

Respiratory tract infections in primary care

Submission date 16/04/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/06/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/07/2023	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Current plain English summary as 13/07/2018:

Background and study aims

Excessive use of antibiotics in human and veterinary medicine is responsible for the worldwide rise of antibiotic resistance. Although, among both experts and non-professional it is well known that acute respiratory tract infections (ARTI) are primarily caused by viruses, in too many cases antibiotics are prescribed, which are only effective against bacteria, not viruses. Reasons for inadequate prescription of antibiotics in primary care include General Practitioners (GP) mistaken belief that patients would expect an antibiotic prescription and a misleading safety culture.

This study tests:

1. whether a public campaign is able to empower the population to actively participate in the decision-making-process for or against antibiotic prescribing when visiting their GP for an ARTI
2. whether practice-specific prescription-feedback and communication training is able to further optimize antibiotic prescribing in primary care.

Who can participate?

Nested cRCT: all patients attending their GP for acute respiratory tract infection (additional patient survey: patients aged over 17 years)

What does the study involve?

Public campaign: During the trial a public campaign informs the population about antibiotics, antibiotic resistance, and issues important for parents of children with ARTI.

Nested cRCT: During two successive winter periods participants who visit their GP because of ARTI are included. GPs are randomly allocated to one of two groups: (1) an intervention that includes a practice-specific prescription-feedback, communication training and information material for patients or (2) control group with care as usual. Antibiotics prescribing rates are compared between these two groups.

Process evaluation: To understand mechanisms of the educational components, a process evaluation accompanies the intervention in the CHANGE-3 study.

What are the possible benefits and risks of participating?

Participants benefit from their own and their GP's awareness of unnecessary antibiotic prescriptions and from a reduction of inappropriate antibiotic usage and related side effects.

Reducing unnecessary antibiotic prescriptions leads to decreasing rates of antibiotic resistance and is a benefit for the whole population. Participants may be at risk from undersupply with antibiotics, although it is unlikely. Participation in the process evaluation provides a possibility to increase health literacy and to contribute to optimizing future care. Participants might view future antibiotic treatment of patients with ARTI more critically. Probability of negative effects is considered to be low and harm to participants is not to be expected.

Where is the study run from?

1. University of Rostock (Germany)
2. University of Heidelberg (Germany)
3. University of Applied Sciences, Technology, Business and Design in Wismar (Germany),
4. AQUA-Institute for Applied Quality Improvement and Research in Health Care GmbH, Göttingen (Germany)

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

February 2017 to January 2020

Who is funding the study?

Federal Ministry of Health (Germany)

Who is the main contact?

Prof. Attila Altiner (Scientific)

ifa.sekretariat@med.uni-rostock.de

Previous plain English summary:

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Contact information

Type(s)

Scientific

Contact name

Prof Attila Altiner

Contact details

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+49 381 494 2481

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Converting Habits of Antibiotic Use for Respiratory Tract Infections in German Primary Care

Acronym

CHANGE-3

Study objectives

Current study hypothesis as of 13/07/2018:

The CHANGE-3 trial aims at reducing unnecessary antibiotic prescriptions in primary care and at improving the quality of prescriptions for patients suffering from acute respiratory tract infection (ARTI). Quality of prescriptions is defined as choosing an appropriate antibiotic or avoiding of broad-spectrum antibiotics. The trial consists of a public campaign that shall inform the population of two German regions about the reasons for and against antibiotic prescribing. Patients shall be empowered to actively participate in the decision-making process for or against antibiotics when consulting their General Practitioner (GP) for an ARTI. Within this trial, a cRCT will be nested: We investigate whether practice-specific prescription-feedback and communication training further optimize antibiotic prescribing. Using a mix of qualitative and quantitative research methods, the accompanying process evaluation aims at assessing reach and fidelity of the implementation program, its effects on daily practice of healthcare delivery to patients with ARTI and the impact of diverse context factors.

Previous study hypothesis:

The CHANGE-3 trial aims at reducing unnecessary antibiotic prescriptions in primary care and at improving the quality of prescriptions for patients suffering from acute respiratory tract infection (ARTI). Quality of prescriptions is defined as choosing an appropriate antibiotic or avoiding of broad-spectrum antibiotics. The trial consists of a public campaign that shall inform the population of two German regions about the reasons for and against antibiotic prescribing. Patients shall be empowered to actively participate in the decision-making process for or against antibiotics when consulting their General Practitioner (GP) for an ARTI. Within this trial, a cRCT will be nested: We investigate whether practice-specific prescription-feedback and communication training further optimize antibiotic prescribing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Current ethics approval as of 13/07/2018:

1. Public campaign: Ethics committee at the Rostock University Medical Centre, 04/09/2017, ref: A 2017-0134
2. Nested cRCT: Ethics committee at the Rostock University Medical Centre, 29/09/2017, ref: A 2017-0162
3. Process evaluation: Ethics committee at the Medical Faculty, Heidelberg, 11/06/2018, ref. S-349/2018

Previous ethics approval:

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Study design

Current study design as of 13/07/2018:

Public campaign: population-related intervention

Nested cRCT: nested two-arm cluster-randomized controlled trial

Process evaluation: embedded into cluster-randomized controlled trial

Previous study design:

Public campaign: population-related intervention

Nested cRCT: nested two-arm cluster-randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Respiratory tract infection (RTI)

Interventions

Current interventions as of 13/07/2018:

Public campaign:

Spread of information for and against antibiotic prescribing via media, like posters, special website or handouts. The campaign starts in September 2018 and lasts until the end of the trial in January 2020. However, online information on treating ARTI and antibiotics will be available even after the trial.

Nested cRCT

Clusters consist of participating primary care physicians and their patients. After recruitment, GP surgeries are randomized into intervention and control group. Randomization is stratified by antibiotic prescription rate of the GP.

1. Intervention: The intervention focuses on GP surgeries, including both GPs as well as medical assistants. GP surgeries receive practice-specific antibiotic prescribing-feedback and E-Learning modules with doctor-patient and nurse-patient communication training as focal points. The latter includes communication strategies e.g. on how to handle patients expecting the prescription of antibiotics. Both, the feedback and the E-Learning modules are delivered and discussed during a practice visit performed by outreach visitors. Furthermore, during their wait at the practice, patients of the intervention group are offered tablet computers with multimedia

information material on antibiotics and the treatment of ARTI. The material is tailored to different groups of patients e.g. parents of children with ARTI, or elderly. Communication designers are involved in developing appealing material.

2. Control (care as usual):

Data collection of the antibiotic prescriptions takes place at the beginning of the trial, during the intervention and after the intervention for both study arms. This data is retrieved in a pseudonymised way from the German statutory health insurance company AOK and includes all patients aged 0 to 100 years with ARTI who received medical treatment during the trial. Using this data, overall and practice-specific antibiotic prescribing rates are generated. All patients of participating practices insured with the AOK are included. In addition, over two successive winter seasons participating GP surgeries recruit up to 50 patients to fill in a questionnaire measuring patient knowledge on antibiotics and the treatment of ARTI.

3. Process evaluation:

The process evaluation will be conducted alongside the intervention using a mix of methods. In the intervention group, data collection will occur through telephone and face-to-face interviews with general practitioners, medical assistants, patients and outreach visitors as well as surveys for healthcare providers. In the control group, patient interviews and provider surveys will be used to collect data. All collected data will be pseudonymized for analysis.

Previous interventions:

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Intervention Type

Other

Primary outcome measure

Public campaign:

Prescription rate of antibiotics for acute respiratory tract infections is assessed using data from the AOK health insurance company for all GPs in both German regions, before and after the intervention.

Nested cRCT:

GPs prescription rate of antibiotics for acute respiratory infections is assessed from the data of the AOK health insurance company before and after the intervention.

Secondary outcome measures

Public campaign and Nested cRCT:

1. Antibiotics usage per 1000 citizens and day is measured from the data of the AOK health insurance company before and after the intervention.
2. Choice of active ingredient (broad- vs. narrow-spectrum antibiotics) is measured from the data of the AOK health insurance company before and after the intervention.
3. Number of patients with ARTI without antibiotic prescription is measured from the data of the AOK health insurance company before and after the intervention.
4. Number of patients with ARTI with recommended antibiotic prescription is measured from the data of the AOK health insurance company before and after the intervention.

Overall study start date

01/02/2017

Completion date

31/01/2020

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 13/07/2018:

Public campaign: not applicable given the design of the study.

Nested cRCT:

1. Patients of >17 years
2. Consult their GP for an acute respiratory tract infection

Process evaluation:

1. Participants >18 years
2. Full command of German language

Previous participant inclusion criteria:

Public campaign: not applicable given the design of the study.

Nested cRCT:

1. Patients of >17 years
2. Consult their GP for an acute respiratory tract infection

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Nested cRCT: 114 general practitioner practices recruit about 11,000 patients with RTI. Process evaluation: Interviews in the intervention group: 20 physicians and medical assistants, 10 patients and 5 outreach visitors. Interviews in the control group: 10 patients. Surveys: all participants in the intervention group and in the control group

Key exclusion criteria

Current participant exclusion criteria as of 13/07/2018:

Public campaign: not applicable given the design of the study.

Nested cRCT:

1. Deficient knowledge of the German language
2. Any form of dementia

Process evaluation:

1. Deficient knowledge of German language
2. Mentally incapacitated
3. Less than 18 years old

Previous participant exclusion criteria:

Public campaign: not applicable given the design of the study.

Nested cRCT:

1. Deficient knowledge of the German language
2. Any form of dementia

Date of first enrolment

01/08/2017

Date of final enrolment

30/09/2018

Locations**Countries of recruitment**

Germany

Study participating centre
Rostock University Medical Center (lead centre)
Institute of General Practice
Rostock
Germany
18057

Study participating centre
University Hospital of Heidelberg
Department of General Practice and Health Services Research
Heidelberg
Germany
69120

Study participating centre
AQUA-Institute for Applied Quality Improvement and Research in Health Care GmbH
Maschmühlenweg 8-10
Göttingen
Germany
37073

Study participating centre
University of Applied Sciences
Technology, Business and Design
Department of Communication Design and Media
Philipp-Müller-Straße 14
Wismar
Germany
23966

Study participating centre
University Hospital Heidelberg
Institute of Medical Biometry and Informatics
Marsilius-Arkaden
Im Neuenheimer Feld 130.3, Turm West
Heidelberg
Germany
69120

Sponsor information

Organisation

Federal Office of Administration

Sponsor details

Bundesverwaltungsamt

ZMV I 1

Frau Rogler

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+49 22899358 5212

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Sponsor type

Government

ROR

<https://ror.org/04n9aye53>

Funder(s)**Funder type**

Government

Funder Name

Bundesministerium für Gesundheit

Alternative Name(s)

Federal Ministry of Health, Germany, Federal Ministry of Health, BMG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications**Publication and dissemination plan**

Planned publication in an international peer reviewed journal.

Intention to publish date

31/01/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/02/2019		Yes	No
Results article	mixed-methods study results	07/10/2020	23/09/2020	Yes	No
Other publications	process evaluation	19/12/2020	22/12/2020	Yes	No
Results article		04/05/2023	14/07/2023	Yes	No