

Chlorhexidine Oral Rinses to Alter the Oral and Sputum Microbiota in COPD (CLIMB):



UNIVERSITY OF MINNESOTA

a Randomized, Double-blinded, Placebo-controlled, Parallel-group Pilot Study

Alexa A. Pragman,^{1,2} Ann M. Fieberg,² Cavan S. Reilly,² and Chris H. Wendt^{1,2}

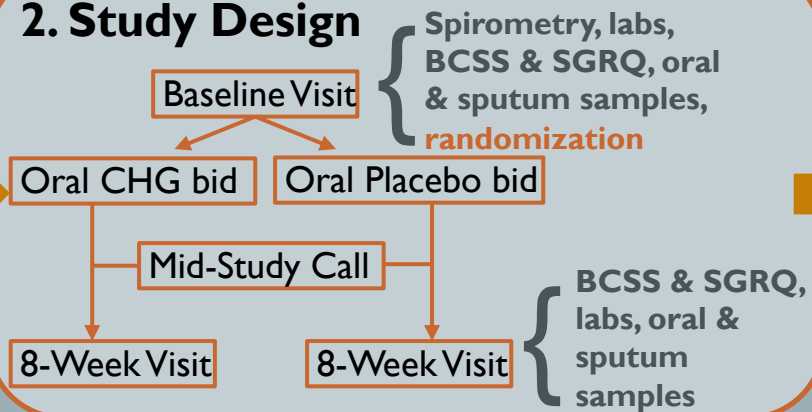
¹Minneapolis VA Medical Center and ²University of Minnesota, Minneapolis, MN

alexa@umn.edu
612-467-6671 (p)
612-725-2273 (f)

1. Introduction

- COPD is associated with oral & sputum microbiota dysbiosis
- Oral microbiota is the source of the lung microbiota
- Chlorhexidine (**CHG**) alters the oral microbiota
- Chlorhexidine oral use may improve COPD symptoms

2. Study Design



3. Criteria

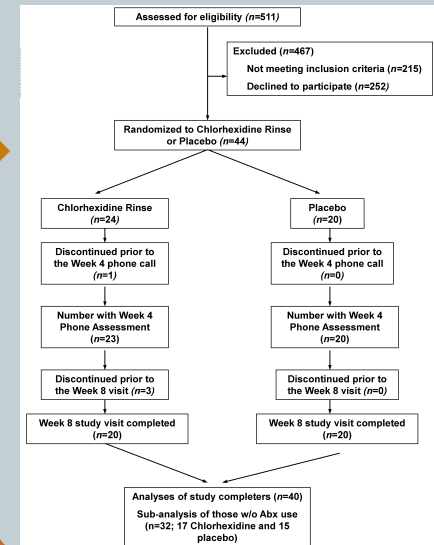
Inclusion:

- 40-85 years old
- COPD
- ≥ 4 natural teeth

Exclusion:

- Exacerbation (≤ 30 days)
- Antibiotic use (≤ 60 days)
- Active oral infection

4. Consort Diagram



5. Outcomes

Primary outcome:

Change in oral and sputum microbiota biomass from baseline

Secondary outcomes:

- Alpha diversity (Shannon diversity)
- Inflammatory markers (WBC, CRP, fibrinogen)
- Breathlessness Cough and Sputum Scale (**BCSS**) scores
- St. George's Respiratory Questionnaire (**SGRQ**) scores

6. Summary of Results

Primary Outcome, N	Mean Diff.	95% CI	p-value
Δ oral biomass, 40	-0.10	-0.59, 0.38	0.660 ^a
Δ sputum biomass, 27	0.80	-0.15, 1.75	0.096 ^a
Secondary Outcomes, N	Effect Size	95% CI	p-value
Δ oral α diversity, 40	-0.35	-0.53, -0.16	0.001 ^b
Δ sputum α diversity, 35	-0.62	-0.97, -0.29	0.001 ^b
Δ WBC, 39	-0.32	-1.42, 0.78	0.560 ^b
Δ CRP, 40	1.54	-2.72, 5.80	0.467 ^b
Δ fibrinogen, 39	20.19	-28.52, 68.91	0.406 ^b
Δ BCSS, 37	-0.28	-1.45, 0.89	0.630 ^b
Δ SGRQ, 40	-6.22	-11.87, -0.57	0.032 ^b

^aTwo-sample t-test, CHG vs. placebo; ^bLinear regression models adjusted for baseline value

7. Conclusions

Compared with placebo, twice daily chlorhexidine oral rinses:

- Decreased oral and sputum microbiota alpha diversity
- Improved quality of life
- Did not change oral or sputum microbiota biomass, as assessed by molecular techniques

8. Funding

- Flight Attendant Medical Research Institute (FAMRI) #150014 to CHW
- Department of Veterans Affairs I1K2CX001095 to AAP
- ClinicalTrials.gov NCT02252588