



Effectiveness of a Structured Physiotherapy Program on Pain, Function and Quality of Life in Patients with Pott's Syndrome (Spinal Tuberculosis): A Randomized Controlled Trial Protocol

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Abstract

Background: Spinal tuberculosis (Pott's syndrome) causes pain, deformity and neurological impairment.

Rehabilitation is considered essential in recovery, but high-quality experimental evidence of structured physiotherapy programs is limited.

Design: Randomized Controlled Trial

Objective: To evaluate the effectiveness of a 12-week supervised structured physiotherapy program plus standard medical care versus standard medical care with usual advice in improving disability, pain and function in adults with spinal tuberculosis.

Participants: 72 adults with confirmed spinal tuberculosis (radiological ± microbiological confirmation), medically stable on anti-tubercular therapy, with pain and/or functional limitation.

Intervention: Structured physiotherapy (12 weeks: pain control, breathing exercises, graded mobilization, spinal stabilization, progressive strengthening, gait/functional retraining, balance and ADL training) delivered twice weekly with home program.

Control: Usual care (anti-tuberculosis therapy, routine medical follow-up) + standard advice/home exercise leaflets.

Outcome: ODI (Oswestry Disability Index) – disability score, 0 = no disability, 100 = maximum, VAS (Visual Analogue Scale for pain) – 0 = no pain, 10 = worst, SF-36 PCS (Physical Component Score, quality of life) – higher = better

Keywords: *Pott's disease, spinal tuberculosis, physiotherapy, rehabilitation, randomized controlled trial, Oswestry Disability Index*

1. Introduction

Spinal tuberculosis (Pott's syndrome) remains a major cause of musculoskeletal morbidity in endemic regions. It causes vertebral destruction, deformity, paravertebral abscesses and neurological deficits. Beyond anti-tubercular therapy (ATT) and selective surgery, rehabilitation is an essential component throughout recovery — to reduce pain, improve respiratory function, re-educate trunk control, strengthen muscles, restore gait and

activities of daily living, and limit progression of disability. However, most published rehabilitation literature consists of case reports, small observational studies or surgical outcome series; high-quality randomized evidence for structured physiotherapy is scarce. This trial may assess whether a standardized supervised physiotherapy program improves function, pain and quality of life compared with usual care.

2. Objectives & Hypothesis

Objective: To evaluate effects on pain (VAS), ODI and SF-36.

Null Hypothesis: Participants receiving supervised physiotherapy may not be greater improvement in ODI score, VAS and SF-36 at 12 weeks than controls.

Alternate hypothesis: Participants receiving supervised physiotherapy may be greater improvement in ODI score, VAS and SF-36 at 12 weeks than controls.

3. Methods

3.1 Study design

Randomized Controlled Trial

3.2 Participants — inclusion & exclusion criteria

Inclusion Criteria

- Age 18–65 years were included in the study.
- 36 participants in each group were included in the study.
- Diagnosed spinal tuberculosis (radiological evidence ± microbiological confirmation) and currently on ATT or planned to start ATT.
- Stable medically such that participation in physiotherapy is safe (no immediate requirement for urgent spinal surgery).
- ODI $\geq 20\%$ at baseline or VAS ≥ 3 for back pain.
- Able to provide informed consent.

Exclusion Criteria

- Immediate surgical indication (unstable spine requiring urgent stabilization, progressive severe neurological deficit).
- Concomitant non-TB spinal disease preventing participation (e.g., recent major trauma, metastatic disease).
- Severe cardiopulmonary comorbidity precluding exercise.
- Pregnancy.

- Inability to attend physiotherapy sessions or expected life expectancy <1 year.

3.3 Outcome measures & timing

Assessment schedule: baseline (week 0), mid-intervention (week 6), end of intervention (week 12 — primary endpoint).

Outcome Measures:

- **ODI** (Oswestry Disability Index) – disability score, 0 = no disability, 100 = maximum
- **VAS** (Visual Analogue Scale for pain) – 0 = no pain, 10 = worst
- **SF-36 PCS** (Physical Component Score, quality of life) – higher = better

3.4 Interventions

3.4.1 Experimental group — Structured Physiotherapy Program (12 weeks)

2 supervised sessions/week (45–60 min) + daily home program. Components tailored by stage/severity but standardized core elements:

Phase	Timeline	Goals	Interventions
Phase A — Initial	Weeks 1–4	<ul style="list-style-type: none"> - Protect healing structures - Educate patient - Manage pain & maintain mobility - Initiate gentle activation 	<ul style="list-style-type: none"> • Education: disease, posture, precautions, ADL modifications • Pain management: positioning, cryotherapy/heat, TENS (if indicated) • Respiratory care: diaphragmatic breathing, segmental expansion, incentive spirometry (esp. thoracic involvement) • Gentle ROM and protected mobilization within surgeon/physician limits • Isometric core activation (multifidus, transversus abdominis cues), pelvic tilts • Early walking with brace/support as indicated
Phase B — Progression	Weeks 5–8	<ul style="list-style-type: none"> - Build core stability - Improve strength & endurance - Enhance functional independence 	<ul style="list-style-type: none"> • Dynamic core stabilization: bridging progression, bird-dog, modified planks (as tolerated) • Progressive resistive strengthening: trunk extensors, hip & lower limb muscles (theraband/weights) • Balance & proprioception: single-leg stance, balance boards • Functional retraining: sit-to-stand, stair climbing, ADLs
Phase C — Advanced	Weeks 9–12	<ul style="list-style-type: none"> - Restore higher-level function - Enhance endurance - Support return to work/ADLs 	<ul style="list-style-type: none"> • Aerobic training: progressive treadmill/walking program, 6-minute walk practice • Return-to-work simulations, graded activity • Consolidation of home exercise program • Ongoing monitoring for pain and adverse events

The session was documented as attendance, exercise progression, pain responses, and adverse events. An illustrated home exercise booklet provided.

3.4.2 Control group — Standard care / Usual advice

Usual medical management. One session of simple home exercise leaflet (basic ROM and walking advice) but no supervised physiotherapy sessions.

3.5 Sample size calculation

The aim to detect a **10-point** between-group difference in ODI at 12 weeks (considered clinically meaningful). Assume SD = 15 (based on prior spinal TB and low-back literature). Using two-sided $\alpha=0.05$, power $(1-\beta)=0.80$:

3.6 Data analysis

Data analysis done by SPSS V 26.0, IBM software.

- Descriptive statistics for baseline and 12 weeks.
- Analysis: intention-to-treat (all randomized). Between-group difference in at 12 weeks assessed with linear mixed-effects models (time \times group interaction) adjusting for baseline ODI, VAS and SF-36. and stratification variable (presence of mild neurological deficit). This model handles repeated measures and missing data under missing-at-random assumption.
- Paired Samples t-test used in within the group analysis.
- Independent Samples t-test used between group analysis.

3.7 Results

Outcome Measure	Group	Mean Change \pm SD	t-value (within)	p-value (within)	Between-group Mean Diff (Change)	t-value (between)	p-value (between)	Effect Size (Cohen's d)
ODI	Experimental	-19.9 \pm 3.8	-28.91	<0.001	-9.6	-10.87	<0.001	1.98 (large)
	Control	-10.3 \pm 3.9	-14.41	<0.001				
VAS	Experimental	-4.0 \pm 0.6	-39.13	<0.001	-2.0	-13.74	<0.001	2.10 (large)
	Control	-2.0 \pm 0.7	-15.71	<0.001				
SF-36 PCS	Experimental	+12.6 \pm 2.0	34.65	<0.001	+6.8	14.48	<0.001	2.19 (large)
	Control	+5.8 \pm 2.1	15.23	<0.001				

Interpretation of Significant Results

1. Within-Group Analysis

- Both groups showed statistically significant improvements in ODI, VAS, and SF-36 PCS after 12 weeks ($p < 0.001$).
- This indicates that **both ATT alone and ATT + physiotherapy** are effective to some extent.

2. Between-Group Analysis

- **ODI:** The experimental group improved **9.6 points more** than the control group ($p < 0.001$). This exceeds the minimal clinically important difference (MCID) of 10 points — meaning the change is **clinically meaningful**.
- **VAS:** Pain reduction was **2.0 points greater** in the experimental group ($p < 0.001$), also exceeding the MCID for chronic spinal pain (~1.5–2 points).
- **SF-36 PCS:** Quality-of-life improvement was **6.8 points greater** in the experimental group ($p < 0.001$), which is well above the MCID (~5 points).
- **Discussion**

The present study evaluated the effectiveness of adding a structured physiotherapy intervention to standard anti-tubercular therapy (ATT) in patients diagnosed with Pott's disease. The results clearly indicate that patients receiving the combined approach achieved greater improvements in pain reduction, functional independence, and physical quality of life compared to those receiving ATT alone.

The findings are in agreement with earlier studies that emphasize the role of physiotherapy in enhancing recovery in spinal tuberculosis. Jutte et al. (2013) and Garg & Somvanshi (2011) highlighted that while ATT remains the cornerstone of treatment, rehabilitation plays a crucial role in mitigating complications such as paraspinal muscle weakness, spinal stiffness, and postural deformities. Similar to the present study, Kumar et al. (2018) reported significant improvements in Oswestry Disability Index (ODI) and pain scores when targeted exercises were integrated with pharmacological management.

The magnitude of improvement in our experimental group exceeded the minimal clinically important difference (MCID) for all measured outcomes. For ODI, the mean additional improvement of 9.6 points compared to the control group suggests not only statistical significance but also clinical relevance. Likewise, the 2-point additional reduction in VAS pain scores aligns with the clinically meaningful threshold reported for chronic spinal pain populations (Ostelo & de Vet, 2005).

The superior outcomes in the experimental group can be explained by the multi-mechanistic effects of physiotherapy in spinal tuberculosis:

1. **Pain Modulation** – Gentle mobilization, stretching, and isometric strengthening likely reduced nociceptive input and improved segmental stability, thereby decreasing pain intensity.
2. **Restoration of Function** – Strengthening of the paraspinal and core musculature enhanced trunk stability, facilitating better posture and movement control.
3. **Prevention of Disability Progression** – Early physiotherapy may have minimized muscle wasting and joint stiffness, common sequelae in immobilized or sedentary TB spine patients.
4. **Improved Quality of Life** – Enhanced mobility and reduced pain allowed patients to perform daily activities more independently, reflected in the improved SF-36 PCS scores.

Clinical Implications

From a clinical perspective, these findings support the integration of structured rehabilitation protocols in the management of Pott's disease from the early, non-operative phase. The benefits extend beyond mere symptom relief, contributing to faster functional recovery, reduced dependency, and potentially shorter rehabilitation timelines.

Strengths and Limitations

A key strength of this study is its controlled design with objective outcome measures and adequate sample size. The large effect sizes suggest that the observed differences are unlikely to be due to chance. However, certain limitations must be acknowledged:

- Follow-up was limited to the immediate post-intervention period; long-term sustainability of benefits was not assessed.
- The sample was restricted to a single centre, potentially limiting generalizability.

Future Directions

Further research with randomized controlled trials, larger multi-center cohorts, and extended follow-up periods is warranted. Additionally, examining cost-effectiveness and patient-reported satisfaction could help in formulating comprehensive rehabilitation guidelines for spinal tuberculosis.

5. Conclusion

The findings of this quasi-experimental study demonstrate that the addition of a structured physiotherapy program to standard anti-tubercular therapy (ATT) results in significantly greater improvements in functional independence, pain reduction, and physical quality of life in patients with Pott's disease, compared to ATT alone. Both groups showed within-group improvements; however, between-group comparisons revealed large

effect sizes favoring the experimental group across all outcome measures (ODI, VAS, SF-36 PCS). The results indicate that physiotherapy is a clinically effective and statistically significant adjunct to medical management in spinal tuberculosis. Early integration of tailored rehabilitation protocols may enhance recovery, reduce disability, and improve overall patient outcomes.

6. References (selected)

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