Randomised controlled trials in general practice

PhD course at the Norwegian research school in General Practice

This course addresses methods in performing randomised controlled trials in general practice with a special emphasize on cluster randomised trials. Students will develop an understanding of how to plan, implement, analyze, report and evaluate RCTs. Original research will be presented by principal investigators, followed by discussions of papers with focus on design options and analytic strategies. The lectures will provide methodological background and will cover applied issues typically encountered in studies in general practice. This course is intended primarily for PhD students in general practice. The course includes a qualification in Good Clinical Practice (GCP) for studies in a general practice setting.

Aim: To give insight in how to perform RCTs in a general practice setting.

Learning outcomes: At the end of the course the students will be able to

1. describe how to plan, implement, analyze, report and evaluate RCTs
2. write an outline of a research protocol for RCT in a general practice setting

Course team:
Prof. Elin Olaug Rosvold (EOR), Prof. Jørund Straand (JS), Svein Gjelstad (SG), MD, PhD, Prof. Morten Lindbæk (ML)

Lecturers: Ingvild Vik (IV), MD, Kirsten Valebjørg Knudsen (KVK), MD, Irene Syse (IS), RN, MNSc, Knut Eirik Eliassen (KEE) MD, Espen Saxhaug Kristoffersen (SEK) MD, PhD (All from University of Oslo).

External lecturer: Professor Sandra Eldridge (SE), Queen Mary University of London

Language: Norwegian and English (SE)

Number of participants: 40. Open course. Priority: NAFALM students.

Study points: 4 ECTS (4 days with examination. Literature: 360 pages)

Location: University of Oslo

Time: Every second year. First course 3-5 November 2014.
### Randomised controlled trials in general practice

**Location:** University of Oslo, **Time:** 3-5 November 2014

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<th>Monday 3.11</th>
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| 09.00 – 9.45 | **Part 3: Cluster randomised trials**  
*Lecture 7: Design of cluster randomised trials 1. SE* | **Lecture 14:** Complex intervention in general practice: Rx-PAD study. **SG + JS** |
| 10.00 – 10.30 | **Registration** | **Lecture 15:** Example of RCT in general practice: Epicondylitis study. **ML** |
| 10:30–11:15 | **Part 1: Planning**  
*Lecture 1: RCT in general practice. Possibilities and challenges. JS* | **Group session 2:** Discussion of cluster randomised trials. **(EOR et al)** |
| 11:15–12:00 | **Lecture 2:** Overview of data sources and data collection. Power calculation. Registration. **SG** | **Group session 3:** Complex interventions in general practice. **(EOR et al)** |
| 12:00–13:00 | **LUNCH** | **LUNCH** |
| 13.00–13:45 | **Lecture 3:** Protocol. **SG** | **Part 4: Good Clinical Practice**  
*(GCP) in a general practice setting. **Lecture 9: Planning a GCP IS*** |
| 14.00–14:45 | **Lecture 4:** RCT design in general practice. Example: Ibuprofen vs mecillinam for uncomplicated cystitis. **IV, ML** | **Part 5: Reporting**  
*Lecture 16: Analyses. Statistical methods. **SG*** |
| 15.00–15:45 | **Part 2: Implementation**  
*Lecture 5:** Recruitments of participants. Randomization. Interventions. Data capture. **SG** | **Lecture 17:** Analyses. Statistical methods. **SG** |
| 16.00–16:45 | **Lecture 6:** Organizing RCT. Example: Vitamin D study. **KVK** | **Lecture 18:** Writing a RCT paper. Choice of Journal. **JS, SG** |
| 17:00–18:00 | **Group session 1:** Discussion of RCT papers. **(EOR et al)** | **Lecture 12:** Examples of RCT: Comparing 3 antibiotic regimes for erythema migrans in general practice. **KEE** |
| 19:00 | **Dinner** | **Lecture 19:** Discussion **JS and EOR** |
Home tasks, Compulsory reading and Examination

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<th>Home task group session 1</th>
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Compulsory reading

**Text book:** Sandra Eldridge and Sally Kerry: A practical Guide to Cluster Randomised Trials in Health Services Research (278 pages)
