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# Effectiveness of information presentation in drug fact boxes

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|---|---|---|
| **Submission date**<br>06/04/2020 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[X] Individual participant data |
| **Registration date**<br>24/04/2020 | **Overall study status**<br>Completed | |
| **Last Edited**<br>15/02/2023 | **Condition category**<br>Other | |

## Plain English summary of protocol

Background and study aims
Fact boxes are evidence-based health information. They have been developed to represent the indispensable and understandable benefits and harms of drugs. They are offered as one-sided tabular representations of benefits and harms with or without additional texts. Risk information in fact boxes can be presented in different formats: natural frequencies, percentages or graphically. Few previous studies have shown that natural frequencies and percentages are comparable regarding enhancing knowledge and risk perception of health information. In addition, subgroup analyses indicate that people with lower educational levels might benefit from graphical presentations. The aim of this study is to compare three fact boxes (natural frequencies vs percentages vs bar graphs) with regard to knowledge and risk perception, using "antibiotics for acute bronchitis" as an example.

Who can participate?
Adults aged over 18 living in Germany

What does the study involve?
The study involves the provision of fact boxes. Participants are randomly allocated to one of three groups. Each group is provided with a different presentation format (natural frequencies, percentages or graphics). After reading the fact boxes, participants are asked to answer questions that survey the outcomes.

What are the possible benefits and risks of participating?
The researchers do not anticipate any risk for the participants. However, the study may enable the participants to become familiar with the fact box format. It is possible that the participants are sensitized to the way health information can be presented. They will receive detailed information on the risks and benefits of antibiotic therapy for acute bronchitis.

Where is the study run from?
Martin Luther University Halle-Wittenberg (Germany)

When is the study starting and how long is it expected to run for?
August 2019 to January 2021 (updated 30/03/2021, previously: June 2020)

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Dr Anke Steckelberg
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Anke Steckelberg

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
1

# Study information

### Scientific Title
Drug fact boxes: efficacy of presentation formats - natural frequencies, percentages and bar graphs: a pilot study

### Study objectives

It is expected that the presentation formats natural frequencies, percentage and bar graphs are comparable with regard to knowledge and risk perception. Participants with low educational level might benefit from bar graph presentation.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 05/04/2020, ethics committee, Martin Luther University Halle-Wittenberg (Magdeburgerstraße 16, 06112 Halle, Germany; +49 (0)345 557-4476; ethik-kommission@uk-halle.de); ref: 2019-044

## Study design
Randomized controlled pilot study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Other

## Participant information sheet
Not available in web format and only available in German language on request

## Health condition(s) or problem(s) studied
Drug information presentation

## Interventions
Randomisation: each time a participant agreed to participate a random number is generated and the participant is allocated to the presentation format according to that number.

The study involves the provision of fact boxes. Each study arm is provided with a different presentation format about antibiotics in acute bronchitis, presenting risk information on the benefit and harm of antibiotic therapy in three different formats: natural frequencies, percentages and bar graphs. After reading the fact boxes, participants are asked to answer the questions that survey the outcomes.

The outcomes are surveyed immediately after the intervention. There will be no follow-up.

## Intervention Type
Other

## Primary outcome measure

Verbatim knowledge/risk perception, which is surveyed by 9 items coded 1 (correct answer) or 0 (incorrect answer), measured immediately after the intervention

### Secondary outcome measures
Measured immediately after the intervention:
1. Readability/comprehensibility is measured by four questions using a four-point Likert scale
2. Acceptance is measured by three questions using a four-stage interval scale
3. Relevance refers to the importance of the information. This endpoint is measured with one question

### Overall study start date
04/08/2019

### Completion date
25/01/2021

## Eligibility

### Key inclusion criteria
Adults > 18 years who have their primary residence in Germany and belong to the panel

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Pilot study: 300; 100 in each group

### Total final enrolment
227

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
04/05/2020

### Date of final enrolment
30/05/2020

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Martin Luther University Halle-Wittenberg**
Medical Faculty
Center for Health Sciences
Institute of Health and Nursing Science
Magdeburgerstraße 8
Halle (Saale)
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## Sponsor information

### Organisation
Martin Luther University Halle-Wittenberg

### Sponsor details
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### Sponsor type
University/education

### Website
http://www.uni-halle.de/

### ROR
https://ror.org/05gqaka33

## Funder(s)

### Funder type
Other

### Funder Name
Investigator initiated and funded

# Results and Publications

### Publication and dissemination plan
The study protocol is available in German on request.

All the results of the study (including negative results) will be published in international and open-access journals and presented at meetings and congresses. According to the recommendations of the International Committee of Medical Journal Editors (ICMJE), only persons directly involved in the study will be designated as authors.

### Intention to publish date
30/09/2022

### Individual participant data (IPD) sharing plan
The data of the panel are collected and stored at the Institute for Medical Epidemiology, Biometry and Computer Science at Martin Luther University. The study center will coordinate the data sharing process for all the principal investigators. Public sharing of the data is not intended.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Dataset | The submitted dataset contains data for the comparison of different representations of frequencies in fact boxes | 03/09/2022 | 15/02/2023 | No | No |
| Results article | primary and secondary outcome results | 25/01/2023 | 15/02/2023 | Yes | No |