

LESLIE D. ROSENSTEIN

RESEARCH DESIGN AND ANALYSIS

A PRIMER FOR THE NON-STATISTICIAN

WILEY

Research Design and Analysis

Research Design and Analysis

A Primer for the Non-Statistician

Leslie D. Rosenstein

University of Texas Southwestern Medical Center

WILEY

This edition first published 2019
© 2019 John Wiley & Sons Inc.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, except as permitted by law. Advice on how to obtain permission to reuse material from this title is available at <http://www.wiley.com/go/permissions>.

The right of Leslie D. Rosenstein to be identified as the author of this work has been asserted in accordance with law.

Registered Office

John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030, USA

Editorial Office

111 River Street, Hoboken, NJ 07030, USA

For details of our global editorial offices, customer services, and more information about Wiley products visit us at www.wiley.com.

Wiley also publishes its books in a variety of electronic formats and by print-on-demand. Some content that appears in standard print versions of this book may not be available in other formats.

Limit of Liability/Disclaimer of Warranty

While the publisher and authors have used their best efforts in preparing this work, they make no representations or warranties with respect to the accuracy or completeness of the contents of this work and specifically disclaim all warranties, including without limitation any implied warranties of merchantability or fitness for a particular purpose. No warranty may be created or extended by sales representatives, written sales materials or promotional statements for this work. The fact that an organization, website, or product is referred to in this work as a citation and/or potential source of further information does not mean that the publisher and authors endorse the information or services the organization, website, or product may provide or recommendations it may make. This work is sold with the understanding that the publisher is not engaged in rendering professional services. The advice and strategies contained herein may not be suitable for your situation. You should consult with a specialist where appropriate. Further, readers should be aware that websites listed in this work may have changed or disappeared between when this work was written and when it is read. Neither the publisher nor authors shall be liable for any loss of profit or any other commercial damages, including but not limited to special, incidental, consequential, or other damages.

Library of Congress Cataloging-in-Publication Data

Names: Rosenstein, Leslie D., author.

Title: Research design and analysis : a primer for the non-statistician /

Leslie D. Rosenstein, UT Southwestern Medical Center.

Description: Hoboken, NJ : Wiley, 2019. | Includes bibliographical references and index. |

Identifiers: LCCN 2019003539 (print) | LCCN 2019017653 (ebook) | ISBN 9781119563624 (Adobe PDF) | ISBN 9781119563617 (ePub) | ISBN 9781119563594 (hardback)

Subjects: LCSH: Medicine—Research—Methodology. | BISAC: SOCIAL SCIENCE / Sociology / General.

Classification: LCC R850 (ebook) | LCC R850 .R67 2019 (print) | DDC 610.72—dc23

LC record available at <https://lccn.loc.gov/2019003539>

Cover image: © oxygen/Getty Images

Cover design by Wiley

Set in 10/12pt WarnockPro by SPi Global, Chennai, India

Printed in the United States of America

10 9 8 7 6 5 4 3 2 1

I am grateful for my loving and supportive family who has helped me overcome some hefty obstacles. I would not have been able to write this book without the support of Jean, Marv, Dana, Shari, Kevin, Cory, and Caleigh.

I also want to acknowledge my students at UT Southwestern Medical Center for their patience and interest. Their reactions during class discussions, though hard to read at times, helped guide me in organizing and formulating the chapters of this primer. I especially want to thank Dr. Mallory Jacobs who inspired me to try to write something succinct and user-friendly for busy physicians who want to be good consumers of clinical research.

Contents

List of Figures *xiii*

List of Tables *xv*

Introduction *xix*

Section 1 The Purpose, Ethics, and Rules of Research 1

- 1 The Purpose and Ethics of Research 3**
- 1.1 The Purpose and Risks of Research 3
- 1.2 History of Harm to Humans 4
- 1.3 Ethical Issues in the Social Sciences 9
- 1.4 History of Harm to Animal Subjects in Research 10
- 1.4.1 Summary 12
- 1.5 Ethics, Principles, and Guidelines 12
- 1.6 Statutes and Regulations Protecting Humans and Animals in Research 16
- 1.7 More About Informed Consent 18
- 1.8 The Importance of Freedom to Withdraw 22
- 1.9 Separation of Provider–Researcher Role 22
- 1.10 Undue Influence 24
- 1.11 Anonymity 24
- 1.12 Summary 25

Section 2 Basic Research Designs and Validity 27

- 2 Research Validity 29**
- 2.1 Internal Validity 30
- 2.1.1 History 30
- 2.1.2 Maturation 31
- 2.1.3 Measurement Error 32

- 2.1.4 Selection Bias and Random Assignment 33
- 2.1.5 Attrition 35
- 2.1.6 Experimenter Bias 35
- 2.1.7 Expectation 36
- 2.1.8 Sensitization and Practice Effects 36
- 2.1.9 Incorrect Conclusions of Causality 37
- 2.2 External Validity 37
- 2.3 Summary 45

3 Research Designs 47

- 3.1 The Lingo 47
- 3.2 Between-Subjects Designs 49
 - 3.2.1 More Examples of Between-Subjects Designs 49
 - 3.2.2 Statistical Analyses for Between-Subjects Designs 50
- 3.3 Within-Subjects Designs/Repeated Measures 52
 - 3.3.1 Statistical Analyses for Within-Subjects Designs 53
- 3.4 Between–Within Subjects Designs (Mixed Factorial/Split-Plot Designs) 54
 - 3.4.1 Statistical Analyses for Between–Within Subjects Designs 55
- 3.5 Latin Square Designs 57
 - 3.5.1 Summary 59
 - 3.5.2 Double Latin Square Designs 59
 - 3.5.3 Graeco-Latin and Hyper Graeco-Latin Square Designs 59
- 3.6 Nesting 60
- 3.7 Matching 60
- 3.8 Blocking 61
- 3.9 Nonexperimental Research 62
- 3.10 Case Studies 62
- 3.11 Summary 64

Section 3 The Nuts and Bolts of Data Analysis 65

4 Interpretation 67

- 4.1 Probability and Significance 67
- 4.2 The Null Hypothesis, Type I (α), and Type II (β) Errors 68
- 4.3 Power 69
- 4.4 Managing Error Variance to Improve Power 71
- 4.5 Power Analyses 72
- 4.6 Effect Size 72
- 4.7 Confidence Intervals and Precision 74
- 4.8 Summary 76

5	Parametric Statistical Techniques	77
5.1	A Little More Lingo	77
5.1.1	Population Parameters Versus Sample Statistics	78
5.1.2	Data	78
5.1.2.1	Ratio and Interval Data	78
5.1.2.2	Ordinal Data	78
5.1.2.3	Nominal Data	79
5.1.3	Central Tendency	79
5.1.3.1	Mode	79
5.1.3.2	Median	79
5.1.3.3	Mean	86
5.1.4	Distributions	86
5.1.5	Dependent Variables	92
5.1.5.1	To Scale or Not to Scale	95
5.1.6	Summary	97
5.2	<i>t</i> Tests	97
5.2.1	Independent Samples <i>t</i> Tests	97
5.2.2	Matched Group Comparison	98
5.2.3	Assumptions of <i>t</i> Tests	99
5.2.4	More Examples of Studies Employing <i>t</i> Tests	100
5.2.5	Statistical Software Packages for Conducting <i>t</i> Tests	101
5.3	The NOVAs and Mixed Linear Model Analysis	101
5.3.1	ANOVA	102
5.3.1.1	ANOVA with a Multifactorial Design	104
5.3.1.2	Main Effects and Interactions	104
5.3.1.3	More Illustrations of Interactions and Main Effects	106
5.3.1.4	Assumptions of ANOVA	107
5.3.2	ANCOVA	109
5.3.3	MANOVA/MANCOVA	111
5.3.4	Statistical Software Packages for Conducting ANOVA/ANCOVA/ MANOVA	114
5.3.5	Repeated Measures: ANOVA-RM and Mixed Linear Model Analysis	114
5.3.5.1	ANOVA-RM	114
5.3.5.2	Mixed Linear Model Analysis	116
5.3.5.3	ANCOVA	117
5.3.5.4	Statistical Software Packages for Conducting Repeated Measures Analyses	117
5.3.6	Summary	119
5.4	Correlation and Regression	120
5.4.1	Correlation and Multiple Correlation	120
5.4.2	Regression and Multiple Regression	121

- 5.4.3 Statistical Software Packages for Conducting Correlation and Regression 124
- 5.5 Logistic Regression 126
- 5.5.1 Statistical Software Packages for Conducting Logistic Regression 128
- 5.6 Discriminant Function Analysis 128
- 5.6.1 Statistical Software Packages for Conducting Discriminant Function Analysis 128
- 5.7 Multiple Comparisons 129
- 5.8 Summary 131

- 6 Nonparametric Statistical Techniques 133**
- 6.1 Chi-Square 134
- 6.1.1 Statistical Software Packages for Conducting Chi-Square 136
- 6.2 Median Test 137
- 6.2.1 Statistical Software Packages for Conducting Median Tests 137
- 6.3 Phi Coefficient 137
- 6.3.1 Statistical Software Packages for Calculating the Phi Coefficient 139
- 6.4 Mann–Whitney U Test (Wilcoxon Rank Sum Test) 139
- 6.4.1 Statistical Software Packages for Conducting a Mann–Whitney U Test 141
- 6.5 Sign Test and Wilcoxon Signed-rank Test 142
- 6.5.1 Statistical Software Packages for Conducting Sign Tests 143
- 6.6 Kruskal–Wallis Test 144
- 6.6.1 Statistical Software Packages for Conducting a Kruskal–Wallis Test 144
- 6.7 Rank-Order Correlation 145
- 6.7.1 Statistical Software Packages for Conducting Rank-order Correlations 146
- 6.8 Summary 147

- 7 Meta-Analytic Studies 149**
- 7.1 The File Drawer Effect 150
- 7.2 Analyzing the Meta-Analytic Data 151
- 7.3 How to Read and Interpret a Paper Reporting a Meta-Analysis 153
- 7.4 Statistical Software Packages for Conducting Meta-Analyses 155
- 7.5 Summary 155

**Section 4 Reporting, Understanding, and Communicating
Research Findings 157****8 Disseminating Your Research Findings 159**

- 8.1 Preparing a Research Report 159
- 8.2 Presenting Your Findings at a Conference 167
- 8.3 Summary 168

9 Concluding Remarks 169

- 9.1 Why Is It Important to Understand Research Design and Analysis
as a Consumer? 169
- 9.2 Research Ethics and Responsibilities of Journalists 175
- 9.3 Responsibilities of Researchers 177
- 9.4 Conclusion 178

Appendix A Data Sets and Databases 179**Appendix B Statistical Analysis Packages 195****Appendix C Helpful Statistics Resources 217****Glossary 221****References 233****Index 243**

List of Figures

- Figure 3.1 Sample Latin square design completion 58
- Figure 3.2 Sample double Latin square design 59
- Figure 5.1 A roughly normal distribution 86
- Figure 5.2 Positively kurtotic distribution 87
- Figure 5.3 Negatively kurtotic distribution 88
- Figure 5.4 A positively skewed distribution 89
- Figure 5.5 A negatively skewed distribution 90
- Figure 5.6 A bimodal distribution 90
- Figure 5.7 Distributions with substantial overlap 92
- Figure 5.8 Distributions with little overlap 92
- Figure 5.9 Interaction between intervention and chronicity 105
- Figure 5.10 Significant main effects of both intervention type and chronicity in the absence of an interaction 106
- Figure 5.11 Significant interaction effect in the absence of main effects of gender or hand preference 107
- Figure 5.12 Significant time \times treatment group interaction in a repeated measures study 115
- Figure 6.1 Illustration of a positively skewed distribution 141
- Figure 7.1 A funnel plot of effect sizes 151

List of Tables

Table 1.1	Timeline of events and the evolution of research ethics	13
Table 1.2	Sample informed consent form	19
Table 1.3	Example of poor separation of investigator–clinician role	23
Table 2.1	Erroneous statements of causality	38
Table 2.2	Erroneous statements of generalizability	43
Table 3.1	Single-factor between-subjects design with two levels of the independent variable	49
Table 3.2	Single-factor between-subjects design with four levels of the independent variable	50
Table 3.3	Single-factor between-subjects design with three levels of the independent variable and three dependent variables	51
Table 3.4	A 2×3 multifactorial between-subjects design with two independent variables	51
Table 3.5	A within-subjects design with three levels of one within-subjects independent variable	53
Table 3.6	A $2 \times 3 \times 2 \times 2$ between–within subjects design with one dependent variable	56
Table 3.7	Single-case A-B-A-B research design	63
Table 4.1	The null hypothesis, power, and errors	69
Table 4.2	The relationship between error variance and the size of the F statistic	70
Table 5.1	Fictional illustration of mode, median, and mean	80
Table 5.2	Data illustrated in the normal distribution in Figure 5.1	87
Table 5.3	Data illustrated in the positively kurtotic distribution in Figure 5.2	88
Table 5.4	Data illustrated in the negatively kurtotic in Figure 5.3	89
Table 5.5	Dependent t test using raw and scaled scores	96
Table 5.6	Example of a t test for independent groups	100
Table 5.7	Example of a t test for matched pairs	100
Table 5.8	Sample study using ANOVA	103
Table 5.9	Example of a multifactorial ANOVA	108

Table 5.10	Example of a single-Factor ANCOVA	111
Table 5.11	Example of a multivariate analysis of variance study	113
Table 5.12	Example of a repeated measures study	118
Table 5.13	Sample study of a correlation between two variables	122
Table 5.14	Sample study using multiple correlation	123
Table 5.15	Multiple regression equation	123
Table 5.16	Sample multiple regression as an extension of the study in Table 5.14	125
Table 5.17	Example of a Logistic Regression Analysis	127
Table 5.18	An example of a study using Discriminant Function Analysis	129
Table 6.1	Hypothetical 2×2 contingency table for hand preference and gender	134
Table 6.2	Sample Chi-square table comparing groups	135
Table 6.3	Formula and sample calculation for χ^2	135
Table 6.4	Example of a study using the median test	138
Table 6.5	Example of a study using Phi	139
Table 6.6	Example of a study using a Mann–Whitney U test	140
Table 6.7	Example of a Wilcoxon signed-rank test	143
Table 6.8	Example of a Kruskal–Wallis test	145
Table 6.9	Example of a study with Spearman’s rank-order correlation	147
Table 7.1	Sample layout of a meta-analytic table with standardized mean differences	154
Table 7.2	Sample layout of a meta-analytic table with r	154
Table 8.1	Abstract of a sample study	160
Table 8.2	Introduction section of a sample study	161
Table 8.3	Sample methods section	163
Table 8.4	Sample fictional results section	165
Table 8.5	Discussion section of a sample research report	166
Table A.1	Sample data set with SAS data step	180
Table A.2	A sample data step	181
Table A.3	Data from a within-subjects study	183
Table A.4	Larger data set with 1000 participants and 16 variables	184
Table A.5	Steps for creating a basic Microsoft Access database with forms	188
Table A.6	Data set created with Microsoft Access	189
Table A.7	Text file exported from Access database	190
Table A.8	SAS data step using pasted data exported from Access as a text file	190
Table A.9	SAS Proc Print output using pasted data from text file	191
Table B.1	Sample SAS program for conducting an analysis of variance	198

Table B.2	Sample SAS Log from an analysis of variance	199
Table B.3	Sample SAS output data for an analysis of variance	200
Table B.4	Sample SAS results for an analysis of variance (selected portions)	201
Table B.5	Sample t test with confidence intervals run using SAS	205
Table B.6	Sample Chi-square analysis run using SAS	207
Table B.7	Sample multiple regression analysis run using SAS	210

Introduction

In this book, I set out to provide a hopefully, pain-free overview of research methods, design, and analysis. The intended audiences include those in the sciences who wish to conduct their own research without investing several semesters completing coursework in statistics and related fields, as well as those in the sciences, clinical fields, education, and the media who wish to read published research in an informed manner. In the former case, this manuscript will provide a general basis for designing and conducting research, though with the assistance of a statistical consultant. In the latter case, I hope this primer will provide a basis for reading, understanding, and critically evaluating research reports.

For health care providers who wish to read studies and make treatment recommendations to their patients based on study outcomes, I hope this book will be a good reference tool. Research publications can sometimes be full of nuances and jargon that are only meaningful to the trained researcher. Without a clear understanding of research design, validity, and interpretation, the results reported in publications can be misunderstood and applied improperly. Sometimes, the research may be poorly conducted or poorly reported, and a basic knowledge of research design and interpretation can be particularly useful in judging when that is the case. At other times, the research is well done, but difficult to understand without a basic knowledge of research methods.

Professionals working in the media are well aware of their great responsibility in reporting research findings to the public. The media has a special role in providing information to the public while avoiding harm as outlined in the *Professional Journalists' Code of Ethics* (Society of Professional Journalists, 2014). That code also mandates that journalists are responsible for the accuracy of their reporting, including verifying the information before it is released.

Carrie Figdor (2017) points out the difficulty presented to journalists in their role of reporting and providing information that is accurate when the material is the product of scientific endeavors. Journalists cannot necessarily rely on authors of scientific reports to provide accurate and valid information, and this quandary has become exponentially worse with the evolution of mass

communication tools. Non-peer-reviewed research reports are more readily available to the masses. Moreover, journalists cannot necessarily count on peer-reviewed journals to publish only sound research. Most do, but journalists must be careful, yet, to review and understand the research design as presented along with the results and conclusions.

Journalists must take care, for instance, to not translate a conclusion of an association between two events or variables into a claim of causality. Oftentimes, the correct language to that effect is included in a research publication, but it is incumbent on the journalist to read and understand such language. Otherwise, there is a real and great risk that the public will be misinformed and harmed as a result. In Chapter 9, I discuss this in more detail with respect to specific instances of marked harm being perpetrated unintentionally (e.g. the unsubstantiated fear of the measles vaccine, misinformation about the true risks of chronic traumatic encephalopathy, and misinterpretation of the Women's Health Initiative findings).

The chapters of this book are laid out into four major sections. In Section 1, I briefly review the purpose of research as well as ethics and rules guiding research involving human participants and animal subjects. In Section 2, I walk you through basic research designs and validity. In Section 3, I provide a cursory review of statistical techniques, just enough to make you conversant with your statistical consultant or to be able to comprehend the jargon you find in many research documents. I have also included a chapter on meta-analytic studies. The goal of that chapter is to help you in sifting through reports of meta-analyses, though I also provide some direction in case you ever consider conducting your own meta-analytic study. In the fourth section, I review the how-tos of disseminating research findings, including reporting and presenting research results. I discuss how to prepare a research paper for submission to a peer-reviewed journal. I also talk about the concept of poster presentations and how to submit research more quickly for presentation at a conference.

In Section 4, I also present my concluding remarks. There, I repeat what I emphasize throughout this primer; that is, research and research findings are only as good as the research design. Most importantly, it is crucial to avoid making statements of claims of causality between two conditions, or variables, when the research design does not permit drawing such conclusions with any degree of confidence. Accurate interpretation of research findings is of critical importance. This does not just apply to the authors of the original research but also to others who report about and share research findings and claims more broadly. In particular, I hope to underline the importance and responsibility carried by journalists and others who discuss research claims. Sadly, when research claims are reported and shared with the public without a critical eye or with misstatements about causality, harm may ensue.

Finally, I have prepared appendices with tools for those who are planning to conduct their own research. These contain information about data sets, databases, statistical software programs, and resources for those who want to learn more about inferential statistics. I have additionally included a glossary of many of the terms included in this primer; in the glossary, terms are alphabetized for quick lookup.

Section 1

The Purpose, Ethics, and Rules of Research

1

The Purpose and Ethics of Research

1.1 The Purpose and Risks of Research

Why do we do research? There are many reasons: to answer a question, to advance understanding of a topic, to evaluate interventions, to predict behavior, to understand differences between groups, and so forth. When we conduct research, we usually start with an inquiry based on theory. We then develop hypotheses. Hypotheses are testable questions or predictions, which are ideally based on theory or pre-existing knowledge about a topic.

Is there ever a time when research should not be conducted? Yes! Logistically, some research ideas may not have benefits that outweigh the costs of conducting the research. These cost considerations include fiscal costs, time, and effort. But there are also ethical considerations in determining *whether* research should be conducted and *how* it is conducted.

In terms of the *whether*, one might ask if there are any potential harms of the research. Consideration of the issue of potential harm typically refers to the harm that may be incurred by the participants or subjects in the process of conducting the research, but harm can also theoretically result from the findings or the knowledge gained by the research. For instance, what if you want to know whether a necessary, life-saving treatment causes long-term cognitive impairments? One might argue that there is no point in “proving” the adverse effects of the treatment if the treatment is required for survival and there are no alternative options. On the other hand, perhaps patients deserve to be fully informed of the potential side effects before deciding whether to pursue treatment versus opting for fate. Perhaps, too, an understanding of negative side effects could lead to the development of strategies and interventions to minimize or reverse them.

As another example, many researchers may be interested in knowing the negative consequences of a certain type and severity of injury. If one stops there in the research, that is, if the research concludes following documentation of the negative impacts of an event or injury, then the research has