

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/06/2024	Condition category Respiratory	<input type="checkbox"/> 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

Contact name

Dr Andreas Plate

ORCID ID

<http://orcid.org/0000-0001-6143-5479>

Contact details

Institut für Hausarztmedizin

University of Zurich

Pestalozzistrasse 24

Zürich

Switzerland

8091

+41 442557503

andreas.plate@usz.ch

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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.ch, ref: BASEC Number: 2022-00369

Study design

Pragmatic intervention study with pre-post intervention comparisons

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 measure

1. Extent of SDM during the consultation in the pre and post interventional period measured using SDM-Q-9

Secondary outcome measures

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.

Overall study start date

01/01/2022

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

Age group

Other

Sex

Both

Target number of participants

7200

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

Sponsor details

Institut für Hausarztmedizin
Pestalozzistrasse 24
Zürich
Switzerland
8091
+41 442559855
andreas.plate@usz.ch

Sponsor type

University/education

Website

<https://www.hausarztmedizin.uzh.ch/de.html>

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

Publication and dissemination plan

The results of the study will be published in a scientific journal and presented at national and international congresses.

Intention to publish date

30/06/2024

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