

Openly prescribed placebos to reduce symptoms of allergic rhinitis

Submission date 06/11/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/05/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/08/2022	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Placebo (a substance or treatment which is designed to have no therapeutic value) can reduce physical symptoms even when provided with full honesty and disclosure. Yet, the precise mechanisms underlying the effects of “open-label placebos” (OLPs) have remained subject of debate. Furthermore, it is unclear whether OLPs are similarly effective when provided remotely, as is sometimes required e.g. in the current COVID-19 pandemic.

Who can participate?

People (at least 18 years old) with allergic rhinitis (inflammation and swelling of the mucous membrane of the nose, characterized by a runny nose and stuffiness and usually caused by the common cold or a seasonal allergy)

What does the study involve?

In a randomized-controlled trial, we examined the effects of OLP plus treatment as usual (TAU) compared to TAU alone on symptom reduction in people with allergic rhinitis over the course of two weeks. Due to the COVID-19 pandemic, OLP was provided remotely (i.e. sent via postal service). To investigate the potential influence of the clinical encounter on the effects of OLP, we manipulated the perception of the virtual clinical encounter, both with respect to verbal and nonverbal factors (augmented vs. limited encounter).

What are the possible benefits and risks of participating?

A possible benefit was that the treatment received would reduce people's symptoms of allergic rhinitis. A possible risk was that the treatment would not help.

Where is the study run from?

University of Koblenz-Landau (Germany)

When is the study starting and how long is it expected to run for?

August 2019 to August 2020

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Dr Tobias Kube, kube@uni-landau.de

Contact information

Type(s)
Scientific

Contact name
Dr Tobias Kube

ORCID ID
<https://orcid.org/0000-0002-5420-4506>

Contact details
Ostbahnstr. 10
Landau
Germany
76829
+49 634128035652
kube@uni-landau.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Providing open-label placebos remotely – a randomized controlled trial in allergic rhinitis

Acronym
OLP_REMOTE

Study objectives
Open-Label Placebos (OLP) plus treatment as usual (TAU) will reduce symptoms of allergic rhinitis more than TAU alone. 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.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 01/04/2020, Local Ethics Committee of the Department of Psychology, University of Koblenz-Landau (Ostbahnstr. 10, 76829 Landau, Germany; +49 06341 280 31460; lek@uni-landau.de), ref: 2020_236

Study design

Single-site interventional randomized-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Allergic rhinitis

Interventions

Participants received either open-label placebo plus treatment as usual (TAU) or TAU alone for their allergic rhinitis over the course of two weeks

TAU+OLP

If participants were randomized to TAU+OLP, participants were sent the placebo pills via postal service. The placebos were in a small glass container, which was sent to the participants in a padded envelope. Participants were asked to swallow the placebos, not to chew or suck them, twice a day (one tablet in the morning and another one in the evening). Participants took the placebos for 14 days. In addition to OLP, participants were allowed to continue to take their regular medication (if there was any), but were asked not to change their medication until the second study visit.

TAU only

Participants from the TAU group did not receive placebos after the first virtual study visit. With respect to their regular treatment, they received the same information as participants from the OLP group. Participants from the TAU group were offered the possibility of receiving the placebos after the second (virtual) study visit ("switch-over").

Randomization and Blinding

Prior to the first virtual appointment, participants were randomly allocated to one of the two clinical encounter styles (augmented vs. limited) using a computer-generated randomization sequence. At the end of the first virtual encounter, the provider randomized participants to either OLP or the control group by opening a concealed container (visible to the participants). Thus, neither the provider nor the participant was blinded with respect to the participants' treatment allocation. Participants were not aware, however, of their allocation in terms of the clinical encounter style, since the variation of this factor was disclosed only at the end of the study.

Intervention Type

Mixed

Primary outcome(s)

Allergic symptoms measured using the combined symptom medication score (CSMS) at baseline and two weeks

Key secondary outcome(s)

Impairment caused by allergic symptoms measured using the adapted version of the Pain Disability Index (PDI) at baseline and two weeks

Completion date

13/08/2020

Eligibility

Key inclusion criteria

1. Diagnosed allergic rhinitis
2. At least 18 years old
3. Sufficient German language skills

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

54

Key exclusion criteria

1. Pregnancy
2. Diabetes
3. Any mental or neurological illness
4. Lactose intolerance

Date of first enrolment

20/04/2020

Date of final enrolment

16/07/2020

Locations

Countries of recruitment

Germany

Study participating centre

University of Koblenz-Landau

Ostbahnstr. 10

Landau

Germany

76829

Sponsor information

Organisation

University of Koblenz and Landau

ROR

<https://ror.org/01j9f6752>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/03/2021	23/08/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes