Statistical Analysis Plan for the Randomized Controlled Trial (RCT) on Self-Comforting Behaviours in the Context of Academic Failure

Study Overview

This Randomized Controlled Trial (RCT) aims to validate the Self-Comforting and Coping Theory (SCCT) by testing whether self-comforting behaviours, such as mindfulness and meditation, improve coping with academic failure in students. A total of 350 participants will be enrolled and randomly assigned to either an intervention group (mindfulness and meditation) or a control group (no intervention). The primary outcome will be assessed using the Self-Comforting and Coping Scale (SCCS), and secondary outcomes will include attitudes towards self-comforting behaviours. The study will assess changes in self-comforting behaviours from baseline, post-intervention, and at a one-month follow-up.

Statistical Analysis Plan

1. Study Population and Randomization

- The study will recruit 350 participants from the Global Banking School across its campuses, focusing on students who have experienced academic failure.
- Participants will be randomly assigned to one of two groups:
    - Intervention Group (mindfulness and meditation)
    - Control Group (no intervention)
- Randomization will be conducted using stratified random sampling to ensure balance between groups for key sociodemographic variables (age, gender).
- Blinding: Both participants and outcome assessors will be blinded to group assignment to minimize bias in outcome assessment.

2. Descriptive Statistics

- Demographic characteristics such as age, gender, academic background, and prior experience with mindfulness will be summarized using frequencies and percentages for categorical variables and means and standard deviations for continuous variables.
- Missing Data: Descriptive statistics will assess missing data. If necessary, multiple imputation or last observation carried forward will be used to handle missing data in repeated measures.

3. Primary Outcome Measure: Self-Comforting Behaviours

- The primary outcome is self-comforting behaviours, assessed using the Self-Comforting and Coping Scale (SCCS). This scale measures the frequency of self-soothing strategies such as mindfulness, positive self-talk, and cognitive reframing.
- Statistical Test: Differences in SCCS scores between groups (intervention vs. control) will be assessed using mixed-design analysis of variance (ANOVA). This analysis will evaluate the interaction between time (baseline, post-intervention, follow-up) and group (intervention vs. control).
- Effect Size: Cohen's d will be calculated to estimate the magnitude of the effect of the intervention on SCCS scores.

4. Secondary Outcome Measure: Attitudes towards Self-Comforting Behaviours

- Attitudes towards self-comforting behaviours will be assessed using the Self-Comforting Attitude Scale (SCAS), a 5-point Likert scale measuring participants' beliefs, perceptions, and attitudes regarding the effectiveness and utility of various self-comforting strategies (e.g., mindfulness, positive self-talk, self-reassurance).
- Statistical Test: Mixed-design ANOVA will be used to analyze changes in attitudes towards self-comforting behaviours from baseline to post-intervention and follow-up.
- Effect Size: Cohen's d will be calculated for changes in attitudes between groups.

5. Predictor Variables

- Sociodemographic factors such as age, gender, and academic background will be analyzed using multiple regression analysis to determine whether these variables predict engagement with the intervention and improvements in self-comforting behaviours.
- A multivariable regression model will be used to assess the relationship between attitudes towards self-comforting (measured by SCAS) and improvements in self-comforting behaviours.

6. Statistical Significance

- The significance level for all statistical tests will be set at $p < 0.05$.
- For multiple comparisons, Bonferroni correction or false discovery rate (FDR) adjustments will be made to account for potential inflation of Type I error.

7. Sample Size Calculation

- Power Analysis: A power analysis was conducted to determine the required sample size. With an expected medium effect size (Cohen's d = 0.5) for the primary outcome (SCCS), and a significance level of α = 0.05, the target sample size of 350 participants provides 80% power to detect significant differences in self-comforting behaviours between groups.
- Adjustments for an expected 10% attrition rate will ensure adequate power.

8. Data Handling and Software

- Data Management: All data will be entered into a secure, encrypted database, and regular checks will be conducted for data accuracy and completeness.
- Software: Statistical analyses will be performed using SPSS Statistics (version 25 or higher).

9. Missing Data Handling

- Missing data will be addressed by multiple imputation for missing values in primary and secondary outcomes. If imputation is not feasible, last observation carried forward will be used for repeated measures. Sensitivity analyses will assess the potential impact of missing data on the study's results.

10. Ethical Considerations

- This study will adhere to ethical guidelines, ensuring participant confidentiality, voluntary participation, and informed consent.
- The study will be registered with ISRCTN to ensure transparency and compliance with clinical trial standards.