**Date:** February 29, 2020 **NCT number**: Not Available

# Official Project Title

Investigating the Role of Yoga in Alleviating Chromosomal Translocations in Security Guards of Chandigarh Police Who Are Responsible for the Safety of VIPs

# Statistical Analysis Plan (SAP)

## 1. Introduction

This Statistical Analysis Plan (SAP) outlines the planned analyses for the study titled "Investigating the Role of Yoga in Alleviating Chromosomal Translocations in Security Guards of Chandigarh Police Who Are Responsible for the Safety of VIPs". It defines the methods for analyzing study endpoints, including descriptive, inferential, and correlation analyses.

## 2. Objectives and Endpoints

1. Analysis of molecular markers related to DNA damage response and repair before and after the practice of yoga on Chandigarh Police.
2. To examine the molecular mechanism by which yoga may modulate DNA damage response and repair.

## 3. Analysis Populations

- **Full Analysis Set (FAS):** All participants meeting eligibility criteria and providing baseline and outcome data.

- **Per-Protocol Set (PPS):** Subset of participants completing the study without major protocol deviations.

## 4. General Statistical Considerations

- All analyses will be conducted using **GraphPad Prism v8.0.2** and **JASP v0.19.3**.
- Two-sided significance level of **$\alpha = 0.05$** will be applied.

- Adjusted p-values from post hoc tests will also use the **0.05 threshold** for significance.
- Continuous variables will be summarized with **mean ± SD** (if normally distributed) or **median with interquartile range** (if non-normal).
- Categorical variables will be summarized as **frequencies and percentages**.

## 5. Assessment of Assumptions

- **Normality:** Assessed using the **Shapiro-Wilk test**.
- **Homogeneity of variance (ANOVA assumption):** Checked using **Levene's test**.

## 6. Statistical Methods

### 6.1 Comparisons of Two Groups

- **Normally distributed data:** Student's *t*-test (paired or unpaired as appropriate).
- **Non-normal data:** Wilcoxon matched-pairs signed rank test (paired) or Mann-Whitney test (independent).

### 6.2 Comparisons of More Than Two Groups

- **Normally distributed data:** One-way ANOVA.
    - **Post hoc:** Dunnett's multiple comparisons test (for comparison against a control group).
- **Non-normal data:** Kruskal-Wallis test.
    - **Post hoc:** Dunn's multiple comparisons test.

### 6.3 Correlation Analyses

- **Normally distributed data:** Pearson's correlation coefficient.
- **Non-normal data:** Spearman's rank correlation coefficient.

## 7. Handling of Missing Data

- Data will be analyzed as observed (complete case analysis).
- No imputation will be performed unless otherwise specified in the protocol.

## 8. Interim and Sensitivity Analyses

- No interim analyses are planned.
- Sensitivity analyses may be conducted to confirm robustness of results (e.g., excluding participants with protocol deviations).

## 9. Reporting

- Results will be presented in accordance with **CONSORT/CONSORT-Extension guidelines**.
- Statistical outputs will include effect sizes, 95% confidence intervals, and exact p-values.

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