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Openly prescribed placebos to reduce symptoms of allergic rhinitis

Submission date	Recruitment status	[_] Prospectively registered
06/11/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/05/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/08/2022	Respiratory	

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

Study website
http://aspredicted.org/blind.php?x=te979n

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 rhinits 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

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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

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

Overall study start date
15/08/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52

Total final enrolment

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
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Sponsor information

Organisation
University of Koblenz and Landau

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Sponsor type
University/education

Website
http://www.uni-koblenz-landau.de/en

ROR
https://ror.org/01j9f6752

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in an open-access peer-reviewed journal.

Intention to publish date
31/03/2021

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