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Protocol

Telerehabilitation in post-tuberculosis lung disease: a protocol for a randomized controlled clinical trial

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ABSTRACT

Background: Few studies have evaluated structured telerehabilitation programs for individuals with post-tuberculosis lung disease (PTLD), resulting in a lack of specific guidelines. This protocol aims to evaluate the physical capacity and quality of life (QoL) of PTLD patients undergoing telerehabilitation.
Methods: This randomized, controlled clinical trial has received internal review board approval and will recruit participants between December 2024 and June 2025, from a referral center in Brazil. Individuals thought to have PTLD, with a mini-mental state examination score >24 and no physical limitations or comorbidities unrelated to pulmonary tuberculosis (TB) will be screened using imaging, total blood count, and biochemical profile. Those with confirmed PTLD will undergo the assessments of: QoL, and physical capacity (spirometry, body composition, calf circumference, six-minute walk test (6MWT), five-times-sit-to-stand test (FTSST), handgrip and isokinetic dynamometry). After that, the participants will be randomly allocated to control or intervention groups. While both groups will receive general guidance on health education and TB prevention, the intervention group will also receive a physiotherapy booklet with instructions for exercises to be performed five times a week for eight weeks. Participants of both groups will be monitored by videoconference, and the same assessment tools will be used to reevaluate QoL and physical capacity outcomes.
Conclusions: The results may demonstrate the benefits of a telerehabilitation program on the physical capacity and QoL of PTLD patients, and may improve accessibility, cost savings, and personalized care through home-based therapy by videoconferencing.
Trial registration: CAAE: 10481219.9.0000.5257. This study was registered at ClinicalTrials.gov (NCT04844502).

Keywords: Pulmonary TB, Physiotherapy, Telerehabilitation, Telemonitoring, Physical capacity, QoL

INTRODUCTION

In 2022, 10.3 million individuals are estimated to have developed TB worldwide, with 90% of these cases involving pulmonary TB. Approximately 180 million individuals are estimated to be alive after having undergone pharmaceutical treatment for TB in the past five years.[1] Around 50% of that population lives with some degree of functional limitation, characterizing PTLD, a condition that requires multi-professional care and for which pulmonary rehabilitation is indicated.[2,3]

Pulmonary rehabilitation programs have demonstrated significant benefits in the functional recovery of patients with chronic lung diseases, including those with sequelae from pulmonary TB. The active involvement of physiotherapists through face-to-face consultations and educational guidance has been well-documented. These interventions consistently show strong evidence of

improving health status, exercise capacity, fatigue, and social functioning.[3-5]

The COVID-19 pandemic highlighted the scarcity of rehabilitation centers and showed how healthcare professionals can deliver rehabilitation remotely (telerehabilitation), assuring the required supervision through easily accessible and affordable technology strategies.[6-14] Nevertheless, despite the inherent benefits of avoiding intra-urban mobility problems and decreasing health-related costs, studies that include well-structured telerehabilitation protocols for individuals with PTLD are limited, resulting in insufficient evidence for establishing guidelines.[15-17]

This paper aims to present a protocol for assessing whether a home-based physiotherapy program using telemonitoring can improve the physical capacity and QoL of individuals with PTLD.

METHODS

Study design and setting

This randomized, controlled clinical trial will be developed in a single research center at the federal university of Rio de Janeiro (UFRJ)-Brazil, follow the SPIRIT guidelines (Standard protocol items: Recommendation for Interventional Trials). The study flowchart is shown in Figure 1.

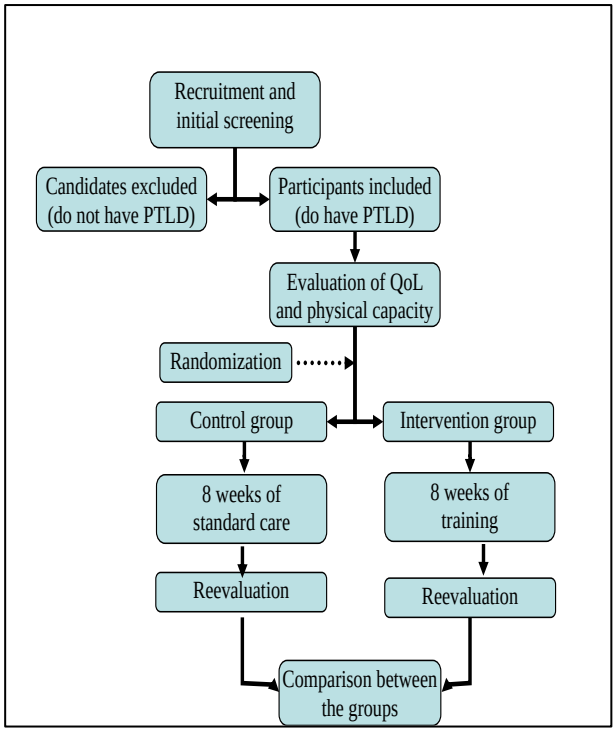

Figure 1: Study flowchart of steps involved in recruitment, admission, evaluation, randomization, management of the groups (control and intervention), reevaluation and comparative analysis.

Participants

The participants will be recruited at UFRJ's TB outpatient unit, between December 2024 and June 2025. The goal is to recruit 40 participants for the study. With a predicted discontinuation rate of 10%, the final analysis would consequently include 44 participants. Based on a preliminary analysis involving a pilot study with the distance covered in the 6MWT, using Student's t-test with an alpha of 5% and for a power of 80%, it is estimated that 30 participants will be required to achieve statistical significance.

All the participants will undergo initial screening with clinical interview-dyspnea recorded using modified medical research council (mMRC), imaging tests (chest radiography or computed tomography of the chest), complete blood count, and biochemical profile. Next, the selected individuals, i.e., with confirmed PTLD, will undergo QoL assessment and physical capacity evaluation.

In summary, patients with confirmed PTLD, a MMSE score >24 (0-30), peripheral muscle weakness and low cardiorespiratory fitness, with no comorbidities that would affect the evaluation of these variables and who are available for telemonitoring by videoconference will be included in the study.[18] Participants who do not comply with the set protocol due to any adverse event precluding weekly contact by videoconference and preventing them from carrying out the proposed exercises at least four times a week will be excluded from the study.

Evaluation of QoL

The Saint George's respiratory questionnaire (SGRQ), a specific instrument for evaluating QoL in respiratory diseases, will be used in this study. The SGRQ deals with the impact of disease on individuals, covering three areas or domains: symptoms, activities, and psychosocial aspects. The points given for each answer are added together, with the total score referring to a percentage of the maximum score possible for each answer. QoL is considered impaired when the values obtained exceed 10% in each domain. Changes of ≥4% following an intervention are considered the minimal meaningful difference in QoL.[19]

The 36-item short form health survey (SF-36), a generic questionnaire that can be self-administered or administered at an interview, will also be used to evaluate QoL. The 36 items evaluate eight domains of health status: physical functioning, physical role limitations, bodily pain, general health perceptions, energy/vitality, social functioning, emotional role limitations, and mental health. Scores for each domain range from 0 to 100, with 0 reflecting maximum impairment and 100 no impairment. The participants will receive instructions from an interviewer and answer the 11 questions related

to the eight different QoL domains, with answers being scored according to the scale defined for each question. The measurement of the scores and analysis of the results will follow the 36-item health survey scoring guidelines and scoring calculation.[20]

Control variables and outcome measures

General physical examination including body weight and height measurement using anthropometric mechanical scales with a stadiometer (Welmy 110®); systemic blood pressure based on an analog measurement to the nearest two mmHg using an aneroid sphygmomanometer (Premium®) certified by the Brazilian national institute of metrology, standardization and industrial quality (INMETRO); peripheral oxygen saturation and heart rate using a portable pulse oximeter (Nonin medical Inc., Minneapolis, MN, USA), model 9500; and respiratory rate measured by counting the movements of the chest wall/abdomen and quantified as number of breaths per minute (bpm).

Standard spirometry will be performed using spirometer equipment single user (Koko Sx® 2014 nSpire Health, Inc. 5.0) and analyzed following the guidelines for pulmonary function tests of the Brazilian society of lung disease and TB.[21, 22]

Body composition to measure total body mass, skeletal muscle mass, body fat mass and body fat percentage using tetrapolar multi-frequency bioimpedance analysis (InBody 230® body composition analyzer, Gangnamgu, Seoul, Korea).

Calf circumference will be evaluated on both lower limbs at the point of maximum circumference perpendicular to the longitudinal axis of the leg using a lockable, non-stretchable measuring tape, with the individual standing erect with their feet 20 cm apart. Muscle mass will be considered reduced when calf circumference is <33 cm in women and <34 cm in men.[23,24]

6MWT to be administered following the recommendations of the American thoracic society. The analysis will be conducted considering the expected value of the distance covered as registered for the Brazilian population.[25,26]

The FTSST using a chair with seat height of 47 cm. The exercise will be performed five times in succession in the shortest possible time and without using the upper limbs. The strength of the lower limbs will be considered reduced when the time used in the test is >14 seconds.[27,28]

Handheld dynamometry to evaluate the muscle strength of the handgrip (manual muscle test) using the Jamar hydraulic hand dynamometer (Sammons Preston, Bolingbrook, IL, USA). The results expressed as kg/f will be compared with the reference values for the Brazilian population.[29,30]

Isokinetic dynamometry in a lower limb using a Biodex® isokinetic dynamometer to evaluate the muscle strength and fatigue of the dominant leg, based on peak torques of the quadriceps and hamstring muscles. The participants will adopt a seated position on the device, inclined at ±95 degrees (internal angle), with the motor axis in line with the articular axis of the knee joint and stabilizations at the trunk, hip and thigh to avoid compensations associated with exerting maximum effort. The lever arm is positioned in the distal third of the leg being evaluated (3 cm from the medial malleolus) and the speed at which the tests for the quadriceps and hamstrings are performed will be 70º/second (5 repetitions) and 240º/second (15 repetitions) at amplitudes of 100º-0º, with a resting time of two minutes. There will be a warming-up period before testing, using the same movement as in dynamometry to familiarize the individual with the procedure. During the test, the examiner will provide visual and auditory feedback.[31]

Randomization and masking

Participants in this study will be randomly assigned to either the intervention group or the control group using a block randomization method. The block size will be set at four, and a computer-generated randomization sequence will be created using a random number generator. The allocation list will be prepared by an independent statistician not involved in recruiting, treating, or assessing participants. The list will be securely stored and only accessed by the designated study coordinator responsible for assigning participants to their respective groups. Treatment assignments will be concealed in opaque, sealed envelopes, and opened sequentially after participants provide informed consent and complete baseline assessments.

Intervention and reevaluation

General guidance on the symptoms and prevention of pulmonary TB, will be given to the intervention and the control group participants at the first face-to-face consultation and weekly videoconferences.

The intervention group will undergo physiotherapy care provided through telemonitoring (telerehabilitation) once a week, consisting of an initial face-to-face consultation at which a program of exercises will be prescribed and taught to the participant. The individual will be instructed to perform the exercises for 45 minutes a day, five days a week (>200 minutes/week) for eight consecutive weeks. During the videoconference, the number of days in the week the participant performed the exercise will be verified, any questions will be answered, and any necessary adjustments to the exercise program will be made, though modifications to the reps, sets, or the timing.[32]

The program will be provided in the form of an illustrated booklet, including a page for recording when the

exercises are performed. The exercises are arranged into four parts (aerobic training, breathing exercise, strength training, and stretching). The volume of exercises will be prescribed according to the individuals' functional capacity, with a 20 seconds interval between them (Table 1).[4,14-17]

Table 1: Stages, components, and exercises in the intervention group.

Steps	Components	Exercise/Activity
Aerobic training	Walk	A 20-minute 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	Upper limbs*	Push-ups with a trunk inclination of 60 degrees. Two series of 10 repetitions.
	Lower limbs*	Squats, with knees flexion until 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**	Upper limbs	Horizontal abduction and bilateral extension, in the standing position, while supported (e.g. a doorframe).
	Lower limbs	Trunk flexion in 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 lower limb and leaning against a wall (pushing position).

(*) The volume of strength training will be individualized at the initial consultation when the exercise is prescribed. (**) Stretching exercises will be maintained for 20 seconds in each position, considering the individual's range of motion, and pain threshold. The recommended time interval between each exercise will be 20 seconds.

At the 8-week reevaluation, the same instruments will be used to measure QoL and the physical capacity of the participants of both groups.

Statistical analysis

The statistical analysis will be performed using SigmaStat, version 3.1 (SYSTAT Software, Inc., Point Richmond, CA, USA). The Kolmogorov-Smirnov test will assess data distribution. Measures of association between variables will be analyzed using Spearman's or Pearson's correlation, as appropriate. Analysis of variance (ANOVA) and Student's t-test, or their corresponding nonparametric tests, will be used for comparisons. Differences and correlations will be considered statistically significant at $p<0.05$.

Ethical procedures and funding

The institution's internal review board approved the study protocol under reference CAAE: 10481219.9.0000.5257. All participants will sign an informed consent form.

For the procedures involved in this study, participants may experience the following risks and discomforts: unease when answering certain items in the questionnaires, tiredness/muscle fatigue, perspiration, and increased heart rate, respiratory rate, and blood pressure associated with some functional tests and the intervention program. The potential benefits include the positive effects of physical activity on cardiopulmonary and musculoskeletal conditioning, which may result in an improved QoL.

There will be no external funding for this study. The resources required will be provided by the respective laboratories and departments involved. There will be no cost whatsoever to the participants. The evaluations will be carried out on scheduled consultation days. The exams performed will be used to monitor the participants clinically, regardless of the study.

DISCUSSION

Obtaining more information on the physical limitations and perceived QoL of individuals with PTLD is essential in deciding whether continued therapy is necessary for complete recovery.[14,15,33] A well-defined physiotherapy program that includes structured learning steps telemonitoring, and the periodic assessment of functional outcomes underscores the practical relevance of this study. This approach has the potential to increase the accessibility and adherence to such rehabilitation programs, representing comprehensive and dignified care for a large proportion of the population affected by pulmonary TB.[32-34]

The rational use of resources considering how physiotherapists can connect with patients and how patients benefit from adequate guidance even when therapy is delivered remotely leads to efficiency in health actions. This is particularly relevant in low- and middle-income countries where there is often a deficit of professionals in the healthcare system trying to cope with an increasing demand.[12]

The potential limitations of this study include poor compliance with telerehabilitation therapy due to possible communication difficulties during telemonitoring, partial or inadequate adherence to the intervention program, and participants falsely claiming to have performed the exercises when they have not. Additionally, participants may discontinue the program because they do not wish to continue or due to adverse events.

CONCLUSION

In conclusion, this research aims to assess the potential effects of a physiotherapy telemonitoring protocol on the physical capacity and QoL of patients with PTLD. This therapeutic option may improve accessibility, cost savings, and personalized care through home-based therapy and real-time support via videoconferencing.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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