



## DEPARTMENT OF CLINICAL NEUROSCIENCE

### **K8F6087, How to Conduct Clinical Research in Psychiatry: From Theory to Practice , 1.5 credits (hec)**

Hur man bedriver klinisk forskning inom psykiatri: från teori till praktik, 1,5

högskolepoäng

*Third-cycle level / Forskarnivå*

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#### **Approval**

This syllabus was approved by The Committee for Doctoral Education on 2025-09-07, and is valid from spring semester 2026.

#### ***Responsible department***

Department of Clinical Neuroscience, Faculty of Medicine

#### **Prerequisite courses, or equivalent**

60 hp in psychology or psychiatry on an advanced level.

#### **Purpose & Intended learning outcomes**

##### **Purpose**

The course aims to cover a range of methods, procedures, and considerations when conducting clinical trials involving people with psychiatric disorders, including testing of psychological and psychiatric (e.g., pharmacological) treatments. The course will provide knowledge about theoretical, methodological, and practical aspects of clinical trials focusing mainly on children and adolescents, but its content is also relevant to people in other age groups (e.g., adults).

Participants will learn about the entire process of conducting a clinical trial, including randomized controlled trials (RCTs) but also feasibility/pilot trials, from developing research questions and study coordination to implementation and publishing of the results.

##### **Intended learning outcomes**

After completing the course, participants should be able to:

- Conduct preparatory groundwork for clinical trials in psychiatric research, including

development of a study protocol and trial registration

- Describe study monitoring and study documentation routines during the conduction of a clinical trial
- Register and report adverse events during the conduction of a clinical trial
- Account for relevant considerations in the choice of assessment method and explain the implications of having multiple informants in clinical trials
- Describe procedures for blind assessments when conducting an RCT

## Course content

- Methodological aspects of clinical trials in psychiatric research
- Reading and discussing published papers relating to psychiatric assessments and psychological as well as pharmacological treatments
- Reading and discussing scientific articles about methodological considerations in clinical trials with children and adolescents and adults
- Conducting group presentations followed by a session discussing various aspects of conducting research in psychiatric settings

## Forms of teaching and learning

Lectures, seminars, group presentations.

### *Language of instruction*

The course is given in English

## Grading scale

Pass (G) /Fail (U)

## Compulsory components & forms of assessment

### Compulsory components

Compulsory attendance at lectures and seminars. Absence can be compensated for by written assignments.

### Forms of assessment

Examination seminar with group presentations and discussions. All students are assessed individually on their ability to present, discuss, and reason about clinical research in psychiatric research. Particularly, students need to actively be able to show their acquired knowledge about methodology in psychiatry research, both during their presentations and in the subsequent discussions. All intended learning outcomes have to be attained to pass the course.

## Course literature

Reference literature:

- Chang, A., Boutron, I., Hopewell, S., Moher, D., Schilz, K.F., Collins, G.S., et al. (2025). SPIRIT 2025 statement: updated guideline for protocols of randomised trials. *BMJ*, 389:e081477.
  - Creswell, C., Nauta, M., Hudson, J., March, S., Reardon, T., Arendt, K., et al. (2021). Research Review: Recommendations for reporting on treatment trials for child and adolescent anxiety disorders - an international consensus statement. *Journal of Child Psychology and Psychiatry*, 62(3):255-269.
  - Freedland, K., Mohr, D., Davidson, K., & Schwartz, J. (2011). Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. *Psychosomatic Medicine*, 73(4), 323–335.
  - Good Clinical Practice Network. Guideline for Good Clinical Practice integrated addendum to ICH. Available at: <https://ichgcp.net/4-investigator>
  - Hopewell, S., Chang, A., Collins, G.S., Hróbjartsson, A., Moher, D., Schulz, K.F., et al. (2025). CONSORT 2025 statement: updated guideline for reporting randomised trials. *BMJ*, 389:e081123.
  - Mataix-Cols, D. & Andersson, E. (2021). Ten practical recommendations for improving blinding integrity and reporting in psychotherapy trials. *JAMA Psychiatry*, 79(9): 943-944.
  - Mohammadi, M. R., & Mostafavi, S. A. (2017). Good Clinical Practice in Children and Adolescents. In: *Clinical Trials in Vulnerable Populations*. Prostran, M. (Ed). IntechOpen.
- Additional readings will be provided during the course.

## Other information

Replacing K8F5287 (title change).