**Edinburgh Imaging**
www.ed.ac.uk/edinburgh-imaging

# Study Design

**Semester 2 / January                    10 Credits**

**Each Course is composed of Modules & Activities.**

**Modules:**

| | | |
|---|---|---|
| What's my question | IMSc | NI4R |
| Sources of bias | IMSc | NI4R |
| Blinding | IMSc | NI4R |
| Randomisation | IMSc | NI4R |
| How many subjects | IMSc | NI4R |

**Each Module is composed of Lectures, Reading Lists, MCQ self-assessments, & Discussion Boards.**

These Modules are taught on the following Programmes, or are incorporated into blended Courses which teach students enrolled outwith the Edinburgh Imaging Academy:

- NI4R - Neuroimaging for Research programme
- IMSc - Imaging programme

**Modules:**

**What's my question:**
   What's my question?

**Sources of bias:**
   Sources of bias in the design of studies assessing diagnostic tests

**Blinding:**
   Blinding

**Randomisation:**
   Randomisation – when and why?
   What can go wrong and some practicalities

**How many subjects:**
   Introduction
   Calculating sample size

# What's my question?

Lecture 1
**Title: What's my question?**
Description: An introduction to how to design good imaging studies
Author(s): Prof. Joanna Wardlaw
**Learning Objectives**
- Specify your research question
- Design your study to address that question whether imaging is being used:
    - as a diagnostic test
    - to explain disease pathophysiology
    - to understand normal brain function

# Sources of bias

Lecture 1
**Title: Sources of bias in the design of studies assessing diagnostic tests**
Description: A summary of the main factors which can bias research results
Author(s): Prof. Joanna Wardlaw
**Learning Objectives**
- List major sources of bias in the design of imaging studies
- Describe each type of bias
- Describe the effect that each bias would have on the results of the research
- Describe how to recognize and avoid such bias when designing future studies

# Blinding

Lecture 1
**Title: Blinding**
Description: An introduction to the importance of blinding in the design of good imaging studies
Author(s): Prof. Joanna Wardlaw
**Learning Objectives**
- Explain why blinding of assessments is important in research studies using imaging
- Give examples of where lack of blinding may have influenced results
- Give examples of how failure to blind can influence study results
- Give examples of how assessments can be blinded

# Randomisation

Lecture 1
**Title: Randomisation – when and why?**
Description: An outline of reasons for randomisation and its benefits
Author(s): Prof. Joanna Wardlaw
**Learning Objectives**
- Explain why randomisation is important in research studies using imaging
- Outline benefits of randomisation
- Discuss when and why randomisation is necessary
- Discuss the principles of randomisation including stratification and minimisation

Lecture 2
**Title: What can go wrong and some practicalities**
Description: Some examples of randomisation problems with studies and practicalities of randomisation
Author(s): Prof. Joanna Wardlaw
**Learning Objectives**
- Describe how lack of random allocation of images to observers or of subjects to imaging techniques may influence results
- Give examples of different types of problem that have arisen when studies did not use randomisation properly
- Give practical examples of how assessments can be randomised

# How many subjects?

Lecture 1
**Title: Introduction**
Description: An introduction to why sample size is important and how to calculate it
Author(s): Dr Francesca Chappell, Prof. Joanna Wardlaw
**Learning Objectives**
- Describe why sample size is an important determinant of the reliability of research results and a crucial step in study design
- Explain why different methods of sample size calculations may be appropriate for different studies
- Find more information on sample size calculation

Lecture 2
**Title: Calculating sample size**
Description: Worked and practice examples of sample size calculation based on evaluation of diagnostic accuracy (sensitivity and specificity)
Author(s): Dr Francesca Chappell, Prof. Joanna Wardlaw
**Learning Objectives**
- Perform a simple sample size estimation
- Find more information on sample size calculation