Short Statistical Analysis Plan

Pediatric VR exergaming and neuromuscular performance randomized trial

Protocol ID: PED-VR-EMG-2026-01	**Planned enrollment: N = 360**
Design: two-arm, single-visit stratified RCT	Status: prospective draft; before enrollment

1. Study population and analysis principle

The study will enroll 120 rhythmic gymnasts, 120 athletes from other competitive sports, and 120 non-athlete/low-active children aged 10–14 years. Within each athletic-background stratum, 60 children will be randomized to immersive VR exergaming and 60 to matched non-VR exercise (total: 180 per arm). The main comparison will follow randomized assignment. All randomized participants will be accounted for, with reasons for missing outcome measurements and deviations reported by arm.

2. Primary outcome and analysis

The primary outcome is the median reaction time (milliseconds) for correct responses in the computerized two-choice task, calculated from 30 scored trials at baseline and after intervention. Change (post minus baseline) will be summarized descriptively; a negative change indicates faster responses. The prespecified inferential analysis will use analysis of covariance (ANCOVA), with post-intervention reaction time as the dependent variable, randomized arm as the predictor, baseline reaction time as a covariate, and athletic-background stratum as a fixed factor. The primary effect will be the adjusted mean difference (VR minus non-VR), with a 95% confidence interval and two-sided P value. Lower reaction time will not be taken as beneficial without considering response accuracy.

3. Athletic-background effect modification and multiplicity

A separate ANCOVA will add the intervention × athletic-background interaction. A joint two-degree-of-freedom test will assess whether the treatment effect differs among the three strata. Adjusted intervention effects and 95% confidence intervals will be reported within each stratum; differences between stratum effects will not be inferred from their individual P values. If the overall treatment effect and the interaction are both designated confirmatory before recruitment, Holm adjustment will control the two-test familywise error rate at two-sided $\alpha = 0.05$. Confirmatory status of the interaction remains conditional on a documented a priori power analysis.

4. Secondary and additional outcomes

Five Times Sit-to-Stand completion time (seconds) will be analyzed by baseline-adjusted ANCOVA. Mean single-leg balance errors per trial will be analyzed with a suitable count-data model, accounting for baseline performance and overdispersion where relevant. Prespecified additional outcomes include choice-task accuracy (%), normalized bilateral rectus femoris EMG root-mean-square amplitude during sit-to-stand, and shank IMU angular-speed variability during balance. These will be summarized with between-arm estimates and 95% confidence intervals using outcome-appropriate models. Other muscle-specific EMG/IMU measurements will be descriptive or exploratory unless a separate prespecified multiplicity-controlled analysis is finalized.

5. Data quality, missing data, and sensitivity analyses

Reaction-time validity thresholds, sensor processing rules, and handling of incomplete or invalid trials must be fixed before data collection. Distributional assumptions, influential observations, heteroskedasticity, and overdispersion will be evaluated. The number and reasons for missing values will be presented by randomized arm and stratum. The main analysis will include available valid observations under randomized assignment; where missingness could materially affect inference, appropriately justified multiple-imputation or model-based sensitivity analyses will be considered. If multiple sites contribute participants, clustering by site will be addressed in a prespecified sensitivity analysis when feasible.

6. Reporting and outstanding decisions

Baseline characteristics will be reported descriptively by arm and athletic-background stratum. Results will include analyzed sample sizes, appropriate descriptive statistics, adjusted between-group estimates, 95% confidence intervals, test statistics, and exact P values. No causal claim will be made about athletic background itself. Analyses will be performed in R (version recorded); the allocation sequence may be created using R Commander (Rcmdr). Before enrollment, the team must complete the a priori sample-size calculation (including interaction power if confirmatory), exact data-cleaning and EMG/IMU processing specifications, site-handling strategy, and final signed analysis plan.