

A new format for plain language summaries:
◦ does it improve understanding, and is it useful and preferable?

A randomised controlled trial

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Initial concern for quality of plain language summaries

- Work for German Cochrane Centre 2004 (Falk-Ytter, 2004)
- Random sample of 243 plain language summaries

“A substantial number of synopses have errors and some do not have a sufficient quality for publication”

Plain Language Summaries Opportunities Fund

Explore possibility of creating a Plain Language Summary format and template

1. Redesign and feedback
2. User testing
3. RCT comparing Plain Language Summaries
4. User testing of template to create Plain Language Summaries

Across Cochrane entities

User Testing of 3 different formats showed....

- A short version was not enough
 - approx 450 words
 - standard sentences about effect and the quality of the evidence,
 - no numbers
- People liked a table of the results
- People wanted more detailed information about the effect using numbers (e.g. number of people who improved)

The effect of Vitamin C on the common cold

Douglas RM, Hemilä H, Chalker E, Treacy B. Vitamin C for preventing and treating the common cold. *Cochrane Database of Systematic Reviews* 2007, Issue 3.

Plain Language Summary of a Cochrane Review

A review of the effect of vitamin C on the common cold was conducted by researchers in the [Cochrane Collaboration](#). After searching for all relevant studies, they found 30 studies done by other researchers. Their findings are summarised below.

What is the common cold and why take Vitamin C?

Symptoms of the common cold are well-known and can include runny nose, sore throat, fever and headache. Most adults, who are at normal risk, will have two to three colds a year that last about 3 to 4 days. However, adults doing intense physical activity or working outside in sub-arctic conditions, as well as children, may be at *high risk of colds* and have colds that last about 6 days.

The common cold is caused by a virus and cannot be cured by antibiotics. Since it cannot be cured, much research has been done to find ways to prevent a cold or to reduce the symptoms. The effect of taking more vitamin C than what is recommended for a usual diet has been researched for over 60 years. Most countries recommend that adults have about 40 to 90 mg of vitamin C a day in their diet to be healthy.

The 30 studies in this review have tested taking Vitamin C supplements (usually pills) which provide about 1000 to 2000 mg (1 to 2 grams) a day – which is much more than the recommended doses. Vitamin C was either taken before a cold to prevent one and reduce symptoms, or as soon as the cold started to reduce the symptoms.

What the research says

Not all research provides the same quality of evidence. The higher the quality, the more certain we are about what will happen. Below we describe what will happen when taking vitamin C. The words *will* (high quality evidence), *probably* (moderate quality evidence) or *may* (low quality evidence) describe different levels of how certain we are about what will happen. The word *slightly* means that there is a small effect.

Taking 1 to 2 grams of vitamin C per day for about 12 weeks to prevent a cold

In people at normal risk, vitamin C

- will not decrease the chance of catching a cold
- will decrease how long a cold lasts by a few hours
- will not lead to side effects

In people at high risk, vitamin C

- may decrease the chance of catching a cold
- probably decreases how long the cold lasts by a few hours
- will not lead to side effects

Taking 1 to 2 grams of vitamin C per day as soon as a cold starts

- probably will not decrease how long the cold lasts

The effect of mega-doses of Vitamin C, such as 4 to 8 grams per day, is not known.

What happens to people who take vitamin C

This table calculates what happens to people using the best estimates from research. Numbers have been provided where possible.

What happens	Not taking Vitamin C	Taking Vitamin C (1 to 2 g per day)	Quality of evidence
	People at normal risk		
Will decrease how long the cold lasts if vitamin C taken before the cold	The cold lasts 84 hours or 3 ½ days	The cold lasts 7 fewer hours (3 to 11 fewer hours)*	⊕⊕⊕○ Moderate
	People at high risk		
Probably decreases how long the cold lasts if vitamin C taken before the cold	The cold lasts 134 hours or 6 days	The cold lasts 19 fewer hours (8 to 30 fewer hours)	⊕⊕⊕○ Moderate
Probably will not decrease how long the cold lasts if vitamin C taken as soon as the cold starts	The cold lasts 84 hours or 3 ½ days	The cold lasts 2 fewer hours (9 fewer to 4 more hours)	⊕⊕⊕○ Moderate
	People at normal risk		
Will not decrease the chance of catching a cold	50 per 100 people	49 per 100 people (48 to 50 per 100)	⊕⊕⊕⊕ High
	People at high risk		
May decrease the chance of catching a cold	70 per 100 people	35 per 100 people (27 to 46 per 100)	⊕⊕○○ Low
Will not lead to side effects	6 per 100 people	6 per 100 people	⊕⊕⊕○ Moderate
Quality of evidence: The quality of the evidence is either ranked as high, moderate, low or very low. The higher the quality, the more certain we are about what will happen.			
*The numbers in brackets show the range where the actual effect may be.			

Wanted to test.....

- Is it really better than what we have now?
- Isn't too long?
- Surely people would prefer a short summary?
- Does the table really improve their understanding?
- Do you need a PhD to understand this?

Randomised Controlled Trial

- 2 groups:
 - Old format
 - New format
- Literature suggests a 40% difference in understanding between groups
- Needed at least 32 people in each group
- Convenience sample from each Cochrane entity
 - Canada, Norway, Spain, Argentina and Italy

Randomised Controlled Trial

- Block randomisation
- 191 people randomised to new or old format
- 143 completed the study

	English	Non-English	Total
New summary	41	33	74
Old summary	38	31	69
TOTALS	79	64	143

3. Preparation for survey

[Exit this survey](#)

In the following pages, you will be shown a Plain Language Summary and asked questions about the content of that summary.

We have written an example summary about a common topic: vitamin C and the common cold. The summary is shown at the top of the page and followed by questions. These questions are specific, so feel free to read over the summary as often as you wish.

Remember that we are not testing you, but the summary and how we present the information.

[Prev](#) [Next](#)

http://www.surveymonkey.com/s.aspx?sm=2bcDFA2QnacP9M4QJAnA0Q%3d%3d - Windows Internet Explorer
http://www.surveymonkey.com/s.aspx?sm=2bcDFA2QnacP9M4QJAnA0Q%3d%3d

Please indicate how much you disagree or agree with the following statement.

	I strongly disagree	I disagree	I somewhat disagree	Not sure	I somewhat agree	I agree	I strongly agree
The information is reliable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate how much you agree or disagree with the following.

	I strongly disagree	I disagree	I somewhat disagree	Not sure	I somewhat agree	I agree	I strongly agree
The summary presents the most important effects of vitamin C for the common cold.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It was easy to find the information about the effects.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It was easy to understand the information.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The information is presented in a way that would help me make a decision.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Overall, how would you rate the accessibility of the main findings of this review? By "accessibility" we mean the extent to which the main findings are easy to find, to understand and to use by someone making a decision.

	Very inaccessible	Inaccessible	Not sure	Accessible	Very accessible
Overall accessibility of the findings of the review.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In people at high risk of catching a cold (such as people in extreme cold conditions), what is more certain?

- Vitamin C decreases the chance of catching a cold.
- Vitamin C decreases how long a cold lasts (or the length of cold)
- Vitamin C does not lead to more side effects
- Mega doses (4 to 8 mg) decreases how long a cold lasts

PLAIN LANGUAGE SUMMARY

Vitamin C for preventing and treating the common cold

The term 'the common cold' does not denote a precisely defined disease, yet the characteristics of this illness are familiar to most people. It is a major cause of visits to a doctor in Western countries and of absenteeism from work and school. It is usually caused by respiratory viruses for which antibiotics are useless. Other potential treatment options are of substantial public health interest.

Since vitamin C was isolated in the 1930s it has been proposed for respiratory infections, and became particularly popular in the 1970s for the common cold when (Nobel Prize winner) Linus Pauling drew conclusions from earlier placebo-controlled trials of large dose vitamin C on the incidence of colds. New trials were undertaken.

This review is restricted to placebo-controlled trials testing at least 0.2 g per day of vitamin C. Thirty trials involving 11,350 participants suggest that regular ingestion of vitamin C has no effect on common cold incidence in the ordinary population. It reduced the duration and severity of common cold symptoms slightly, although the magnitude of the effect was so small its clinical usefulness is doubtful. Nevertheless, in six trials with participants exposed to short periods of extreme physical or cold stress or both (including marathon runners and skiers) vitamin C reduced the common cold risk by half.

Trials of high doses of vitamin C administered therapeutically (starting after the onset of symptoms), showed no consistent effect on either duration or severity of symptoms. However, there were only a few therapeutic trials and their quality was variable. One large trial reported equivocal benefit from an 8 g therapeutic dose at the onset of symptoms, and two trials using five-day supplementation reported benefit. More therapeutic trials are necessary to settle the question, especially in children who have not entered these trials.

- Edited slightly to include similar background information
- Results – exact wording of the author

What did we measure?

- **Understanding**

- What results from the systematic review would we want people to understand?
 - Magnitude of effects
 - Certainty of the results

- **Accessibility**

- Is it reliable information?
- Easy to understand?

- **Preference**

In people at high risk of catching a cold (such as people in extreme cold conditions), what is more certain?

- Vitamin C decreases the chance of catching a cold.
- Vitamin C decreases how long a cold lasts (or the length of cold)
- Vitamin C does not lead to more side effects
- Mega doses (4 to 8 mg) decreases how long a cold lasts
- All of the above are just as certain

In an ordinary population (such as people at normal risk) will vitamin C decrease the chance of catching a cold?

- it will not
- it may not
- it probably will not
- it will
- it may

How many people at normal risk (such as in an ordinary population) will catch a cold if they take vitamin C?

- 5 per 100 people or around that number
- 10 per 100 people or around that number
- 35 per 100 people or around that number
- 49 per 100 people or around that number
- 70 or more per 100 people or around that number

When people take 8 grams or high doses of vitamin C as soon as a cold starts,

- they will probably see a benefit
- they will see a benefit
- they will not see a benefit
- they will probably not see a benefit
- the benefits are not known

In people at normal risk of catching a cold (or in an ordinary population), how many fewer hours will their cold last if they took vitamin C regularly before the cold even started?

- 2 fewer hours or around that much
- 7 fewer hours or around that much
- 15 fewer hours or around that much
- 19 fewer hours or around that much
- 24 fewer hours or around that much

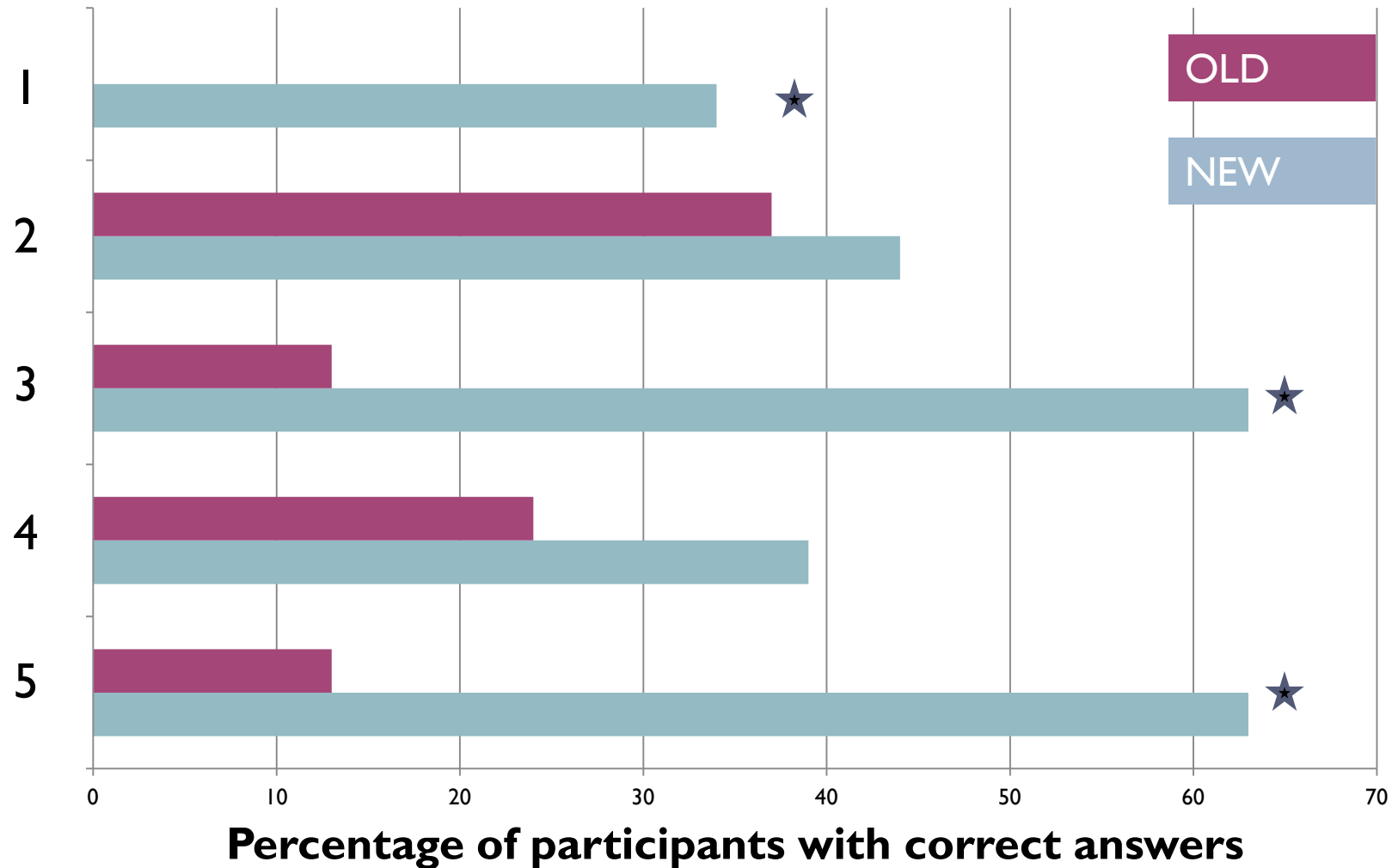
Participants

	OLD FORMAT	NEW FORMAT
Male/Female (%)	87/13	85/15
Age (median)	36 to 45	26 to 35
Education		
High school	45	39
College	13	32
University	44	39
Seeking health information on the Internet	Once per month	Once per month

Accessibility

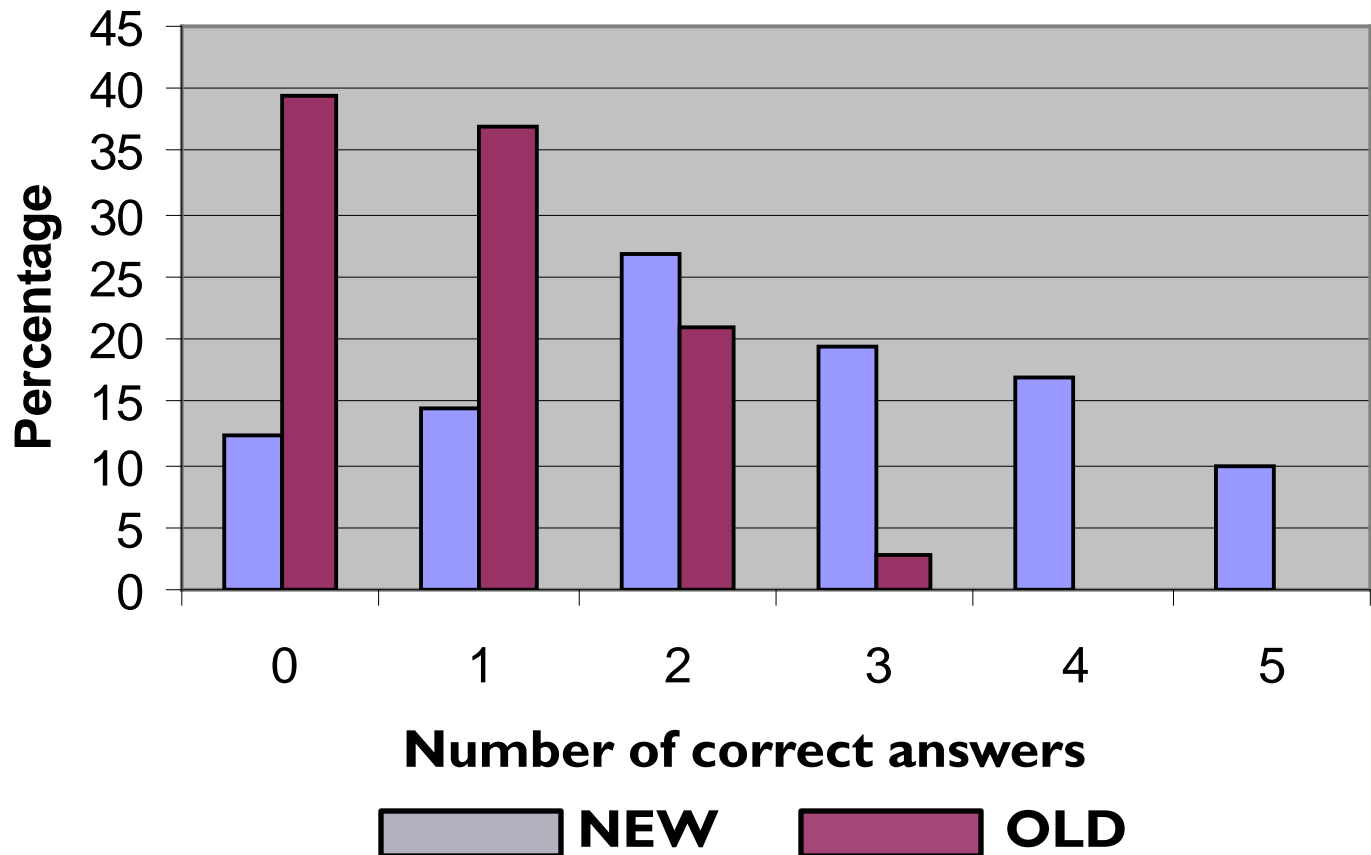
- Significantly more people indicated that the new format
 - Was reliable
 - Presented the important effects
 - Was easy to find information about effects
 - Presented information in a way that would help with decision making
- No significant difference in “easy to understand” ($p=0.55$)
 - New Format 78% easy to understand
 - Old Format 84% easy to understand

Understanding by question



★ P < 0.0001

Overall number of correct answers (out of 5 questions)



Mean

NEW FORMAT 2.3

OLD FORMAT 0.9

significantly different pvalue <0.0001

Preference of New or Old format

- More people preferred the new version
- People tended to choose the second format they were given



English and Non-English participants

Similar results

- Mean number of correct answers

	English only	English and Non-English
New Format	2.3	2.6
Old Format	0.9	0.9
P value	<0.0001	<0.0001

- Preference for second format was also found

Some limitations

- Did we ask the right questions? Was the wording understood?
- Was the electronic format of the questionnaire cumbersome?
- Is vitamin C really of interest to people?
- What was the degree of engagement

What now?

- Some evidence that doing something right with this new format
- Should provide something different than what providing now
- Potential to test in people who need to make a health care related decision with a summary of interest (testing in different reviews)
- How to fit within the Cochrane review format?
- Separate patient information ?cochrane.org?
- Test the 'how to' guide for writing plain language summaries'