

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)

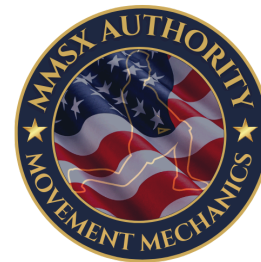
Version History:

- 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 ≥ 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 <i>when</i> 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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