Swiss Epidemiology Winter School 2023

Tools to Assess Risk of Bias in Randomized and Non-Randomized Studies: Cochrane RoB 2, ROBINS-I and ROBINS-E

16–18 January 2023

Faculty	**Prof. Jonathan Sterne** Population Health Sciences, Bristol Medical School, University of Bristol, United Kingdom **Prof. Julian Higgins** Population Health Sciences, Bristol Medical School, University of Bristol, United Kingdom
Venue	**CH – 3823 Wengen | SWITZERLAND** Hotel Edelweiss (map)
Course description	Randomized controlled trials (RCTs), and systematic reviews of such trials, provide the most reliable evidence about the effects of healthcare interventions. Randomization should ensure that there are no systematic differences between participants in the intervention and comparison groups so that differences (beyond sampling variation) 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 and analyses, and by 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 *risk of bias* in results of the included trials. Non-randomized studies of interventions 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 some organizational or public health interventions, non-randomized studies are the main source of evidence about the likely impact of the intervention because RCTs are difficult or impossible to conduct on an area-wide basis. Therefore systematic reviews addressing the effects of healthcare interventions often include non-randomized studies. Systematic reviews of studies of the effects of exposures on outcomes usually include only non-randomized (observational) studies. 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

Contact:
University of Bern | Institute of Social and Preventive Medicine
Mittelstrasse 43
3012 Bern | Switzerland
www.epi-winterschool.org | winterschool@ispm.unibe.ch

	move from checklists and numeric scores towards domain-based assessments in which different types of bias are considered in turn. This course trains participants to use widely-applied tools for assessing risk of bias: version 2 of the Cochrane tool for assessing risk of bias in RCTs (RoB 2, 2019), an updated version of the 2016 ROBINS-I tool for assessing risk of bias in non-randomized studies of interventions, and the newly launched ROBINS-E tool for non-randomized studies of exposures. These tools share similar approaches including the use of structured signalling questions within each domain, algorithms to suggest risk of bias judgements, and guidance on assessing the overall risk of bias in a particular study result by combining domain-specific judgements. Some of the bias domains assessed differ between the tools: for non-randomized studies but not RCTs it is necessary to assess the risk of bias due to confounding; selection bias; and bias in classification (or measurement) of interventions or exposures.
Course objectives	By the end of this course participants will be able to: • describe the empirical and theoretical evidence for bias in RCTs and non-randomized studies • list the types of bias that can undermine the internal validity of RCTs and non-randomized studies • use version 2 of the Cochrane tool to assess risk of bias in RCTs (RoB 2) • use the updated ROBINS-I tool to assess risk of bias in non-randomized studies of interventions • describe the new ROBINS-E tool to assess risk of bias in observational studies of the effects of exposures • access software implementations of these tools
Course audience	The course is suitable for systematic reviewers, epidemiologists and statisticians wishing to learn about a formal framework for assessing risk of bias in studies of the effects of interventions and exposures.
Course outline	The course runs over three days and consists of lectures and group work. We start early in the morning with an extended afternoon break (when participants can review course materials, catch up on email, or ski) before reconvening at 4:30 pm. ***Monday, 16 January 8:00 am – 12:00 pm | 4:30 pm – 6:30 pm*** ***Tuesday, 17 January 8:00 am – 12:00 pm | 4:30 pm – 6:30 pm*** ***Wednesday, 18 January 8:00 am – 12:00 pm | 1:00 pm – 3:00 pm***
Credits	1.0 ECTS
Course materials	Bring a portable computer. Onsite University of Bern IT staff provides support upon request (it@ispm.unibe.ch) request.
Course fee	PhD Bern Students: CHF 350 PhD Students: CHF 700 Academic: CHF 900 Industry: CHF 2000
Registration	Register on the Winter School website. Pre-Registration starts 29 August 2022 at 12:00 pm (CET).
Accomodation	Book your accommodation separately. Please see recommendations for special prices.

Contact:
University of Bern | Institute of Social and Preventive Medicine
Mittelstrasse 43
3012 Bern | Switzerland
www.epi-winterschool.org | winterschool@ispm.unibe.ch

Contact:
University of Bern | Institute of Social and Preventive Medicine
Mittelstrasse 43
3012 Bern | Switzerland
www.epi-winterschool.org | winterschool@ispm.unibe.ch