

MINCAP Study Protocol and Statistical Analysis Plan

Official Title:

A Multilevel Study on the Effects of a Mindfulness-Based Intervention Targeting Psychological Capital on Job Burnout Among Nurses: A Randomized Controlled Trial

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1. Background and Rationale

Job burnout is a widespread issue among nurses, particularly exacerbated during the recent time due to prolonged clinical stress, staff shortages, and work-family conflicts. Burnout is associated with emotional exhaustion, depersonalization, and a diminished sense of personal accomplishment, ultimately impairing both individual well-being and organizational performance.

Psychological capital (PsyCap)-a construct from positive psychology comprising self-efficacy, hope, resilience, and optimism-has been shown to be a developable internal resource that may buffer stress and improve occupational outcomes. Despite its growing use in organizational psychology, PsyCap has been underexplored as a protective factor against nurse burnout. Furthermore, mindfulness-based interventions (MBIs) have demonstrated efficacy in improving emotional regulation and resilience but lack long-term evaluation in occupational settings.

This study aims to investigate whether a mindfulness-based intervention can enhance psychological capital and reduce burnout in nurses, and to explore the multilevel influences of PsyCap from the individual, organizational, and family perspectives.

2. Objectives

- Primary Objective
 1. To evaluate the effectiveness of a mindfulness-based intervention in enhancing psychological capital and reducing job burnout among hospital nurses.
- Secondary Objectives
 1. To assess the sustainability of intervention effects at 1, 3, and 6 months post-intervention.
 2. To explore the relationship between psychological capital (at individual, leader, and family levels) and nurse burnout.
 3. To assess changes in mindfulness traits using the Five Facet Mindfulness Questionnaire (FFMQ).

3. Study Design

- Study Type: Interventional (Clinical Trial)
- Design: Randomized, Parallel Assignment, Open Label

- Number of Arms: 2
- Intervention Arm: Mindfulness Practice
- Control Arm: No additional intervention
- Allocation: Randomized (1:1)
- Estimated Enrollment: 124 participants
- Study Duration: 40-day intervention + 4-month follow-up

4. Participants

- Inclusion Criteria:
 1. Registered nurses aged 22–50
 2. Employed full-time in tertiary hospitals in Taizhou, China
 3. Moderate or high levels of burnout (MBI-GS screening)
 4. Informed consent provided
- Exclusion Criteria:
 1. Diagnosed psychiatric disorders or ongoing psychotropic medication
 2. Prior formal mindfulness training
 3. Inability to use mobile applications

5. Intervention

- Mindfulness Practice (Intervention Group)

Participants will receive a structured 40-day mindfulness program via a custom mobile application. The program includes guided meditation, breathing exercises, and mindful body awareness. Practice is self-paced (approx. 15–20 minutes/day) and integrated into nurses' daily routine.

- Control Group

Participants will continue their routine nursing work with no additional training or intervention during the study period.

6. Outcome Measures

- Primary Outcomes:

1. Psychological Capital

Tool: Psychological Capital Questionnaire (PCQ-24)

Timepoints: Day 0, 40, 2 month, 4 months

2. Job Burnout

Tool: Maslach Burnout Inventory – General Survey (MBI-GS)

Timepoints: Same as above

● Secondary Outcome:

1. Mindfulness Level

Tool: Five Facet Mindfulness Questionnaire (FFMQ)

Timepoints: Same as above

7. Statistical Analysis Plan

Descriptive statistics will summarize participant characteristics and baseline scores.

Repeated-measures ANOVA and mixed-effects models will be used to evaluate changes over time between groups.

Structural equation modeling (SEM) will be applied to explore multilevel relationships between psychological capital sources and burnout outcomes.

8. Ethical Considerations

This study has received approval from the Medical Ethics Review Committee of Taizhou Central Hospital affiliated to Taizhou University.

All participants will provide informed consent.

Participant confidentiality will be protected; all data will be anonymized.