Contents

List of Figures, Boxes and Tables Preface Acknowledgements		V
		viii x
1	Background to Controlled Trials	1
2	The Limitations of Before and After Designs	9
3	History of Controlled Trials	17
4	What is Special About Randomisation?	22
5	Sources of Bias Within Randomised Trials	44
6	Placebo and Sham Trials	71
7	Pragmatic and Explanatory Trials	76
8	Designs to Deal with Participant Preference	87
9	Cluster Randomised Controlled Trials	99
10	Unequal Randomisation	108
11	Factorial Randomised Controlled Trials	114
12	Pilot Randomised Controlled Trials	119
13	Sample Size and Analytical Issues	127
14	Measuring Outcomes	147
15	Recruitment into Randomised Trials	152
16	Systematic Reviews of Randomised Controlled Trials	160
17	Economic Evaluation Alongside Randomised Trials	175
18	Conclusions	185
References		192
Index		209

List of Figures, Boxes and Tables

1.1	Schematic outline of a randomised trial	2
2.1		13
5.1	Example of consent bias	55
	Composition of participants for two alternative	
	interventions	90
8.2	Composition of participants in a fully randomised	
	preference design	91
8.3	Preference results of neck pain trial	92
	Zelen's single consent method	94
	Cluster and individually randomised trials of hip	
	protectors	104
16.1	CONSORT flow diagram	167
	Meta-analysis and Forest plot of systematic phonics	
	teaching on reading skills	168
Box	es	
1.1	The CAST trial	5
1.2	Scared straight	7
7.1	Evidence for the use of a balanced design	83
8.1	Evidence for preference effects in education	89
8.2	Evidence for Zelen's method	97
10.1	Review of unequal allocation	111
12.1	Review of pilot trials	120
Tabl	es	
4.1	Stratified randomisation by blocking	33
4.2	Example of minimisation	38
5.1	Numerical disparity in a blocked randomised trial	47
5.2	Paired randomisation of ten pupils paired on gender	53
5.3	Imbalance caused by attrition	53
	Attempting to correct for drop-out	53
5.5	Characteristics of participants at recruitment by allocated	
	group for managing back pain in the UK BEAM	
	pilot study	56

5.6	Baseline characteristics of a trial with two distinct	
	subgroups	64
5.7	Follow-up scores after excluding those who did not get	
	the intervention	64
5.8	Follow-up scores after using 'on-treatment' analysis	65
5.9	Comparison of on-treatment versus intention to treat	
	analysis	66
7.1	Summary of different trial characteristics of pragmatic	
	versus explanatory trials	84
8.1	Theoretical impact of preferences	88
8.2		
	preference design	93
10.1	Effect on detectable difference by increasing size of	
	control group	110
10.2		113
11.1	Factorial trial of learning the highway code	115
11.2	3 × 2 factorial design	116
11.3	Factorial design of incentives trial	117
11.4		117
13.1	Effect size and numbers needed to treat or teach	131
13.2	Effect sizes and confidence intervals	136
13.3	Different strategies for comparing pre-test characteristics	
	of randomised groups	140
13.4		142
13.5		145
14.1		149
15.1	Recruitment problems in a sample of trials	153
16.1	Modified CONSORT quality criteria	165
16.2		166
16.3		170
16.4		171
18.1		
	or no different to alternative interventions, as	
	demonstrated by RCTs	189