Informed Health Choices

A plain language Glossary of Evaluation Terms for Informed Treatment choices (GET-IT) at www.getitglossary.org

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Colophon

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Plain language summary

Well-informed choices about how to intervene to improve health outcomes depend on access to reliable information, including research evidence. Many people (not only the public, but health professionals and policymakers too) have problems understanding some of the terminology used in describing evaluations of treatments. We have developed a glossary to provide plain language explanations and illustrations of 242 commonly used terms. The glossary is freely available at http://getitglossary.org and can be incorporated into documents providing support for evidence-informed healthcare decisions, and embedded in other websites serving a wide variety of functions.

Background

Well-informed choices about treatments to improve health depend on being able to access and understand reliable information, particularly research evidence. Jargon, and the inconsistent use of terms, can be a barrier to understanding and using research evidence.

This glossary – which we have named GET-IT - aims to facilitate informed choices about treatments by (i) promoting consistent use of plain language; and (ii) providing explanations of the concepts and terms that may be needed to assess claims about treatments.

The glossary is intended to be useful to people with no research background, particularly those who want to make a choice about a treatment, communicate research evidence to the public, or teach others about how to assess treatment claims.

Jargon-laden claims about treatment effects may arise from summaries of research evidence (systematic reviews of comparisons of treatments) or evidence-informed recommendations (e.g. from evidence-based clinical practice guidelines). Because we have failed to find a suitable plain language alternative to the term 'treatment', we have used this word to refer to any preventive, therapeutic, rehabilitative or palliative action intended to improve the health or wellbeing of individuals or communities. This includes, for example, drugs, cells and other biological products, surgical procedures, radiological procedures, physical therapies, devices, psychological or behavioural treatments, screening and other types of preventive care, public health actions, and changes in how healthcare is delivered or financed.

The GET-IT glossary was developed collaboratively by three international projects:

> DECIDE (Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence) was a 5-year project (from 2011 to 2015) co-funded by the European Commission under the Seventh Framework Programme.[1] It aimed to improve the dissemination of

evidence-based recommendations by developing and evaluating methods that address the targeted dissemination of guidelines.

Informed Health Choices (IHC) is a project with funding support from the Research Council of Norway. It aims to develop and evaluate resources to teach children and parents how to assess claims about treatment effects.

Testing Treatments interactive (TTi) is a website developed by the James Lind Initiative with funding support from the English National Institute for Health Research. It contains the Critical thinking and Appraisal Resource Library (CARL) for teachers promoting critical thinking and appraisal of claims about the effects of treatments.[2]

GET-IT is intended to facilitate understanding and use of a variety of resources about the effects of treatments, including:

- Plain language summaries of comparisons of treatments, evaluations of health technologies, health economic evaluations, reviews, and guidelines[3]
- Summaries of findings from systematic reviews[4,5]
- Explanations of how evidence has been used to arrive at a recommendation (Evidence-to-Decision frameworks)[6,7]
- Databases of systematic reviews, recommendations or information for patients, carers and the public
- Websites and tools that support careful appraisal of claims about the effects of treatments, or the understanding of what constitutes a fair comparison of the effects of treatments.

Method

We designed and implemented the glossary iteratively, guided by a review of other glossaries and consultation with end-users.

Identification of terms for inclusion

We identified terms for inclusion in the glossary by screening:

- The index of the 2nd edition of *Testing Treatments*[8] (IC)
- Terms used to code learning resources in TTi English (DB)
- Explanations of key concepts that that people need to understand to assess claims about treatment effects, developed by the Informed Health Choices project[9] (AA-D)
- Terms used to code resources identified in the ECRAN project[10] (IC)
- Cochrane Diagnostic Test Accuracy Working Group Glossary (JM)
- Explanatory Essays in the James Lind Library[11] (IC)
- A sample of existing glossaries (see below) (IC, PA)
- Summaries of Findings of systematic reviews (JM)
- Evidence-to-Decision frameworks (JM)
- Patient versions of guidelines (RH)
- Indexes of books written for the public, including *Smart Health Choices*,[12] *Know Your Chances*,[13] and *Bad Science*.[14]

Drawing on a sample of four existing glossaries

To create a first draft glossary of terms relevant to the assessment of treatment effects we selected, from many alternatives (Box 1), four existing glossaries created specifically to support websites concerned with trials of treatments:

- EU Clinical Trials Register Glossary
- ClinicalTrials.Gov Glossary
- Clinical Trials Toolkit Glossary
- CONSORT Glossary

Box 1 *Links to glossaries relevant to health research assembled for the ECRAN Project*[10]

English

1. Bandolier, an independent journal about evidence-based healthcare
2. Centre for Evidence Based Medicine Oxford
3. Centrewatch. Overview of Clinical Trials
4. IFA, Italian Medicines Agency
5. IFPMA Clinical Trials Portal
6. MRC Clinical Trials Unit
7. National Cancer Institute
8. NIHR Clinical Research Network
9. Stanford School of Medicine, Stanford Cancer Institutes
10. U.S. National Institutes of Health

French

1. Euro Stem Cell
2. IFPMA Clinical Trials Portal

German

1. Deutsches Netzwerk Evidenzbasierte Medizin e.V.
2. Deutsches Register Klinischer Studien
3. GLOSSAR ZUR BIOSTATISTIK in klinischen Studien
4. Horten-Zentrum für praxisorientierte Forschung und Wissenstransfer
5. IFPMA Clinical Trials Portal
6. MSD Sharp & Dohme GmbH
7. Myeloma Euronet
8. The Klinikum Nürnberg Glossary

Italian

1. Agenzia Italiana del Farmaco: Come nasce un farmaco
2. Associazione Italiana Malati di Cancro, parenti e amici. Gli studi clinici sul cancro
3. Euro Stem Cell. Che cos'è un trial clinico?
4. La ricerca contro la SMA. Capire i trial clinici
5. Partecipasalute: Glossario della ricerca clinica
6. Saperidoc: Valutare le prove di efficacia

Polish

1. Euro Stem Cell

Spanish

1. Euro Stem Cell
2. IFPMA Clinical Trials Portal
3. National Cancer Institute

Other relevant glossaries

1. American Family Physician EBM Glossary
2. Boston University Medical Center

3. CDISC Clinical Research Glossary
4. Centre for Evidence-Based Medicine Toronto
5. Clinical Epidemiology Glossary
6. Clinical Evidence glossary of EBM terms
7. Clinical Evidence Glossary of Economic Terms
8. Clinical Practice Guideline for the Assessment and Prevention of Falls in Older People
9. ClinicalTrials.gov
10. Cochrane Collaboration
11. Health Economics Information Resources
12. HTAi consumer and patient glossary
13. National Guideline Clearing House
14. NICE National Institute for Health and Care Excellence
15. SUPPORT Tools for evidence-informed health Policymaking (STP)
16. Wikipedia Glossary of clinical research

Of these four glossaries, only The Clinical Trials Toolkit makes explicit its target user group, and provides some information about how it has been developed: it was launched in 2012 by the National Institute for Health Research to help clinical trialists and R&D managers to understand the regulations and requirements for conducting clinical trials.

As a first step to developing our plain language glossary we listed terms contained in each of these four glossaries alphabetically, then tabulated the definitions from the different glossaries side by side so that they could be compared conveniently. When a term only appeared in one glossary, we adopted its definition for the first iteration of GET-IT; when more than one definition was available for a topic, whichever definition judged to be the most lay-friendly was adopted for the composite glossary. We listed synonyms, for example, 'blinding' and 'masking'. We edited the entries in the glossary to exclude words outside our focus on supporting choices about treatments, or to provide additional clarification.

Incorporation of terms and definitions in a spreadsheet

We collated all the terms identified from the sources listed above and all the definitions assembled from the glossaries listed above into a single Google Docs spreadsheet comprising the following columns:

- Term
- Synonyms
- Suggested plain language term
- See also (links to related terms)
- Short definition (approx. 130-character limit)

- Alternative definition(s) (approx. 130-character limit) (for use when more than one definition is proposed, and consideration by the editorial team was necessary)
- Technical definition (from *A Dictionary of Epidemiology*)[15]
- Full explanation
- Links to Testing Treatments[8]
- Links to the James Lind Library[11]
- Links to other resources
- Offline resources
- Suggestions for resources

We filled in the spreadsheet iteratively, drawing on other glossaries and resources, commenting on content provided by each other, and then discussed and revised the content. Five of the authors met for a one-day meeting to go through the glossary line-by-line, with remaining authors commenting electronically on changes. To check completeness, we also compared our list of terms with terms listed in other English language glossaries selected because their aims overlapped with those of GET-IT (i.e. to help people make informed choices about treatments).

We checked the glossaries listed in Box 1 and selected the following for our completeness check:

1. AHRQ Effective Health Care Program Glossary
2. American Family Physician EBM Glossary
3. Bandolier (an independent journal about evidence-based healthcare) Glossary
4. Centre for Evidence Based Medicine Oxford Glossary
5. Centre for Evidence-Based Medicine Toronto Glossary
6. Clinical Epidemiology Glossary
7. Clinical Evidence Glossary of Economic Terms
8. Cochrane Collaboration Glossary
9. NICE National Institute for Health and Care Excellence Glossary
10. US National Institutes of Health Glossary

The glossary content was then transferred to a Word document and refined iteratively by all authors, but especially JM, IC, AA-D, and AO. We used readability software available online to try to ensure that the language used in the definitions and explanations is as simple as possible, and that it could be easily read and understood by people who have completed high school education. All authors reviewed all the content and agreed on the version sent to a professional copyeditor. The copy editor's version was checked by IC and JM.

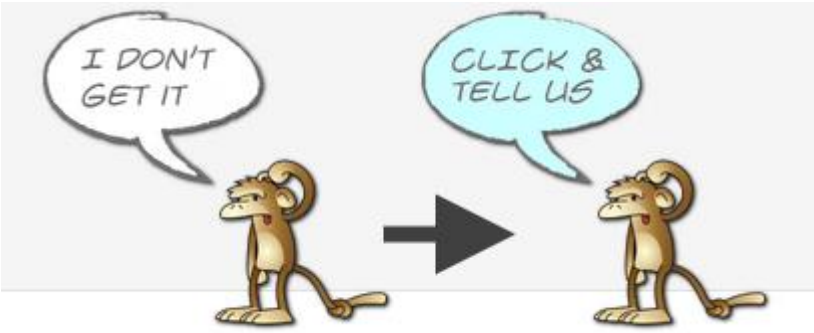
Putting terms onto a website

The terms included in the Word document were then put into a website version of the glossary. After discussion by the GET-IT project group, the following columns from the Word document were implemented on the website:

- Suggested preferred term (plain language term)
- Short definition (approx. 130-character limit)
- Synonyms
- Full explanation
- See also (links to related terms)

We created a simple Content Management System (CMS) that allows editors to manage the content of the glossary, including reviewer comments and version control. Additionally, we added a system for end-users to send feedback when they find definitions of explanations unhelpful. By clicking an "I don't get it!" button in the form of the "IDGI" Monkey, the terms are flagged (Figure 1). These data are tracked and presented to the editors through the CMS so they can see which terms might need improvement.

Figure 1 *The "IDGI" Monkey*



Finally, we carried out user-testing of 10 terms to assess whether rewriting some definitions would be required to try to make them simpler. We interviewed four people and obtained feedback on content and the website. We also commissioned an interaction designer to carry out a heuristic evaluation to identify any usability issues.

Results

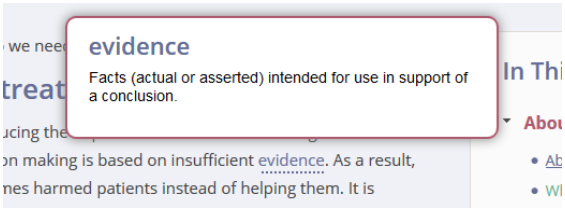
The resulting GET-IT Glossary is freely available online at getitglossary.org. The GET-IT CMS supports translation to other languages and the creation of bespoke glossaries. A master glossary is used to populate new versions of the glossary, which can then be translated or edited using the CMS. Spanish and Finnish versions of the GET-IT glossary are currently being prepared.

The glossary can be embedded on third party websites in two ways:

1. A WordPress plugin
2. An Application Process Interface (API)

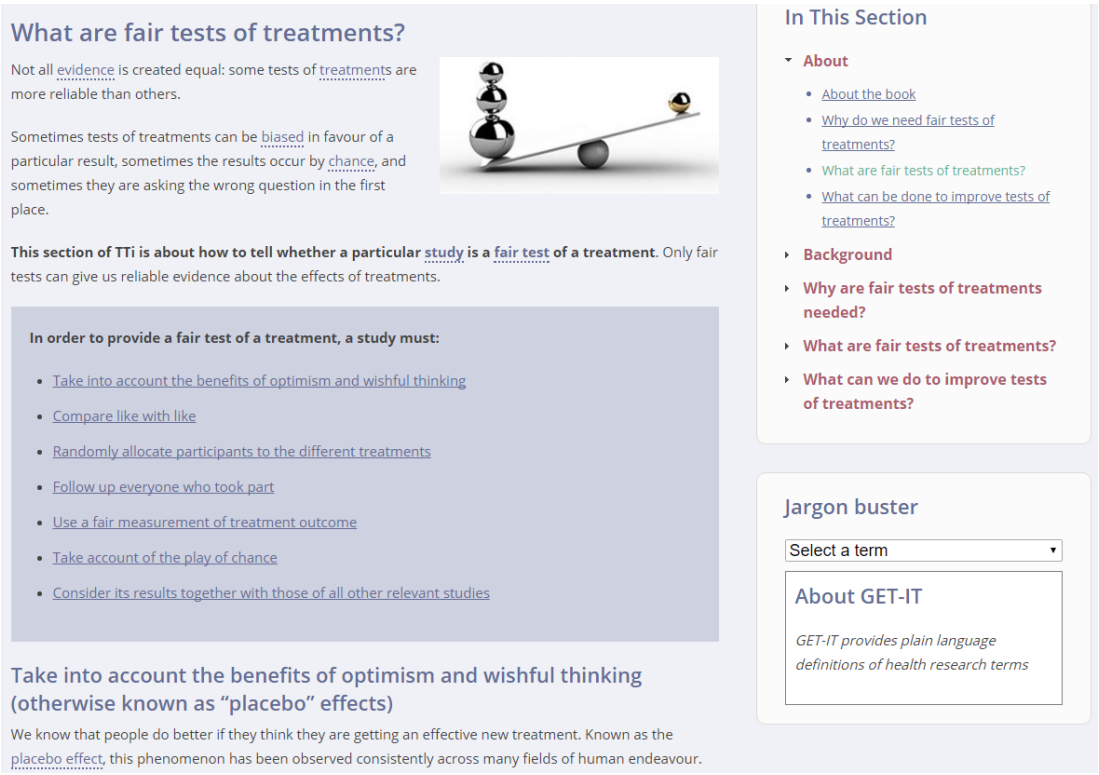
These tools allow other websites to install GET-IT as a drop-down menu in a sidebar widget, and as 'pop-up' boxes that appear over jargon terms when the user clicks on them (Figure 2).

Figure 2 *Example of a 'pop-up' definition*



An example of the GET-IT glossary embedded in a website can be viewed here: (Figure 3).

Figure 3 *Example of the GET-IT glossary embedded in a website*



After multiple iterations and revisions, the glossary currently contains 242 terms. Although the primary focus of the glossary is on the effects of treatments, we included terms that are relevant to going from evidence to decisions,[6] although they are not directly relevant to treatment effects. This includes terms that are relevant to diagnostic tests (e.g. sensitivity and specificity) and economic analyses (e.g. cost-effectiveness and quality-adjusted life years).

Terms we recommend not using

In identifying terms for inclusion in GET-IT we came across some that were frequently ambiguous or misinterpreted. The word 'significant' is an example of such a term. We have included and have provided explanations of these terms, and have explained why we advise against using them. We have used a warning symbol on terms in the glossary that we advise against using. These are summarized in Box 2.

Box 2 *Terms that we recommend not using*
• single blinding (single masking), double blinding (double masking), and triple blinding (triple masking) Because the meaning of single blind, double blind, and triple blind are ambiguous - in terms of who was blinded - we recommend not using it.[16,17] It is better to consider explicitly who was blinded, and who was not blinded, and how that might

have protected against or led to a risk of bias, including placebo effects, differences in the care provided to the participants in a study other than the treatments being compared (performance bias), or differences in how outcomes are measured, in treatment comparison groups (measurement bias).

- efficacy
  Efficacy is sometimes used to indicate the desirable effects of treatments under ideal conditions, as measured in explanatory trials. However, efficacy is also commonly used as a synonym for effectiveness. Because of this, the meaning of "efficacy" is often unclear and we recommend against using that term. In addition, pragmatic and explanatory trials can differ in a variety of ways and to different extents.[18]

- level of evidence (hierarchy of evidence)
  "Level of evidence" is an ambiguous term, which sometimes refers to where a type of study (study design) lies in a hierarchy of evidence. Some have less risk of bias for a particular type of question. For example, randomized studies have less risk of bias than non-randomized studies for questions about treatment effects. However, there are other factors that can increase or decrease the risk of bias in both randomized and non-randomized studies. Hierarchies of evidence (based on study design) can be useful, for example, in deciding which study designs to include in a systematic review. However, they should not be confused with assessments of the risk of bias, or the certainty of the evidence, which should be assessed using explicit criteria. Because "level of evidence" can also refer to (or be confused with) the risk of bias, or the certainty of the evidence, we recommend against using this term.
- modified intention-to-treat analysis
  There is no clear definition of what a modified intention-to-treat analysis is, and descriptions of these analyses vary greatly from study to study. Studies that report modified intention-to-treat analyses often have industry funding and authors' conflicts of interest, and might have a higher risk of bias than studies that report an intention-to-treat analysis, due to disruption of the baseline equivalence established by random allocation and reporting bias. Because modified intention-to-treat analysis is an ambiguous term, we recommend against using it.

- natural history
  "Natural course" of health problems is preferable to "natural history" and "natural progression" because "course" avoids inappropriate reference to "history" (and associations with natural history museums), and because "course" is more neutral than "progression". "Course" covers amelioration and deterioration, whereas "progression" often implies "deterioration".

- random selection
  "Random selection" is most clearly appropriate when it refers to drawing a representative sample from a defined population. It is sometimes used inappropriately to refer to "random allocation" to treatment comparison.[19] Because of this, its meaning is ambiguous and is best avoided.

- significant

  Because clinical significance is often confused with statistical significance, we recommend against using the term significant to describe treatment effects, especially without specifying what is meant. When scientific papers call results significant, they usually mean statistically significant. Using 'important' when referring to such effects deals with this ambiguity because it prompts consideration of to whom the treatment effect is important.

- statistically significant

  "Statistical significance" is so commonly misreported and misinterpreted, that we recommend that terms such as "not significant", "not statistically significant", "significant", "statistically significant", "trend towards [an effect]", and "borderline significant") should not be used.[20] These terms are based on an arbitrary cut-off for statistical significance (typically 0.05).

  "Statistical significance" (a "positive" study) is often confused with "clinical significance" (importance), especially when "significant" is used rather than "statistically significant". If also is often misinterpreted as meaning that the certainty of the evidence is high, when it might not be for other reasons, such as a high risk of bias.

  Conversely, "statistically non-significant" is ambiguous. It is often misinterpreted as evidence of "no effect" (a "negative" study). However, results that are "not statistically significant" can either be informative (if the confidence interval (and the certainty of the evidence) suggests that there is unlikely to be an important effect) or uninformative (inconclusive, if the confidence interval does not rule out an important effect).

  It is better to consider explicitly estimates of effect and confidence intervals, and to use plain language to describe effects based on the size of the effect and the certainty of the evidence.[21]

- subjects

  Participants in a study are sometimes referred to as 'subjects'. We recommend against using this term, because it is demeaning.[22]

Discussion

There are other glossaries that cover many of the terms used in connection with comparisons of treatments (Box 1) and going from evidence to decisions, but GET-IT combines four features that we believe make it distinctive:

- ***Use of plain language*:** GET-IT definitions and explanations have been written in plain language to facilitate understanding by a wide range of people.
- ***Provision of short definitions, explanations and examples*:** GET-IT provides 130-character definitions that can be accessed as 'pop-ups' within text, as well as longer explanations, and illustrative examples, when needed.
- ***Designed for sharing and adaptation:*** GET-IT has been designed so that definitions and explanations can be adapted for specific user groups, translated into other languages, and embedded in other resources.
- ***Development through international collaboration*:** GET-IT has resulted from collaboration among three international projects, to reduce redundancy and promote consistent use of language.

To assess claims about treatments, people need to be able to understand the terms used in those claims. Without this understanding it is not possible for them to make informed decisions about treatments. The GET-IT glossary aims to support informed choices about treatments by people who do not have a research background; in other words, most people. It does this by promoting consistent use of plain language and providing plain language definitions and explanations of terms used in claims about treatment effects. GET-IT will be useful to people making choices about treatments for themselves, family members, or friends; or decisions about health policies. In addition, it will be useful to people whose job it is to communicate research evidence to the general public and to those who teach others how to assess claims made about the effects of treatments.

We anticipate that GET-IT will be an ongoing endeavour, with improvements made in the light of comments and suggestions from users. We encourage anyone interested in learning more about GET-IT, using it on their own website, or evaluating it, to contact us at info@getitglossary.org.

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References

1. Treweek S, Oxman AD, Alderson P, Bossuyt P, Brożek J, Davoli M, et al. Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence (DECIDE): Protocol and preliminary results. Implement Sci 2013; 8:6.
2. Castle J, Chalmers I, Atkinson P, Badenoch D, Oxman AD, Austvoll-Dahlgren A, et al. Establishing a library of resources to help people understand Key Concepts in assessing treatment claims – The Critical thinking and Appraisal Resource Library (CARL). Submitted.
3. Glenton C, Santesso N, Rosenbaum S, Nilsen ES, Rader T, Ciapponi A, et al. Presenting the results of Cochrane Systematic Reviews to a consumer audience: a qualitative study. Med Decis Making 2010; 30:566-77.
4. Rosenbaum SE, Glenton C, Nylund HK, Oxman AD. User testing and stakeholder feedback contributed to the development of understandable and useful Summary of Findings tables for Cochrane Reviews. J Clin Epidemiol 2010; 63:607-19.
5. Rosenbaum SE, Glenton C, Oxman AD. Summary of Findings tables improved understanding and rapid retrieval of key information in Cochrane Reviews. J Clin Epidemiol 2010; 63:620-6.
6. Alonso-Coello P, Schünemann HJ, Moberg J, Brignardello-Petersen R, Akl E, Davoli M, et al. GRADE Evidence to Decision (EtD) frameworks: A systematic and transparent approach to making well-informed healthcare choices. 1. Introduction. BMJ 2016; 353:i2016.
7. Alonso-Coello P, Oxman AD, Moberg J, Brignardello-Petersen R, Akl e, Davoli M, et al. GRADE Evidence to Decision (EtD) frameworks: 2. Clinical practice guidelines. BMJ 2016; 353:i2089.
8. Evans I, Thornton H, Chalmers I, Glasziou P. Testing Treatments: Better Research for Better Healthcare. Second Edition. London: Pinter & Martin Ltd, 2011.
9. Austvoll-Dahlgren A, Oxman AD, Chalmers I, Nsangi A, Glenton C, Lewin S, et al. Key concepts that people need to understand to assess claims about treatment effects. J Evid Based Med 2015; 8:112-25.

10. Mosconi P, Antes G, Barbareschi G, Burls A, Demotes-Mainard J, Chalmers I, et al. A European multi-language initiative to make the general population aware of independent clinical research: the European Communication on Research Awareness Need (ECRAN) project. Trials 2016; 17:19.
11. The James Lind Library Editorial Team: Chalmers I, Milne I, Tröhler U, Vandenbroucke J, Morabia A, Tait G, Dukan E. The James Lind Library: explaining and illustrating the evolution of fair tests of medical treatments. J R Coll Physicians Edinb 2008; 38:259-64.
12. Irwig L, Irwig J, Trevena L, Sweet M. Smart Health Choices. London: Hammersmith Press, 2008.
13. Woloshin S, Schwartz LM, Welch HG. Know Your Chances: Understanding Health Statistics. Berkeley: University of California Press, 2008.
14. Goldacre B. Bad Science: Quacks, Hacks, and Big Pharma Flacks. New York: Faber & Faber, 2010.
15. Porta M. A Dictionary of Epidemiology. Oxford: Oxford University Press, Kindle Edition 2008.
16. Devereaux PJ, Manns BJ, Ghali WA, Quan H, Lacchetti C, Montori VM, et al. Physician interpretations and textbook definitions of blinding terminology in randomized controlled trials. JAMA 2001; 285:2000-3.
17. Schulz KF, Chalmers I, Altman D. The landscape and lexicon of blinding. Ann Int Med 2002; 136:254-9.
18. Thorpe KE, Zwarenstein M, Oxman AD, Treweek S, Furberg CD, Altman DG, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. J Clin Epidemiol 2009; 62: 464-75.
19. Forsetlund L, Chalmers I, Bjørndal A. When was random allocation first used to generate comparison groups in experiments to assess the effects of social interventions? Econ Innovation New Tech 2007; 16:371-84.
20. Effective Practice and Organisation of Care (EPOC). Results should not be reported as statistically significant or statistically non-significant. EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services; 2013. Available at: http://epoc.cochrane.org/epoc-specific-resources-review-authors
21. Effective Practice and Organisation of Care (EPOC). Reporting the effects of an intervention in EPOC reviews. EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services; 2016. Available at: http://epoc.cochrane.org/epoc-specific-resources-review-authors
22. Chalmers I. People are "participants" in research. BMJ 1999; 318:1141.