

# Understanding of the standard language version versus the plain language version of recommendations from guidelines by parents, youth, and adults in the Czech Republic

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<b>Registration date</b> 26/02/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/01/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Clinicians, policymakers, and the public are provided with many recommendations from healthcare professionals. These recommendations vary in trustworthiness. Guideline developers typically create recommendations for healthcare professionals. It can be challenging to decide which recommendations to follow. Many members of the public and some policymakers do not have the skills to decide which recommendations are trustworthy. Plain language recommendations (PLRs) can make health advice easier to understand for specific groups. Plain language versions of recommendations (PLRs) still need to be researched. The main goal of this project is to test simplified versions of important public recommendations for the wide lay population. This includes a follow-up interview to get more details.

### Who can participate?

Three populations are included: adults, parents and youth in the Czech Republic - the later interview will be held with a subset of participants. The study is open to the general public (wide lay population). Volunteers, both male and female, can participate if they can read Czech and understand the text. Participants must be within the specified age range. The category "youth" (teenagers) will include participants aged 15-18 years inclusive. Participants in the "parent" category are 19 years or older and are the parent, guardian, or legal representative of a child under 18. In the "adult" category, all participants aged 19+ years who do not meet the "parent" category will be included.

### What does the study involve?

The intervention has two parts. First, participants receive optimized PLRs. Then, they fill out the online questionnaire. The control group will receive the standard recommendations in the format from the original guideline (the format for healthcare workers). Once participants join the study, they can provide their email if they want to join the next (second) study phase of interviews. The researchers will interview selected participants from all three population categories (adults, parents and youth).

What are the possible benefits and risks of participating?

By participating in the project, the respondent can improve the clarity and use of recommendations for infectious disease decision-making. There is no financial reward for participation in the study.

The risks associated with participation in the study are minimal. No direct health intervention is being tested (including drugs or new devices).

Where is the study run from?

Masaryk University (Czech Republic)

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

November 2023 to June 2026

Who is funding the study?

Czech Health Research Council (Czech Republic)

Who is the main contact?

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2. Dr. Dana Dolanová, [dana.dolanova@med.muni.cz](mailto:dana.dolanova@med.muni.cz)

### **Study website**

<https://uzv.med.muni.cz/veda-a-vyzkum/projekt-plr>

## **Contact information**

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

NU23-09-00328

**Study information****Scientific Title**

Understanding of the standard language version versus plain language version of recommendation from guidelines for the use of protective face masks in the context of COVID-19 infection by parents, youth, and adults in the Czech Republic

**Study objectives**

The researchers assume there is a difference in understanding of the standard language version (SLV) of the recommendations and the plain language version (PLR) of the recommendations from guideline by parents, youth, and adults.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 16/11/2023, Ethics Committee of the Faculty of Medicine of Masaryk University (Kamenice 753/5, Brno, 625 00, Czech Republic; +420 (0)549 49 7826; mvanhar@med.muni.cz), ref: MU-IS/273724/2023/2190592/LF

**Study design**

Randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community, Home, Internet/virtual, School, Workplace

**Study type(s)**

Other

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Understanding of the standard language version and the plain language version of recommendations from guidelines by parents, youth, and adults

**Interventions**

Participants will enter the trial via a website where they will provide consent and demographic information and be allocated to a specific recommendation in the intervention or control group (see recruitment below) using the concealed allocation code of the intervention platform, Survey Monkey (surveymonkey.com). The experimental arm will receive a Plain Language Recommendation (PLR). The active comparator is the Standard Language Version (SLV): the original translated recommendation as initially published by the guideline developer. The online questionnaire consists of 7-point Likert scale questions, multiple-choice questions, open-ended questions, and questions regarding more detailed demographic information.

**Intervention Type**

Other

**Primary outcome measure**

Understanding of Plain Language Recommendation (PLR) and related information as measured by a knowledge test (time period for data collection and measurement: March 2024 to May 2025)

**Secondary outcome measures**

### 1. Accessibility and usability:

- 1.1. The ease of locating desired information within the PLR or SLV (orientation)
  - 1.2. The clarity and comprehensibility of the information (perception)
  - 1.3. Whether the information is presented in a way that aids decision-making (destructiveness).
- Participants will express their level of agreement with statements using a 7-point Likert scale. Additionally, there will be an overall accessibility rating on the same scale. An open-ended question will provide an opportunity for participants to provide more detailed feedback.

2. Satisfaction: Participants will be asked to rate their satisfaction with various features of the PLR or SLV, such as the explanation of conditions in a conditional recommendation, using a 7-point Likert scale. Two open-ended questions will gather specific feedback on what participants liked and disliked.

3. Intended behavior: The researchers will inquire whether participants have already adhered to the recommendations and, if not, how likely they are to follow them. Responses will be assessed using a 7-point Likert scale.

4. Preference: After completing tasks in their assigned group, participants will compare two different recommendation formats (PLR or SLV) and indicate their preference using a 7-point Likert scale. Additionally, they will have the opportunity to explain their choice in a text box.

Time period for data collection and measurement: October 2024 to November 2025. Data collection for both primary and secondary outcome measures will overlap in time.

### Overall study start date

16/11/2023

### Completion date

30/06/2026

## Eligibility

### Key inclusion criteria

1. For youth population: between the ages of 15 and 18 years
2. For parents population: 19 years and above and making decisions with or for their children (parent, caregiver, the legal guardian of a child <18 years)
3. For adults: 19 years of age or older
4. Ability to complete the survey in Czech language

### Participant type(s)

All

### Age group

Mixed

### Lower age limit

15 Years

### Sex

Both

### Target number of participants

850

**Key exclusion criteria**

Individuals not fitting any of the above age categories or language requirement

**Date of first enrolment**

01/03/2024

**Date of final enrolment**

31/12/2025

**Locations****Countries of recruitment**

Czech Republic

**Study participating centre**

**Masaryk University**

Faculty of Medicine

Department of Health Sciences

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**Sponsor information****Organisation**

Agentura Pro Zdravotnický Výzkum České Republiky

**Sponsor details**

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**Sponsor type**

Research council

**Website**

<https://www.azvcr.cz/>

**ROR**

<https://ror.org/05m8t8e28>

# Funder(s)

## Funder type

Research council

## Funder Name

Agentura Pro Zdravotnický Výzkum České Republiky

## Alternative Name(s)

Czech Health Research Council, AZV ČR

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

Czech Republic

# Results and Publications

## Publication and dissemination plan

1. Publications in domestic and foreign scientific journals.
2. Promotion through websites and social media of the Faculty of Medicine of Masaryk University and websites of the Ministry of Health (e.g. National Health Information Portal).
3. In the following years, all team members will present their results at conferences to be scheduled.

## Intention to publish date

31/12/2026

## Individual participant data (IPD) sharing plan

Only members of the research team will always have access to personal data. These persons are obliged to ensure and maintain the confidentiality of personal data. Anonymised data will be collected and processed using the Data Stewardship Wizard tool, in accordance with Act No. 101/2000 Coll., as amended. The processed data will not contain any personal identifying information that could lead to the identification of individuals (see below). Only members of the research team authorised by the research supervisor will have the encryption key to the identity of individuals. Other researchers involved in the study will only have access to the encrypted data. The key, along with the measured data, will be stored on a password-protected computer disk. Access to the PC containing the data will be restricted to members of the research team authorised by the project research manager.

The questionnaire will be hosted on the SurveyMonkey platform. SurveyMonkey has a GDPR compliant privacy policy and is licensed. The encryption key will be stored on a password

protected computer disk along with the measured data. Only members of the research team authorised by the project principal investigator will have access to the PC containing the data.

**IPD sharing plan summary**

Stored in non-publicly available repository