



## Assessing Bias in Randomized and Non-Randomized Studies: New Approaches, New Tools

January 15<sup>th</sup> – 17<sup>th</sup>, 2018

### Course description

**Faculty** **Prof. Jonathan Sterne**  
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School of Social and Community Medicine, University of Bristol, United Kingdom

**Place** **CH – 3823 Wengen | SWITZERLAND**  
Room Edelweiss (see map at <http://www.epi-winterschool.org/hotels>)

**Introduction** Randomized controlled trials (RCTs), and systematic reviews of such trials, provide the most reliable evidence about the effects of healthcare interventions. Providing enough participants are randomized, randomization should ensure similarity of participants in the intervention and comparison groups so that differences in outcomes of interest between these groups can be ascribed to the causal effect of the intervention. Causal inferences from RCTs can, however, be undermined by flaws in design, conduct, analyses and selective reporting. Although there is good empirical evidence that flaws in RCTs may lead to bias, it is usually impossible to know the extent to which biases have affected the results of a particular trial. Therefore systematic reviews of RCTs typically include assessments of the validity of the included trials.

Non-randomized studies of interventions (NRSI) can provide evidence additional to that available from RCTs about long-term outcomes, rare events, adverse effects and populations that are typical of real world practice. For many types of organizational or public health interventions, NRSI are the main source of evidence about the likely impact of the intervention because RCTs are difficult or impossible to conduct on an area-

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wide basis. Therefore systematic reviews addressing the effects of healthcare interventions often include NRSI.

In the last decade, major developments have been made in tools to assess study validity. A shift in focus from methodological quality to risk of bias has been accompanied by a move from checklists and numeric scores towards domain-based assessments in which different types of bias are considered in turn. Examples are the Cochrane Risk of Bias tool for randomized trials, the QUADAS 2 tool for diagnostic test accuracy studies and the ROBIS tool for systematic reviews.

This course introduces two newly-developed tools for assessing the risk of bias: version 2 of the Cochrane tool for assessing risk of bias in RCTs, and the ROBINS-I tool for assessing risk of bias in NRSI. These tools share similar approaches including the use of signalling questions to help reviewers judge the risk of bias within each domain, specification of the effect of interest, and guidance on assessing the overall risk of bias in a particular study result. However some of the bias domains assessed differ between the tools: for NRSI but not RCTs it is necessary to assess the risk of bias due to confounding; selection bias; and bias in classification of interventions. Work extending ROBINS-I to assess studies of exposures will be described.

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**Course objectives**

By the end of this short course participants will:

- Understand the empirical and theoretical evidence for bias in RCTs and NRSI
- Understand the types of bias that can undermine the internal validity of RCTs and NRSI
- Be able to use version 2 of the Cochrane tool to assess risk of bias in RCTs
- Be able to use the ROBINS-I tool to assess risk of bias in NRSI

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**What you have to bring**

Students should bring their own portable computers.

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**Outline of course**

The course will run over three days and consists of lectures and practical sessions in the morning and evening. During the extended break in the afternoon, participants review course materials, catch up on emails or go skiing.

**Monday, January 15<sup>th</sup>**

- Bias in randomized trials: empirical evidence and theoretical considerations.
  - Version 2 of the Cochrane tool for assessing risk of bias in randomized trials.
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- Lecture and practical work: Assessing risk of bias arising from the randomization process and due to deviations from intended interventions.
- Lecture and practical work: Assessing risk of bias due to missing outcome data, measurement of the outcome and selection of the reported result.

**Tuesday, January 16<sup>th</sup>**

- Introduction to confounding and selection bias.
- The ROBINS-I tool for assessing risk of bias in non-randomized studies of interventions.
- Practical work: Assessing risk of bias due to confounding and selection bias.
- Lecture and practical work: Assessing risk of bias due to measurement of interventions and departures from intended interventions.

**Wednesday, January 17<sup>st</sup>**

- Lecture and practical work: Assessing risk of bias due to missing data, measurement of outcomes and selection of the reported result.
- Lecture and practical work: Assessing overall risk of bias in a study result, and incorporating assessments into meta-analyses.
- Lecture: Assessing bias in studies of exposures

<b>Credit</b>	1.5 ECTS
<b>Course fee</b>	SSPH+: CHF 0 Academic: CHF 900 Industry: CHF 2000
<b>Registration</b>	You can register on the Winter School website <a href="http://www.epi-winterschool.org">www.epi-winterschool.org</a> .
<b>Course hotels</b>	Participants must book their accommodations themselves (see map and recommendations on <a href="http://www.epi-winterschool.org/hotels">www.epi-winterschool.org/hotels</a> ).