BPIT_2024_Statistical Analysis Plan (SAP) – Version 1.0

Protocol Title: A Prospective, Single-Center, Interventional Study to Evaluate the 5-Line Principle of Balanced Intensity Training (BPIT) for Enhancing Physical Performance and Reducing Injury Risk
Protocol ID: BPIT-GFFI-2024-001
ClinicalTrials.gov ID: WAITING (or the final NCT number once released)
SAP Version: 1.0
Date: 30 November 2024
Principal Investigator: Dr. Neeraj Mehta, PhD

Statistician: [Dr. Anupama Mahagan (PhD), Mathematics]

1. Objectives (directly from protocol)

Primary

- To assess change from baseline to Week 6 in 1-repetition maximum (1RM) for squat, bench press, and deadlift
- To assess the incidence of training-related injuries over the 6-week period

Secondary

- Change in resting heart rate and heart rate variability (HRV – RMSSD)
- Change in heart rate recovery (HRR) – if measured
- Change in muscle activation (EMG %MVC) for rectus abdominis and quadriceps
- Change in knee valgus angle and spinal curvature (degrees)

2. Analysis Populations

- Intention-to-Treat (ITT): All 23 enrolled participants
- Per-Protocol (PP): Participants with ≥80% session adherence (actual adherence was 94.9%, so PP ≈ ITT)
- Safety population: All participants who received at least one training session

3. Primary Efficacy Analysis

- Paired t-test (or Wilcoxon signed-rank test if normality violated) comparing baseline vs. Week 6 for each 1RM exercise
- Effect size: Cohen's d (paired)
- Summary: Mean ± SD at baseline and Week 6, mean change, 95% CI, p-value, Cohen's d

4. Injury Incidence

- Proportion of participants with ≥1 training-related injury (with 95% Clopper-Pearson exact CI)
- Injury rate per 1,000 training hours

5. Secondary Efficacy Analyses

All continuous secondary endpoints analysed exactly as primary (paired t-test/Wilcoxon, Cohen's d, 95% CI)

6. Missing Data

No missing primary outcome data expected (all 23 participants completed the study). If any missing values occur, listwise deletion will be used (sensitivity analysis with last-observation-carried-forward if >5% missing).

7. Multiplicity

No adjustment for multiplicity is planned (exploratory single-arm study).

8. Interim Analysis

None planned.

9. Software

IBM SPSS 29 or R 4.4.x

10. Tables & Figures (to be produced)

Exactly the same tables and figures that already appear in your final report (Tables 2–5, Figures 1–4).

Approved by:

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Dr. Neeraj Mehta (PI)   Date: 30 November 2024

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Dr. Anupama Mahajan (Statistician)   Date: 30 November 2024