**Study Protocol and Statistical Analysis Plan**

**Official Title:** *Acute Effects of a Single 60-Minute Baduanjin Qigong Session on Anxiety, Mood, and Reaction Time in Undergraduate Students: A Randomized, Double-Blind, Crossover Trial*
**NCT Number:** [to be assigned by ClinicalTrials.gov]
**Date:** [25.08.2025]

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## 1. Background and Rationale

Baduanjin Qigong, a traditional mind-body exercise combining breathing awareness, slow rhythmic movements, and mental focus, has been shown to reduce anxiety, stress, and depressive symptoms while improving cognitive and physiological outcomes. However, there is limited evidence regarding its **acute psychological and cognitive effects** in healthy young adults.
This randomized, double-blind, crossover trial will examine the short-term effects of a single 60-minute Baduanjin Qigong session compared with passive rest in undergraduate students.

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## 2. Study Objectives

**Primary Objective:**

To evaluate the acute effect of Baduanjin Qigong on **state anxiety (STAI-Y1)** immediately before and after the intervention.

**Secondary Objectives:**

To assess the effects on **mood profile (POMS)**.

To evaluate changes in **reaction time** measured by a computerized visual stimulus test.

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## 3. Study Design

**Design:** Randomized, double-blind, crossover trial

**Arms:**

**Arm 1 – Baduanjin Qigong**: Standardized 60-minute protocol (15 minutes breathing-focused warm-up, eight movements of 5 minutes each, 10 minutes breathing-focused closing) led by experienced occupational therapists.

**Arm 2 – Passive Rest Control**: 60 minutes of seated rest in a quiet room without access to electronic devices or distracting materials.

**Crossover:** All participants will complete both arms in a randomized sequence with a **1-day wash-out period** between conditions.

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## 4. Participants

**Population:** Undergraduate occupational therapy students (18–25 years) at Medipol University.

**Sample Size:** Power analysis (G*Power 3.1.9.4) indicated a minimum of 70 participants (95% power, 5% significance level).

**Inclusion Criteria:**

Age 18–25 years

No chronic illness, psychiatric diagnosis, or contraindication for physical exercise

No prior regular practice of Qigong, yoga, or similar mind-body exercises

Voluntary participation with informed consent

**Exclusion Criteria:**

Use of antidepressants or psychotropic medication

Acute pain, infection, or chronic cardiorespiratory disease

Inability to complete computerized reaction time testing

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**5. Blinding**

**Participants**: Unaware of which condition is considered the active intervention

**Outcome Assessors**: Independent evaluators blinded to group allocation

**Double-Blind Integrity**: Randomization and session scheduling managed by separate researchers not involved in data collection

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**6. Outcome Measures**

**Primary Outcome:**

**State Anxiety (STAI-Y1)** – assessed immediately before and after each intervention session.

**Secondary Outcomes:**

**Mood Profile (POMS)** – assessed immediately before and after each session.

**Reaction Time** – measured using a computerized visual stimulus response test before and after each session.

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**7. Statistical Analysis Plan (SAP)**

**Software:** SPSS v26.0

**Data Screening:** Normality checked using Shapiro–Wilk test; homogeneity of variance assessed.

**Primary Analysis:**

Paired t-tests (or Wilcoxon signed-rank test if non-parametric) for within-condition pre/post changes.

Repeated measures ANOVA for condition × time effects in crossover design.

**Secondary Analysis:**

Correlation analyses (Pearson/Spearman) between anxiety, mood, and reaction time changes.

**Effect Size:** Cohen's d or partial eta squared reported.

**Significance Level:** $\alpha = 0.05$ (two-tailed).

**Missing Data:** Intention-to-treat (ITT) principle; last observation carried forward for missing post-test values.

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**8. Ethical Considerations**

Approved by the [Insert University Name] Ethics Committee.

All participants will provide informed consent prior to study entry.

Confidentiality of participant data will be maintained; data will be stored in encrypted format.

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**9. Dissemination Plan**

Results will be published in peer-reviewed journals and presented at scientific conferences.

De-identified data may be shared upon reasonable request.