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Respiratory tract infections in primary care

Submission date	Recruitment status	[_] Prospectively registered
16/04/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/06/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/07/2023	Respiratory	

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 traeatment 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

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Contact information

Type(s)
Scientific

Contact name
Prof Attila Altiner

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ZMVI1-2516FSB100

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 pogram, 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:
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

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 evalaution: 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 practitoners, 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
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Wismar
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23966

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

Sponsor information

Organisation
Federal Office of Administration

Sponsor details
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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