Randomised controlled trials in nursing and midwifery research - establishing the evidence for healthcare practice - a case study of current trials

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Evidence for practice in acute care nursing

• Largely based on expert opinion
  – Examples of previous care based on expert opinion – bedrest following AMI, egg white and oxygen for pressure injury prevention

• Research development in Nursing
  – Previously based in other disciplines e.g. psychology, sociology etc
Why RCTs are done

• Evidence of efficacy
• Minimise bias in the testing process
  - Randomised group allocation
  - Blinding of participants, health professionals, outcome assessors etc
  - Standardisation of outcome assessment
• Maximise safety for participants
Issues for non-pharmacological trials

- Intervention may not be a singularity
- True placebo/control may not be available or ethical
- Cannot randomise patients if a bundled nursing intervention is being tested
- Blinding of intervention administrator may not be possible
Design modifications

- Non-inferiority trial
- Cluster randomised controlled trial
- Case control
- Pragmatic clinical trial – non-equivalent control
- Cohort studies
Examples and issues

• Vascular access devices

• Pressure injury prevention
Issues in clinical trials

- Team construction
- Approvals processes
- Recruitment and retention of participants
- Randomisation
- Intervention fidelity
- Outcome assessment
- Publication
My research matters because:

• Impact
  - Reduction in mortality
  - Reduction in suffering
  - Reduction in healthcare cost

• Development of skills and systems to undertake rigorous trials