonary telerehabilitation program led to significant improvements in peripheral muscle strength and endurance, as well as in the physical functioning and mental health domains of the SF-36. When we evaluated pre- and post-intervention differences, the telerehabilitation group alone demonstrated improvements across all the study variables. However, the differences were not fully reflected in the betweengroup analysis, likely because of the small sample size.

In one study, (32) 85 patients with PTLD (26 females and 59 males) were evaluated, and a slight reduction



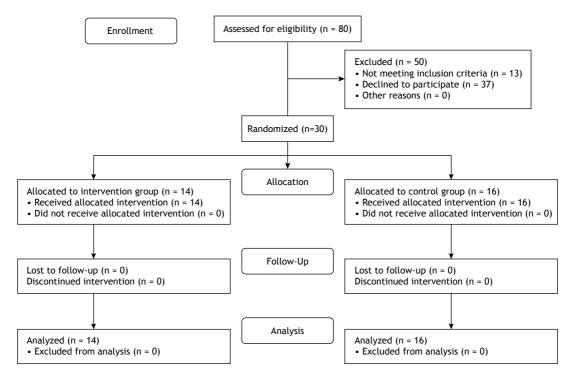


Figure 1. Flow chart of the recruitment, admission, randomization, follow-up, and analysis steps, in accordance with the Consolidated Standards of Reporting Trials statement.⁽¹⁷⁾

Table 1. Baseline characteristics of the total sample, as well as those of the intervention and control groups.^a

Characteristic	Total sample (n = 30)	Predicted value	Intervention group (n = 14)	Control group (n = 16)	p*
Age, years	44 ± 11.1	-	48.3 ± 12.8	41.4 ± 8.2	0.15
Sex					
Male	19 (63.3)	-	10 (71.4)	9 (56.3)	0.46
Female	11 (36.7)	-	4 (28.6)	7 (43.7)	0.46
Smoking history	9 (30)	-	4 (28.5)	5 (31.5)	0.8
Dyspnea	14 (46.6)	-	7 (50)	7 (43.7)	0.75
Another symptom	16 (53.4)	-	7 (50)	9 (56.3)	0.77
Radiological injury ^b					
Minimal	11 (61.1)	-	5 (45.4)	6 (54.6)	1.0
Moderate	7 (38.9)	-	3 (42.8)	4 (57.2)	1.0
MMSE score	29 [24-30]	> 24	29 [25-30]	29 [24-30]	0.91
BMI, kg/m ²	23.7 ± 4.8	18.5-25	23.9 ± 4.9	23.4 ± 4.4	0.66
Body fat, %	27.1 ± 8.2)	10-20	29.8 ± 10.6	24.7 ± 6.5	0.12
Muscular mass, %	39.6 ± 6.1)	> 30	37.3 ± 7.1	41.5 ± 4.3	0.06
Calf circumference, cm	35 [28-46]	> 34	34.5 [29-47]	36 [28-42]	0.90
mMRC dyspnea scale score	2 [0-4]	0	2 [0-4]	2 [0-3]	0.76
FEV ₁ , % predicted	80.2 ± 20.1	> 80	80.6 ± 19.3	79.9 ± 21.5	0.92
FVC, % predicted	83.9 ± 17.7	> 80	83.7 ± 16.1	84.2 ± 19.5	0.88
FEV ₁ /FVC	94.2 ± 13.1	> 70	95.6 ± 13.8	93.1 ± 12.6	0.42
6MWD, m	503.6 ± 120.5	622.6 ± 54.4	501.5 ± 146.6	505.5 ± 97.1	0.91

MMSE: Mini-Mental State Examination; mMRC: modified Medical Research Council; and 6MWD: six-minute walk distance. a Data presented as n (%), mean \pm SD, or median [IQR]. b In accordance with National Tuberculosis Association criteria. * Differences were considered significant if p < 0.05.

in physical capacity, as measured by the 6MWT, was found, along with significant radiographic abnormalities and pulmonary function impairment in 70% of the cases. Patients with more significant

radiographic sequelae showed impaired performance on the 6MWT when compared with those with smaller residual lesions (85.07 \pm 12.27 vs. 90.96 \pm 6.18% of the predicted value).⁽³²⁾ This result reinforces the



Table 2. Comparison of physical capacity and quality of life between the intervention and control groups.

Variable Intervention (group (reha n = 14)	group (rehabilitation) n = 14)		Control group (no rehabilitation) (n = 16)	no rehab = 16)	litation)	Value of p for differences
	Pre-rehabilitation	Post- rehabilitation	۵	Difference between post- and pre-rehabilitation (95% CI)	Initial evaluation	Reevaluation (at 8 weeks)	٩	Difference between reevaluation and initial evaluation (95% CI)	between post- rehabilitation and initial evaluation
6МWD, т	501.5 ± 146.6	571.2 ± 134.4	< 0.001*	69.7 (39.1-100.2)	505.5 ± 97.1	511.2 ± 96.9	*900.0	5.7 (1.90-9.59)	0.133
5STS, s	11.0 ± 2.4	9.2 ± 2.3	0.002*	1.74 (0.7-2.7)	10.8 ± 3.1	10.9 ± 3.1	0.215	0.12 (-0.08 to 0.3)	0.148
MIP, cmH ₂ 0	95.3 ± 24.4	103.5 ± 20.1	0.034*	8.2 (0.7-15.6)	92.6 ± 33.3	88.7 ± 18.5	0.401	-3.9 (-13.6 to 5.7)	0.266
MEP, cmH ₂ O	98.2 ± 22.4	108.5 ± 19.4	0.024*	10.3 (1.6-19.0)	94.6 ± 25.6	95.6 ± 21.8	0.654	0.93 (-3.4 to 5.3)	0.110
Handgrip strength, kgf	33.5 ± 8.2	39.2 ± 9.2	0.034*	5.6 (0.48-10.8)	31 ± 12.1	30.1 ± 7.3	0.732	-0.93 (-6.6 to 4.7)	0.050*
Peak torque on knee extension at 75°/s, Nm	89.7 ± 36.7	142.1 ± 77.2	0.007*	52.3 (16.7-87.9)	89.4 ± 47.2	89.3 ± 42.9	0.950	-0.10 (-3.6 to 3.4)	0.030*
Peak torque on knee extension at 240°/s, Nm	61.7 ± 20.7	90.1 ± 37.8	< 0.001*	28.3 (15.6-40.9)	65.0 ± 32.6	64.9 ± 32.4	0.756	-0.08 (-0.6 to 0.4)	0.044*
SGRQ, %	28.8 ± 21.6	17.6 ± 13.9	*900.0	-11.2 (-18.6 to -3.8)	28.8 ± 16.9	27.9 ± 17.5	0.333	-0.87 (-2.7 to 0.9)	0.074
SF-36 physical functioning domain, %	62.8 ± 19.9	74.0 ± 19.3	0.037*	11.1 (0.76-21.6)	50.0 ± 19.1	49.7 ± 18.6	0.474	-0.29 (-1.1 to 0.5)	0.002*
SF-36 mental health domain, %	59.9 ± 21.4	74.0 ± 21.8	0.004*	14.0 (5.4-22.7)	51.6 ± 18.3	50.9 ± 17.7	0.326	0.32 (-0.3 to 1.0)	0.005*

6MWD: six-minute walk distance; 5STS: five-repetition sit-to-stand test; SGRQ: Saint George's Respiratory Questionnaire; and SF-36: Medical Outcomes Study 36-Item Short-Form Health Survey. *Data presented as mean ± SD, except where otherwise indicated. *p < 0.05.



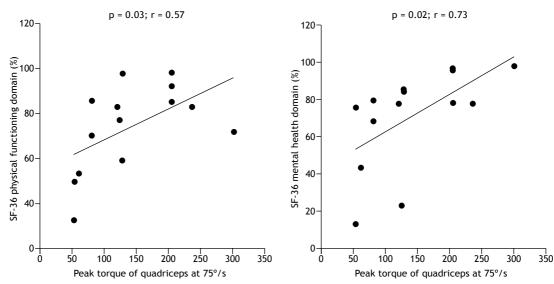


Figure 2. Positive association of Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) physical functioning and mental health domains with peak torque of quadriceps at 75° /s obtained with isokinetic dynamometry after eight weeks in the intervention group. The level of significance was set at p < 0.05.

need for rehabilitation programs for this population. Similarly, in our study, an improvement corresponding to 14.1% of the predicted value was observed after the intervention.

In another study, (33) positive outcomes from a six-week rehabilitation therapy program were demonstrated. The study included 29 patients, of whom 52% were female. The study participants completed a supervised group-based rehabilitation protocol twice per week combined with daily home-based exercise instructions. The supervised rehabilitation program consisted of educational sessions on health topics (including the effects of respiratory diseases, self-care, exercise, and diet), 30 min of walking, and anaerobic exercises for the arms and legs. After six weeks, the group showed a significant reduction in symptoms, improvements in functional tests (including the incremental shuttle walk test and the 5STS), and enhanced QoL (as assessed by the Clinical COPD Questionnaire and the Patient Health Questionnaire-9), which persisted for an additional six weeks after the intervention. (33) Our study did not employ the same instruments for assessing QoL; however, despite the fact that we used a telerehabilitation approach, we observed similar results, with a significant improvement in 5STS performance when comparing the pre- and post-intervention groups.

In a study involving 26 patients, $^{(34)}$ of whom 54% were female, a supervised rehabilitation protocol was implemented twice per week. After six weeks, the authors observed a nonsignificant improvement in functional performance on the 6MWT (an increase of 34 m in the 6MWD; p = 0.3), which contrasts with our findings (an increase of 69.7 m in the 6MWD; p < 0.001). However, they reported a significant improvement in QoL, as measured by the SGRQ

(a reduction of 17% in the scores; p = 0.002),⁽³⁴⁾ consistent with our results (i.e., a reduction of 11% in the scores; p = 0.006).

In yet another study, (35) the benefits of a home-based rehabilitation program for this population were assessed in an RCT involving a six-week intervention and 67 participants. The rehabilitation program consisted of low-impact exercises for the arms and legs (wall push-ups, repeated sit-to-stand movements, and calf raises), and participants were encouraged to "walk faster" each day during the walking component of the program. Specific pulmonary exercises included pursed-lip breathing, diaphragmatic breathing, postural correction, and cough facilitation exercises. Exercise tolerance was assessed by the 6MWT, demonstrating a significant improvement in the intervention group in comparison with the control group (p = 0.007; 95% CI, 15.37-92.7), (35) which contrasts with our findings (p. = 0.133). This might be due to differences in sample size or in patient engagement and commitment to carrying out the home-based protocol. (35)

Post-intervention pulmonary function was not specifically assessed in the present study. However, one study conducted a comparative analysis of pre- and post-intervention groups and reported no significant differences in FEV $_1$ (p = 0.1; 95% CI, -0.07 to 0.51) or FVC (p = 0.2; 95% CI, -0.9 to 0.51). These findings contrast with those of a multicenter study by Silva et al., (36) who reported significant improvements (p < 0.01) in pulmonary function outcomes following in-person rehabilitation programs lasting at least five weeks (20 nonconsecutive days) in a sample of 85 patients with PTLD. These discrepancies are likely due to differences in sample size and intervention protocols. (35,36)



There have been no studies examining the use of isokinetic dynamometry as the primary tool for objectively assessing changes in physical capacity in patients with PTLD.⁽²⁹⁾ However, one study demonstrated the effectiveness of this assessment method in more than 3,000 participants with COPD.⁽³⁷⁾ In our study, the sensitivity and applicability of isokinetic dynamometry were evident, highlighting muscle strength and fatigue (peak torque on knee extension) as key outcomes in the initial assessment and their improvement when we compared pre- and post-intervention measurements, as well as their association with perceived QoL.

The limitations of the present study include the absence of a disease-specific QoL questionnaire for patients with PTLD and the impossibility of replicating the research protocol in centers lacking isokinetic dynamometry equipment, which may have restricted the number of participants. The low sample size did not allow us to stratify results by COPD status, given that approximately one third of our patients had a smoking history. Furthermore, because we did not perform pre- and post-rehabilitation spirometry, we were unable to confirm the functional improvement reported elsewhere. (38)

The implementation of rehabilitation programs with innovative, effective, and low-cost strategies for PTLD treatment is currently a topic of discussion in clinical practice. (39) We sought to contribute through a simple, safe, low-cost, and effective telerehabilitation protocol. This approach seeks to facilitate the implementation of public health policies in regions with a high prevalence of PTLD and a limited number of rehabilitation centers. The only basic requirement to implement similar projects is the availability of a smartphone and an internet connection.

The present study demonstrated that an eightweek telemonitored rehabilitation program using videoconferencing had a positive effect on physical capacity and overall QoL in patients with PTLD. These findings reinforce current recommendations for continued care following the pharmacological treatment of pulmonary tuberculosis and highlights telemonitoring as a valuable tool in the functional recovery process.

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AUTHOR CONTRIBUTIONS

DFMT: design and planning of the study, as well as interpretation of findings; writing of all preliminary drafts and the final version; and approval of the final version. FSG: design and planning of the study; revision of all preliminary drafts and the final version. NASM: interpretation of findings and writing of all preliminary drafts. APC: design and planning of the study; and revision the final version. GBM: design and planning of the study; and revision of all preliminary drafts and the final version. FCQM: design and planning of the study, as well as interpretation of findings; and revision and approval of the final version.

CONFLICTS OF INTEREST

None declared.

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