

## **Protocol:**

### **Presenting summary information from Cochrane systematic reviews: randomized controlled trial of infographics presentation vs. standard word summaries**

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#### Protocol version

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#### Roles and responsibilities

The idea for the study was provided by AM and ŽA. Research group from the University of Split (IB, AM, MM, LW, LP) drafted the study design. Research group from the University of Liverpool (ŽA, FK, HW) provided the infographics material and contributed to question development. All authors contributed to the refinement of the study protocol and approved the final manuscript.

## **Introduction**

#### Background

The presentation of research evidence to the lay audience has become an important aspect of the Cochrane. Results of studies on evidence presentation are not always easy to interpret (Mazur & Hickam, 1991; Mazur & Merz, 1994; Carrasco-Labra et al, 2015) and the efforts continue to develop more understandable ways of scientific data presentation to the lay public, and ultimately better knowledge translation.

Key messages of individual Cochrane Systematic reviews are presented in two ways. One is a scientific summary (SciSumm), aimed at researchers and health practitioners and

the other is a plain language summary (PLS), aimed at the lay public (Santesso et al, 2014). Recently, Cochrane started developing infographics, where short textual information about

research is supported by visual representations of the main findings and is also aimed at the lay public ([www.visuallycochrane.net](http://www.visuallycochrane.net).)

A recent systematic review (Gagliardi et al, 2015) showed that there was no clear evidence for the best type of intervention for healthcare knowledge information translation, so further research about different interventions is needed.

### Objectives

The objective of our study is to evaluate the efficacy of infographics in presenting information, in terms of understanding and remembering research results, compared to standard PLS formats and scientific summary format.

The null hypothesis is that the proportion of the correct answers in all three groups is not going to differ significantly. The equation for that hypothesis is:

H0: Infographic = PLS = SciSumm

The alternative hypothesis is that participants in the infographic group (Infographics) will have significantly more correctly answered questions about the topic than those in PLS group (PLS), meaning that infographics enables a better understanding of scientific findings than PLS. Also, the scientific summary group will have the lowest knowledge score of the three groups, meaning than scientific summary is not the suitable way of data presentation about a Cochrane review for lay population. The equation for that hypothesis is:

Ha: Infographic > PLS >SciSumm

### Trial design

We will conduct a randomized control trial (RCT) with three different formats of the same systematic review summary (infographics, PLS and scientific summary). The content of these three formats is based on the same systematic review, but the ways of data presentation will differ: visual presentation in plain language, plain language, and scientific language. The trial will be performed at the beginning of the 2016/2017 academic year, with first year university students as participants. The trial will be voluntary and anonymous. The survey will consist of 4 parts: 1) demographic data, 2) one format of the summary (randomly assigned), 3) comprehension test of the information given in the summary, 4) accessibility of information and overall satisfaction with the given summary assessed by survey and 5) health

numeracy test. All materials will be in Croatian. The materials used in this research will be assessed by experts in order to confirm face validity of the survey.

## **Methods: Participants, interventions, and outcomes**

### Setting and recruitment

The setting of the trial will be at the two schools of the University of Split: the School of Medicine and the Faculty of Humanities and Social Sciences. The students attending the first year Medical Humanities course at the School of Medicine and the students attending a course in psychology at the Faculty of Humanities and Social Sciences will be invited to participate in the trial.

### Eligibility criteria

Eligible participants will be first-year university students without experience with Cochrane review summaries, because prior familiarization with Cochrane summaries could make information uptake easier for those participants. Participants who give the positive answer to the survey question about the familiarity with the Cochrane will be excluded from the study analysis.

### Interventions

Infographics format of a Cochrane systematic review summary represents the experimental intervention in the trial. The control groups will receive either PLS (which represent text format with simple explanation of the survey topic main findings and is intended for lay audience) or the scientific summary (the text written for the academic population and practitioners) groups. We will use formats already available for the systematic review on external cephalic version for breech presentation before term (Hutton et al, 2015.).

All three types of Cochrane summaries will be translated into Croatian by the trial organizers, and back translated to English by an independent language expert to ensure the quality of the Croatian translation. The survey instrument will be in Croatian.

The students will come to the course group according to the group assignment published on the course web-site. Before the course break on the first day, the tutor will invite the students to participate in research regarding reading of medical research information. After the students have read the text the students will have to close the computer monitors and will continue with the course teaching after the break. The course activity will consist of a

video-material related to the topic of the course (unrelated to the topic of the infographics) and lasting for about 30 minutes. We will use a delayed testing method because it has been shown that, although immediate knowledge post tests can show significant improvement in knowledge retention, such knowledge is mostly rapidly lost with time (Bell et al, 2008.). As our aim is to examine what amount of information is kept after reading the summaries so it can be used at a later time, we will use a delayed testing format. The students will be asked to turn off the monitors of the computers in the teaching lab.

After the end of the course day, the participants will be asked to complete a survey about the text they have read at the beginning of the course day. All study groups will have the same time allocated to this task, and the time each individual participant takes to complete the survey will be noted. The participants will not be able to use the Internet to get more information about the topic or to look at each other computers. Two tutors will be overseeing the survey and ensuring that cell phones are turned off and put on the desk; they will not otherwise interact with the participants.

### Outcomes

The results for each participant will be the sum of correct answers at the knowledge test as the primary outcome, while secondary outcomes will be the number of correct answers on health numeracy and the scores on Likert-type scales for of accessibility and satisfaction.

#### a) Demographic characteristics

Participants will first provide information about their gender, age, knowledge about or prior experiences with Cochrane reviews and Cochrane Library, as well as habits in searching for health information.

#### b) Primary outcome: Understanding the information from the review summary

The primary outcome of the study is the score on a knowledge test with ten questions about information contained in all three forms of presentation. The questions will focus on understanding the benefits and risks of the intervention and the quality of evidence described in the systematic review.

Each correctly answered question will be awarded one point, with a maximum of 10 points. Prior research on PLSs (Vandvik et al., 2012) used multiple choice questions with a single correct answer to assess understanding of PLS. However, multiple choice questions are closed questions and the correct answer may provide a visual reminder to the participant and

thus do not measure real understanding of the material (Choi & Pak, 2005). In order to reduce this measurement bias, we will use open questions to assess knowledge of the participants.

c) Secondary outcomes

C.1. Reading experience: This section of the survey will include 5 questions about the experience of participants about the text they read, measured on a 10-point Likert type scale, where 1 means *do not agree at all* and 10 means *fully agree*. The total score is the sum of scores on all five answers (maximum 50).

**Survey C1**

Please tell us how much you agree with the following statements:

1. *I am satisfied with the overall look of how the information was presented.*



2. *I would understand the text better if there was more information about ECV procedure when turning babies.\**



3. *I wish this information was presented with more pictures or graphs.\**



4. *This information was hard to follow.\**



5. *I think this way of information presentation is easily memorized.*



\*Reverse scored item.

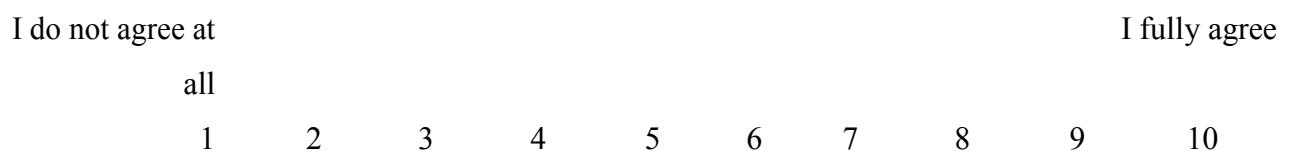
C.2. Accessibility of relevant information: This section of the survey will have 5 questions concerning how easy it was for the participant to find relevant information, measured by a 10-point Likert type scale where the answer 1 means *I do not agree at all* and 10 means *I fully agree*. The total score is the sum of scores on all the answers (maximum 50). The items for measuring accessibility of information will be:

## Survey C2

1. *It was easy to recall the information about EVC procedure needed to answer the test questions.*



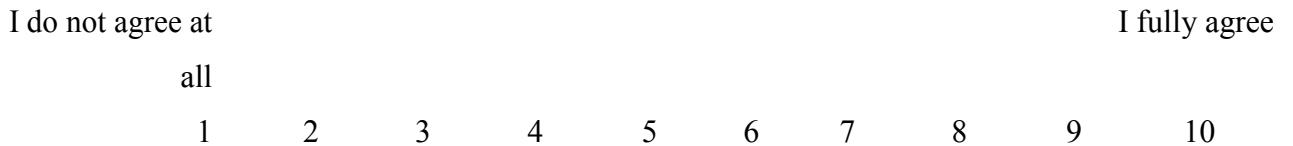
2. *I think this information is understandable to someone who does not have an experience with the topic.*



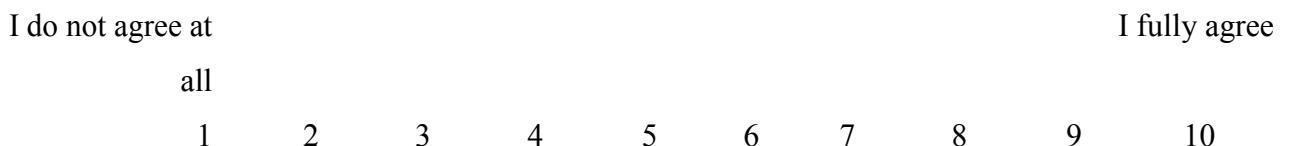
3. *This topic is not possible to grasp with this small amount of information.\**



4. *I think I need more information in order to decide about the benefits of ECV procedure.\**



5. *I think I could explain to someone the benefits of ECV procedure using the information from this text only.*



*\*Reverse scored item*

C3. Health numeracy: This section will use 6-item General health numeracy test (Osborne et al., 2013) in order to determine how much our participants understand the basic health instructions regarding numeracy dimension. For each correct answer, the participants receive one point and the total score is the sum of all correct answers.

### **Survey C3**

1. Call your physician if you have a temperature of 38°C or higher. The thermometer shows the following temperature:

**37.9°C**

Will you call your physician?

**ANSWER:**      YES      NO

2. If 4 out of 20 persons are at risk of getting a cold, what would the risk of getting a cold be?

**ANSWER:** \_\_\_\_\_.%

3. Let us assume that a 60-year-old woman has a maximum heartrate of 160 heartbeats per minute and that she was told to exercise until she reaches 80% of her maximum heartrate. How many heartbeats per minute is equal to 80% of her maximum heartrate?

**ANSWER:** \_\_\_\_\_ heartbeats per minute

4. You have eaten half a bowl of carrots. How many grams of carbohydrates have you eaten?

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**Food information**

Serving: 1 portion (85 g)  
Portions per bowl: 2.5



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**Amount per portion**

Calories 45	Calories from fat 0	Daily amount %
<b>Fats</b> 0g		0%
Saturated fats 0g		0%
<b>Cholesterol</b> 0g		0%
<b>Sodium</b> 55g		2%
<b>Total carbohydrates</b> 10g		3%
Dietary fiber 3g		12%
Sugars 5g		
<b>Protein</b> 1g		

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**ANSWER:** \_\_\_\_\_ grams

5. Your physician has informed you that your cholesterol is high. He explains to you that you have a 10% chance (risk) of having a heart attack in the next 5 years. If you start taking anti-cholesterol medication, you can reduce your risk by 30%.

What is your risk of heart attack in the next five years if you take the medication?

Answer: \_\_\_\_\_ %

6. Mammography is used to discover breast cancer in women. False positive tests are those tests that erroneously show a positive result. 85% positive mammographs are actually false positives. If 1000 women get mammography results, and 200 of them are informed that the results are abnormal, how many women are likely to actually have breast cancer?

Answer: \_\_\_\_\_ women

### Participant timeline

The participants from the School of Medicine will be tested at the first course at the beginning of the first academic year. The participants from the School of Humanities will be tested during their course on psychology in the same academic year. The testing is completed in a single day.

### Sample size

The sample size was calculated using the Sample Size Calculator (Medcalc, Ostend, Belgium).

We calculated the sample size based on the main outcome of the study: score on the knowledge/understanding test. We used the alpha of 0.05 and 80% power to detect the difference of average result in groups of people who correctly answered the questions. We used the data from the studies by Santesso et al. (2015) and Schwartz et al.(2009) to estimate that the difference of 40% in the knowledge score would be the size of effect relevant for our study. In those studies, 80% of the participants who received a summary of information in a table with event rates answered questions correctly compared with 20-40% of those who did not receive this information. We thus estimated that, at a minimum, 15 people in each group need to complete the survey so it can be compared between with the other group. As the number of students in the Medical Humanities course is about 90, we will include all of them, which should ensure that each group has at least 25 participants, taking into account that some students will refuse to participate.

## **Methods: Assignment of interventions**

### Sequence generation

The curriculum for the Medical Humanities course is organized in three seminar groups, to which students are normally assigned in alphabetical order. For the purposes of this research, we will use a computer program ([www.randomisation.com](http://www.randomisation.com), permuted block method) to randomly assign students to one of the three groups and this list will be posted on the course web-site, as is usual practice for courses at the School. The familiarity of the students with Cochrane summaries will be controlled by the following questions in the survey: 1. “Have you heard of Cochrane systematic reviews before?”, 2. “Have you ever used Cochrane library?” and 3. “What is your primary source of health information?” The participants positively answering the questions 1 and 2 will be excluded from the trial analysis.

### Concealment of allocation

The participants will not be aware of intervention allocation before and during the trial. Each participant will have his or her own computer, with computer screens all showing the same instructions for the research and informed consent, which they will read in a given time. The student will be seated in such a way that they will not be able to see each other screens and the tutors present during the intervention will ensure that there is no exchange of information among the students.

### Blinding

The participants will be blinded to the group they will be allocated to because they will not see each other's computer screens. The lecturer and two tutors will be able to look at the monitors, but they will not be familiar with the study and its design. None of the researchers will not be involved as the instructor of the course.

## **Methods: Data collection, management, and analysis**

Data will be collected electronically, using the SurveyMonkey platform. The data will be fully anonymous and will be kept on a secure server of the School of Medicine.

### Descriptive statistics

Descriptive statistics will include participants' baseline characteristics and outcomes, means and standard deviations for continuous variables and proportions for dichotomous variables.

### Claiming of the non-inferiority

For the primary outcome, non-inferiority of the experiment format to the control formats will be claimed if the lower limit of the CI (for the difference in average results between intervention group and control groups) is higher than the non-inferiority margin of 20%. The tests of superiority will be applied to the secondary outcomes. We want to perform the non-inferiority testing in order to prove that infographic is no worse than PLS and scientific summaries for information translation in terms of understanding of information. Also, the superiority tests will show that the infographic is better in terms of user satisfaction and accessibility of information compared to standard PLS and scientific summaries.

### Inferential statistics

The primary outcome of the trial understands of research results presented in various summary formats by lay persons. Each question has a single possible answer and the participant's result is the sum of the correct answers. Also, it is possible to determine how each one of the demographic characteristics predicts correct answer on the knowledge test using logistic regression.

For overall reading experience and accessibility of information between group testing we plan to test the distributions of the variables, and then to choose the non-parametric test (Kruskall-Wallis test) if the distribution of results is not normal or to choose the parametric test (ANOVA) if the distribution of results is normal.

Table 1 Overview of the outcome measures

Outcome	Scale	Measure	Methods of analysis
Understanding	Dichotomous	Sum of correct answers	Kruskall-Wallis/ANOVA
Accessibility of information	Continuous	Likert-type scale from 1 to 10	Kruskall-Wallis/ANOVA
Reading experience	Continuous	Likert-type scale from 1 to 10	Kruskall-Wallis/ANOVA
Health numeracy	Dichotomous	Sum of correct answers	Kruskall-Wallis/ANOVA; Spearman correlation coefficient with understanding outcome

### Data Management

Since the trial will be performed during the first lecture of a mandatory graduate course, we do not expect significant dropout. If a participant decides to leave during the trial, his or her results will not be included in the analysis. The participants will be not able to learn about their results after the trial as the identity of the participants will be unknown to the researchers. We will try to reduce the possibility of missing data in a way that the testing interface will not allow the respondent to move to the next page until all questions on the current page are answered. As the primary outcome is knowledge examination, the order of

the questions will be the same for all the participants so that we could avoid interference of other contents, which could have an adverse impact to the results.

### **Ethics and dissemination**

The approval of the Ethical Committee of University of Split School of Medicine has been obtained under the ethics approval for the grant “Professionalism and Health” funded by the Croatian Science Foundation (Grant No. IP-2014-09-7672). The approval of the Faculty of Humanities and Social Sciences will be obtained before the trial.

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