

Designing Clinical Research for Beginning Investigators

Course schedule Fall Semester 2024

Topic	Date and time	Theme	Lecturer	Readings
1	17.09.2024 10:10-12:00	Research Question and Study Plan	Prof. Dr Maria C. Katapodi	<p>Readings week 1: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapters 1 and 2, pages 2-22 and Chapter 5, pages 43-46.</p> <p>Reading for Journal Club: Matthys et al. (2021) Effectiveness of a nurse-delivered FOCUS+ and a web-based (iFOCUS) psychoeducational intervention for people with advanced cancer and their family caregivers (DIAdIC): Study protocol for an international randomized controlled trial. <i>BMC Palliative Care</i> ;20(1):193. doi: 10.1186/s12904-021-00895-z.</p>
2	24.09.2024 10:10-12:00	Study participants	Prof. Dr Maria C. Katapodi	<p>Readings week 2: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 3, pages 23-31.</p> <p>Reading for Journal Club: Briel M, et al. (2019) Comparison of randomized controlled trials discontinued or revised for poor recruitment and completed trials with the same research question: a matched qualitative study. <i>Trials</i> 20:800 https://doi.org/10.1186/s13063-019-3957-4</p>
3	15.10.2024 10:10-12:00	Measurement	Prof. Dr. Maria C. Katapodi	<p>Readings week 3: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 4, pages 32-42.</p> <p>Reading for Journal Club: Li et al. (2024) Validity of Patient-Reported Outcome Measures in Evaluating Nerve Damage Following Chemotherapy. <i>JAMA Network Open</i>; 7(8):e2424139. doi: 10.1001/jamanetworkopen.2024.24139.</p>
4	22.10.2024 10:10-12:00	Observational Studies I – Cross sectional and cohort studies	Prof. Dr Maria C. Katapodi	<p>Readings week 4: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 7, pages 85-96.</p> <p>Reading for Journal Club:</p>

				Weber et al. (2024) Time Trends in Causes of Death in People With HIV: Insights From the Swiss HIV Cohort Study. <i>Clinical Infectious Diseases</i> ; 79(1):177-188. doi: 10.1093/cid/ciae014.
5	29.10.2024 10:10-12:00	Observational Studies II – Case control studies	Prof. Dr Maria C. Katapodi	<p>Readings week 5: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 8, pages 97-116.</p> <p>Reading for Journal Club: Aguiló O, et al. (2022) Prevalence, Related Factors and Association of Left Bundle Branch Block With Prognosis in Patients With Acute Heart Failure: a Simultaneous Analysis in 3 Independent Cohorts. <i>Journal of Cardiac Failure</i>; 28(7):1104-1115. doi: 10.1016/j.cardfail.2021.11.022.</p> <p>OR</p> <p>Murphy et al. (2024) Cardiovascular Disease in Patients With Breast Cancer Treated in the Modern Era. <i>Heart Lung and Circulation</i>;33(5):648-656. doi: 10.1016/j.hlc.2023.05.021.</p>
6	05.11.2024 10:10-12:00	Observational Studies III – Causal inference, DAG	Dr. Chang Ming	<p>Readings week 6: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 9, pages 117-136.</p> <p>Reading for Journal Club: Zhang Y, et al. (2021) Estimation of causal effect in integrating randomized clinical trial and observational data - An example application to cardiovascular outcome trial. <i>Contemporary Clinical Trials</i>; 107:106492. doi: 10.1016/j.cct.2021.106492.</p>
7	12.11.2024 10:10-12:00	Experimental studies I – Randomized blinded trials	Prof. Dr Maria C. Katapodi	<p>Readings week 7: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 10, pages 137-150.</p> <p>Reading for Journal Club: Goodwin et al. (2024) A Cluster Randomised Controlled Trial of a Targeted Distributed Toothpaste and Toothbrushing Programme. <i>Caries Research</i>; 1-9. doi: 10.1159/000539416.</p>
8	19.11.2024 10:10-12:00	Experimental studies II – Alternative clinical trial designs and implementation	Prof. Dr Maria C. Katapodi	<p>Readings week 8: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 11, pages 151-170.</p>

				Reading for Journal Club: Amstutz A, et al. (2024) Characteristics, consent patterns, and challenges of randomized trials using the Trials within Cohorts (TwiCs) design - A scoping review. <i>J Clinical Epidemiology</i> ; 174:111469. doi: 10.1016/j.jclinepi.2024.111469.
9	26.11.2024 10:10-12:00	Studies of medical tests	Dr. Chang Ming	<p>Readings week 9: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 12, pages 171-190.</p> <p>Reading for Journal Club: Ming C et al. (2020) Machine learning-based lifetime breast cancer risk reclassification compared with the BOADICEA model: impact on screening recommendations. <i>British Journal of Cancer</i>; 123(5):860-867. doi: 10.1038/s41416-020-0937-0. Epub 2020 Jun 22. PMID: 32565540</p>
10	03.12.2024 10:10-12:00	Research using existing data	Prof. Dr. Maria C. Katapodi	<p>Readings week 10: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 13 pages, 192-197.</p> <p>Reading for Journal Club: Khera et al. (2021) Use of Machine Learning Models to Predict Death After Acute Myocardial Infarction <i>JAMA Cardiology</i>; 6(6):633-641. doi: 10.1001/jamacardio.2021.0122.</p> <p>OR</p> <p>Dal Cero et al. (2024) International External Validation of Risk Prediction Model of 90-Day Mortality after Gastrectomy for Cancer Using Machine Learning. <i>Cancers (Basel)</i>; 16(13):2463. doi: 10.3390/cancers16132463.</p>
11	10.12.2024 10:10-12:00	Community and international studies	Prof. Dr. Maria C. Katapodi	<p>Readings week 11: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 18 pages, 268-276.</p> <p>Reading for Journal Club: Barnoy et al. (2023) Privacy and utility of genetic testing in families with hereditary cancer syndromes living in three countries: the international cascade genetic screening experience. <i>Frontiers in Genetics</i>; 14:1109431. doi: 10.3389/fgene.2023.1109431.</p>

Required Book:

Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing Clinical Research, 4th Edition, Lippincott Williams & Wilkins

Course Evaluation:

1. Written response to weekly assignments related to the course content: 50%
2. Leading and moderating one of the weekly journal clubs: 30%
3. Active participation in weekly discussions: 20%