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Effectiveness of information presentation in drug fact boxes

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomized controlled pilot study

Study type(s)
Other

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
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Sponsor information

Organisation

Martin Luther University Halle-Wittenberg

ROR
https://ror.org/05gqaka33

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Results article	primary and secondary outcome results	25/01/2023	15/02/2023	Yes	No
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