DEPARTMENT OF CLINICAL NEUROSCIENCE

K8F5287, Clinical Research in Child and Adolescent Psychiatry: Methods and Practice, 1.5 credits (hec)

Klinisk forskning inom barn- och ungdomspsykiatri: Metod och praktik, 1,5 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus was approved by the The Committee for Doctoral Education on 2023-12-07, and was last revised on 2024-02-23. The revised course syllabus is valid from autumn semester 2024.

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

To facilitate acquirement of broad as well as in-depth knowledge about methodological and practical aspects of clinical psychiatric research focusing on children and adolescents. The course aims to cover a range of methodological factors in clinical trials on youths with psychiatric disorders, including psychiatric assessment and psychological as well as pharmacological treatment. The course also addresses attitudes, Swedish and international rules and laws relevant to clinical research involving young individuals.

Intended learning outcomes

After completing the course, participants should:
- Be able to explain ethical issues related to having children and adolescents as research subjects
- Be able to conduct preparatory groundwork for clinical trials in psychiatric research, including development of a study protocol, ethical application and trial registration
- Be able to describe study monitoring and study documentation routines in child psychiatric

research
- Be able to register and report adverse events and side effects in studies with children and adolescents
- Be able to account for relevant considerations in the choice of assessment method (e.g., child-adapted diagnostic interviews) and explain the implications of having multiple informants (children, parents and clinicians) in clinical trials with youths
- Be able to desribe procedures for blind assessments with children and adolescents

Course content

During the course participants will:
- Participate in lectures about ethical and methodological aspects of clinical trials with children and adolescents in psychiatric research
- Participate in seminars where participants will discuss published papers relating to psychiatric assessments and psychological as well as pharmacological treatments
- Read scientific articles about methodological considerations in clinical trials with children and adolescents
- Learn how to prepare ethical applications as well as research information and informed consents for research on children and adolescents
- Conduct group presentations where they present their analyses and conclusions about various aspects of conducting research in child 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 child and adolescent psychiatric research. Particularly, students need to actively be able to show their aquired knowledge about methodology in child and adolescents psychiatry research, during their presentations and in the following discussions. All intended learning outcomes have to be

attained to pass the course.

Course literature

Mandatory literature:

Fargas-Malet, M., McSherry, D., Larkin, E., & Robinson, C. (2010). Research with children: methodological issues and innovative techniques. Journal of Early Childhood Research: ECR, 8(2), 175–192.

Mohammadi, M. R., & Mostafavi, S. A. (2017). Good Clinical Practice in Children and Adolescents. In Clinical Trials in Vulnerable Populations. IntechOpen.

Creswell, C., Nauta, M., Hudson, J., March, S., Reardon, T., Arendt, K., Bodden, D., Cobham, V., Donovan, C., Halldorsson, B., In-Albon, T., Ishikawa, S., Johnsen, D., Jolstedt, M., Jong, R., Kreuze, L., Mobach, L., Rapee, R., Spence, S., … Kendall, P. (2020). Research Review: Recommendations for reporting on treatment trials for child and adolescent anxiety disorders - an international consensus statement. Journal of Child Psychology and Psychiatry.

Kirk, S. (2007). Methodological and ethical issues in conducting qualitative research with children and young people: A literature review. International Journal of Nursing Studies, 44(7), 1250–1260.

De Los Reyes, A., & Kazdin, A. (2005). Informant Discrepancies in the Assessment of Childhood Psychopathology: A Critical Review, Theoretical Framework, and Recommendations for Further Study. Psychological Bulletin, 131(4), 483–509.

Reference literature:

Guideline for Good Clinical Practice integrated addendum to ICH. Available at: https://ichgcp.net/4-investigator.

Chan, A., Tetzlaff, J., Gøtzsche, P., Altman, D., Mann, H., Berlin, J., Dickersin, K., Hróbjartsson, A., Schulz, K., Parulekar, W., Krleža-Jeric, K., Laupacis, A., & Moher, D. (2013). SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ: British Medical Journal, 346, e7586–e7586. https://doi.org/10.1136/bmj.e7586

Grills, A., & Ollendick, T. (2003). Multiple Informant Agreement and the Anxiety Disorders Interview Schedule for Parents and Children. Journal of the American Academy of Child and Adolescent Psychiatry, 42(1), 30–40.

Hróbjartsson A, Thomsen AS, Emanuelsson F, Tendal B, Hilden J, Boutron I, et al. Observer bias in randomised clinical trials with binary outcomes: systematic review of trials with both blinded and nonblinded outcome assessors. BM; 344 : e1119

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.

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: recommendations for good practice. Journal of evaluation in clinical practice, 10(2), 307-312