Clinical research: getting started

Lisa Harvey

Rehabilitation Studies Unit
Faculty of Medicine
University of Sydney

Moorong Spinal Unit
Royal Rehabilitation Centre Sydney
Role:

- teach graduate medical and allied health students
- conduct research
- advocate for people with disabilities
- advise policy makers
- supervise masters, PhD and post graduate students
- encourage evidence-based practice
Overview

During this session:

1. why do research
2. benefits for clinical sites
3. how to get started
4. picking a doable project
5. key design features
6. getting published
1. Why do research

Motivating factors for clinicians:

- answer a question
- improve understanding of research
- increase job satisfaction and intellectual stimulation
- develop new skills
- broaden knowledge in topic area
- to achieve something tangible
- progress career
2. Benefits for clinical sites

These include:

- creates a more dynamic and intellectually stimulating work environment
- attracts and keeps high quality staff
- enhances reputation of clinical site
2. Benefits for clinical sites

The risks:

- waste your, your hospital’s and your patient’s time, money and effort
- final product = poor and unpublishable study with misleading results
3. How to get started

To get started:

- enroll in research-based post graduate degree
- team up with someone with experience
- participate in an up-and-running trial
- upgrade your quality projects
- participate in journal clubs
3. How to get started

Master the following skills:

- understanding of research design
- IT skills – word, excel, powerpoint, graphical software, statistical software, reference manager software, file management
- database searching
- writing, writing ……..and more writing
- presenting
3. How to get started

General principles

- lower your ambitions - your first research project is primarily about learning the process

- do not start data collection until you have run the project past someone with experience
4. Picking a doable project

General principles

- start with something small and containable
- mould the question around the characteristics of your patients/subjects
- try to get financial support but....difficult
4. Picking a doable project

Make sure you know what is out there

- do comprehensive search of PEDrO, medline, pubmed etc.
- set-up automated searches
- search trial registries
5. Key design features

Types of studies

- reliability/validity studies
- clinical trials
- prognostic studies
- aetiology studies
- systematic reviews
5. Key design features

Reliability/validity studies:

➤ easiest

➤ do not be tempted to design a new assessment tool

➤ ensure your sample is representative of intended population
5. Key design features

Clinical trials (treatment effectiveness):

- ambitious but doable
- aim for quality with minimal susceptibility to bias
- do not look at treatments for prevention unless what you are trying to prevent is EXTREMELY common
- follow the CONSORT guidelines
- quantify size of treatment effects (not statistical significance)
Prognostic studies (prediction):

- difficult to do well
- must have consecutive and representative sample
- no more than one predictor for every 10 subjects
- must follow-up everyone
- need to quantify strength of predictors (not statistical significance)
- must not be tempted to imply causation
5. Key design features

Aetiology studies:

- avoid at ALL cost – extremely difficult to do well
- must have consecutive and representative sample
- must measure every factor which could influence outcome
- must account for confounding between variables
5. Key design features

Systematic reviews:

- requires good understanding of stats
- could do as first project but tricky
- avoid just tabulating and paraphrasing authors’ conclusions
- read the Cochrane manual
- follow PRISMA guidelines
6. Getting published

Key points:

- aim for appropriate journal
- start writing the paper from day one
- attention to detail
- work on expression
- don’t make is unnecessarily complex
- say is as it is – don’t talk it up
- understand the review process
Your ideas
Lisa Harvey
l.harvey@usyd.edu.au

Moorong Spinal Unit
Royal Rehabilitation Centre Sydney

Rehabilitation Studies Unit
University of Sydney