

DATA MONITORING COMMITTEE (DMC) CHARTER

1. Study Title

Effectiveness of Inspiratory–Expiratory (I:E) Ratio in Pursed-Lip Breathing on Respiratory Outcomes in Patients with Chronic Obstructive Pulmonary Disease (COPD)

2. Purpose of the DMC

The Data Monitoring Committee (DMC) is established to provide independent oversight of participant safety, data integrity, and study conduct.

The DMC will:

- Monitor participant safety and well-being
 - Review study progress and protocol adherence
 - Evaluate data quality and completeness
 - Provide recommendations on study continuation, modification, or termination
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3. Scope of Responsibilities

3.1 Safety Monitoring

- Review any adverse events (e.g., dizziness, fatigue during PLB)
- Ensure risks remain minimal and acceptable
- Recommend actions if safety concerns arise

3.2 Data Monitoring

- Assess completeness and accuracy of collected data
- Review consistency of outcome measurements (RR, SpO₂, dyspnea)
- Ensure adherence to data collection procedures

3.3 Study Conduct

- Monitor recruitment progress
 - Review protocol compliance
 - Identify any deviations or operational issues
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4. DMC Composition

The DMC will consist of independent members with no direct involvement in the study:

- **Chairperson:** Clinician with expertise in respiratory care
- **Statistician:** Experienced in clinical trial analysis
- **Clinical Expert:** Pulmonology or nursing specialist

(Optional: Ethics expert if required by committee)

5. Independence and Conflict of Interest

All DMC members must:

- Be independent from the research team
 - Declare any potential conflicts of interest
 - Maintain objectivity in all assessments
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6. Meetings

6.1 Frequency

- At least **one formal review meeting** during the study
- Additional meetings if safety concerns arise

6.2 Format

- Meetings may be conducted in person or virtually

6.3 Documentation

- Minutes will be recorded for each meeting
 - Recommendations will be documented and communicated to the principal investigator
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7. Data Review Plan

The DMC will review:

- Recruitment and dropout rates
- Baseline characteristics
- Outcome trends (RR, SpO₂, dyspnea)
- Adverse events (if any)

Given the short intervention duration, **no formal interim efficacy analysis is planned.**

8. Stopping Rules

The DMC may recommend pausing or terminating the study if:

- Unexpected safety concerns arise
- Protocol violations significantly affect validity
- Ethical concerns are identified

9. Communication

- The DMC will provide written recommendations to the Principal Investigator (PI)
- The PI is responsible for implementing actions and informing the ethics committee if required

10. Confidentiality

- All data reviewed by the DMC will remain confidential
- No unauthorized disclosure is permitted

11. Amendments to the Charter

Any changes to this charter must be:

- Agreed upon by DMC members
- Documented and approved before implementation