

Contents

	<i>Preface</i>	<i>page xi</i>
1	Introduction	1
	1.1 Why study interventions?	1
	1.2 How can you tell whether an intervention is effective?	3
2	Interventions	15
	2.1 What type of interventions are commonly evaluated in medicine and public health?	15
	2.2 How do I design an intervention?	15
3	Evaluating an intervention	23
	3.1 How do I engage stakeholders?	23
	3.2 What data should I collect for evaluating my intervention?	23
	3.3 How do I choose a control group for evaluating my intervention?	24
	3.4 How do I collect data and choose a control group for an intervention that I did not develop?	28
	3.5 What outcomes of an intervention should I assess?	33
	3.6 Why measure the exposure of subjects to an intervention?	34
	3.7 Should I use a longitudinal cohort or a serial cross-sectional design?	35
	3.8 How do I develop measurement instruments?	37
	3.9 How do I state the hypothesis of an intervention study?	38
	3.10 Can an intervention study have more than one hypothesis?	40
	3.11 Why should I have an analysis plan?	40
	3.12 How do I calculate sample size for an intervention study?	42
	3.13 How do I obtain an institutional review board (IRB) review for a study?	43

3.14	When do I need an independent data and safety monitoring committee?	45
3.15	Why should I register my trial?	45

4**Randomized designs****47**

4.1	What are randomized studies?	47
4.2	What are the advantages of randomization?	47
4.3	What are the disadvantages of randomization?	49
4.4	What are the different methods of allocating subjects?	50
4.5	What is clustered (group) randomization?	52
4.6	What can be randomized besides individuals or clusters of individuals?	54
4.7	When should subjects and researchers be masked (blinded) to treatment assignment?	55
4.8	How do I account for subjects who do not adhere to their treatment?	56

5**Nonrandomized studies****61**

5.1	What are nonrandomized studies?	61
5.2	Why perform nonrandomized studies?	61
5.3	What are the disadvantages of nonrandomization?	65
5.4	How can I assemble comparable samples in the design phase without randomization?	68

6**Statistical analysis of intervention trials****73**

6.1	How do I test whether my intervention has had a statistically significant effect?	73
6.2	Is the difference between the pre-intervention and the post-intervention assessment statistically significant in a longitudinal study?	74
6.3	Is the difference between the pre-intervention and the post-intervention assessment statistically significant in a serial cross-sectional study?	81
6.4	Is the difference between the pre-intervention and the post-intervention assessment of the intervention group statistically greater (lesser) than that seen in the comparison group(s) in a longitudinal cohort study?	83

- 6.5 Is the difference between the pre-intervention and the post-intervention assessment of the intervention group statistically greater (lesser) than that seen in the comparison group(s) in a serial cross-sectional study? 95
- 6.6 Is the post-intervention assessment of the intervention group significantly different than the corresponding assessment of the comparison group? 97

7**Methods for adjusting for baseline differences between treatment groups****101**

- 7.1 How do I adjust for baseline differences between persons who receive the intervention and those who don't? 101
- 7.2 What are propensity scores? How are they calculated? 101
- 7.3 Which variables should be included in a propensity score? 105
- 7.4 How do you assess the adequacy of a propensity score? 106
- 7.5 How are propensity scores used to adjust for baseline differences? 108
- 7.6 What is instrumental variable analysis? How is it used to adjust for baseline differences between groups? 115
- 7.7 What are the underlying assumptions of instrumental variable analysis? 119
- 7.8 How is instrumental variable analysis performed? 124
- 7.9 What are the limitations of instrumental variable analysis? 125
- 7.10 How do the results of multivariable adjustment alone, propensity scores, and instrumental variable analysis compare? 126
- 7.11 What is sensitivity analysis? 126

8**Time series analysis****128**

- 8.1 How do I use time series analysis to analyze how an intervention affects a series of observations over time? 128
- 8.2 How many observations are needed for performing an interrupted time series analysis? 133

9**Special topics****135**

- 9.1 What methods are available for evaluating interventions that do not occur to all subjects at the same time? 135
- 9.2 What if I want to prove that an intervention is not inferior or is equivalent to another intervention? 138

Cambridge University Press

978-0-521-51488-0 - Evaluating Clinical and Public Health Interventions: A Practical Guide to Study Design and Statistics

Mitchell H. Katz

Table of Contents

[More information](#)

x

Contents

9.3	How do I adjust for multiple comparisons?	140
9.4	Should a trial have pre-specified interim analyses with early stopping rules?	143
9.5	How do I analyze subgroup differences in the response to an intervention?	146
9.6	How should I deal with missing data in my intervention study?	148
9.7	What special considerations are there for publishing the results of intervention trials?	149
9.8	What special considerations are there for publishing negative studies?	152

10

Research to action

154

10.1	How do you translate research into practice?	154
10.2	How is the translation of interventions assessed?	156

11

Conclusion

158

	<i>Index</i>	159
--	--------------	-----