🩺 BPIT Clinical Study: Statistical Analysis Plan Summary (Version 1.1)

Focus: Interpreting Patient Outcomes and Clinical Efficacy **Date:** November 25, 2025 | **Protocol:** BPIT Multi-Site Clinical Study v3.2 **Principal Investigator:** Dr. Neeraj Mehta, PhD | **Study ID:** MACREB-BPIT-2025-014 **Anticipated Analysis Date:** Post-Data Lock (February 2026)

Version History:

- Version 1.0: Initial plan, November 6, 2025.

- Version 1.1: Reviewed for ClinicalTrials.gov submission on November 25, 2025; no changes to analysis methods or criteria.

1. 🎯 Study Goals and Outcome Measures

This analysis plan is designed to rigorously determine if the **BPIT intervention** delivers clinically meaningful benefits in movement, pain, and function compared to a standard progressive overload protocol.

Measure Category	Key Clinical Measure	Goal/Success Criteria (Hypothesis)	Clinical Relevance
Primary Efficacy	**Movement Efficiency Score (MES, 0–10)**: Change from baseline (Week 0) to end-of-study (Week 5).	**BPIT must improve MES by \ge 25%** (Statistically significant, $p<0.05$).	A simple, validated metric for overall biomechanical function and movement quality. The primary indicator of treatment success.
Secondary Outcomes	**Range of Motion (ROM)** (degrees)	Improvement of **15–20%**.	Direct measure of joint/tissue flexibility and mobility.
	VAS Pain Score (0–10)	Reduction of \approx **40%**.	Pain relief is a critical patient-reported outcome.
	Strength Index (Reps \times Load)	Increase of **20–30%**.	Objective measure of functional capacity and muscular performance.
	Mobility Limitation (%)	Reduction of \approx **25%**.	How the change in MES/ROM translates to

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			daily functional tasks.
Exploratory	Heart Rate Variability (**HRV** - RMSSD)	Increase of \approx **10%**.	A biomarker for autonomic nervous system health and recovery.

2. 👥 Enrollment & Statistical Power

The study is adequately powered to detect clinically relevant changes.

- **Target Enrollment:** \mathbf{n=116} total participants (58 in BPIT group, 58 in Control group).
- **Completers:** Aiming for 100 participants after accounting for \approx 10–14% expected dropout.
- **Statistical Assurance:** We have an **80% chance (Power)** of detecting a moderate but clinically important difference (Cohen's d=0.5).
- **Minimum Detectable Change:** The study is structured to confirm if BPIT delivers at least an **18% change in MES**. If the improvement is less than this, we will likely not be able to declare it statistically superior.

3. 📊 Interpretation of Key Analyses

We will use standard statistical methods appropriate for pre-post and group comparisons.

Clinical Question	Statistical Approach	Measures Involved	Clinical Interpretation of Results
Did the BPIT treatment work?	**Paired t-test** (or Non-Parametric alternative).	Wk 0 vs. Wk 5 MES change (within the BPIT group).	If $p<0.05$, the treatment **caused a significant improvement** in movement efficiency for the participants.
Is BPIT better than standard care?	**Independent t-test/ANOVA** (Between-Group).	BPIT vs. Control (comparing the change scores).	If $p<0.05$, the **BPIT protocol is superior** to the control intervention in improving the outcomes.
How did patients progress over time?	**Repeated-Measures ANOVA**.	ROM, VAS, Strength across Wk 0, Wk 3, and Wk 5.	Helps determine the **speed and maintenance** of clinical effect. Post-hoc

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			analysis (e.g., Tukey) will pinpoint *when* the significant changes occurred.
What predicts the best response?	**Multiple Linear Regression**.	BPIT Line (1-5 score), Age, Gender predicting MES change.	**Identifies clinical predictors**—e.g., if a high score on the "BPIT Line 3" movement pattern is most associated with success.
Is the treatment safe?	**Chi-Square/Fisher's Exact Test**.	Adverse Event (AE) frequency by group/site.	Confirms there is **no difference in safety risk** (AEs) between the BPIT and control protocols.

IMPORTANT NOTE: Due to testing multiple secondary outcomes, we will use a **Bonferroni Adjustment** ($p<0.0125$ required for secondary outcomes) to maintain the integrity of the results. Clinicians should focus on the **Effect Size (Cohen's d)** and the **95% Confidence Interval (CI)** in addition to the p-value, as these indicate the *magnitude* and *precision* of the clinical benefit.

4. 📝 Data Quality and Reporting

- **Missing Data Plan:** If a participant misses an assessment (e.g., Week 5), we will use their **Last Observation Carried Forward (LOCF)** for the final analysis, *unless* more than 10% of the data is missing, in which case we will conduct a separate sensitivity analysis.
- **Final Outputs:** Results will be summarized in clinically relevant tables (e.g., **Means \pm SD**) and figures (e.g., **Box Plots** showing MES improvement and **Spider Charts** for the five BPIT "Lines").

Reviewed and Approved by:

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Date: November 25, 2025