FULL STUDY PROTOCOL AND

STATISTICAL ANALYSIS PLAN (SAP)

Effectiveness of Liuzijue and Box Breathing Techniques on Inspiratory Capacity and Blood Pressure Following Femoral Neck Fracture Immobilization: A Retrospective Comparative Study

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1. Personnel

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2. Introduction

2.1 Background & Aims

Femoral neck fractures are a significant source of morbidity and mortality among the aged population. Due in large part to prolonged immobilization and related systemic consequences. Hip fractures among the elderly have increased dramatically worldwide, from 1.7 million in 1990 to an anticipated 6.3 million in 2050. Immobilization following a fracture frequently leads to decreased inspiratory capacity, compromised pulmonary mechanics and altered cardiovascular regulation, which raises the risk of pneumonia, hypertension and delayed functional recovery. Early cardiopulmonary rehabilitation during the immobilization phase is crucial since respiratory infections and cardiovascular problems have been found to be major causes of early mortality after hip fractures.

Due to medical comorbidities and logistical limitations, prolonged bed rest and delays in surgical intervention are still typical in older patients despite advancements in surgical management. These elements worsen hemodynamic instability and pulmonary deconditioning. While respiratory and cardiovascular components receive less attention during early immobility, musculoskeletal recovery is frequently given priority in conventional therapy.

Breathing-based therapies provide a practical and affordable way to deal with these issues. In patients with chronic respiratory diseases, Liuzijue Qigong, a traditional Chinese breathing practice that combines controlled expiration with sound vibration, has been shown to improve lung function, respiratory muscle efficiency and overall quality of life. In a similar vein, Box Breathing is an organized breathing method that has been demonstrated to improve blood pressure control, autonomic balance and lung volumes.

In cardiopulmonary rehabilitation, breathing-based therapies have become more popular because of their ease of use, affordability and viability for older people who are fragile and immobile. Respiratory

efficiency and hemodynamic stability can be enhanced by methods like Box Breathing and Liuzijue Qigong, which are known to affect autonomic regulation, respiratory muscle function and cardiovascular responses. These treatments are especially important for older patients who have suffered femur neck fractures since prolonged immobility frequently results in decreased lung volumes, decreased inspiratory capacity and altered blood pressure control.

Comparative research assessing the efficacy of these breathing methods in elderly individuals immobilized after femur neck fractures is, however, lacking. Furthermore, only a few studies have used objective measurement instruments like volume-oriented incentive spirometry to look at their combined effects on blood pressure and inspiratory capacity. By methodically contrasting Box Breathing with Liuzijue Qigong, this randomized controlled experiment seeks to close this evidence gap and advance evidence-based cardiopulmonary rehabilitation techniques for this susceptible group.

2.2 Background Literature Review

Femoral neck fractures are a major contributor to morbidity and mortality among older adults, particularly due to prolonged immobilization and associated systemic complications. In a three-year follow-up study, **Berggren et al. (2016)** reported a high prevalence of cardiovascular, respiratory, and metabolic comorbidities in individuals with femoral neck fractures, with complications during immobilization significantly contributing to mortality. The authors emphasized the necessity of early supportive interventions to reduce secondary physiological decline and improve survival outcomes [(1)].

Expanding on fracture-related risks, **Gouzoulis et al. (2025)** analyzed the incidence and contributing factors of femoral neck fractures and subsequent surgical outcomes. Their findings indicated that advanced age, prolonged inactivity, and compromised cardiopulmonary reserve adversely affect recovery and increase postoperative complications. The study highlights the importance of adjunctive non-

pharmacological strategies to optimize cardiopulmonary function during the immobilization period [2].

Mind–body interventions have shown promise in addressing respiratory dysfunction in older populations. **Feng et al. (2020)** evaluated the role of Qigong practices in elderly individuals and demonstrated improvements in respiratory efficiency, autonomic regulation, and psychological well-being. Although conducted in the context of COVID-19 rehabilitation, the study supports the applicability of Qigong-based exercises, such as Liuzijue, in enhancing inspiratory capacity in populations with restricted mobility [3].

Further evidence is provided by **Xu et al. (2022)** through a systematic review and meta-analysis examining the efficacy of Liuzijue Qigong in patients with chronic obstructive pulmonary disease. The analysis revealed significant improvements in inspiratory capacity, pulmonary function, and exercise tolerance, confirming Liuzijue as a safe and effective respiratory rehabilitation modality suitable for elderly individuals with limited physical capacity [4].

Breathing-focused interventions have also demonstrated cardiovascular benefits. In a randomized controlled trial, **Zaliene et al. (2025)** reported that structured breathing techniques significantly improved autonomic balance, respiratory efficiency, and stress regulation. Notably, reductions in blood pressure and enhanced parasympathetic activity were observed, supporting the clinical relevance of Box Breathing in managing cardiovascular strain associated with immobilization [5].

Collectively, existing literature supports the use of Liuzijue Qigong and Box Breathing techniques in improving respiratory and cardiovascular parameters in elderly populations. However, comparative evidence assessing their effectiveness specifically in patients following femoral neck fracture immobilization remains limited, warranting further investigation.

3. Study Protocol

3.1 Research Design Outline

The study aims to perform a Comparative study on older people who have been immobilized due to femur neck fractures.in Saveetha Medical College and Hospital.

Formerly titled “Effectiveness of Liuzijue and Box Breathing Techniques on Inspiratory Capacity and Blood Pressure Following Femoral Neck Fracture Immobilization: A Retrospective Comparative Study” involves elderly with femoral neck fracture immobilization by Inspiratory capacity and blood pressure were assessed using a volumetric incentive spirometer and a digital sphygmomanometer, respectively. Improvement in inspiratory capacity was defined as an increase in measured values, with ranges progressing from approximately 1300 mL to 3000 mL. Improvement in cardiovascular status was considered when blood pressure remained within a stable range, with systolic values between 120-150 mmHg and diastolic values between 70-90 mmHg.

3.2 Participants

This retrospective study included elderly individuals diagnosed with femoral neck fracture who had undergone a period of immobilization and subsequently received either Liuzijue Qi Gong exercise or Box Breathing technique as part of their rehabilitation program. Participants were identified through a review of medical and physiotherapy records from Saveetha Medical College and Hospital. Eligibility was determined based on inclusion and exclusion criteria documented in the clinical records.

3.3 Recruitment

For this retrospective analysis, medical and physiotherapy records of patients with femoral neck fracture immobilization treated at the Saveetha Medical College and Hospital were reviewed.

Records of participants who had completed a four-week intervention program and had documented outcome measures were included in the study. No direct recruitment or prospective enrollment was undertaken.

Data related to inspiratory capacity measured using a volumetric spirometer and blood pressure assessed using a digital sphygmomanometer were extracted from patient records. Outcome measures recorded at baseline (pre-intervention), at the second week and at the fourth week were included for analysis. Confidentiality of patient information was maintained and the study procedures were conducted under the approval and supervision of the institutional ethics committee and the principal investigator.

3.4 Administration

Parameter	Liuzijue Qi Gong Exercise Group	Box Breathing Technique Group
Position	Semi-fowlers position or Supine lying or half lying	Semi-fowlers position or Supine lying or half lying
Session duration	20 minutes per session	20 minutes per session
Frequency	Twice daily	Twice daily
Weekly schedule	6 days per week	6 days per week
Total duration	4 weeks	4 weeks
Intervention description	Coordinated slow breathing while expiration producing six distinct sounds are produced: (“XU,” “HE,” “HU,” “SI,” “CHUI,” and “XI”)	Structured breathing cycle consisting of inhaling for a count of four, holding for four, exhaling for four and holding again for four
Rest intervals	Provided as required and documented	Provided between breathing cycles and documented
Supervision	Administered under physiotherapist supervision	Administered under physiotherapist supervision
Outcome assessment points	Baseline (pre-intervention), 2nd week, 4th week	Baseline (pre-intervention), 2nd week, 4th week

3.5 Assessment & Outcomes Measures

3.5.1 Primary outcomes

- Inspiratory Capacity -Volume-Oriented Incentive Spirometer
    - To measure inspiratory capacity in elderly participants, post femoral neck fracture immobilization. To objectively monitor changes in pulmonary function.
    - Instructed to inhale slowly and deeply through the mouthpiece after normal expiration.
    - Maximum volume achieved recorded as inspiratory capacity.

3.5.2 Secondary outcomes

- Blood Pressure - Digital Blood Pressure Monitor (Digital Sphygmomanometer)
    - To measure systolic and diastolic blood pressure. To evaluate cardiovascular response to breathing interventions. To monitor physiological changes over the intervention period
    - Automated, non-invasive device using Oscillo metric methods.
    - Consists of inflatable cuff and digital display.
    - Blood pressure recorded after adequate rest

4. Statistical Analysis Plan (SAP)

Descriptive and inferential statistics will be used. Normally distributed data will be presented by mean and standard deviation (SD) and non-normally distributed data will be presented by median and interquartile range. Categorical data will be presented using percentages. SPSS (version 27.0) will be used for all statistical analyses.

4.1 Primary Outcomes

Statistical analysis will be performed using appropriate statistical software. Descriptive statistics, including mean and standard deviation, will be calculated for the primary outcome variables: Inspiratory capacity (mL) for both intervention groups.

To evaluate changes over time and differences between groups, a mixed-design repeated measures analysis of variance (ANOVA) will be used, with time (baseline, 2nd week, and 4th week) as the within-subject factor and group (Liuzijue Qi Gong exercise and Box Breathing technique) as the between-subject factor. This analysis will determine the effectiveness of the interventions across the different time intervals.

Post-hoc pairwise comparisons with Bonferroni correction will be conducted when significant main effects or interactions are observed. Mauchly's test of sphericity will be applied, and if the assumption of sphericity is violated ($p < 0.05$), the Greenhouse–Geisser correction will be used. A p-value < 0.05 will be considered statistically significant.

4.2 Secondary Outcomes

Secondary outcome analysis will include systolic and diastolic blood pressure parameters to assess cardiovascular responses to the interventions. Descriptive statistics (mean ± standard deviation) will be computed for each time point within and between groups.

A repeated measures ANOVA will be performed to examine within-group changes across time and between-group differences in blood pressure values. Where significant effects are identified, post-hoc analysis with Bonferroni adjustment will be carried out to explore pairwise differences between baseline, 2nd week, and 4^{th} week measurements. In cases of sphericity violation, the Greenhouse-Geisser correction will be applied. Statistical significance will be set at $p < 0.05$.

4.3 Missing Data

In the event of missing data due to incomplete clinical records, appropriate statistical handling will be undertaken. Where feasible, missing values will be addressed using mean imputation within the respective intervention group, provided the proportion of missing data is minimal and missing at random. Cases with substantial missing data will be excluded from the final analysis.

4.4 Informed Consent Forms (ICF)

Written informed consent had been obtained from participants at the time of clinical treatment as part of routine hospital protocol. For the present analysis, waiver of fresh informed consent will be sought from the Institutional Ethics Committee, as the study involves reviewing existing medical and physiotherapy records without direct participant contact.

4.4.1 Rights and Risks to participants

Rights

Participants' rights to autonomy, dignity and confidentiality will be fully respected. Participation in the retrospective analysis will not affect the standard of care received by the patients. Individuals retain the right to withdraw their clinical data from analysis if required by institutional policy. No remuneration or reimbursement is associated with participation in this study.

Risks

No foreseeable physical, psychological or social risks are anticipated, as the study involves secondary analysis of previously collected clinical data and does not include any additional interventions or assessments.

4.4.2 Privacy and Confidentiality

All patient data will be de-identified prior to analysis. Each participant will be assigned a unique study identification code to ensure anonymity. Identifiable information will not be accessed, disclosed or published. Data extraction and analysis will be conducted solely by the principal investigator and authorized research personnel in accordance with institutional ethical guidelines.

5 References

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