

Effects of open placebos and the clinical encounter in allergic rhinitis (#35241)

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1) Have any data been collected for this study already?

No, no data have been collected for this study yet.

2) What's the main question being asked or hypothesis being tested in this study?

Open-Label Placebos (OLP) will reduce symptoms of allergic rhinitis more than treatment as usual (TAU). Additionally, the influence of the clinical encounter and its potential interaction with OLP vs. TAU on symptom improvement will be examined in a 2 (treatment: OLP vs. TAU) x 2 (clinical encounter: augmented vs. limited) design.

3) Describe the key dependent variable(s) specifying how they will be measured.

As the primary outcome, we will examine changes in symptoms of allergic rhinitis as measured with the Combined Symptom Medication Score (CSMS). The primary will be assessed twice: at the first study visit and after two weeks.

4) How many and which conditions will participants be assigned to?

Four conditions:
Open-Label Placebo provided in an augmented clinical encounter
Open-Label Placebo provided in a limited clinical encounter
Treatment as usual provided in an augmented clinical encounter
Treatment as usual provided in a limited clinical encounter

5) Specify exactly which analyses you will conduct to examine the main question/hypothesis.

For the main analysis, we will conduct a 2 (Time: before treatment vs. after treatment) x 2 (Treatment: open-label placebo vs. treatment as usual) x 2 (Clinical Encounter: augmented vs. limited) mixed ANOVA with allergic symptoms as the dependent variable.

6) Describe exactly how outliers will be defined and handled, and your precise rule(s) for excluding observations.

- 1) We will compute the overall mean and standard deviation across all conditions and will exclude participants > 3 SD above/below the mean on the dependent variable.
- 2) We will exclude participants from subsequent analyses if they discontinue participation in the study before entering 2/3 of all data points.
- 3) We will exclude participants from subsequent analyses if they report on not having taken the placebo pills as discussed or having changed their regular medication during the duration of the study.

7) How many observations will be collected or what will determine sample size? No need to justify decision, but be precise about exactly how the number will be determined.

With reference to previous work by Schäfer et al. (2016; 2018), we expect a large effect ($F=0.4$) of Open-Label Placebo (vs. treatment as usual) on symptom improvement. Accordingly, the power analysis using G*Power indicated a required sample size of at least 52 people ($\alpha .05$; power .80). Assuming a drop-out rate of approximately 15%, we plan to include 60 participants.

8) Anything else you would like to pre-register? (e.g., secondary analyses, variables collected for exploratory purposes, unusual analyses planned?)

Nothing else to pre-register.