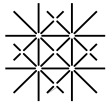


Designing Clinical Research for Beginning Investigators

Course schedule Fall Semester 2025

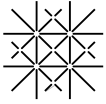
Topic	Date and time	Theme	Lecturer	Readings
1	16.09.2025 10:10-12:00	Research Question and Study Plan	Prof. Dr. Maria C. Katapodi	<p>Readings week 1: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapters 1 and 2, pages 2-22 and Chapter 5, pages 43-46.</p> <p>Reading for Journal Club: 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	23.09.2025 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	30.09.2025 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	21.10.2025 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. <u>Clinical Infectious Diseases</u> ; 79(1):177-188. doi: 10.1093/cid/ciae014.
5	28.10.2025 10:10-12:00	Observational Studies II – Case control studies	Prof. Dr Maria C. Katapodi	Readings week 5: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 8, pages 97-116. Reading for Journal Club: Ferguson LD, Molenberghs G, Verbeke G, Rahimi K, Rao S, McInnes IB, McMurray JJ, Sattar N, Conrad N. Gout and incidence of 12 cardiovascular diseases: a case–control study including 152 663 individuals with gout and 709 981 matched controls. <u>The Lancet Rheumatology</u> . 2024 Mar 1;6(3):e156-67.
6	04.11.2025 10:10-12:00	Observational Studies III – Causal inference, DAG	Dr. Hong Sun	Readings week 6: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 9, pages 117-136. Reading for Journal Club: Zhang Y, et al. Estimation of causal effect in integrating randomized clinical trial and observational data - An example application to cardiovascular outcome trial. <u>Contemporary Clinical Trials</u> . 2021 Aug; 107:106492. doi: 10.1016/j.cct.2021.106492.
7	11.11.2025 10:10-12:00	Experimental studies I – Randomized blinded trials	Prof. Dr Maria C. Katapodi	Readings week 7: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 10, pages 137-150. Reading for Journal Club: Goodwin et al. (2024) A Cluster Randomised Controlled Trial of a Targeted Distributed Toothpaste and Toothbrushing Programme. <u>Caries Research</u> ; 1-9. doi: 10.1159/000539416.
8	18.11.2025 10:10-12:00	Experimental studies II – Alternative clinical trial designs and implementation	Prof. Dr Maria C. Katapodi	Readings week 8: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 11, pages 151-170. 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. <u>J Clinical Epidemiology</u> ; 174:111469. doi: 10.1016/j.jclinepi.2024.111469.



9	25.11.2025 10:10-12:00	Studies of medical tests	Dr. Hong Sun	<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. <u>British Journal of Cancer</u>; 123(5):860-867. doi: 10.1038/s41416-020-0937-0. Epub 2020 Jun 22. PMID: 32565540</p>
10	02.12.2025 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 <u>JAMA Cardiology</u>;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. <u>Cancers (Basel)</u>;16(13):2463. doi: 10.3390/cancers16132463.</p>
11	09.12.2025 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. <u>Frontiers in Genetics</u>;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%