STATISTICAL ANALYSIS PLAN (SAP)

Effects of Recreational Badminton on Sleep Quality and Salivary Melatonin in Physically Inactive Young Adults: A Randomized Controlled Trial

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Statistical Software: IBM SPSS Statistics, Version 26.0

Statistical Significance Level: Two-sided $p < 0.05$

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1. PURPOSE OF THE STATISTICAL ANALYSIS PLAN

This Statistical Analysis Plan (SAP) describes the statistical methods that will be used to analyze data collected in the trial evaluating the effects of a 4-week recreational badminton intervention versus a sedentary control group on sleep quality and salivary melatonin levels in young adults.

The purpose of this SAP is to prespecify the statistical methods used for the primary and secondary outcomes, describe the statistical assumptions underlying the planned analyses, specify how assumptions will be assessed, describe the handling and reporting of missing data, and define the approach to the interpretation and presentation of statistical results.

2. STUDY DESIGN & SAMPLE SIZE CALCULATION

This is a 2-arm parallel-group controlled intervention study. Participants are allocated to one of two study groups:

- Recreational Badminton Group: Engaging in at least 150 minutes/week of moderate-intensity recreational badminton for 4 weeks.
- Control Group: Physically inactive healthy young adults engaging in less than 30 minutes/week of exercise.

The intervention period is four weeks. Outcome assessments are performed at baseline and after completion of the 4- week period. The study population consists of healthy university students aged 18–30 years.

Sample Size and Power Calculation:

Sample size estimation was conducted prior to study initiation using G*Power software (version 3.1.9.7) based on sleep quality changes following exercise interventions reported by Jurado-Fasoli et al. (2020).

- Effect Size (f): 0.40 (corresponding to Partial Eta Squared $\eta p^2 = 0.138$)
- Alpha Level (α): 0.05 (two-tailed)
- Statistical Power ($1 - \beta$): 0.95
- Design Parameters: 2 groups × 3 repeated measurement time points.
- Calculation Result: A minimum of 9 participants per group (Total N=18) was determined to be statistically sufficient to detect significant main and interaction effects.

3. STATISTICAL SOFTWARE

All statistical analyses will be performed using IBM SPSS Statistics version 26.0. Data will be checked for completeness, consistency, coding errors, and implausible values before inferential statistical analyses are performed.

4. ANALYSIS POPULATIONS

- 4.1 Randomized Study Population: Includes all participants formally randomized/assigned to either the intervention group or the control group.
- 4.2 Per-Protocol (PP) Population: Primary outcome analyses will be conducted primarily on the Per-Protocol (PP) population, defined as participants who complete baseline and 4-week evaluations, adhere fully to the study protocol, and complete all 3 salivary melatonin collections.

- 4.3 Safety Population: Safety analyses will include all participants for whom information regarding exercise- related adverse events is available.

5. GENERAL DATA PRESENTATION

Continuous variables will be summarized using Mean ± Standard Deviation (Mean ± SD) when the distribution is approximately normal, and Median and Interquartile Range (IQR}) when non-normal. Categorical variables will be summarized using frequency (n) and percentage (%). All statistical tests will be two-sided with a significance threshold set at $p < 0.05$.

6. DATA QUALITY AND PRE-ANALYSIS CHECKS

Before statistical analysis, the dataset will be examined for missing observations, duplicate records, implausible values, incorrect group coding, outliers, and consistency between baseline and post-intervention measurements. Values will not be altered solely because they appear statistically unusual.

7. BASELINE CHARACTERISTICS

Baseline demographic and relevant characteristics will be summarized separately for both groups. For normally distributed continuous variables, baseline comparisons will be conducted using the Independent-Samples t-test. For non-normal continuous variables, the Mann–Whitney U test will be used. Categorical variables will be compared using the Chi-Square test or Fisher's Exact test.

8. PRIMARY OUTCOME

- 8.1 Definition: Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) total score (range 0–21; lower scores indicate superior sleep quality) assessed at Baseline and 4 Weeks.
- 8.2 Statistical Analysis: Between-group differences at Baseline and Week 4 will be evaluated using the Independent-Samples t-test. To evaluate the overall intervention efficacy, a 2 × 2 Mixed-Design Repeated Measures ANOVA (Group: Badminton vs. Control × Time: Baseline vs. 4 Weeks) will be conducted. The principal effect of interest will be the Group-by-Time interaction (Group × Time).

9. SECONDARY OUTCOME

- 9.1 Definition: Salivary melatonin concentration (pg/mL}) measured via Enzyme-Linked Immunosorbent Assay (ELISA) at three specific diurnal times: 08:00, 20:00, and 00:00 at Baseline and 4 Weeks.
- 9.2 Statistical Analysis: Diurnal melatonin levels will be compared between groups at individual time points using the Independent-Samples t-test. To assess time-dependent circadian variation and intervention impact, a 2 × 2 × 3 Mixed-Design Repeated Measures ANOVA will be conducted:

o Between-Subjects Factor: Group (Badminton vs. Control)

o Within-Subjects Factor 1: Period (Baseline vs. 4 Weeks)

o Within-Subjects Factor 2: Diurnal Time Point (08:00, 20:00, 00:00)

The primary interaction effect of interest will be Group × Period × time.

10. ASSESSMENT OF STATISTICAL ASSUMPTIONS

- 10.1 Normality: Assessed using the Shapiro-Wilk test (due to $N < 50$), skewness/kurtosis values, and visual inspection of Q-Q plots.
- 10.2 Homogeneity of Variance: Assessed using Levene's test.
- 10.3 Sphericity: Assessed using Mauchly's Test of Sphericity. If sphericity is violated, the Greenhouse-Geisser correction will be applied.
- 10.4 Outliers: Evaluated via standardized residuals; genuine observations will not be excluded solely for being extreme.

11. ALTERNATIVE ANALYSES WHEN ASSUMPTIONS ARE NOT MET

If normality assumptions are violated, appropriate non-parametric alternatives (e.g., Mann–Whitney U test for between-group comparisons, Wilcoxon Signed-Rank test for within-group comparisons, or Friedman test) will be applied and documented.

12. MISSING DATA

The extent and pattern of missing data will be reported. Due to the precise nature of laboratory ELISA assays and the small sample size, listwise deletion will be applied for missing paired samples. No mean imputation or LOCF will be performed.

13. MULTIPLE COMPARISONS & MULTIPLICITY ADJUSTMENT

To control for Type I error inflation resulting from pairwise post-hoc comparisons across study time points and diurnal melatonin sampling times, the Bonferroni correction procedure will be strictly applied.

14. EFFECT ESTIMATES AND CONFIDENCE INTERVALS

Effect estimates will be reported alongside p-values and 95% Confidence Intervals (95% CI):

- For RM-ANOVA models: Partial Eta Squared (ηp^2) will be reported (0.01 = small, 0.06 = medium, 0.14 = large).
- For t-tests: Cohen's d will be reported (0.2 = small, 0.5 = medium, 0.8 = large).

15. WITHIN-GROUP ANALYSES

Changes from baseline to four weeks within each group will be analyzed using the Paired-Samples t-test for normally distributed data or the Wilcoxon Signed-Rank test for non-normally distributed data.

16. SAFETY AND ADVERSE EVENTS

Exercise-related adverse events during the 4-week badminton intervention will be recorded and summarized descriptively (counts, severity, relation to intervention).

17. PROTOCOL DEVIATIONS

Any deviations affecting eligibility, intervention exposure, or outcome assessment will be documented and summarized by study group.

18. INTERVENTION ADHERENCE

Adherence to the badminton sessions will be summarized descriptively based on attendance logs. Participants attending < 80% of scheduled sessions will be excluded from the Per-Protocol analysis.

19. EXPLORATORY ANALYSES

Any non-prespecified analyses will be explicitly designated as exploratory/post-hoc in reports and publications.

20. PRESENTATION OF RESULTS

Results will be presented using structured summary tables:

- Table 1: Baseline demographic and physical activity characteristics.
- Table 2: PSQI scores at baseline and 4 weeks by group (with RM-ANOVA results).
- Table 3: Salivary melatonin concentrations at 08:00, 20:00, and 00:00 at baseline and 4 weeks.
- Table 4: Repeated-measures ANOVA summary for melatonin circadian profile (Group × Period × Time).

21. STATISTICAL SIGNIFICANCE

Statistical significance is defined as two-sided $p<0.05$. Both statistical significance and effect sizes will be interpreted together to determine practical importance.

22. SOFTWARE

All data entry, management, and inferential analyses will be executed using IBM SPSS Statistics Version 26.0.

23. DEVIATIONS FROM THE STATISTICAL ANALYSIS PLAN

Any substantive deviations from this SAP during actual analysis will be fully documented and justified in the final study manuscript.

24. FINAL ANALYTICAL PRINCIPLE

The primary analytical inference relies on evaluating whether 4 weeks of recreational badminton induces significantly greater improvements in subjective sleep quality (PSQI) and favorable shifts in diurnal salivary melatonin rhythms compared to the sedentary control group using the prespecified 2 × 2 and 2 × 2 × 3 RM-ANOVA models.