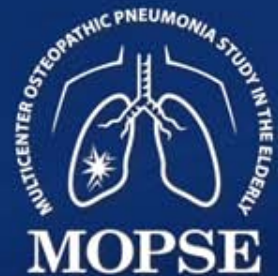
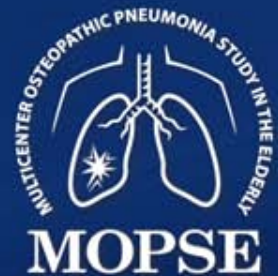


Multicenter Osteopathic Pneumonia Study in the Elderly (MOPSE)

The Primary Outcomes



BACKGROUND



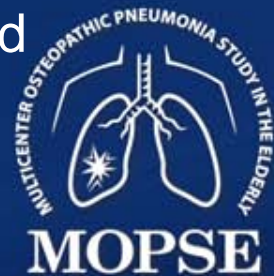
MOPSE

- A registered study at www.clinicaltrials.gov
- Conducted between March 2004 and April 2007
- Protocol Paper: www.jaoa.org

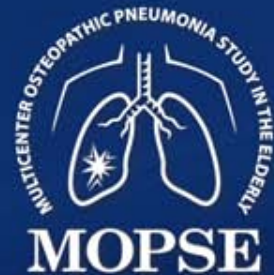
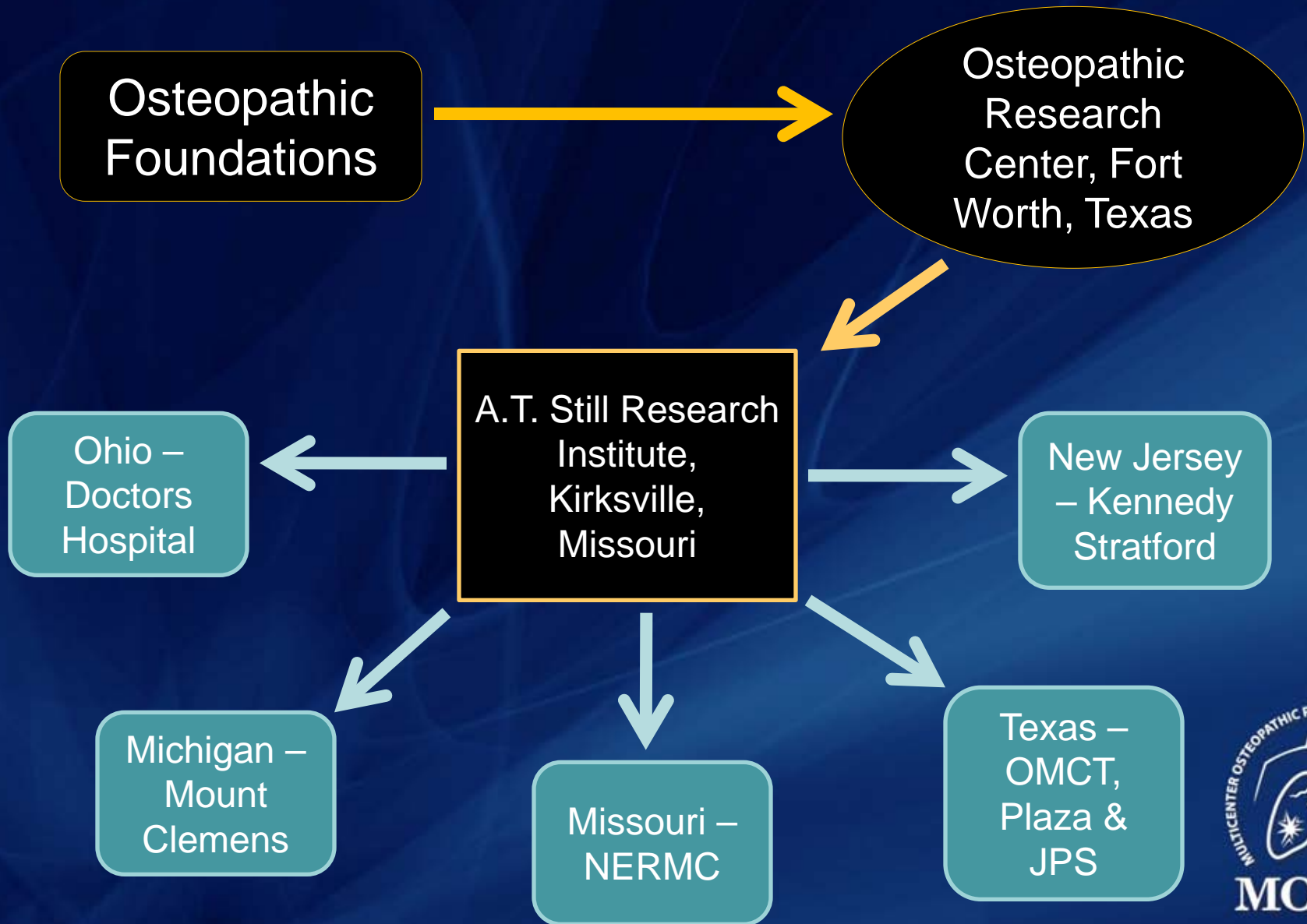
Noll DR, Degenhardt BF, Fossum C, and Hensel K. Clinical and research protocol for osteopathic manipulative treatment of elderly patients with pneumonia. *J Am Osteopath Assoc*. September 2008; 108(9): 508-516.

- Main Outcomes Paper: www.om-pc.com

Noll DR, Degenhardt BF, Morley TF, Blais FX, Hortos KA, Hensel K, Johnson JC, Pasta DJ, and Stoll ST. Efficacy of osteopathic manipulation as an adjunctive treatment for hospitalized patients with pneumonia: a randomized controlled trial. *Osteopath Med Prim Care*. 2010; 4:2.

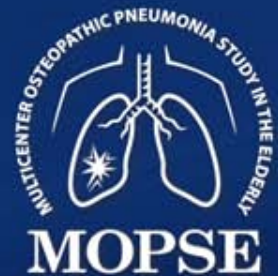


Multicenter Study Structure

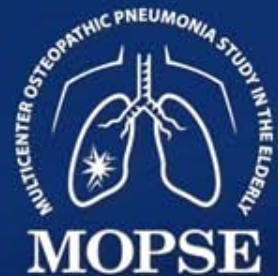


Funded by a consortium of Osteopathic Foundations

- Brentwood Foundation (Ohio)
- Colorado Springs Osteopathic Foundation (Colorado)
- Foundation for Osteopathic Health Services (Maryland)
- Muskegon General Osteopathic Foundation (Michigan)
- Northwest Oklahoma Osteopathic Foundation (Oklahoma)
- Osteopathic Founders Foundation (Oklahoma)
- Osteopathic Institute of the South (Georgia)
- Osteopathic Heritage Foundation (Ohio)
- Quad City Osteopathic Foundation (Iowa)

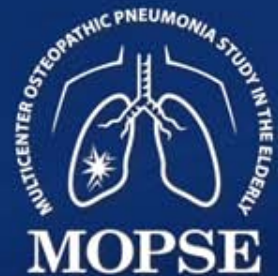


Study Methods



Primary Hypothesis

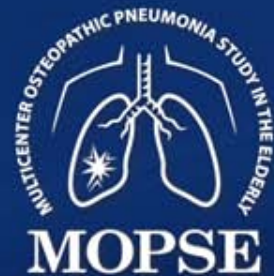
- Osteopathic Manipulative Treatment (OMT) will:
 - Reduce length of stay (LOS)
 - Reduce time to clinical stability
 - Improve the symptomatic and functional recovery score



Time to Clinical Stability

- Measured daily- The number of days it takes for all seven clinical measures to be “stable.”
 - Lowest Systolic Blood Pressure ≥ 90 mmHg
 - Highest Heart Rate ≤ 100 beats / minute
 - Highest Respiratory Rate ≤ 24 breaths / minute
 - Highest Temperature ≤ 38 °C
 - Lowest Oxygen Saturation $\geq 90\%$
 - Ability to Eat by Mouth or Feeding Tube
 - Mental Status Grossly Back to Baseline

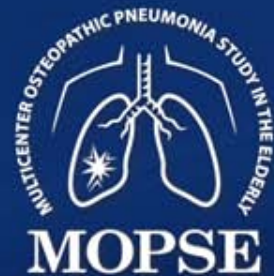
Halm EA, Fine MJ, Marrie TJ, et al. Time to clinical stability in patients hospitalized with community-acquired pneumonia: implications for practice guidelines. *JAMA*. 1998,279(18):1452-1457.



Symptomatic and Functional Recovery Score (SFRS)

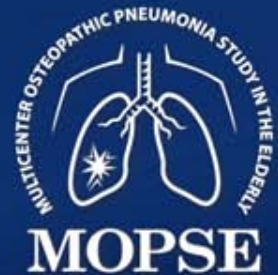
- Calculated from a Pneumonia-Specific Validated Questionnaire
 - Cough, dyspnea, sputum production, pleuritic chest pain, and fatigue
- Higher SFRS = Worse Symptoms
- Measured on:
 - Admission (Day 1), Day 14, Day 30 and Day 60

Metlay JP, Fine, MJ, Schulz R, et al. Measuring symptomatic and functional recovery in patient with community-acquired pneumonia. *J Gen Intern Med.* 1997;12(7):423-430.



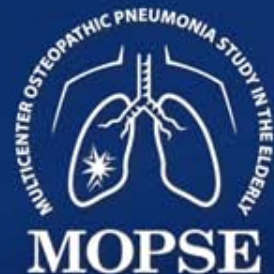
MOPSE Key Aspects

1. Randomized Controlled Clinical Trial
 - Efficacy study, not a mechanistic study
2. Seamless Design
 - Not to interfere with usual care
3. Blinded Study
 - For the decision makers
4. Three Arm Study Design
 - OMT group
 - Light-touch (LT) “sham” group
 - Conventional care only (CCO) group



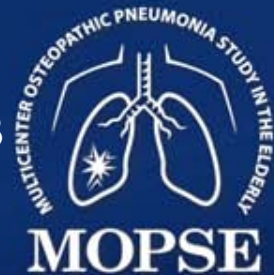
MOPSE Key Aspects (Continued)

5. OMT is an Adjunctive Treatment Modality
 - Does not replace conventional care
6. Balances Uniformity with Individualization
 - 10 minutes standard, 5 minutes specific
7. Best Effect Design over Pragmatic Design
 - Build upon the previous studies
8. 24 Hour Window
 - From admission to first treatment



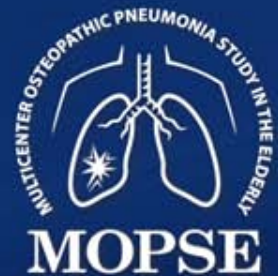
Inclusion Criteria

- Age \geq 50 years
- New pulmonary infiltrate on x-ray
- Two of the following:
 - New or increased cough
 - Fever \geq 38 °C
 - Pleuritic chest pain
 - New physical findings on chest examination
 - Respiratory rate \geq 25 beats per minute
 - Deteriorating mental or functional status
 - White Blood Cell count $>$ 12,000 cells/mm³



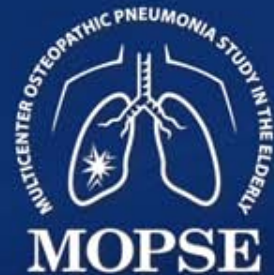
Exclusion Criteria

- Nosocomial Pneumonia
- Lung Abscess
- Advancing Pulmonary Fibrosis
- Bronchiectasis
- Pulmonary Tuberculosis
- Lung Cancer
- Metastatic Cancer
- Acute Rib or Vertebral Fracture
- Previous Participation

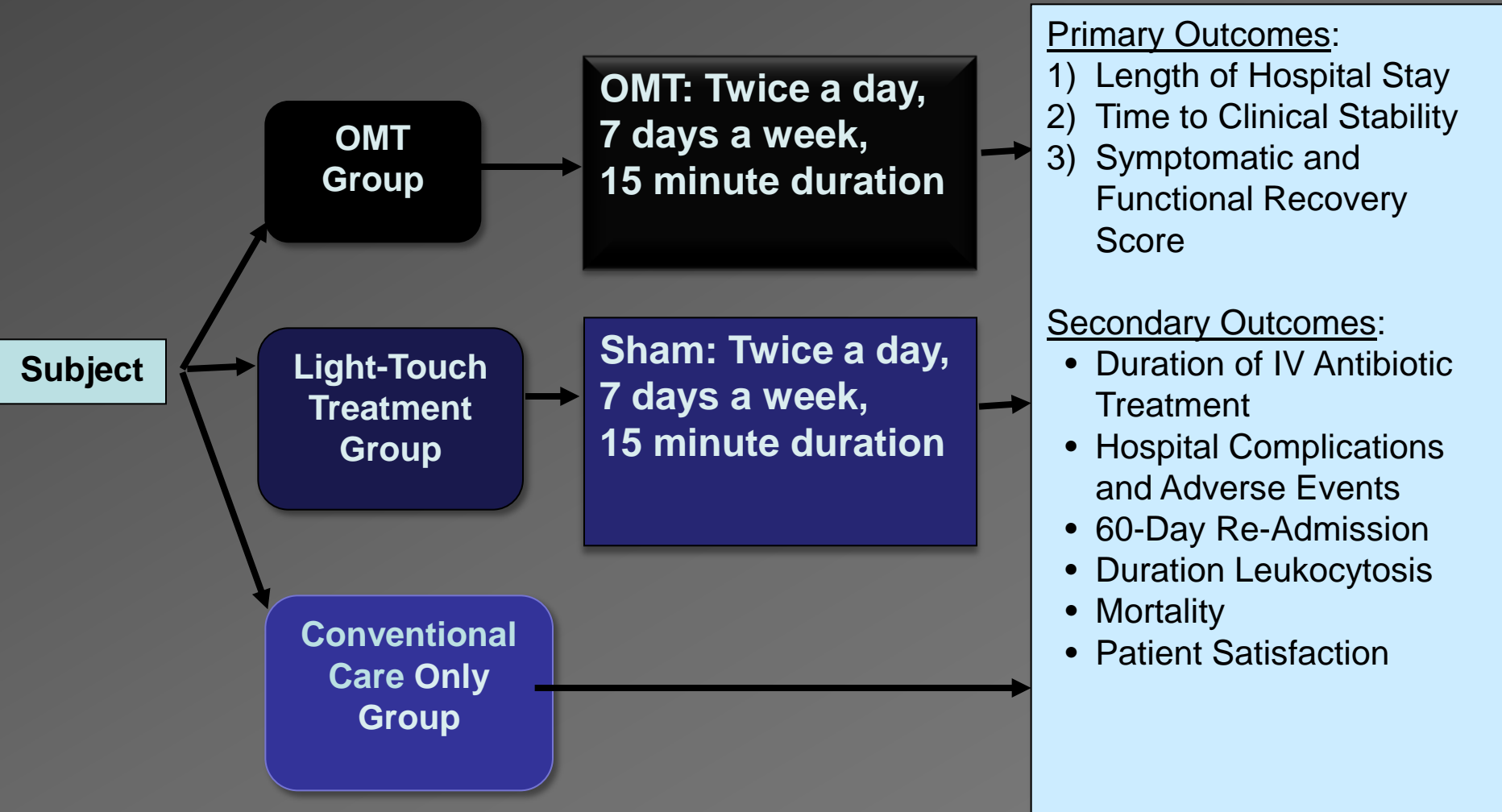


Eight Standardized Techniques

1. Thoracolumbar Soft Tissue
2. Rib Raising
3. Doming of the Diaphragm Myofascial Release
4. Cervical Soft Tissue
5. Suboccipital Inhibition
6. Thoracic Inlet Myofascial Release
7. Thoracic Lymphatic Pump
8. Pedal Lymphatic Pump

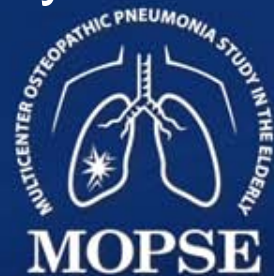


MOPSE Study Design Summary

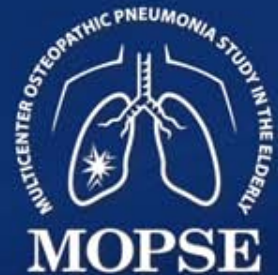


Two Categories of Statistical Analysis

- Intention-to-Treat (ITT) Analysis
 - Everyone who was randomized into the study
 - Excludes for change in diagnosis
 - Excludes for first treatment beyond 30 hours
- Per-Protocol (PP) Analysis
 - Everyone who got the protocol as designed
 - Excludes for first treatment beyond 24 hours
 - Excludes for treatment contrary to protocol
 - Excludes subjects who dropped out of the study
 - Excludes for missing a treatment session

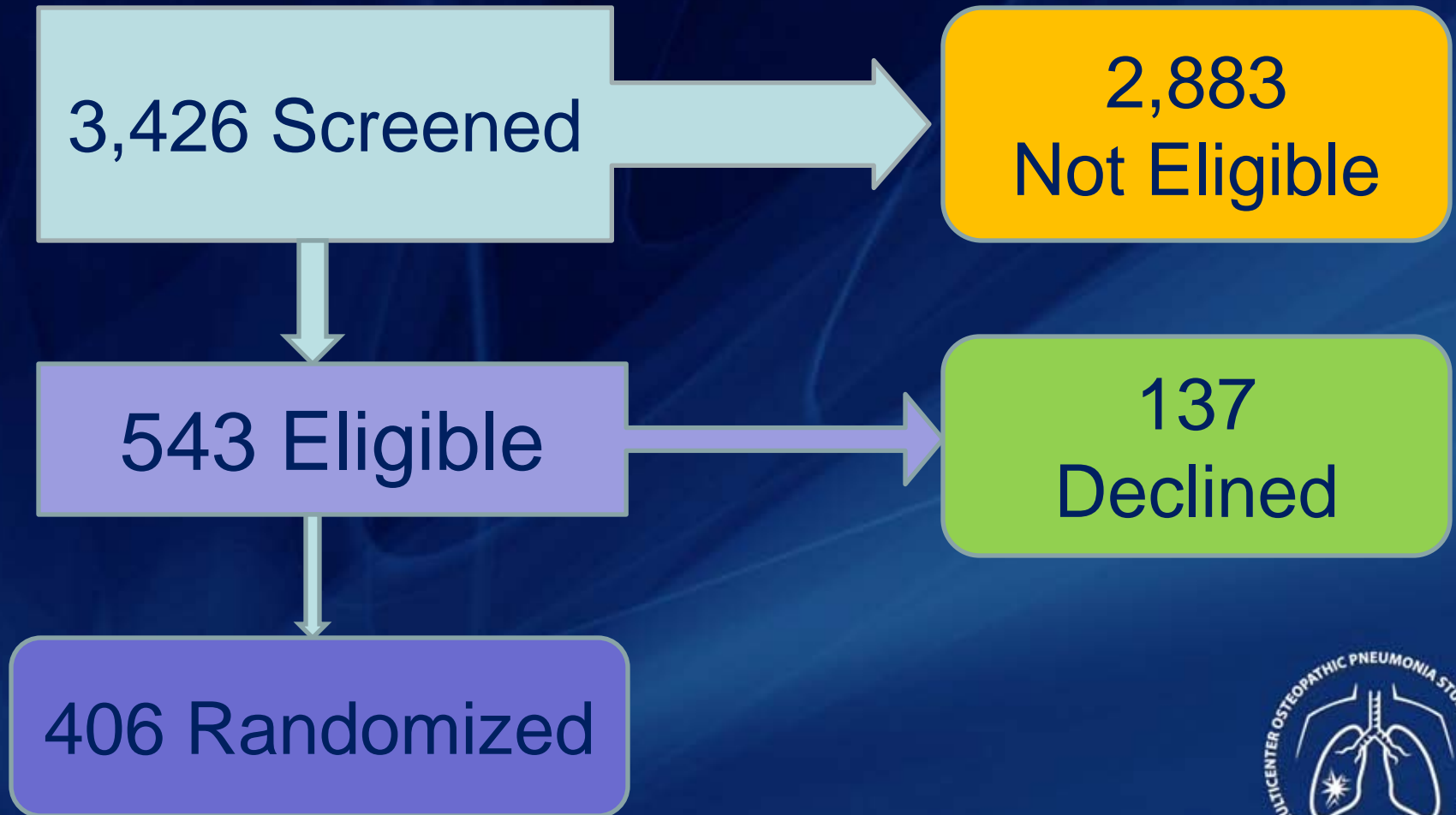


RESULTS

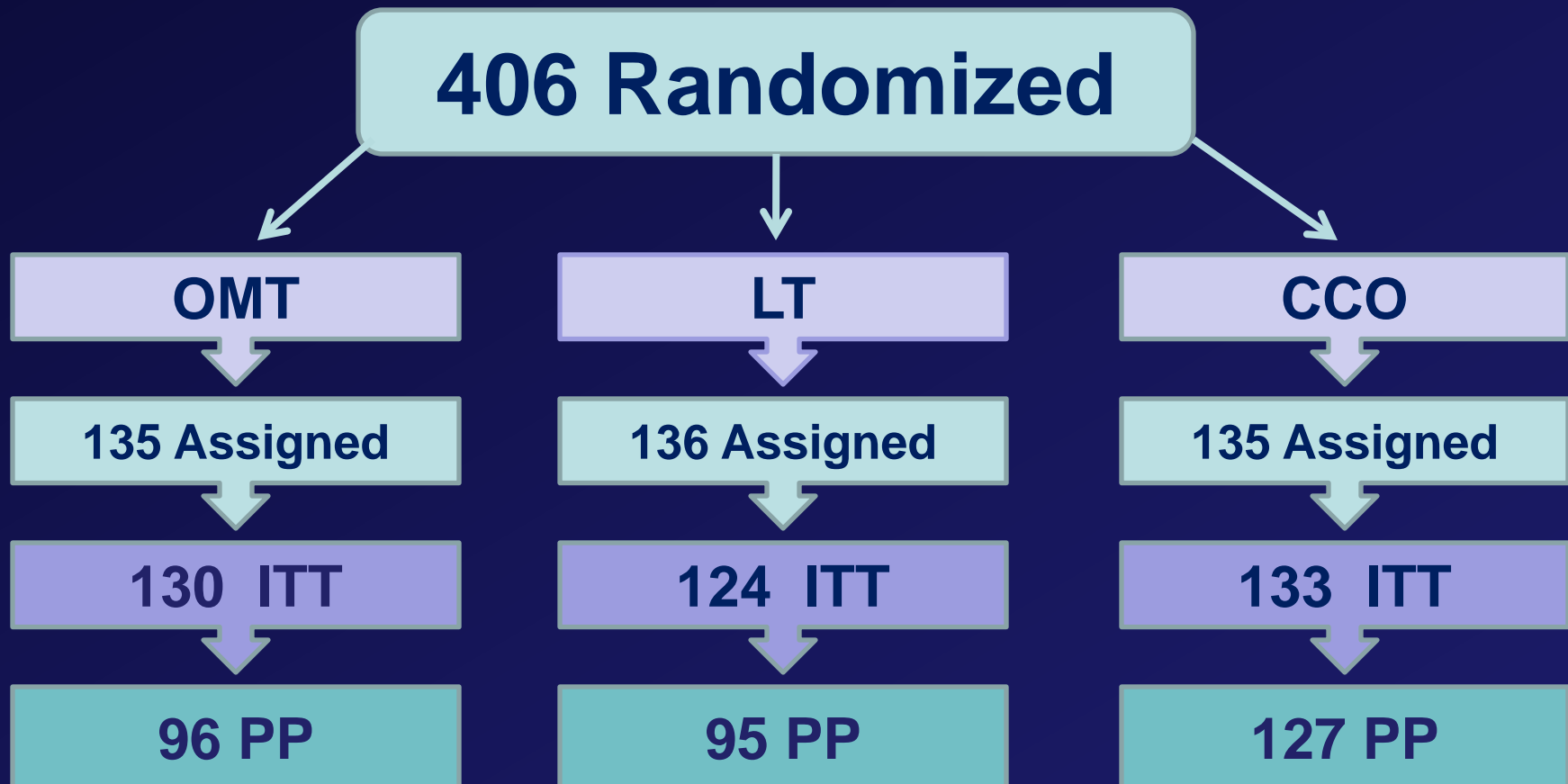


Subject Recruitment

(From Seven Community Hospitals)



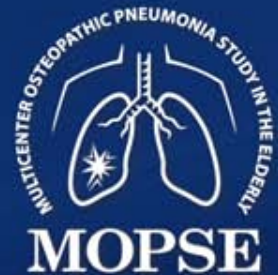
Randomization and Numbers



ITT: Intention-to-treat analysis
PP: Per-protocol analysis

Demographics

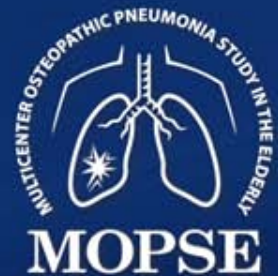
- Antibiotic Selection
 - 84% agreement with practice guidelines
- Demographics
 - No differences, except:
 - Aspiration risk (LT > CCO) by ITT analysis
 - Current Alcohol Use (OMT < LT, CCO) by PP analysis
- Pneumonia Severity Index
 - No between group differences



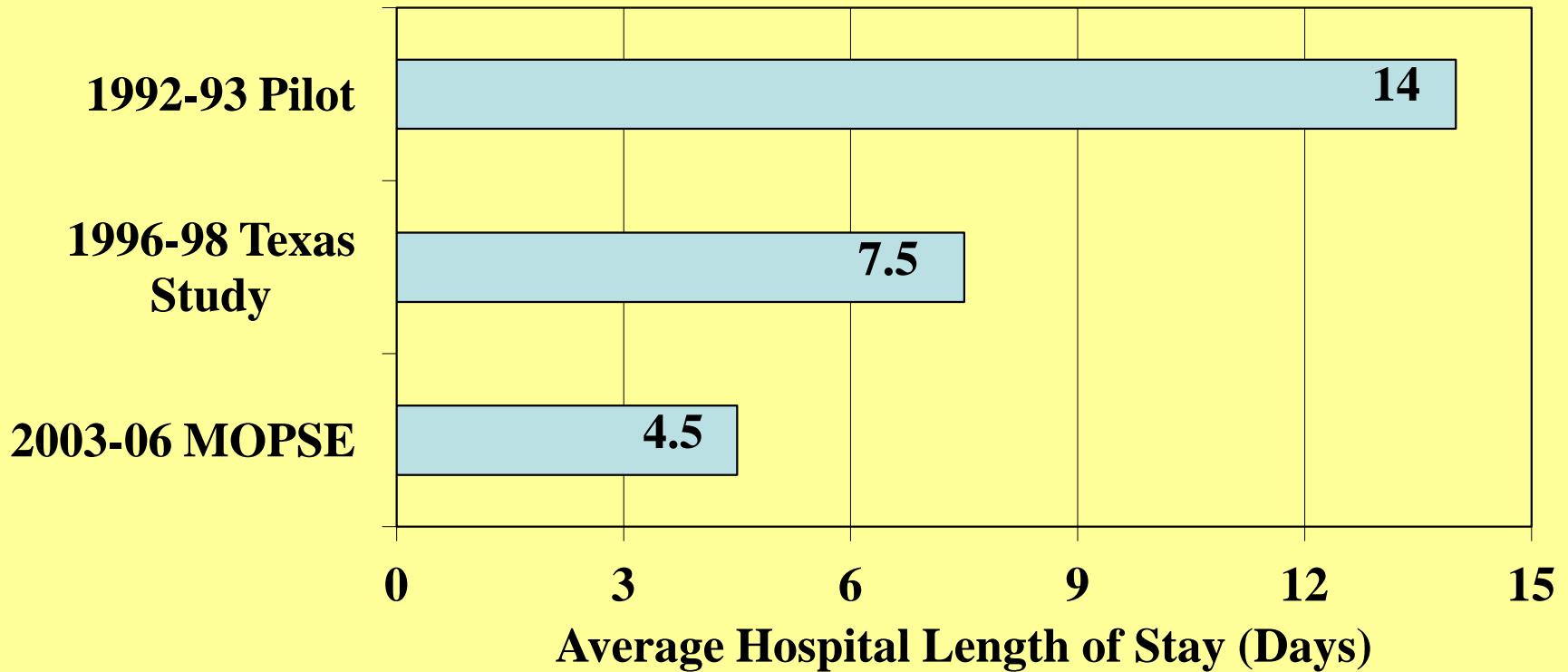
Mean Length of Stay

| OMT | LT | CCO | |
|----------------------|----------------------|----------------------|--------------------------------|
| n = 130 | n = 124 | n = 133 | ITT analysis |
| 4.5 days (SD 2.7) | 4.9 days (SD 2.7) | 4.5 days (SD 2.6) | <i>P</i> = 0.53 |
| n = 96 | n = 95 | n = 127 | PP analysis |
| 4.0 days (SD 2.0) | 4.4 days (SD 2.4) | 4.5 days (SD 2.6) | <i>P</i> = 0.01 (OMT < CCO) |

Duration of antibiotic therapy mirrors these findings for the per-protocol analysis.



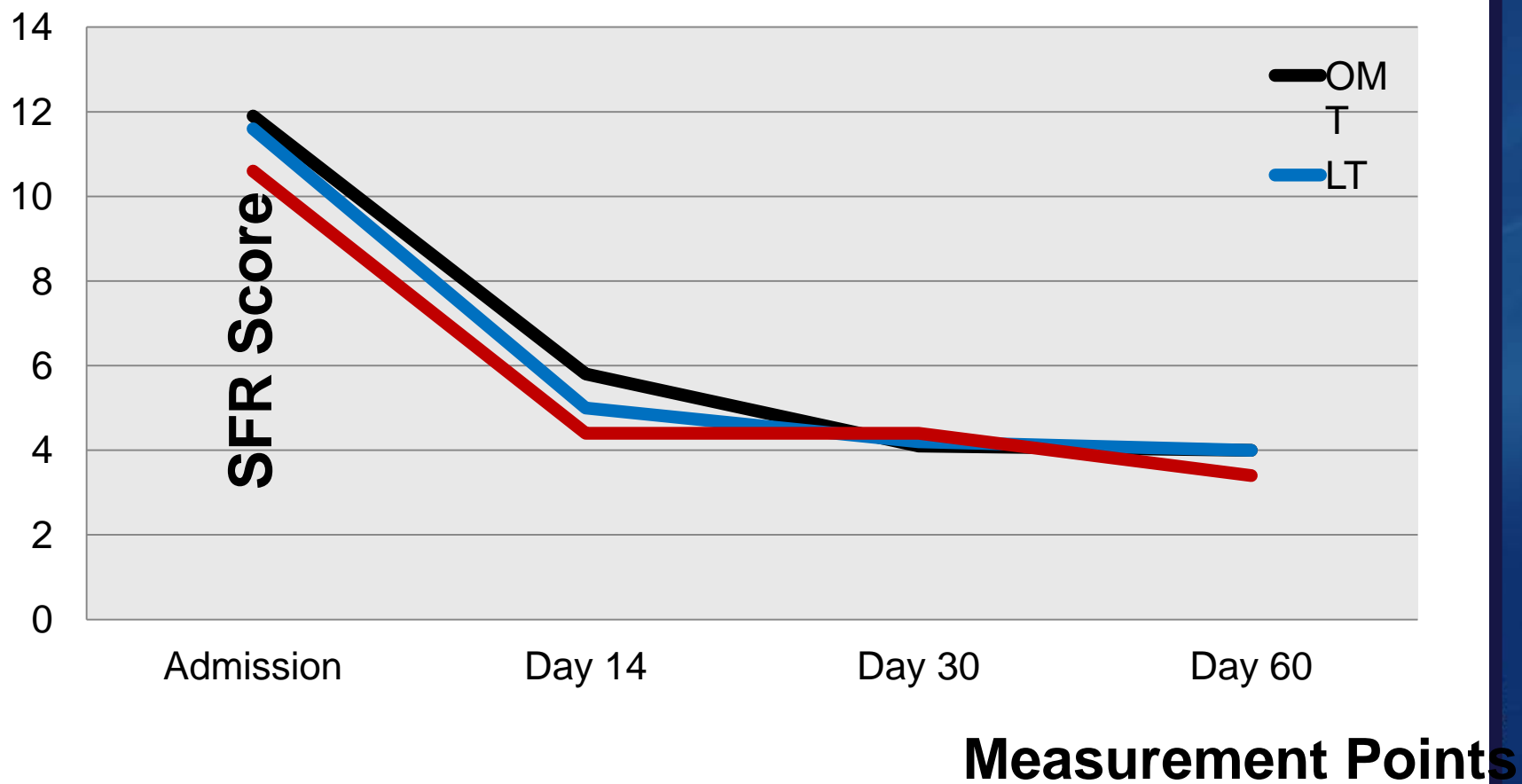
Changing Mean Length of Stay for Pneumonia in the Elderly



Mean Time to Clinical Stability

| OMT | LT | CCO | |
|----------------------|----------------------|----------------------|--------------|
| n = 121 | n = 118 | n = 130 | ITT analysis |
| 2.5 days (SD 1.6) | 2.5 days (SD 1.4) | 2.6 days (SD 1.6) | $P = 0.97$ |
| n = 90 | n = 90 | n = 124 | PP analysis |
| 2.3 days (SD 1.4) | 2.5 days (SD 1.5) | 2.6 days (SD 1.6) | $P = 0.47$ |

Symptomatic and Functional Recovery ITT Analysis – Not Statistically Different (PP Analysis is Similar)



Treatment End Point Data: Intention-to-Treat Analysis

| | OMT | LT | CCO | |
|---------------------|------------|-----------|------------|-----------------|
| | n = 124 | n = 124 | n = 132 | |
| Death | 2% | 3% | 6% | |
| Respiratory Failure | 3% | 3% | 8% | |
| Discharged Alive | 95% | 94% | 86% | <i>P</i> = 0.08 |

Treatment End Point Data: Per-Protocol Analysis

| | OMT | LT | CCO | |
|---------------------|------------|-----------|------------|------------------|
| | n = 96 | n = 95 | n = 127 | |
| Death | 0% | 3% | 6% | |
| Respiratory Failure | 1% | 2% | 7% | |
| Discharged Alive | 99% | 95% | 87% | <i>P</i> = 0.006 |

60-Day Readmission Rate

By Intention-to-Treat Analysis

| OMT | LT | CCO | |
|------------|-----------|------------|-----------------|
| n = 93 | n = 96 | n = 96 | |
| 17 % | 21 % | 22 % | <i>P</i> = 0.64 |

By Per-Protocol Analysis

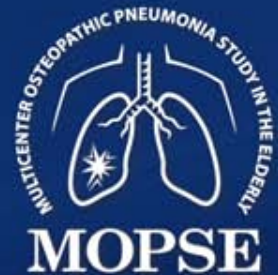
| OMT | LT | CCO | |
|------------|-----------|------------|-----------------|
| n = 80 | n = 79 | n = 92 | |
| 11 % | 20 % | 21 % | <i>P</i> = 0.16 |

Blinding: Percent Correctly Identifying Their Group

| OMT | LT | CCO |
|------------|-----------|------------|
| 53 % | 44 % | 49 % |

Eight Standardized Techniques

1. Thoracolumbar Soft Tissue
2. Rib Raising
3. Doming of the Diaphragm Myofascial Release
4. Cervical Soft Tissue
5. Suboccipital Inhibition
6. Thoracic Inlet Myofascial Release
7. Thoracic Lymphatic Pump
8. Pedal Lymphatic Pump



http://mfile.akamai.com/29070/wmv/multicastmed.download.akamai.com/29070/ATSRI/MOPSE_9-20-10.wmv

