

## Introduction to RCT - HEL-8018

**This year all lectures will be conducted digitally using Teams.**

For information and inquiries, please, contact [Klinisk.forskningsavdeling@unn.no](mailto:Klinisk.forskningsavdeling@unn.no)

### Schedule

Time	Duration	Lecture	Lecturer
<b>Day 1</b>	<b>Min.</b>	<b>September 7</b>	
08.45-09.00	15	Registration and coffee	
09.00-09.15	15	Introduction and information	Svetlana Zykova
09.15-10.00	45	Introduction to evidence – ways to deal with confounding	Mike Clarke
10.00-10.15	15	Coffee break	
10.15-11.00	45	Defining the research question. Choice of study population, intervention and group comparison. Avoidance of bias, outcomes, <b>part I</b>	Mike Clarke
11.00-11.15	15	Coffee	
11.15-12.00	45	Defining the research question. Choice of study population, intervention and group comparison. Avoidance of bias, outcomes, <b>part II</b>	Mike Clarke
12.00-13.15	75	Lunchbreak	
13.15-14.00	45	Randomization and concealed allocation. How to randomize in real life?	Mike Clarke
14.00-14.15	15	Coffee break	
14.15-15.00	45	Alternative trial design (explanatory/pragmatic, multi arm, cluster, cross-over, factorial, non-inferiority studies) I	Mike Clarke
15.00-15.15	15	Coffee break	
15.15-16.00	45	Alternative trial design (explanatory/pragmatic, multi arm, cluster, cross-over, factorial, non-inferiority studies) II	Mike Clarke
<b>Day 2</b>		<b>September 8</b>	
08.15-09.00	45	Complex interventions I	Sameline Grimsgaard
09.00-09.15	15	Coffee break	
09.15-10.00	45	Complex interventions II	Sameline Grimsgaard
10.00-	15	Coffee break	

10.15			
10.15-11.00	45	Sample size and power calculation, interim analysis and adaptive study design	Tom Wilsgaard
11.00-12.15	75	Lunchbreak	
12.15-13.00	45	Practical approach to sample size calculation. Examples.	Tom Wilsgaard
13.00-13.15	15	Coffee break	
13.15-14.00	45	Incomplete data	Mike Clarke
14.00-14.15	15	Coffee break	
14.15-15.00	45	Multiple testing and subgroup analysis	Mike Clarke
15.00-15.15	15	Coffee break	
15.15-16.00	45	How to write a protocol	Sameline Grimsgaard
<b>Day 3</b>		<b>September 9</b>	
08.15-09.00	45	Ethical considerations in RCTs	Åge Wifstad
09.00-09.15	15	Coffee break	
09.15-10.00	45	Patient Reported Outcomes/ Health related quality of life in RCTs	Tove Aminda Hanssen
10.00-10.15	15	Coffee break	
10.15-11.00	45	Patient Reported Outcomes/ Health related quality of life in RCTs	Tove Aminda Hanssen
11.00-12.15	75	Lunchbreak	
12.15-13.00	45	Clinical trial regulation, monitoring and data quality.	Gunn-Janne Paulsen
13.00-13.15	15	Coffee break	
13.15-14.00	45	Consort and Equator network	Elin Evensen
14.00-14.15	15	Coffee break	
14.15-15.00	45	From idea to results. Challenges in implementation of RCTs	Claus Klingenberg

15.00-15.15	15	Coffee break	
15.15-15.45	30	Registration of clinical studies and research support at UNN	Elin Evensen
15.45-16.00	15	Exam and evaluation	Svetlana Zykova and Kari Jenssen Lægreid

**Course leader:**

**Svetlana Zykova**, Associate Professor II, The Department of Clinical Medicine, UiT The Arctic University of Norway and Department of Clinical Research, University Hospital of North Norway

**Lecturers:**

**Mike Clarke**, DPhil, Professor of Clinical Epidemiology, University of Oxford, UK and Director of the Northern Ireland Hub for Trials Methodology Research, Queen's University Belfast, UK.

**Sameline Grimsgaard**, Professor, The Department of Community Medicine, UiT The Arctic University of Norway and Department of Clinical Research, University Hospital of North Norway

**Tom Wilsgaard**, Professor, The Department of Community Medicine, UiT The Arctic University of Norway and Department of Clinical Research, University Hospital of North Norway

**Åge Wifstad**, associate professor, UiT The Arctic University of Norway and University Hospital of North Norway

**Claus Klingenberg**, professor, University Hospital of North Norway and The Department of Clinical Medicine, UiT The Arctic University of Norway

**Tove Aminda Hanssen**, professor, Department of Health and Care Sciences, UiT The Arctic University of Norway and University Hospital of North Norway

**Gunn-Janne Paulsen**, Clinical Monitor, Department of Clinical Research, University Hospital of North Norway

**Elin Evensen**, MPH, PhD, Advisor, Department of Clinical Research, University Hospital of North Norway