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Nota di contenuto	A Practical Guide to Cluster Randomised Trials in Health Services Research; CONTENTS; Preface; Notation; Table of cases: Trials used as examples in more than one chapter in the book; 1: Introduction; 1.1 Introduction to randomised trials; 1.2 Explanatory or pragmatic trials; 1.3 How does a cluster randomised trial differ from other trials?; 1.3.1 Recruitment, randomisation and consent; 1.3.2 Definition of cluster size; 1.3.3 Analysis and sample size; 1.3.4 Interventions used in cluster randomised trials; 1.4 Between-cluster variability 1.4.1 Factors that contribute to between-cluster variability1.4.1.1 Geographical reasons; 1.4.1.2 Individuals choose the cluster to belong to; 1.4.1.3 Healthcare provided to the cluster; 1.4.2 Measuring between-cluster variability; 1.5 Why carry out cluster randomised trials?; 1.5.1 The intervention necessarily acts at the cluster level; 1.5.2 Practical and/or ethical difficulties in randomising at individual level; 1.5.3 Contamination at health professional level; 1.5.4 Contamination between members of a cluster; 1.5.5 Cost or administrative convenience 1.5.6 Ensuring intervention is fully implemented1.5.7 Access to routine

data; 1.6 Quality of evidence from cluster randomised trials; 1.6.1 External validity; 1.6.2 Internal validity; 1.6.3 Balancing internal validity, external validity and ethical issues; 1.7 Historical perspectives; 1.7.1 Early cluster randomised trials; 1.7.2 Early cluster randomised trials in health up to 2000; 1.7.3 Recent methodological developments; 1.7.3.1 Methods of analysis; 1.7.3.2 Sample size; 1.7.3.3 Estimating the intra-cluster correlation coefficient; 1.7.3.4 Reporting guidelines
1.7.3.5 Recruitment and consent1.7.3.6 Complex interventions; 1.7.3.7 Other topics; 1.8 Summary; References; 2: Recruitment and ethics; 2.1 Selecting clusters and participants to enhance external validity; 2.1.1 Clusters; 2.1.2 Participants; 2.2 Ethics of cluster randomised trials; 2.2.1 Components of consent; 2.2.2 Classification of interventions and implications for individual participant consent; 2.2.2.1 Individual-cluster interventions; 2.2.2.2 Professional-cluster interventions; 2.2.2.3 External-cluster interventions; 2.2.2.4 Cluster-cluster interventions
2.2.2.5 Multifaceted interventions2.2.3 Cluster guardians; 2.2.4 Timing of cluster consent; 2.2.5 Fully informed consent for educational and awareness campaigns; 2.2.6 Protecting the privacy of individuals; 2.2.7 Duty of care to control participants; 2.2.8 Summary of consent issues; 2.3 Selection and recruitment of participants to enhance internal validity; 2.3.1 Trials which identify and recruit individual participants before randomisation (scenario 1); 2.3.2 Trials where individual participants are not recruited (scenario 2)
2.3.3 Trials where participants are recruited after randomisation but blind to allocation status (scenario 3)

Sommario/riassunto

Cluster randomisedtrials are trials in which groups (or clusters) of individuals are randomly allocated to different forms of treatment. In health care, these trials often compare different ways of managing a disease or promoting healthy living, in contrast to conventional randomised trials which randomise individuals to different treatments, classically comparing new drugs with a placebo. They are increasingly common in health services research. This book addresses the statistical, practical, and ethical issues arising from allocating groups of individuals, or clusters, to different intervent