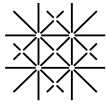


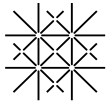
# Designing Clinical Research for Beginning Investigators

## Course schedule Spring Semester 2023

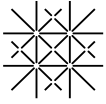
Topic	Date and time	Theme	Lecturer	Readings
1	07.03.2023 10:10-12:00	Research Question and Study Plan	Prof. Dr Maria C. Katapodi	Readings week 1: Designing Clinical Research by Hulley SB, et al. 4 <sup>th</sup> Edition Chapters 1 and 2, pages 2-22 and Chapter 5, pages 43-46.  Reading for Journal Club: Hecksteden A, et al. How to Construct, Conduct and Analyze an Exercise Training Study? <i>Frontiers in Physiology</i> . 2018 Jul 26;9:1007. doi: 10.3389/fphys.2018.01007. PMID: 30140237;
2	14.03.2023 10:10-12:00	Study participants	Dr. Alexandra Kulinkina	Readings week 2: Designing Clinical Research by Hulley SB, et al. 4 <sup>th</sup> Edition Chapter 3, pages 23-31.  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. <i>Trials</i> (2019) 20:800 <a href="https://doi.org/10.1186/s13063-019-3957-4">https://doi.org/10.1186/s13063-019-3957-4</a>
3	21.03.2023 10:10-12:00	Measurement	Prof. Dr. Maria C. Katapodi	Readings week 3: Designing Clinical Research by Hulley SB, et al. 4 <sup>th</sup> Edition Chapter 4, pages 32-42.  Reading for Journal Club: Metral M, et al; Neurocognitive Assessment in the Metabolic and Aging Cohort (NAMACO) study group, Swiss HIV Cohort Study. How helpful are the European AIDS Clinical Society cognitive screening questions in predicting cognitive impairment in an aging, well-treated HIV-positive population? <i>HIV Medicine</i> . 2020 May;21(5):342-348. doi: 10.1111/hiv.12828.
4	28.03.2023 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. 4 <sup>th</sup> Edition Chapter 7, pages 85-96.  Reading for Journal Club: Kuderer NM, et al; COVID-19 and Cancer Consortium. Clinical



				impact of COVID-19 on patients with cancer (CCC19): a cohort study. <u>Lancet</u> . 2020 Jun 20;395(10241):1907-1918. doi: 10.1016/S0140-6736(20)31187-9. Epub 2020 May 28. PMID: 32473681
5	18.04.2023 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: Michels N, et al. Chronic inflammation towards cancer incidence: A systematic review and meta-analysis of epidemiological studies. <u>Critical Reviews in Oncology and Hematology</u> . 2021 doi: 10.1016/j.critrevonc.2020.103177. PMID: 33264718
6	25.04.2023 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. <u>Contemporary Clinical Trials</u> . 2021 Aug;107:106492. doi: 10.1016/j.cct.2021.106492.
7	02.05.2023 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, <u>Cancers</u> , 2020 Sep 5;12(9):2526. doi: 10.3390/cancers12092526. PMID: 32899538
8	09.05.2023 10:10-12:00	Experimental studies II – Alternative clinical trial designs and implementation	Prof. Dr. Maria Katapodi	Readings week 8: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 11, pages 151-170.  Reading for Journal Club: Dionne-Odom JN, et al.. An Early Palliative Care Telehealth Coaching Intervention to Enhance Advanced Cancer Family Caregivers' Decision Support Skills: The CASCADE Pilot Factorial Trial. <u>Journal of Pain and Symptom Management</u> . 2021



				Jul 31:S0885-3924(21)00478-4. doi: 10.1016/j.jpainsymman.2021.07.023. Epub ahead of print. PMID: 34343621.10.1016/j.jpainsymman.2020.11.017.PMID: 33253787
9	16.05.2023 10:10-12:00	Studies of medical tests	Dr. Chang Ming	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. 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
10	23.05.2023 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: Mazzoni AS, et al. Exercise adherence and effect of self- regulatory behavior change techniques in patients undergoing curative cancer treatment: secondary analysis from the Phys- Can randomized controlled trial. <u>Integrative Cancer Therapy</u> . 2020 Jan-Dec;19:1534735420946834. doi: 10.1177/1534735420946834. PMID: 32909467
11	30.05.2023 10:10-12:00	Community and international studies	Dr. Alexandra Kulinkina	Readings week 11: Designing Clinical Research by Hulley SB, et al. 4th Edition Chapter 18 pages, 268-276.  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



**Required Book:**

Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing Clinical Research, 4<sup>th</sup> 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%