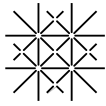


Designing Clinical Research for Beginning Investigators

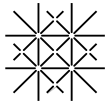
Course schedule Fall Semester 2026

The lecture will take place in Biozentrum, Spitalstr. 41, 4056 Basel, Room TBD

Topic	Date and time	Theme	Lecturer	Readings
1	15.09.2026 10:10-12:00	Research Question and Study Plan	Prof. Dr. Maria C. Katapodi	Readings week 1: Designing Clinical Research by Hulley SB, et al. 4 th Edition Chapters 1 and 2, pages 2-22 and Chapter 5, pages 43-46. 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.
2	22.09.2026 10:10-12:00	Study participants	Prof. Dr. Maria C. Katapodi	Readings week 2: Designing Clinical Research by Hulley SB, et al. 4 th Edition Chapter 3, pages 23-31. 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
3	29.09.2026 10:10-12:00	Measurement	Prof. Dr. Maria C. Katapodi	Readings week 3: Designing Clinical Research by Hulley SB, et al. 4 th Edition Chapter 4, pages 32-42. 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.



4	20.10.2026 10:10-12:00	Observational Studies I – Cross sectional and cohort studies	Prof. Dr Maria C. Katapodi	Readings week 4: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 7, pages 85-96. Reading for Journal Club: 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	27.10.2026 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	03.11.2026 10:10-12:00	Observational Studies III – Causal inference, DAG	Ms. Lisa C. Schiess	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	10.11.2026 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	17.11.2026 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	24.11.2026 10:10-12:00	Studies of medical tests	Prof. Dr. Maria C. Katapodi	Readings week 9: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 12, pages 171-190. 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
10	01.12.2026 10:10-12:00	Research using existing data	Prof. Dr. Maria C. Katapodi	Readings week 10: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 13 pages, 192-197. 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. OR 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.
11	08.12.2026 10:10-12:00	Community and international studies	Prof. Dr. Maria C. Katapodi	Readings week 11: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 18 pages, 268-276. 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.

Required Book:

Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing Clinical Research, 5th Edition, Lippincott Williams & Wilkins

Course Evaluation:

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