

Workshop Timetable

Thursday, July 21, 2022

		Speaker
08:00	<i>Breakfast</i>	
08:30	Welcome	Tianjing Li
08:45	Introduction to risk-of-bias assessment	Julian Higgins
	RoB 2: Overview of the tool	Julian Higgins
	RoB 2: Bias arising from the randomization process	Jelena Savović
10:30	<i>Break</i>	
11:00	RoB 2: Intention-to-treat and per-protocol effects of intervention	Jonathan Sterne
	RoB 2: Bias due to deviations from intended interventions	Jonathan Sterne
12:30	<i>Lunch</i>	
13:30	ROBINS-I: Overview of the tool	Julian Higgins
	ROBINS-I: The target trial	Julian Higgins
	ROBINS-I: Bias due to confounding	Jonathan Sterne
15:30	<i>Break</i>	
16:00	ROBINS-I: Bias in selection of participants into the study	Jonathan Sterne
	ROBINS-I: Bias due to deviations from intended interventions	Jonathan Sterne
17:00	<i>Close</i>	
18:00	<i>Happy (office) hour at Stanley Beer Hall</i> <i>Address: 2501 Dallas St #100, Aurora, CO 80010 (look for outdoor reserved tables under "Tianjing Li")</i>	All

Friday, July 22, 2022

08:30	<i>Breakfast</i>	
09:00	ROBINS-I: Bias in classification of intervention	Julian Higgins
	ROBINS-E: Overview of the tool	Julian Higgins
10:30	<i>Break</i>	
11:00	ROBINS-E: Bias arising from measurement of the exposure	Julian Higgins
	ROBINS-E: Risk of bias due to post-exposure interventions	Jonathan Sterne
12:30	<i>Lunch</i>	
13:30	All tools: Bias due to missing data	Jonathan Sterne
15:15	<i>Break</i>	
15:45	All tools: Bias arising from measurement of the outcome	Tianjing Li
	All tools: Bias in selection of the reported result	Matt Page
17:00	<i>Close</i>	

Workshop Required and Recommended Readings

Required readings:

Mansournia MA, Higgins JP, Sterne JA, Hernán MA. Biases in Randomized Trials: A Conversation Between Trialists and Epidemiologists. *Epidemiology*. 2017 Jan;28(1):54-59. doi: 10.1097/EDE.0000000000000564. Erratum in: *Epidemiology*. 2018 Sep;29(5):e49. PMID: 27748683. Available at:

https://journals.lww.com/epidem/fulltext/2017/01000/biases_in_randomized_trials_a_conversation.9.aspx

ROBINS-I:

Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, Henry D, Altman DG, Ansari MT, Boutron I, Carpenter JR, Chan AW, Churchill R, Deeks JJ, Hróbjartsson A, Kirkham J, Jüni P, Loke YK, Pigott TD, Ramsay CR, Regidor D, Rothstein HR, Sandhu L, Santaguida PL, Schünemann HJ, Shea B, Shrier I, Tugwell P, Turner L, Valentine JC, Waddington H, Waters E, Wells GA, Whiting PF, Higgins JP. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*. 2016 Oct 12;355:i4919. doi: 10.1136/bmj.i4919. PMID: 27733354. Available at:

<https://www.bmj.com/content/355/bmj.i4919>

RoB 2:

Sterne JAC, Savović J, Page MJ, Elbers RG, Blencowe NS, Boutron I, Cates CJ, Cheng HY, Corbett MS, Eldridge SM, Emberson JR, Hernán MA, Hopewell S, Hróbjartsson A, Junqueira DR, Jüni P, Kirkham JJ, Lasserson T, Li T, McAleenan A, Reeves BC, Shepperd S, Shrier I, Stewart LA, Tilling K, White IR, Whiting PF, Higgins JPT. RoB 2: a revised tool for assessing risk of bias in randomised trials. *BMJ*. 2019 Aug 28;366:l4898. doi: 10.1136/bmj.l4898. PMID: 31462531. Available at:

<https://www.bmj.com/content/366/bmj.l4898>

Articles for risk of bias assessment:

Engelbrechtsen K, Grotle M, Bautz-Holter E, Sandvik L, Juel NG, Ekeberg OM, Brox JI. Radial extracorporeal shockwave treatment compared with supervised exercises in patients with subacromial pain syndrome: single blind randomised study. *BMJ*. 2009 Sep 15;339:b3360. doi: 10.1136/bmj.b3360. PMID: 19755551. Available at:

<https://pubmed.ncbi.nlm.nih.gov/19755551/>

Stampfer MJ, Colditz GA, Willett WC, Manson JE, Rosner B, Speizer FE, Hennekens CH. Postmenopausal estrogen therapy and cardiovascular disease. Ten-year follow-up from the nurses' health study. *N Engl J Med*. 1991 Sep 12;325(11):756-62. doi: 10.1056/NEJM199109123251102. PMID: 1870648. Available at: <https://pubmed.ncbi.nlm.nih.gov/1870648/>

Recommended readings:

The detailed guidance documents for the three tools, at www.riskofbias.info.

Other workshop materials:

We will share other workshop materials including slides through a Dropbox folder.

Workshop Faculty Biographies

Julian Higgins



Dr. Julian Higgins is Professor of Evidence Synthesis in the Population Health Sciences department of Bristol Medical School, where he leads the Bristol Appraisal and Review of Research (BARR) group. Wide-ranging research interests span all areas of systematic review and meta-analysis. Dr. Higgins has co-authored more than 60 applied systematic reviews and over 150 papers on methodology. Among his methods contributions are: a Bayesian approach to network meta-analysis; the I-squared statistic to quantify inconsistency across studies in a meta-analysis; simple prediction intervals for random-effects meta-analysis; a general framework for individual participant data meta-analysis; a library of prior distributions for between-study variation in a meta-analysis; and risk-of-bias assessment tools for clinical trials and other study designs.

Dr. Higgins was a founding trustee and is a past President of the Society for Research Synthesis Methodology. He has long been an active contributor to Cochrane, and is a former member of Cochrane's Steering Group, Editorial Board and Scientific Committee. He is currently co-convenor of the Cochrane Bias Methods Group and has co-edited the Cochrane Handbook for Systematic Reviews of Interventions since 2003. He is also co-author of the Wiley 2009 textbook Introduction to Meta-analysis. He has more than 300 publications, which have attracted more than 250,000 citations. With a Google Scholar H-index over 125, Julian has been named as a Highly Cited Researcher each year since 2015.

Jonathan Sterne



Dr. Jonathan Sterne is Professor of Medical Statistics and Epidemiology at the University of Bristol UK, Director of the NIHR Bristol Biomedical Research Centre, and Director of Health Data Research UK South-West. Dr. Sterne has longstanding interest in methodology for systematic reviews and meta-analyses, and methodology for epidemiology and health services research, in particular related to causal inference from observational data. He led development of the ROBINS-I tool for assessing risk of bias in non-randomized studies of interventions and version 2 of the Cochrane risk of bias assessment tool (RoB 2) for randomized trials. As co-lead for the Longitudinal Health and Wellbeing UK COVID-19 National Core Study, he leads a large team working on linked whole-population electronic health record data held in Trusted Research Environments. During the pandemic has played a leading role in prospective meta-analyses investigating the effects of corticosteroids, IL-6 antagonists, and anticoagulants in treating hospitalized patients with COVID-19.

Tianjing Li

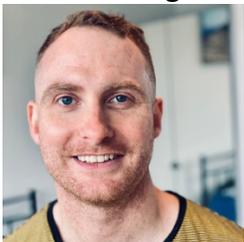


Dr. Tianjing Li is Associate Professor of Ophthalmology and Epidemiology at the University of Colorado Anschutz Medical Campus. The goal of Dr. Li's research is to develop, evaluate, and disseminate methods for comparing healthcare interventions and to provide trust-worthy evidence for decision-making.

Dr. Li has worked with Cochrane for 17 years, including serving as the Associate Director for Cochrane US from 2012 to 2018, as Coordinating Editor for Cochrane Eyes and Vision, the PI of the Cochrane Eyes and Vision US Project, a co-convenor for the Cochrane Comparing Multiple Interventions Methods Group, and an executive member of the Cochrane Methods Board. She is an Associate Scientific Editor for the 2nd edition of the *Cochrane Handbook for Systematic Reviews of Interventions* and was the 2019 recipient of Cochrane's Anne Anderson Award. She contributed to the development of the version 2 of the Cochrane risk of bias assessment tool (RoB 2) for randomized trials.

Outside of Cochrane, Dr. Li serves as an Editor-in-Chief for the journal *Trials*, a Statistical Editor for *Annals of Internal Medicine*, the Review Editor for *JAMA Ophthalmology*, a Section Editor for book *Principles and Practice of Clinical Trials*, an Author and Editor for *Textbook of Epidemiology* (2nd edition), among others. She is an elected member to the Society for Research Synthesis Methodology where she serves as the President-Elect and received its inaugural Early Career Award in 2016.

Matthew Page



Dr. Matthew Page is a Senior Research Fellow and Deputy Head of the Methods in Evidence Synthesis Unit in the School of Public Health and Preventive Medicine at Monash University. His research aims to improve the credibility of syntheses of health and medical research. He has led many studies investigating the transparency, reproducibility, and risk of bias in systematic reviews and the studies they include, and has developed methods to address these issues. He co-led the PRISMA 2020 statement for systematic reviews and was a member of the core group who developed the RoB 2 tool for assessing risk of bias in randomized trials. He was an associate scientific editor for the 2nd edition of the *Cochrane Handbook for Systematic Reviews of Interventions*. Matthew's expertise has been recognized in leadership and editorial appointments at organizations and journals focusing on methods for evidence synthesis, including co-convenor of the Cochrane Bias Methods Group, and member of the editorial board for the *Journal of Clinical Epidemiology* and *PLOS Medicine*.

Jelena Savović



Dr. Jelena Savović is a Senior Lecturer in Evidence Synthesis at the Bristol Medical School, University of Bristol and Evidence Team Lead at the NIHR Applied Research Collaboration West. Dr. Savović has a degree in Pharmacy the University of Belgrade in Serbia, and a PhD in medicinal chemistry from the Department of Pharmacy and Pharmacology at the University of Bath, UK. She was awarded a postdoctoral fellowship in population health and health of the public from the UK Medical Research Council and completed the MSc in Epidemiology from the London School of Hygiene and Tropical Medicine, University of London. Dr. Savović co-led or contributed to the development of several risk of bias assessment tools: for randomized trials (RoB2), non-randomized studies of interventions (ROBINS-I) and for systematic reviews (ROBIS). Her empirical work exploring the sources of bias in randomized trials informed the development of the Cochrane risk of bias tool and the revised RoB2 tool. She also authored many applied systematic reviews in various clinical, public health and health services research topics.