CAS Clinical Research: Writing a Study Protocol – From theory into practice

Nathalie Schwab

Institute of Primary Health Care

University of Bern

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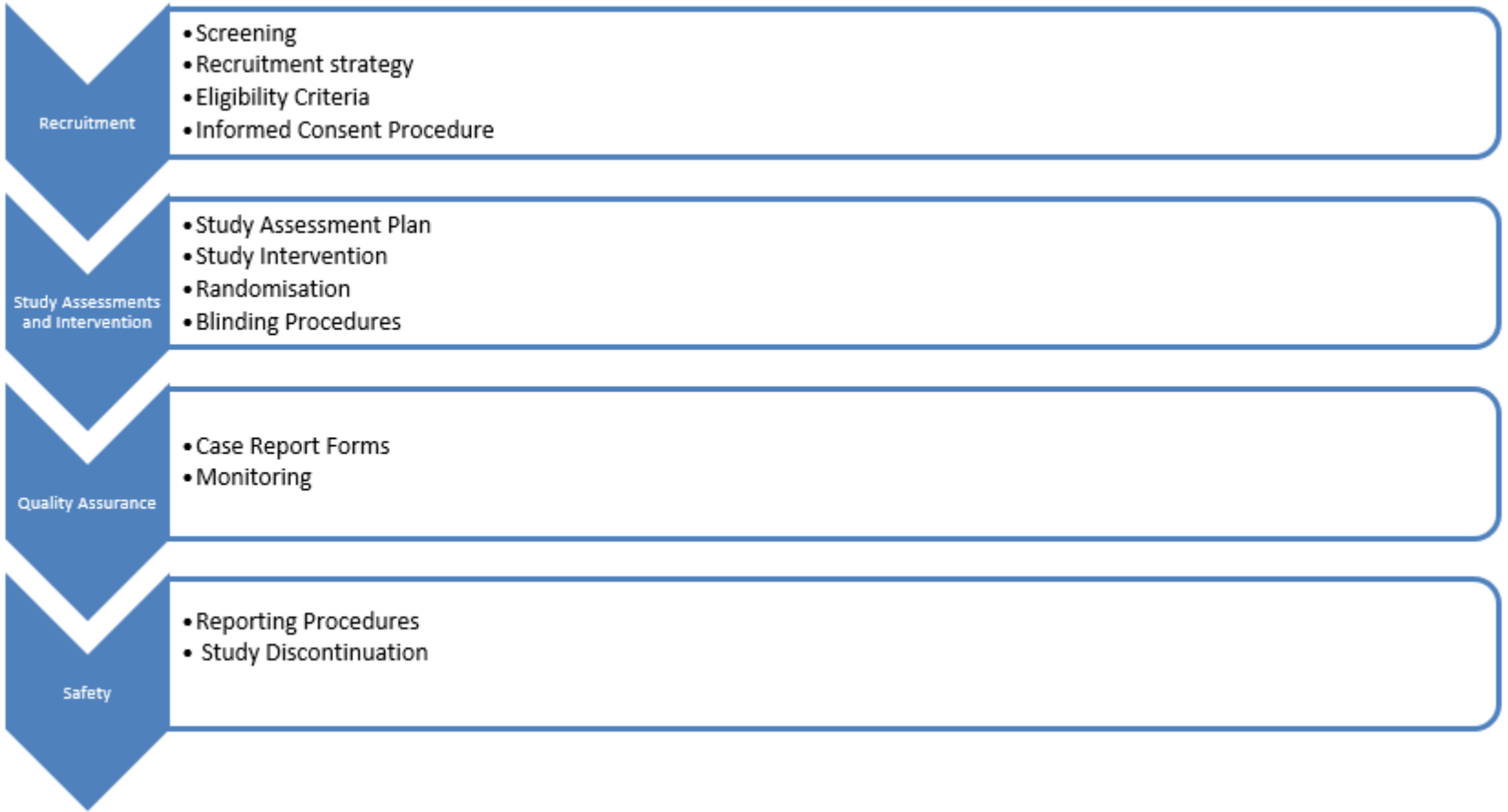
Tafers
Schönberg 10 min
Freiburg 1h 05 min
Pulvermüli 1h 25 min
Tasberg 15 min
St. Ursen 40 min
Alterswil 50 min
1h 45 min
Schürmatt
Bourguillon 15 min
Freiburg 1h
1h 20 min
4
4


Recruitment
• Screening
• Recruitment strategy
• Eligibility Criteria
• Informed Consent Procedure
Study Assessments and Intervention
• Study Assessment Plan
• Study Intervention
• Randomisation
• Blinding Procedures
Quality Assurance
• Case Report Forms
• Monitoring
Safety
• Reporting Procedures
• Study Discontinuation

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Recruitment: practical aspects to think of during the writing process

- How will the screening be done?
  - Electronic health record (by study team member)
  - Automated process (f.ex. IDCL at Inselspital)
  - Out of a pre-defined list/existing study population (f. ex. substudies)
  - By external collaborators (f. ex. GPs)
- What will be the most effective way to approach potential study participants?
  - Flyer / Social Media
  - Personal letter
  - By a study nurse during the hospitalization

☑ The better you plan and describe your recruitment/screening strategy the easier the implementation will be

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Recruitment: practical aspects to think of during the writing process

- Eligibility criteria
  - Use clear definitions
    - → Example: «cancer»: active cancer? All types of cancer?
- Informed consent procedure
  - Who is allowed to sign the informed consent?
    - → Study Nurse / Doctor?
    - → Participant himself / Proxy / legal representative?
  - Describe the procedure itself in detail

> The investigator or the study nurse will explain to each participant (and legal representatives for minors) the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks and benefits and any discomfort it may entail. Each participant will be informed that the participation in the study is voluntary and that they may withdraw from the study at any time and that withdrawal of consent will not affect their subsequent medical assistance and treatment.

☑ The better the exclusion/inclusion criteria are defined, the less questions you will get

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Study assessments and intervention: practical aspects to think of during the writing process

- Provide a clear study flow chart / Assessment Plan
  - Visit windows
  - Split into different parts if needed

	Study Part 1 – Observation phase		Study Part 2 – Intervention phase				Optional follow-up
Visit	Visit 1	*Visit 2*	Visit 3	*Visit 4*	*Visit 5*	Visit 6	*Visits 7,8,9*
	Baseline	*Interim (phone)*	Randomization	*Interim (phone)*	*Interim (phone)*	Closing	*Follow-up (phone)*
Time (adults)	- 4 weeks	*- 2 weeks*	0	*2 months*	*4 months*	6 months	*12, 18, 24 months*
(adolescents)	- 2 weeks	*- 1 week*	0	*2 weeks*	*4 weeks*	6 weeks	*4, 6, 8 months*
Window for assessment	n/a	*± 5 days*	± 5 days	*± 5 days*	*± 5 days*	± 2 weeks	*± 2 weeks*
Study schedule							
Information + Consent	x						
Incl./exclusion criteria	x		x				
Randomization			x				
Measurements							
Demographics	x						
Medical history	x						
Hospitalization and medication	x	x	x	x	x	x	x
Lifestyle	x					x	
Sleeping habits	x					x	
Vital signs	x		x			x	*Weight only*
Blood tests	x		X			x	
Liver steatosis (Fibroscan)			x			x	
Outcomes							
Primary outcome	Short description		Short description				Short description
Secondary outcomes	Short description		Short description				Short description

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Study assessments and intervention: practical aspects to think of during the writing process

- Provide a clear description of the Study Procedures
  - Detailed description of what to do and when
  - Try to anticipate – f.ex. «laboratory values measured at admission or up to 3 months before admission»

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Study assessments and intervention: practical aspects to think of during the writing process

- Study Intervention
  - Clear description of intervention – f. ex. «the intervention will take place during the hospital stay»
  - Clear description of responsibilites - f. ex. «participants in the control group will receive intervention X by the prescribing physician»
- Randomisation
  - Backup-plan if technical issues arise
- Blinding procedures
  - How can blinding be mantained if needed – f.ex. if only part of the team is blinded
  - Unblinding procedures – f.ex. who is responsible for unblinding, what happens during weekends / holidays

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Quality Assurance: practical aspects to think of during the writing process

- Case Report Forms
  - pCRF or eCRF ?
  - Creation of the database - f.ex. user-friendly structure in line with study visit procedures
  - Clear description in the protocol if only eCRF will be used
- Monitoring
  - Central data monitoring – who will be responsible ?

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Safety: practical aspects to think of during the writing process

- Reporting Procedures
  - SAEs and AEs?
  - Clear definition of AEs of special interest
  - Description of responsiblities and reporting procedures to Sponsor / Investigator
- Study discontinuation
  - Clear definition of criteria for study discontinuation

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A project manager‘s view on the protocol

- Recruitment
  - Recruitment numbers:
    → Staff needed to meet the recruitment goal (budget for salaries!)
    → Duration of recruitment phase /overlap with follow-up phase (facilities and staff)
  - In-hospital:
    → Recruitment potential – pilot study?
  - External participants:
    → Budget for recruitment campaign
    → Budget for travel (study nurse and/or participants)
    → Budget for reimbursement

A project manager‘s view on the protocol

- Study Assessments and Intervention
  - Study Visits
    - → Staff needed to perform the visits (budget for salaries, f.ex. study nurse, research fellow, student)
    - → Material needed to perform the visits (budget for blood tubes, shipment costs, IT material, etc.)
- Quality Assurance
  - Staff needed to perform the central data monitoring (salaries, office)
- Safety
  - Staff needed for a data safety monitoring board (reimbursement)
  - Staff needed for adjudication (reimbursement)

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Take-home message

- ☑ Let your study nurse/project manager read the study protocol before the submission
- ☑ Think of the budget !

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Questions ?

Thank you very much for your attention!

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References

- https://www.swissethics.ch/assets/studienprotokollvorlagen/clinicalstudyprotocol_template_e.pdf
- https://www.fedlex.admin.ch/eli/cc/2013/643/en