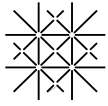


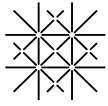
Designing Clinical Research for Beginning Investigators

Course schedule Fall Semester 2024

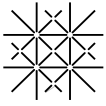
Topic	Date and time	Theme	Lecturer	Readings
1	17.09.2024 10:10-12:00	Research Question and Study Plan	Prof. Dr. Maria C. Katapodi	<p>Readings week 1: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapters 1 and 2, pages 2-22 and Chapter 5, pages 43-46.</p> <p>Reading for Journal Club: 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. BMC Palliat Care ;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. Comparison of randomized controlled trials discontinued or revised for poor recruitment and completed trials with the same research question: a matched qualitative study. Trials (2019) 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: Yeshokumar et al. 2021 Exploration of patient- and relative-reported outcomes of cognitive, emotional, and social function after encephalitis. Brain Inj; 35(2):255-263. doi: 10.1080/02699052.2020.1865567</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>



				Hall et al. 2022 Prenatal Maternal Infections and Children's Neurodevelopment in the UK Millennium Cohort Study: A Focus on ASD and ADHD <i>J Atten Disord</i> ;26(4):616-628. doi: 10.1177/10870547211015422.
5	29.10.2024 10:10-12:00	Observational Studies II – Case control studies	Dr. Zhongxing Zhang	Readings week 5: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 8, pages 97-116. Reading for Journal Club: Dauvilliers et al. Increased risk of narcolepsy in children and adults after pandemic H1N1 vaccination in France. <i>Brain</i> , 2013; 136; 2486–2496
6	05.11.2024 10:10-12:00	Observational Studies III – Causal inference, DAG	Dr. Chang Ming	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. <i>Contemporary Clinical Trials</i> . 2021 Aug; 107:106492. doi: 10.1016/j.cct.2021.106492.
7	12.11.2024 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: Katapodi, MC et al. Genetic testing and surveillance of young breast cancer survivors and blood relatives: a cluster randomized trial, <i>Cancers</i> , 2020 Sep 5;12(9):2526. doi: 10.3390/cancers12092526. PMID: 32899538
8	19.11.2024 10:10-12:00	Experimental studies II – Alternative clinical trial designs and implementation	TBD	Readings week 8: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 11, pages 151-170. Reading for Journal Club: Batthacharya et al 2021 Can patient decision aids reduce decisional conflict in a de-escalation of breast radiotherapy clinical trial? The PRIMETIME Study Within a Trial implemented using a cluster stepped-wedge trial design. <i>Trials</i> 22:397 https://doi.org/10.1186/s13063-021-05345



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. Machine learning-based lifetime breast cancer risk reclassification compared with the BOADICEA model: impact on screening recommendations. <u>British Journal of Cancer</u>. 2020; Sep;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 <u>JAMA Cardiology</u>;6(6):633-641. doi: 10.1001/jamacardio.2021.0122.</p>
11	10.12.2024 10:10-12:00	Community and international studies	TBD	<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: Kim S, et al. Using a Tailored Digital Health Intervention for Family Communication and Cascade Genetic Testing in Swiss and Korean Families with Hereditary Breast and Ovarian Cancer: Protocol for the DIALOGUE Study. <u>JMIR Research Protocols</u>. 2021;10(6):e26264 doi: 10.2196/26264</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%