Clinical research methodology, epidemiology and biostatistics, 7.5 credits

1 Course content

The following topics are discussed on the course:
- Study design for epidemiological observational studies including cohort and case-control.
- Intervention studies, including randomised trials.
- Relevant statistical analysis methods for the above designs.
- Hypothesis testing and causal inference
- Assessing results and considering the influence of error, bias and confounding
- Using statistical software (SPSS)

2 Outcomes

2.1 The course in relation to the doctoral programme

The course shall primarily refer to the following intended learning outcomes for third-cycle courses and study programmes as described in the Higher Education Ordinance, i.e. the doctoral student shall demonstrate:

Knowledge and understanding
- broad knowledge and systematic understanding of the research field (part of outcome 1)
- familiarity with research methodology in general (part of outcome 2)

Competence and skills
- the capacity for scholarly analysis and synthesis (part of outcome 3)
- the capacity to review and assess new and complex phenomena, issues and situations autonomously and critically (part of outcome 3)
- the ability to identify and formulate issues with scholarly precision critically, autonomously and creatively (part of outcome 4)
2.2 Intended course learning outcomes

To obtain a passing grade, the doctoral student shall demonstrate:

- The ability to recognize the main types of epidemiological study design and to describe their advantages and disadvantages
- The ability to plan observational and intervention epidemiological studies to answer specific research questions
- To understand epidemiological concepts such as error, bias and confounding and to be able to identify when studies may suffer from these limitations.
- To understand epidemiological concepts such as occurrence (incidence, prevalence) and association (relative risk, odds ratio), as well as using statistical methods to calculate them.
- The ability to identify relevant statistical methods for studies and draw conclusions from the results, including identifying evidence of influences such as bias or confounding.
- The ability to critically review scientific articles and identify study designs and methods, assessing if the conclusions are supported by the results, and identifying if interpretation of the results is potentially limited by issues such as error, bias and confounding.

3 Reading list and other teaching material

The following course readings and teaching material will be used on the course:

Each item on the following reading list refers to the latest edition.

Fletcher Robert H, Fletcher Suzanne W, Grant S. Clinical Epidemiology The Essentials. Wolters Kluwer | Lippincott Williams & Wilkins (Recommended for all)

Machin, Campbell, Walters. Medical Statistics, A textbook for the health sciences. John Wiley & Sons, Ltd (Recommended for all)


Björk J. Praktisk statistik för medicin och hälsa. Liber AB

4 Teaching formats

Teaching on the course takes the following format:

- Lectures
- Computer laboratory work
- Group discussions
- Independent study

5 Examination

The course is assessed through an examination in the format of
a written examination covering all intended course learning outcomes.

6 Grades

Examinations on third-cycle courses and study programmes are to be assessed according to a two-grade scale with either of the grades ‘fail’ or ‘pass’ (local regulations).

The grade shall be determined by a teacher specifically nominated by the higher education institution (the examiner) (Higher Education Ordinance).

To obtain a passing grade on examinations included in the course, the doctoral student is required to demonstrate that he/she attains the intended course learning outcomes as described in section 2.2. Alternatively, if the course consists of multiple examinations generating credit, the doctoral student is required to demonstrate that he/she attains the outcomes that the examination in question refers to in accordance with section 5.

A student who has failed an examination is entitled to a retake.

If an examination consists of several examination components, and a student fails an examination component, the examiner may, as an alternative to a retake, set a make-up assignment with regard to the examination component in question.

A doctoral student who has failed an examination twice for a specific course or course element is entitled, upon his/her request, to have another examiner appointed to determine the grade.

7 Admission to the course

7.1 Admission requirements

To gain access to the course and complete the examinations included in the course, the applicant must be admitted to a doctoral programme at Örebro University.

In addition, the applicant has passed the doctoral course: General Scientific Methods in Medical Science (15 credits) at Örebro University or a corresponding course that covered the necessary epidemiological and statistical methods.

7.2 Selection

Selection between applicants who have been admitted to doctoral programmes at Örebro University and who otherwise meet the admission requirements as listed above is made according to the following order of precedence:

1. Applicants admitted to doctoral programmes within the school of medicine and health
2. Applicants admitted to doctoral programmes within other faculties at Örebro University

If no other selection criteria are specified in this section, priority shall be given to applicants with a lower number of course credits left before the award of their degree over applicants with a higher number of remaining course credits. Should two or more students have equal number of credits, selection will be done through the drawing of lots. This also applies within any selection groups listed unless otherwise stated.

7.3 Other applicants than doctoral students admitted at Örebro University

Other applicants than doctoral students admitted at Örebro University may be given access to the course on the grounds of provisions for and/or agreements regarding contracted courses, joint degrees, national graduate schools or cooperation in other respects with other universities.
Any decisions on what such other applicants may be given access to the course are made separately and on the basis of the provisions and/or agreements that occasion the student to apply for the course.

For participation in the course in other respects, the same provisions shall apply as for doctoral students admitted to Örebro University.

8 Transfer of credits for courses, study programmes and other experience

Provisions on the transfer of credits can be found in the Higher Education Ordinance and on the university’s webpage.

9 Other information

The language of tuition on the course is English with lecturer-led components concentrated to full-time intensive weeks with compulsory attendance. Doctoral students are expected to undertake independent study reading during and after these course weeks.

Transitional provisions