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A study on the impact of the Smarter Medicine Factsheet on antibiotics in respiratory tract infections

Submission date
11/10/2022

Recruitment status
No longer recruiting

Registration date
12/10/2022

Overall study status
Completed

Last Edited
05/06/2024

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Improving quality in antibiotic prescribing is one of the main priorities in the fight against worldwide rising antimicrobial resistance rates. The Choosing Wisely® and Smarter Medicine campaigns are best-known initiatives to promote quality of care in the medical field according to the principle of “less is more”. One of the most prominent recommendations in the field of general internal medicine is to avoid antibiotics for uncomplicated upper respiratory tract infections (RTI). The Smarter Medicine Initiative provides a fact sheet on the topic of RTI. The fact sheet contains both written text and graphic elements and provides basic knowledge for patients about the aetiology of RTI. It explains in plain language why antibiotics are considered inappropriate in the treatment of RTI, in order to sensitize patients that the avoidance of antibiotic treatment may be appropriate in their current condition. Thus, the fact sheets are intended to serve as a support tool or decision aid for both patients and physicians fostering shared decision-making (SDM) about the treatment decision. The aim of this study is to evaluate the effect of the Smarter Medicine fact sheets among patients with acute RTI in Swiss Primary Care on the extent of SDM during the medical consultation.

Who can participate?
Patients 16 years of age and older and with a diagnosis of uncomplicated respiratory infection are eligible to participate in this study.

What does the study involve?
The study involves passive exposure of participants to the Smarter Medicine fact sheets. These will be displayed in the waiting rooms.

Patients who meet the inclusion criteria will receive an information sheet from their physician. This will have all the information about the study and a link to the online survey. All data for the study will be collected by the patients themselves as part of the survey.

What are the possible benefits and risks of participating?
A direct benefit for patients from participating in the study is that patients are sensitized to the

topic of "antibiotics in RTI". There are no study-specific risks, as participation in the study is independent of any therapies.

Where is the study run from?
The study is being conducted in all language regions of Switzerland and is led by the Institute of Primary Care at the University and University Hospital of Zurich.

When is the study starting and how long is it expected to run for?
January 2022 to December 2023

Who is funding the study?
The study is funded by a grant from Smarter Medicine Switzerland and by funds from the Institute of Primary Care.

Who is the main contact?
Dr. med. Andreas Plate, andreas.plate@usz.ch

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The “Smarter Decision” Study: Does the Smarter Medicine Factsheet on antibiotics in respiratory tract infections promote Shared decision making in Swiss Primary Care? A pragmatic pre-post interventional trial.

Acronym
SDS

Study objectives
The Smarter Medicine fact sheets are well understood among patients with Respiratory tract infections (RTI) and they improve patients’ knowledge and awareness on antibiotic prescribing inappropriateness and patients’ involvement in Shared Decision Making (SDM) between patients and physicians during the medical consultation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study is an evaluation study of an existing instrument (fact sheets) and therefore does not fall under the national Human Research Act. Therefore, an ethics vote is not necessary. Cantonal Ethics Committee Zürich (Stampfenbachstrasse 121, 8090 Zürich, Switzerland; no telephone number provided; info.kek@kek.zh.ch0, ref: BASEC Number: 2022-00369

Study design
Pragmatic intervention study with pre-post intervention comparisons

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Respiratory tract infections

Interventions
The intervention consists of passive exposure of patients to the fact sheets. GPs were provided with the fact sheets. The supply consists on:
- Flyers for the waiting room (mandatory)
- A laminated version of the fact sheets which may be used as a supporting tool or decision aid during the medical consultation. (Use by the GP voluntary)
- A poster, to be posted prominently in the waiting room within the practice (optional)
- An electronic version of the fact sheet in case the practice uses displays to provide information to patients in the waiting room (optional).

Fact sheets will be placed in physician offices halfway through the study period (Jan-Mar 2023). The first half of the study period (Oct - Dec 2022) will serve as a control period.

Intervention Type
Behavioural

Primary outcome(s)
1. Extent of SDM during the consultation in the pre and post interventional period measured using SDM-Q-9

Key secondary outcome(s))
1. Awareness / knowledge of antibiotic prescribing inappropriateness among patients with RTI in Swiss Primary Care.
Measurement: Survey of patients in the pre-and post-intervention period. Patients will be asked a set of specific questions.
2. Comprehension of the Smarter Medicine fact sheets among patients.
Measurement: Specific questions about the facts provided in the fact sheets, and about the perceived relevance of the provided information. Survey among patients in the post-intervention period.
3. Evaluation of the Smarter Medicine fact sheets by the patients and the study GPs
Measurement: Survey among patients in the post-intervention period and a survey among GPs at the end of the whole study period.
4. Perception of the fact sheets by patients in the waiting room and the proportion of encounters for RTI in which the fact sheets were used by the physician, compared to all encounters for RTI.
Measurement: The perception of the fact sheets in the waiting rooms and the use of fact sheets during the consultation will be asked within the patient survey.

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. 16 years of age and older
2. One of the following symptoms/diagnosis:
2.1. Rhinitis/Rhinosinusitis/Sinusitis
2.2. Pharyngitis/Tonsillitis
2.3. Bronchitis
2.4. Streptococci - Pharyngitis
2.5. Influenza
2.6. Covid-19

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria

1. Immunocompromised patients
2. Diagnosis of a exacerbated COPD / asthma
3. Diagnosis of a pneumonia

Date of first enrolment
01/10/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
Institute of Primary Care, University and University Hospital Zürich
Pestalozzistrasse 24
Zürich
Switzerland
8091

Sponsor information

Organisation
University of Zurich

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, Switzerland, University of Zurich, UZH

Funding Body Type

Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Funder Name
Smarter Medicine - Choosing Wisley Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
No individual participant data will be shared. According to the information provided to the patients in the course of their participation in the study, the data will not be passed on to third parties. In accordance with current national legislation, the study data will be kept under lock and key at the study center for 10 years.

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		29/02/2024	05/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes