Provision of methodological knowledge for the quality assessment of primary studies

Training in evidence-based medicine and participation in methodological study

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- Once only in winter semester 2011/12: training in evidence-based medicine and participation in a methodological study instead of exercises and homework (3 ETCS)
- The examination attainment will be delivered in the last session, consisting of the quality assessment of studies by different instruments after being trained in evidence-based medicine.
- Participation in all sessions is absolutely necessary for the data evaluation and analysis, the success of the study, and therefore highly desirable and obligatory. In case of illness, a medical certificate is required.

Dates, Contents

23.11.2011: 14.00-16.00 o‘clock SE005
Theoretical provision of essential terms of EbM and quality criteria, validity assessment of 1 study

18.01.2012: 12.00-16.00 o‘clock SM205
Deepening of the knowledge by simulation of quality aspects, poster presentation, quizz, introduction of assessment instruments, application training

25.01.2012: 14.00-16.00 o‘clock SE005
Execution of the methodological study

Participation in all sessions is absolutely necessary for the data evaluation and analysis, the success of the study, and therefore highly desirable.

Structure of the first session I/III

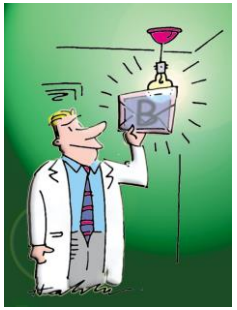
- The concept of evidence-based medicine: the five steps

1. Formulating a well-built question
   - PICO-scheme, example patient from everyday clinical practice
2. Literature research
   - Types of primary and secondary studies, MeSH-terms/Boolean operators, example study as a research result
3. Critical appraisal
   - Validity (internal, external), classification of evidence (G-BA*, AHRQ**), single aspects, assessment of example study
4. Application of results in practice
   - example patient, example study
5. Evaluation

* Gemeinsamer Bundesausschuss = Federal Joint Committee
** Agency for Healthcare Research & Quality

Structure of the first session II/III

- Criteria for the quality assessment
  - Randomisation (single, permuted, cluster, inadequate)
  - Concealment
  - Blinding



Schulz & Grimes. *Lancet 2002; 359:614-618*

The authors: double blinded versus single blinded . *Lancet 2002; 359: 696–700*

  - Drop-out/loss to follow-up
  - ITT (mnemonic: „Once randomised, always analysed“)
  - Sample size calculation (outcome criterion, effect size expected, statistical power, type I-error/level of significance, sample size determined)

Structure of the first session III/III

- Criteria for the quality assessment
  - Sponsoring
  - Bias and its prevention: Selection (Reporting, Publication), Performance, Detection, Attrition, Language, Recall, Citation, Healthy-user, Confirmation
- Assessment of example study
- Limits of evidence-based medicine and criticism

Structure of the second session

- Introduction: Stratification, Reliability/Validity
- Poster presentation
  - Randomisation; concealment; blinding; drop-out, loss to follow-up; ITT- and per-protocol analysis; sample size calculation, confidence intervals, p-values; types of bias
- Simulation of randomisation, blinding, concealment, drop-out, loss to follow-up, ITT
- Introduction of assessment instruments
- Application training
- Verbal quizz between two teams with hangman

Simulation of Randomisation, Blinding, Concealment, Drop-out, ITT

- Random number table in a sealed, opaque envelope
- Prepared dextrose cubes with numbers written on: Blinding of treatment allocation

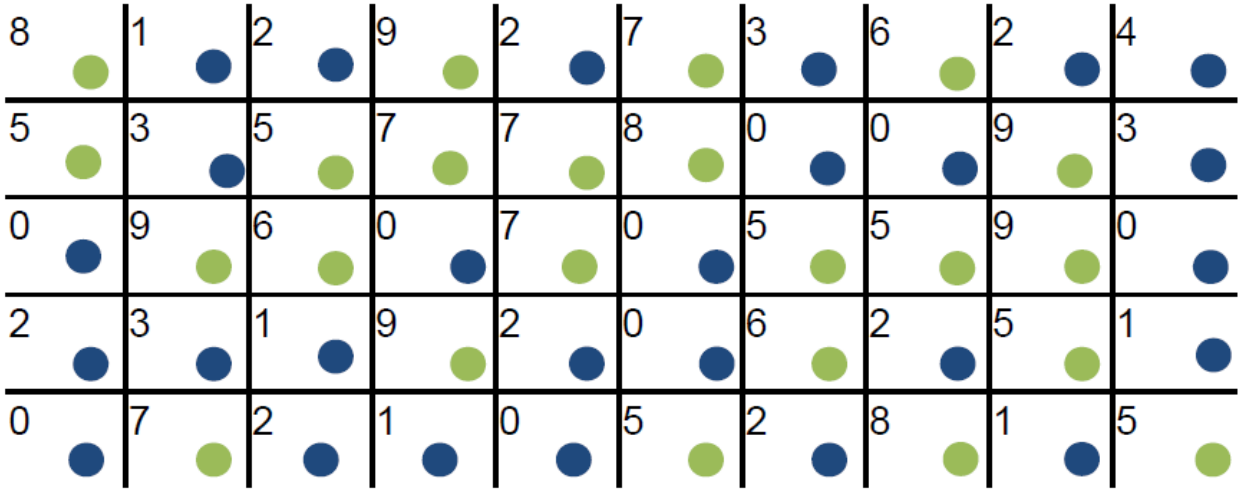
- Stratification
  - By sex
  - By age groups < 25 years and ≥ 25 years

Unblinding (sealed opaque envelope with random number table)

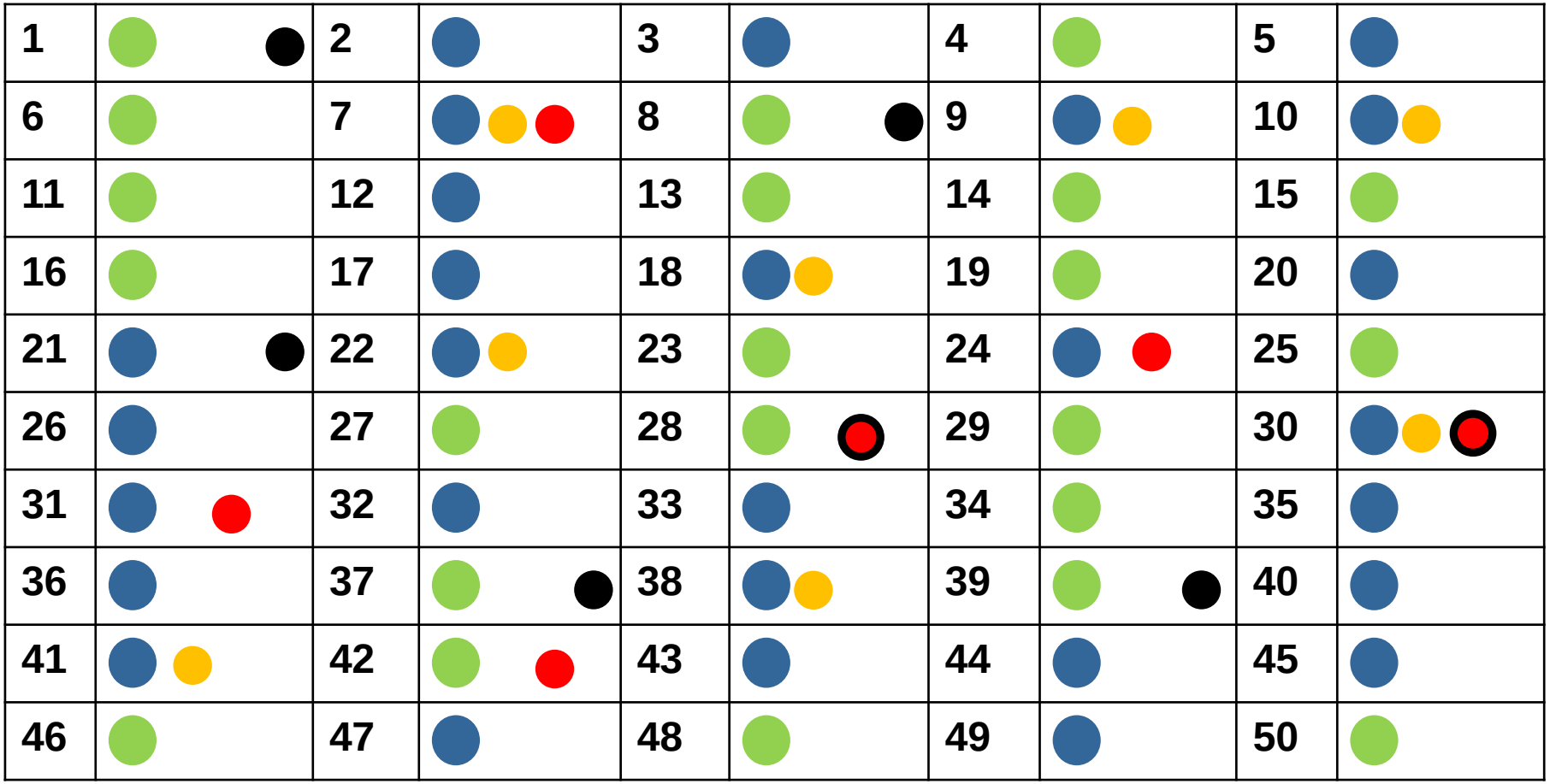
Participant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Random number	8	1	2	9	2	7	3	6	2	4	5	3	5	7	7	8
Participant	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**
Random number	0	0	9	3	0	9	6	0	7	0	5	5	9	0	2	3
Participant	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**
Random number	1	9	2	0	6	2	5	1	0	7	2	1	0	5	2	8

Intervention: **0-4**

Control: **5-9**

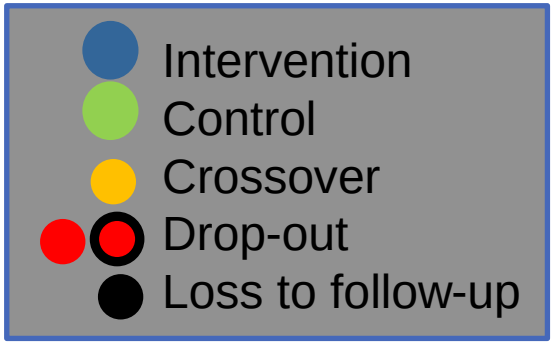


Participants in the study course



Populations for analyses

- **Intention-to-treat population: n=47**
  Intervention: n= 27
  vs. control: n= 20



- **Per-protocol population**
  Intervention: n= 14 (- 8 crossover- 4 drop-out- 1 loss to follow-up)
  vs. control: n= 14 (-2 drop-out- 4 loss to follow-up)

- **As-treated population**
  Intervention: n= 14 (- 8 crossover- 4 drop-out- 1 loss to follow-up)
  vs. control: n= 22 (+ 8 crossover- 2 drop-out- 4 loss to follow-up)

Quality assessment instruments

Julian Higgins

THE COCHRANE COLLABORATION®

Helen Thomas

Catherine L. Hill

Peter Jüni

Jürgen Windeler

IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions 5.1.0. Oxford, UK: The Cochrane Collaboration; 2011

Hill CL, La Valley MP, Felson DT. Arthritis and Rheumatism 2002; 46(3): 779-84.

Huwiler-Müntener K, **Jüni P**, Junker C, Egger M. JAMA 2002; 287(21): 2801-2804.

IQWiG 2008. Früherkennungsuntersuchung von Sehstörungen bei Kindern bis zur Vollendung des 6. Lebensjahres. Abschlussbericht 2008. Köln, IQWiG-Berichte, Nr. 32.

Thomas BH, Ciliska D, Dobbins M, Micucci S. Worldviews on evidence-based nursing 2004; 1(3): 176-184.

Cochrane risk of bias tool

No	Criterion	Judgement		Support for judgement	
1	**Random sequence generation** (selection bias)	High risk Low risk Unclear risk	☐ ☐ ☐	Quote: Comment:	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
2	**Allocation concealment** (selection bias)	High risk Low risk Unclear risk	☐ ☐ ☐	Quote: Comment:	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.
3	**Blinding of participants and personnel** (performance bias)	High risk Low risk Unclear risk	☐ ☐ ☐	Quote: Comment	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.

Thank you for your attention

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