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outcomes; 1.11.1 The model; 1.11.2 The ICC for binary data; 1.11.3 The coefficient of variation
1.11.4 Relationship between cvc and for binary data 1.12 The design effect; 1.13 Commonly asked questions; 1.14 Websources; Exercise; Appendix 1.A; Chapter 2 Design issues; 2.1 Introduction; 2.2 Issues for a simple intervention; 2.2.1 Phases of a trial; 2.2.1.1 Preclinical; 2.2.1.2 Sequence of phases; 2.2.2 'Pragmatic' and 'explanatory' trials; 2.2.3 Intention-to-treat and per-protocol analyses; 2.2.4 Non-inferiority and equivalence trials; 2.3 Complex interventions; 2.3.1 Design of complex interventions; 2.3.1.1 Theory (preclinical); 2.3.2 Phase I modelling/qualitative designs
2.3.3 Pilot or feasibility studies 2.3.4 Example of pilot/feasibility studies in cluster trials; 2.4 Recruitment bias; 2.5 Matched-pair trials; 2.5.1 Design of matched-pair studies; 2.5.2 Limitations of matched-pairs designs; 2.5.3 Example of matched-pair design: The Family Heart Study; 2.6 Other types of designs; 2.6.1 Cluster factorial designs; 2.6.2 Example cluster factorial trial; 2.6.3 Cluster crossover trials; 2.6.4 Example of a cluster crossover trial; 2.6.5 Stepped wedge; 2.6.6 Pseudorandomised trials; 2.7 Other design issues; 2.8 Strategies for improving precision; 2.9 Randomisation
2.9.1 Reasons for randomisation 2.9.2 Simple randomisation; 2.9.3 Stratified randomisation; 2.9.4 Restricted randomisation; 2.9.5 Minimisation; Exercise; Appendix 2.A; Chapter 3 Sample size: How many subjects/clusters do I need for my cluster randomised controlled trial?; 3.1 Introduction; 3.1.1 Justification of the requirement for a sample size; 3.1.2 Significance tests, P-values and power; 3.1.3 Sample size and cluster trials; 3.2 Sample size for continuous data-comparing two means; 3.2.1 Basic formulae; 3.2.2 The design effect (DE) in cluster RCTs; 3.2.3 Example from general practice
3.3 Sample size for binary data-comparing two proportions

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