

STUDY DESIGN TABLE

Study Design Characteristics						
	Distinguishing Features	Questions Answered	Generalizability	Internal Validity	Result	Typical Statistics
Randomized Controlled Trial (RCT)	<ul style="list-style-type: none"> • Random assignment to groups • Investigator manages exposure to the casual agent • Prospective • Can establish cause and effect 	<ul style="list-style-type: none"> • Efficacy--can it work? • What is the magnitude of effect? • What proportion benefit? • Which approach is better? 	<ul style="list-style-type: none"> • sample representative of reference population 	<ul style="list-style-type: none"> • randomization process • adherence to protocol • attrition/withdrawal • blinding <ul style="list-style-type: none"> – patient – provider – data collector 	<ul style="list-style-type: none"> • quantitative measure of outcomes <ul style="list-style-type: none"> – adjusted for confounders • yes/no for outcome • % experimental / % control 	<ul style="list-style-type: none"> • mean, standard deviation <ul style="list-style-type: none"> – t-test – analysis of variance – multivariate analysis • Chi square, logistic regression • RR relative risk
Non-randomized Trial	<ul style="list-style-type: none"> • Natural groups or allocation with nonrandom procedure • Investigator manages exposure to the causal agent • Prospective • Confounders-other factors could affect intervention and/or outcome 	<ul style="list-style-type: none"> • Effectiveness--does it work? • What is the magnitude of effect? • What proportion benefit? • Which approach is better? 	<ul style="list-style-type: none"> • sample representative of reference population 	<ul style="list-style-type: none"> • selectivity bias within groups, baseline differences • details of intervention • attrition/follow up • blinding <ul style="list-style-type: none"> – patient – provider – data collector 	<ul style="list-style-type: none"> • quantitative measure of outcomes <ul style="list-style-type: none"> – adjusted for confounders and covariates • yes/no for outcome • % experimental / % control 	<ul style="list-style-type: none"> • mean, standard deviation <ul style="list-style-type: none"> – t-test – analysis of variance – multivariate analysis • Chi square, logistic regression • RR relative risk
Cohort Study	<ul style="list-style-type: none"> • Group, identified with common characteristic, followed forward in time • No investigator manipulation, analytical • Prospective • “Exposure” data collected before outcome • Can establish temporal sequence 	<ul style="list-style-type: none"> • Does “exposure” lead to “outcome”? • What proportion develops the outcome? • Is there a dose response? • What are the “protective” and the “risk” factors? 	<ul style="list-style-type: none"> • sample representative of reference population 	<ul style="list-style-type: none"> • large enough sample to pick up outcome events • period between exposure and onset • Confounders assessed • Follow up (80%) 	<ul style="list-style-type: none"> • yes/no for outcome • % with outcome in each group • stratified by subgroups • adjusted for confounders 	<ul style="list-style-type: none"> • logistic regression • RR relative risk • Chi square • multivariate analysis
Case-control Study	<ul style="list-style-type: none"> • People with disease (cases) matched with people without (controls) • Look back in time for past exposure to factor • No investigator manipulation, analytical • Retrospective, survey or record review • Association only 	<ul style="list-style-type: none"> • Is outcome associated with presence of factor? • What are risk factors? • What are protective factors? • Is there a dose response? 	<ul style="list-style-type: none"> • sample representative of reference population 	<ul style="list-style-type: none"> • good match between cases and controls/bias • recall bias • ability to find exposure data • blinded data collectors 	<ul style="list-style-type: none"> • proportion (%) with exposure to factor in each group • stratified by subgroups • adjusted for confounders 	<ul style="list-style-type: none"> • OR odds ratio • multivariate analysis • multivariate analysis
Cross-sectional Study	<ul style="list-style-type: none"> • Group identified by some characteristic (outcome) • Look once, exposure and outcome collected at same time • No investigator manipulation • Association only 	<ul style="list-style-type: none"> • Is outcome associated with presence of factor? • What factors are correlated? • Are there clues to suggested a more rigorous study is indicated? 	<ul style="list-style-type: none"> • sample representative of reference population • biologically plausible 	<ul style="list-style-type: none"> • recall bias • blinded data collectors 	<ul style="list-style-type: none"> • % with factor in each group • stratified by subgroups • adjusted for confounders 	<ul style="list-style-type: none"> • OR odds ratio • multivariate analysis • multivariate analysis
Case Series	<ul style="list-style-type: none"> • Patients defined by diagnosis or treatment • Followed prospectively • Observational study, no investigator manipulation 	<ul style="list-style-type: none"> • What is the experience of a set of patients with a disease in common? • What are the details of care provided? 	<ul style="list-style-type: none"> • not representative of reference population 	<ul style="list-style-type: none"> • all cases in time period • inclusion/exclusion criteria • consistent measurement • investigator bias 	<ul style="list-style-type: none"> • data for each subject shown on table • quantitative • qualitative/subjective 	<ul style="list-style-type: none"> • simple descriptive statistics • means, std deviation • range • frequency • percent