Protocol:

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

Authors (provisional by line): Ivan Buljan, Mario Malički, Liz Wager, Livia Puljak, Darko Hren, Frances Kellie, Helen West, Žarko Alfirević, Ana Marušić

Trial registration

NCT03002610

Protocol version

This version of protocol was written in November 2016.

Unique protocol ID:

IP-2014-12-7672

Funding

This research is funded by the Croatian Science Foundation in "Professionalism and Health"scientific project (Grant No. IP-2014-09-7672).Croatian Science Foundation had no role in the design of this study and will not have any role during its execution.

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.)

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 physicians 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 trial will be performed online using SurveyMonkey software (A/B testing method).

Eligibility criteria

Eligible participants will be medical doctors in any specialty or field of work. Authors will make a list of publicly available e-mail addresses of doctors–clinical researchers from the School of Medicine and University Hospital Center in Split to make an email list of potential participants

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 and independent language expert to ensure the quality of the Croatian translation. The survey instrument will be in Croatian.

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, obtained specialization or PhD.

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.*

I do not agree at all									I fully agree
1	2	3	4	5	6	7	8	9	10

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

I do not agree at all — I fully agree

1 2 3 4 5 6 7 8 9 10

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

I do not agree at all — I fully agree

1 2 3 4 5 6 7 8 9 10

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

I do not agree at all — I fully agree

1 2 3 4 5 6 7 8 9 10

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

I do not agree at all — I fully agree

1 2 3 4 5 6 7 8 9 10

*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 a10-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.*

I do not agree at all — I fully agree

1 2 3 4 5 6 7 8 9 10

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

I do not agree at all									I fully agree
1	2	3	4	5	6	7	8	9	10

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

I do not agree at all									I fully agree
1	2	3	4	5	6	7	8	9	10

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

I do not agree at all									I fully agree
1	2	3	4	5	6	7	8	9	10

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

I do not agree at all									I fully agree
1	2	3	4	5	6	7	8	9	10

**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 isequal 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?

Food information	
Serving: 1 portion (85 g)	
Portions per bowl: 2.5	
Amount per portion	
Calories 45	Calories from fat 0
	Daily amount %
Fats 0g	0%
Saturated fats 0g	0%
Cholesterol 0g	0%
Sodium 55g	2%
Total carbohydrates 10g	3%
Dietary fiber 3g	12%
Sugars 5g	
Protein 1g	

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.

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, 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.

Concealment of allocation

The participants will not be aware of intervention allocation before and during the trial as they will be invited to participate in research about the readability of new Cochrane formats.

Blinding

Participants will not be blinded to type of format, but the authors who analyse the answers will be blinded to the type of formats.

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).

References:

Bell DS, Harless CE, Higa JK, Bjork EL, Bjork RA, Bazarghan M et al. Knowledge retention after an online tutorial: A randomized educational experiment among resident physicians. J Gen Intern Med.2008;23:1164–71.

Carrasco-Labra A, Brignardello-Peetersen R, Santesso N, Neumann I, Mustafa RA, Mbuagbaw L, et al. Comparison between the standard and a new alternative format of the Summary-of-Findings tables in Cochrane review users: study protocol for a randomized controlled trial. Trials.2015;16:164.

Choi BC, Pak AW.A catalog of biases in questionnaires. Prev Chronic Dis. 2005;2:A13.

Gagliardi AR, Légaré F, Brouwers MC, Webster F, Badley E, Straus S. Patient-mediated knowledge translation (PKT) interventions for clinical encounters: a systematic review. Implementation Science.2015;11:26.

Osborn CY, Wallston KA, Shpigel A, Cavanaugh K, Kripalani S, Rothman RL. Development and Validation of the General Health Numeracy Test (GHNT). Pat educ counsel.2013;91:350-6.

Hutton EK, Hofmeyr GJ, Dowswell T. External cephalic version for breech presentation before term. Cochrane Database Syst Rev.2015;7:CD000084.

Santesso N, Rader T, Stromme Nilsen E, Glenton C, Rosenbaum S, Ciapponi A, et al. A summary to communicate evidence from systematic reviews to the public improved understanding and accessibility of information: a randomized controlled trial. J Clin Epidemiol.2014;68:182–90.

Schwartz LM, Woloshin S, Welch HG. Using a drug facts box to communicate drug benefits and harms: two randomized trials. Ann Intern Med.2009;150:516–27.

Vandvik PO, Santesso N, Akl EA, You J, Mulla S, Spencer FA, et al. Formatting modifications in GRADE evidence profiles improved guideline panelists comprehension and accessibility to information: a randomized trial. J Clin Epidemiol.2012;65:748–55.