

Study Protocol for Evaluating the Acceptability and Feasibility of the MUSIC-LBD Intervention

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Background

Currently, there are no disease-modifying treatments, and LBD can be difficult to manage due to the wide range of symptoms, which increases the risk of polypharmacy and adverse medication reactions.

Music-based interventions engage numerous neural pathways and therefore offer a promising nonpharmacologic treatment option for a variety of neurologic symptoms; however, rigorous clinical trials are lacking.

We hypothesize that **group-based Therapeutic Instrumental Music Performance® (TIMP®)** will target dysfunctional neural networks involving the basal ganglia, thalamus, cerebellum, and premotor and motor cortices. This intervention is expected to improve motor functioning, including gait speed, bradykinesia, strength, and stride length, in individuals with LBD.

We also anticipate benefits beyond motor functioning, including improvements in neuropsychiatric symptoms and cognition, mediated through the basal ganglia's influence on mesolimbic, mesocortical, and frontostriatal pathways.

MUSIC-based Intervention for Community-dwelling individuals with Lewy Body Disease (MUSIC-LBD) Aims

AIM 1

Evaluate the feasibility and acceptability of conducting an RCT of group-based TIMP® compared to an active comparator group-based relaxation intervention among individuals with LBD.

- Assess success of participant recruitment, randomization, retention, and data collection procedures.
- Characterize the acceptability of and the adherence to TIMP® and the comparator intervention.

AIM 2

Describe the implementation fidelity and replicability of group-based TIMP® for people with LBD.

- Evaluate the ability to deliver the TIMP® and the comparator relaxation intervention manualized protocols as intended.
- Examine whether the TIMP® and relaxation-based protocols can be consistently replicated across different groups of individuals with LBD.

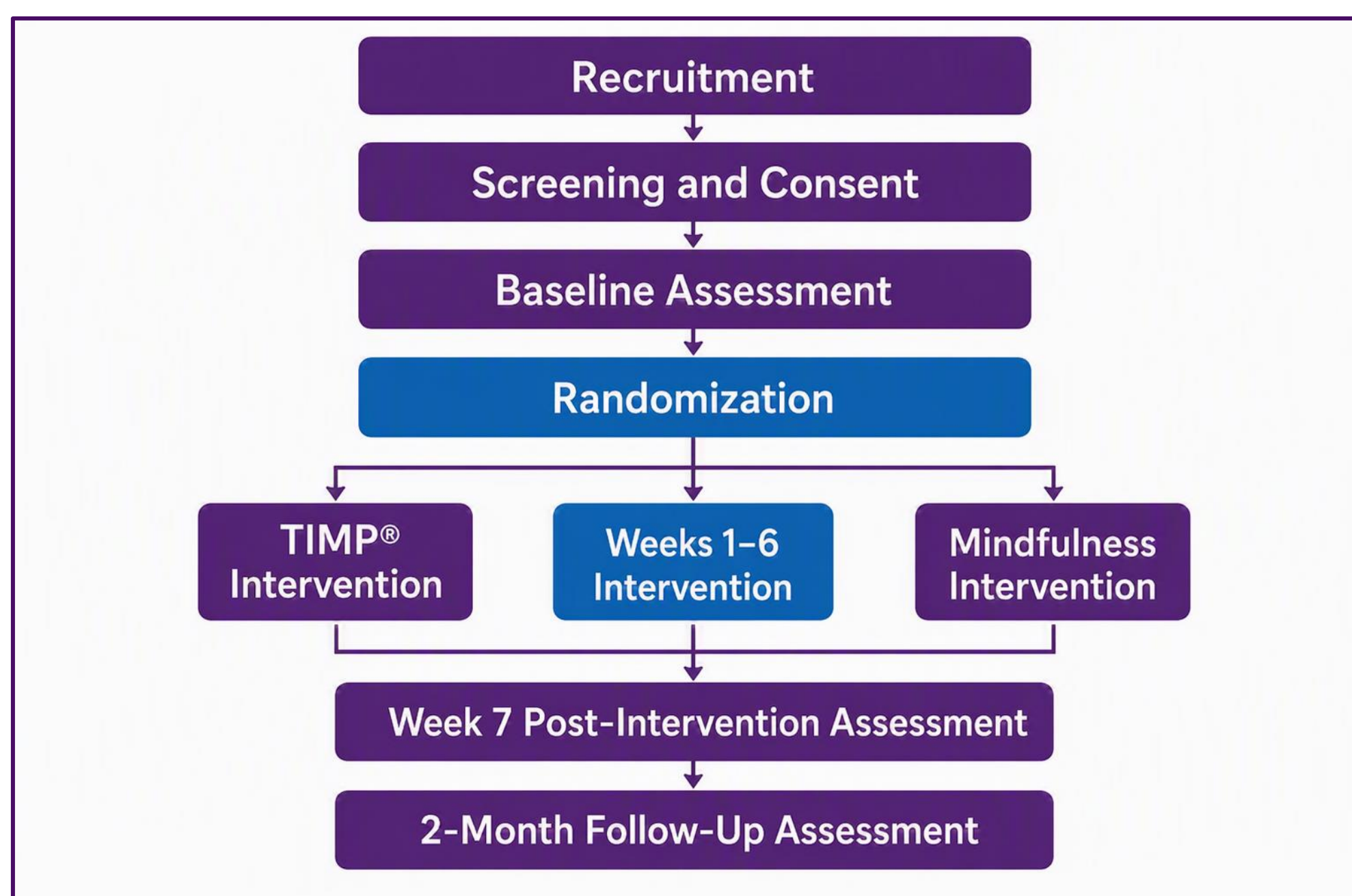
Methods

We designed a 6-week randomized controlled pilot trial investigating a group-based TIMP® intervention compared with a group-based mindfulness and relaxation intervention for individuals with LBD.

The TIMP® intervention (n = 15) includes lower- and upper-extremity movements essential for gait, including hip flexion, trunk rotation, gross upper-extremity movements, and rhythmic foot lifting.

Participants randomized to the comparator group (n = 15) will engage in a 6-week group intervention focused on mindfulness and relaxation through gentle movement and listening to nonrhythmic nature sounds.

The use of specific tracks from the Academy of Neurologic Music Therapy will enhance the replicability of this intervention.



Proposed Neural Framework for TIMP® in LBD

Domain	Neural Pathway	Active Ingredient in TIMP®	Outcome Measures
Motor	Cortico-basal ganglia-thalamo-cortical loop	Rhythmic stimulation; beat anticipation; trunk rotation; hip flexion; coordination; sensorimotor synchronization	MDS-UPDRS ; NIH Toolbox Motor Battery ; APDM Opal Motion Sensors
Neuro-psychiatric	Mesolimbic and mesocortical pathways	Activation of pleasure/reward systems; modulation of monoamines	NIH Toolbox for Assessment of Neurological and Behavioral Function ; Neuropsychiatric Inventory
Cognitive	Frontocortical – striatal networks	Engagement of sustained and divided attention	Montreal Cognitive Assessment ; NIH Toolbox Cognition Battery

Conclusions

Completion of this proposed study will provide critical information regarding the feasibility of outcome measure administration, data collection, recruitment, intervention delivery, and participant engagement and retention.

These findings will inform the development of a large-scale, multisite randomized controlled trial evaluating the efficacy of TIMP® for the growing population of individuals with LBD.

References

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