Study Protocol Cover Page

Official Study Title:

Risk Literacy among Portuguese medical and dentistry students - a cohort study

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A	01.05.2020	Maxim Benz, Alexej Zhogov
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Protocol Outline

Protocol Title: **Risk Literacy among Portuguese medical and dentistry students - a cohort study**
Short Title: **RiskommPT**

Protocol Version:	**1.4**
Protocol Date:	24.10.2019
Principal Investigators:	Maxim Benz, Alexej Zhogov
Research Team:	Maxim Benz, Alexej Zhogov, Henrique Proença da Cunha, Mirjam Jenny, Gerd Gigerenzer, Mário Pereira Pinto, Niklas Keller

I. Abstract

Provide a summary of the study background, aims, and design.

Risk literacy is the competence to deal with probabilistic information in an informed way. In medicine and dentistry (in the following text both referred as medicine), this is crucial to accurately interpret the results of diagnostic tests and to make risk-benefit-assessments for treatment options. Without it, applying medical evidence to clinical practice remains illusory. Previous research showed that there is still a lack of risk literacy among medical personnel in different countries [Garcia-Retamero, Galesic & Gigerenzer, 2011]. It was also shown that this deficit is easy to overcome with simple teaching interventions [Keller, Jenny & Gigerenzer, 2018]. With this investigation we want to assess the current state of risk literacy among Portuguese medical students in order to assess a baseline. This allows measurement of improvement of risk literacy in Portugal in the future and generates data for comparisons of risk literacy between European countries.

We are planning to publish our study in an open access journal, thereby promoting its dissemination. With our findings we want to encourage a dialogue with relevant stakeholders in the Portuguese healthcare system. We have simplified the design of the study, facilitating reproduction and replication through other research groups in the future and in other countries, thereby generating more data for epidemiological mapping of risk literacy in the world.

II. Background and Significance/Preliminary Studies

Describe the current environment that is the basis for the proposed research, including a presentation of the problem (with references) and a review of current literature. Include a critical evaluation of current knowledge and preliminary studies related to the proposed research and describe how this proposal will enhance this knowledge.

Medical risk literacy encompasses the skills to understand medical statistics and numerical medical evidence. It is central to the practice of evidence-based medicine. In diagnostics, it affects the interpretation of test results, such as being able to assess the probability of a lab-result being false-negative or false-positive. In treatment planning, it affects the assessment of the effectiveness of different interventions. Without risk literacy, doctors can be influenced in their treatment decisions for example by framing effects (Gigerenzer & Wegwarth, 2013). Further, risk literacy helps immunize patients

against the influence of non-evidence-based treatment suggestions by physicians (Wegwarth, Wagner & Gigerenzer, 2017). It was shown that a quick, 90-minute intervention can significantly boost medical students' skills in understanding medical evidence and its effect on medical practice (Keller et al., 2017). A big part of the research on risk literacy has been done in Germany and some medical facilities in Germany are beginning to integrate the findings into their teaching curricula.

To give a positive example of this change associated with the research, risk literacy was integrated into the curriculum of the biggest European medical university-clinic, Charité Universitätsmedizin Berlin, in 2014. It is taught in the 9th semester. Due to a student initiative, students also have the opportunity to learn about risk literacy already from the second semester onwards. This voluntary course has received positive feedback from the students. Our opinion is, that risk literacy must be taught earlier, since a lot of probabilistic information is already contained in the curriculum which potentially can be misinterpreted.

Portugal has a very broad medical educational landscape. During our preparatory research, we found out that several Portuguese Universities already offer statistical courses as part of the curriculum for the students and some elements of risk literacy are already taught in medical curricula in Portugal. During our preparatory searches we were not able to identify any course with similar content composition and knowledge packages as proposed and evaluated by Keller et al., 2017.

Several tests have been developed that assess for risk literacy, of which the three most widely used ones are the Quick Risk Test (QRT, Jenny, Keller & Gigerenzer, 2018), the Critical Risk Interpretation Test (CRIT, Caverly et al., 2015) and the Berlin Numeracy Test (BNT, Cokely & Galesic, 2012). The QRT has been specifically developed for physicians and other health professionals.

III. Study Aims

Describe the purpose of the study, including identification of specific primary objectives/hypotheses. Secondary objectives/hypotheses should be described as necessary.

The **primary objective** of the study is the measurement of the risk literacy among all participating Portuguese medical students. We intend to obtain a representative demographic sample from the participating institutions, to assess the baseline in order to be able to document an improvement in the future and to compare these results with students of other European countries.

The **secondary objectives** of the study are to compare students of different years of study with each other to see if there are some differences. This information could help determine the best possible time point(s) for intervention(s).

We will also explore whether students, who have already received statistics training at some point prior to testing receive higher scores in risk literacy.

IV. Administrative Organization

Describe the participating units, including other participating study sites, laboratories, data management center, and coordinating center as applicable.

- Harding Center for Risk Literacy (Max Planck Institute for Human Development), Berlin, Germany
- We hope to obtain the participation of the following Portuguese faculties:
    - Instituto Universitário de Ciências da Saúde
    - Instituto Universitário Egas Moniz
    - Universidade Católica Portuguesa - Centro Regional das Beiras
    - Universidade da Beira Interior
    - Universidade de Coimbra - Faculdade de Medicina
    - Universidade de Lisboa - Faculdade de Medicina
    - Universidade de Lisboa - Faculdade de Medicina Dentária
    - Universidade do Minho
    - Universidade do Porto - Faculdade de Medicina
    - Universidade do Porto - Faculdade de Medicina Dentária
    - Universidade do Porto - Instituto de Ciências Biomédicas Abel Salazar
    - Universidade Fernando Pessoa
    - Universidade Nova de Lisboa - Faculdade de Ciências Médicas
- Presidencia (High Patronage requested)

V. Study Design

a. *Experimental design of the study (e.g., single-blind, double-blind)*
   This exploratory, epidemiological investigation is conducted as an observational, cross-sectional cohort study.
b. *Study population general description*
   The studied population are medical and dentistry students of Portuguese faculties.
c. *Sample size determination and power analyses*
   Not applicable, due to the exploratory character of the study.
d. *Study outcomes/endpoints.*
   The **primary Outcome** is the quantitative measurement of "medical risk literacy" among Portuguese medical students measured with the Quick Risk Test (QRT) [Jenny, Keller & Gigerenzer, 2018] and the multiple choice version of the Berlin Numeracy Test (BNT) [Cokely & Galesic, 2012]. We do not use the CRIT (Caverly et a., 2015) in this study, as it tests for more advanced statistical understanding and is a very extensive test, which would require at least 30 to 45 minutes for completion.

   Secondary outcomes is to investigate, whether study year, faculty, and prior statistical education have an impact on the level of risk literacy.

VI. Study Procedures

a. *Subject selection procedures*
    i. *Sampling plan including Inclusion/Exclusion criteria (subject and disease characteristics)*
       The participants can be included if they have successfully enrolled into medical or dentistry faculty, but have not yet completed the final exam.

ii. *Recruitment procedures*

1. *Where will recruitment occur?*
   We will approach the faculties to determine the local mechanisms to approach the students.
2. *Where and when will consent be obtained?*
   Informed consent will be obtained prior to the initiation of the online-questionnaire. No written consent can be given due to anonymity.
3. *Who will obtain consent?*
   The investigators and the Harding Center for Risk Literacy
4. *What is the advertising plan, if applicable?*
   University mailing lists and if necessary students' associations and social media.
5. *What recruitment materials will be provided to the potential participant (brochures/information sheets/video presentation)?*
   The invitational email will contain some introductory information as to the purpose, duration and incentivization of the study. The complete participant information will be displayed on the introductory page of the online-questionnaire.

iii. *Screening procedures*

Not applicable

1. *What procedures are required for screening?*
   What is the screening schedule (number of visits, length of visits)?
2. *Which screening tests/procedures are part of standard care and which are for research purposes only?*
3. *What happens with screen failures (including any data gathered during screening)?*

b. *Randomization procedures (if applicable)*

Not applicable
(Exploratory study)

c. *Study Intervention*

Not applicable

i. *For Drug/device studies:*
   1. *Active study agents*
   2. *Placebo study agents*
   3. *Blinding/labeling/preparation of agents*
   4. *Storage*
   5. *Administration*
   6. *Toxicities and guidelines for adjustments*

ii. *For Other types of intervention studies:*
   1. *Active intervention description*
   2. *Control group, if applicable*

d. *Study Assessments and Activities*

i. *Describe all study procedures, assessments, and subject activities*

Students receive an email with some introductory information on the study (goal of the study, expected duration, incentivization). Students are

then led via URL to the online questionnaire, the first page of which contains the full participant information. Students declare their consent to participation by clicking a button that leads begins the questionnaire containing the QRT, BNT and additional information. Participants can abort the questionnaire at any time by closing the browser. The time of the completion of the questionnaire will be recorded. After completion of the questionnaire, on the final page, participants receive an individual code which which they can use to receive a free 2-week subscription to the AMBOSS medical learning platform. A link to the AMBOSS website will also be displayed. They may also use this code to enter into a lottery to win one of three six-month-subscriptions. Note that registration with AMBOSS is only possible with provision of a valid email address of the faculty. Each code can only be entered once. There are no mechanisms that allow the exchange of study data with the personal information provided during the AMBOSS registration process.

ii. *Provide a schedule of all study assessments and subject activities, including a tabular representation or timeline as applicable*

VII. Safety Monitoring Plan

a. *Definition of adverse events, serious adverse events*

not necessary

b. *What procedures will be used to monitor subject safety?*

not necessary

c. *Who (list names) will identify, document, and report adverse events?*

not necessary

d. *What is the frequency for review of summarized safety information and who will perform the review (e.g., safety monitoring board)?*

not necessary

e. *What are the stopping rules with regard to efficacy and safety?*

not necessary

VIII. Analysis Plan

Describe statistical analysis methods as appropriate. For example, will intention-to-treat methodology be used in the analysis? Will there be any sample stratification?.

We will conduct an exploratory analysis of the current level of risk literacy among Portuguese medical students as a baseline for international comparison and measurement of improvement in the future. We will only perform descriptive analyses as well as exploratory correlational analyses. No hypotheses are tested. Representativeness of the sample to the population of Portuguese medical students will be assessed after data collection is completed.

IX. Literature Cited

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