

Obstructive Sleep Apnea Clinical Trials: A 10-year analysis of clinicaltrials.gov

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Introduction

Obstructive sleep apnea (OSA) is a highly prevalent condition in the United States that is estimated to affect up to 38% of the population.¹ Whether treated or untreated, it has a significant, negative impact on quality of life.² While the gold standard treatment for OSA has historically been (and continues to be) continuous positive airway pressure (cPAP) devices,³ such devices are uncomfortable and often subject to reported poor compliance.⁴ Thus, many clinical trials are underway studying alternatives to cPAP. However, the efficacy of various treatment is likely to vary depending on the cohort studied, as the cause of sleep apnea can be highly variable, ranging from genetic⁵ causes to obesity.⁶

Given the need for new treatments of obstructive sleep apnea, the potential of bias in these studies, and the regulatory landscape that may influence these studies, we sought to explore the current landscape of randomized controlled trials in the United States for treatment of OSA. We utilized clinicaltrials.gov. Clinicaltrials.gov is a registry of all clinical trials in the United States, where particular characteristics of clinical trials can be searched and downloaded.⁷

Herein, we seek to explore the landscape of randomized clinical trials in the United States in a variety of ways. The specific questions that we hope to answer include: 1) How have the number of new clinical trials in the United States changed over time? 2) What are the characteristics of the populations studied by these clinical trials? 3) What is being studied in these clinical trials, and by whom?

Methods

ClinicalTrials.gov was utilized to collect data on clinical trials for OSA treatment. To find clinical trials, the search term “Obstructive Sleep Apnea” was queried with filters “Not yet recruiting,” “Recruiting,” “Active, not recruiting” and “Completed” selected in the United States for studies beginning between January 1, 2013 and December 31, 2022. All data criteria available were selected for download, including study status, study design, intervention, primary outcome measures, sponsor, sex, age, phases, funder types, study design, and locations.

Before analysis, text mining was utilized to ensure inclusion of only randomized control trials. Only interventional study types were included. Finally, study start date was recoded to be organized by year of data collection start. All data processing and statistical analysis was completed in R (2023, version 3.2.1).

Results:

Question 1: How have the number of new clinical trials changed over time?

On average, 11.9 new randomized clinical trials have been started each year for the treatment of obstructive sleep apnea in the United States. The maximum number per year was 17 in 2017 and 2019, and the minimum number was 2018. While the number per year has been variable, there has not been a clear increase or decrease in clinical trial number over time (Figure 1).

Question 2: What are the characteristics of the populations studied?

For the majority (n, %) of clinical trials (108, 90.7%), adults and older adults were the population studied (Figure 2). Only 9 studies investigate pediatric OSA. Studies nearly unanimously investigate treatment of OSA in both sexes (117, 98.3%; Figure 3)).

Question 3: What treatments are being studied in these clinical trials, and by whom?

A wide variety of intervention types are being investigated (Figure 4). To summarize (n, %), the leading treatments being investigated are medications (47, 39.5%), behavioral interventions and therapies (23, 19.3%), positive airway pressure variants (22, 18.5%), other physical appliances (11, 9.2%), physical therapy (6, 5.0%), and nerve simulation devices (2, 1.7%).

These studies were most commonly funded by academic organizations (83, 69.7%), followed by industry (27, 22.7%), veteran's affairs (8, 6.7%), and charitable foundations (1, 0.8%; Figure 5). Among all clinical trials, 69.7% had a clinical trial recruitment location in the Midwest, 66.5% in the South, 59.7% in the West, and 58.8% in the Northeast (Figure 6).

Figure 1: Annual Number of New Clinical Trials.

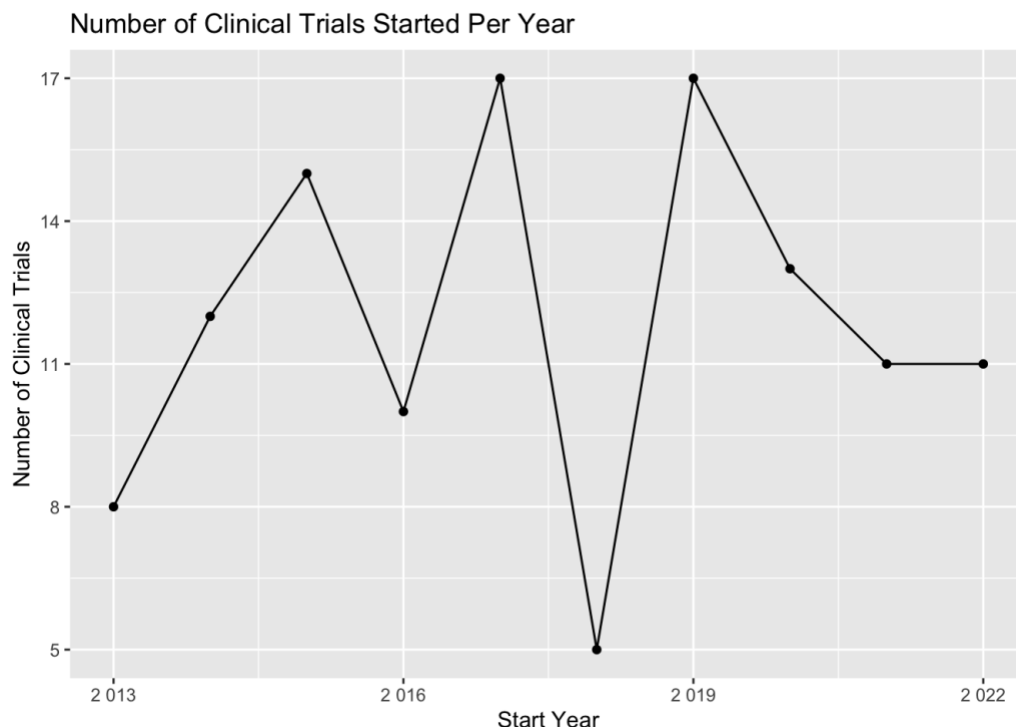


Figure 2: Description of Clinical Trial Participants by Age

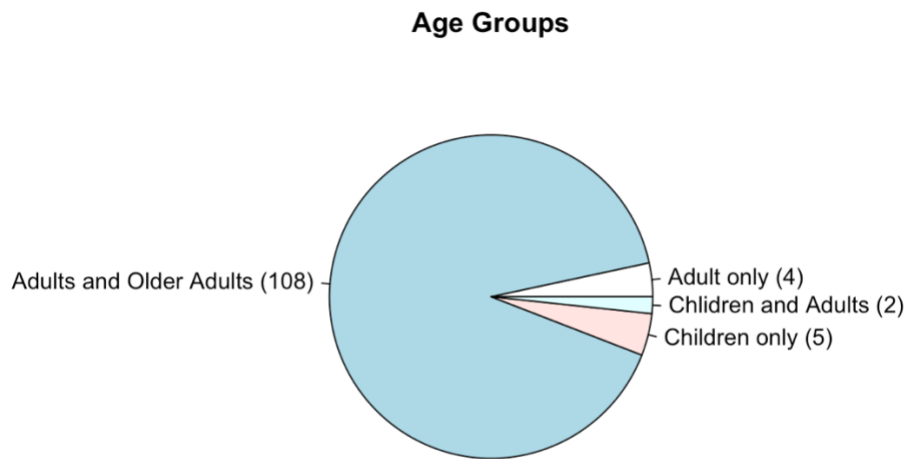


Figure 3: Description of Clinical Trial Participants by Gender

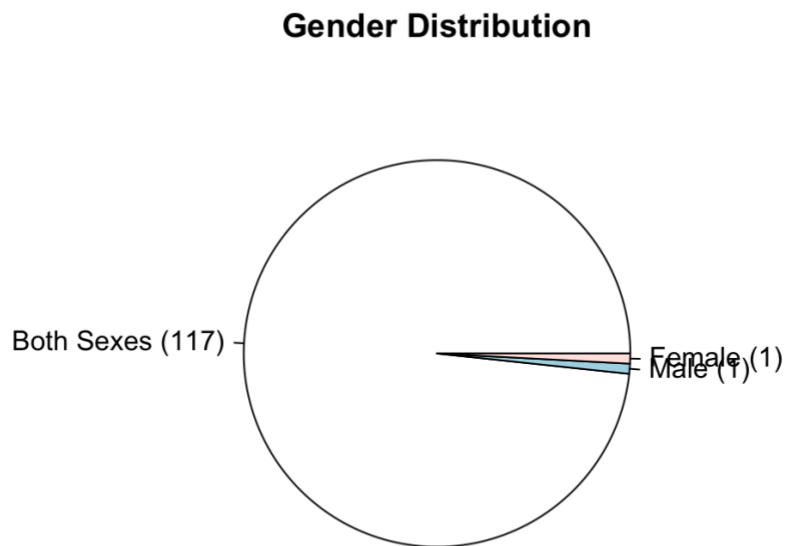


Figure 4: Description of Clinical Trial Interventions

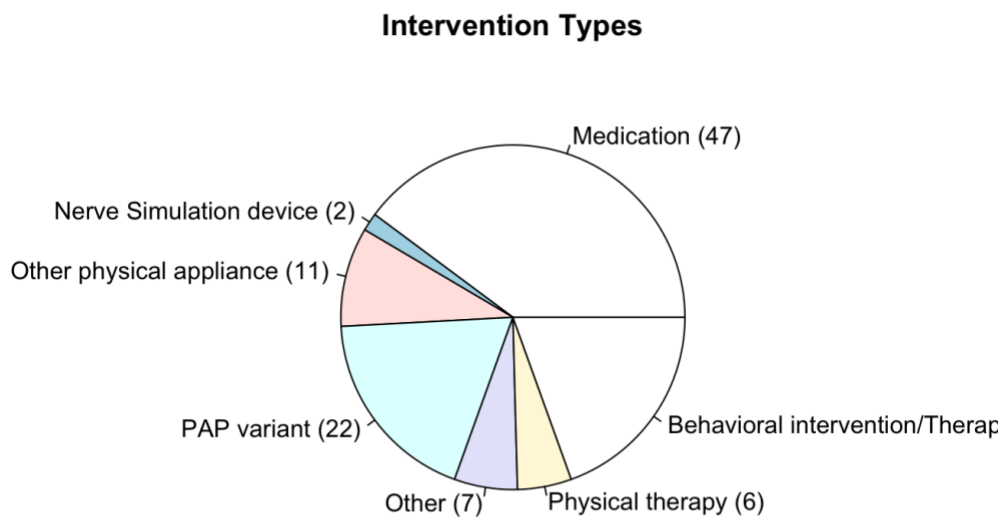


Figure 5: Description of Clinical Trial Sponsor Types

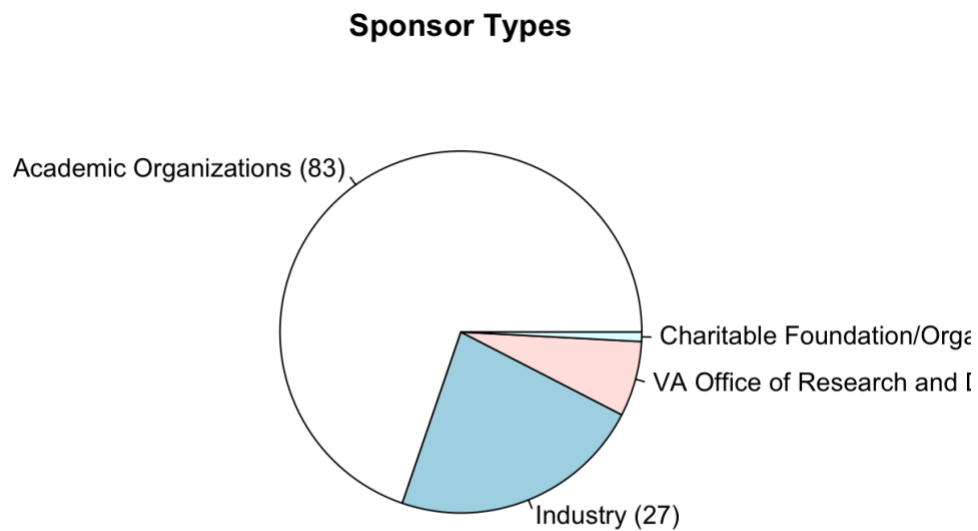
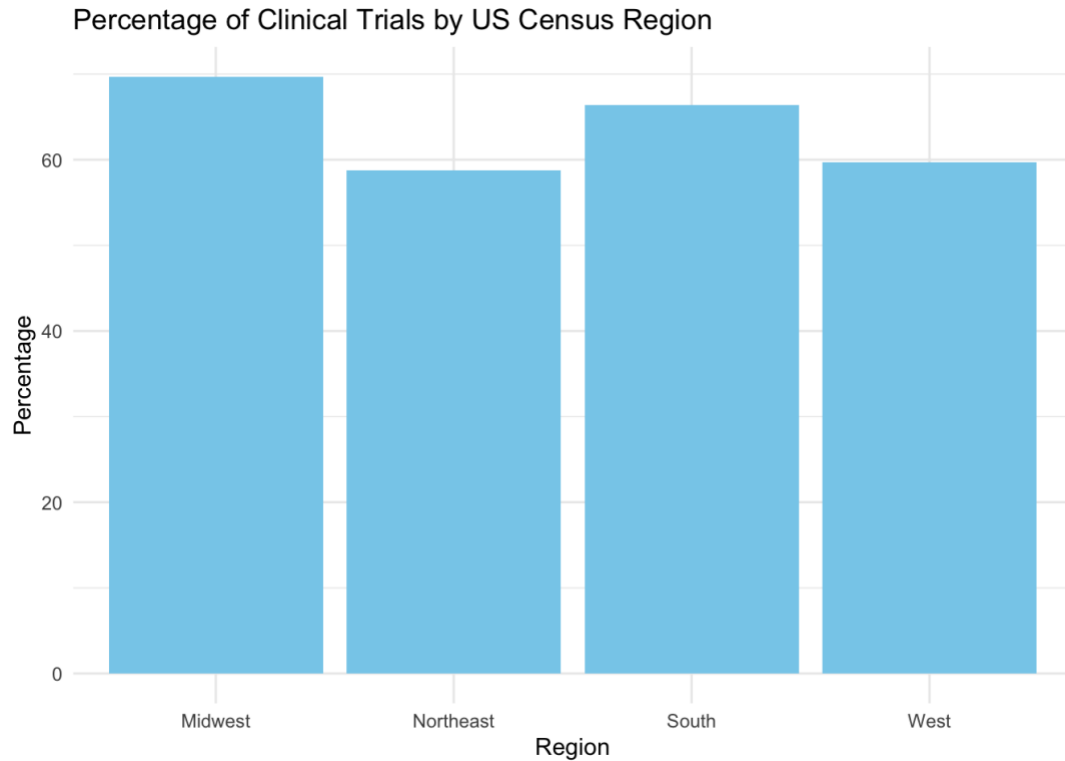


Figure 6: Description of Clinical Trials by Location of Recruitment*



*Some clinical trials recruit in multiple regions and will be counted in each region. Thus, percentage is representative of percent of clinical trials with at least one recruitment location in that region.

Conclusions:

This study provides a summary of randomized clinical trials for the treatment of OSA in the United States over the past 10 years (2013-2022). Over the time period, the average number of new clinical trials each year was approximately 12, and the numbers of new clinical trials started each year has been variable but demonstrated no increase or decrease over time. Most clinical trials are targeted for adults (>95%) and all sexes (>98%) with the most common intervention being medication (39.5%). Academic organizations were the most common funders of such projects (69.7%), with most being conducted at a site in the Midwest (69.7%) and least in the Northeast (58.8%). This study provides context on the current landscape of clinical trials for Obstructive Sleep Apnea in the United States.

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