## Study Design Table

### Study Design Characteristics

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| **Randomized Controlled Trial (RCT)** | ● Random assignment to groups  
● Investigator manages exposure to the casual agent  
● Prospective  
● Can establish cause and effect | ● Efficacy—can it work?  
● What is the magnitude of effect?  
● What proportion benefit?  
● Which approach is better? | ● randomization process  
● adherence to protocol  
● attrition/withdrawal  
● blinding  
● provider  
● data collector | ● quantitative measure of outcomes  
– adjusted for confounders  
● yes/no for outcome  
● % experimental / % control | ● mean, standard deviation  
– t-test  
– analysis of variance  
– multivariate analysis  
● Chi square, logistic regression  
● RR relative risk |
| **Non-randomized Trial** | ● Natural groups or allocation with nonrandom procedure  
● Investigator manages exposure to the casual agent  
● Prospective  
● Confounders—other factors could affect intervention and/or outcome | ● Effectiveness—does it work?  
● What is the magnitude of effect?  
● What proportion benefit?  
● Which approach is better? | ● selectivity bias within groups, baseline differences  
● details of intervention  
● attrition/follow up  
● blinding  
● patient  
● provider  
● data collector | ● quantitative measure of outcomes  
– adjusted for confounders and covariates  
● yes/no for outcome  
● % experimental / % control | ● mean, standard deviation  
– t-test  
– analysis of variance  
– multivariate analysis  
● Chi square, logistic regression  
● RR relative risk |
| **Cohort Study** | ● Group, identified with common characteristic, followed forward in time  
● No investigator manipulation, analytical  
● Prospective  
● “Exposure” data collected before outcome  
● Can establish temporal sequence | ● Does “exposure” lead to “outcome”?  
● What proportion develops the outcome?  
● Is there a dose response?  
● What are the “protective” and the “risk” factors? | ● sample representative of reference population  
● large enough sample to pick up outcome events  
● period between exposure and onset  
● Confounders assessed  
● Follow up (80%) | ● yes/no for outcome  
● % with outcome in each group  
● stratified by subgroups  
● adjusted for confounders | ● logistic regression  
● RR relative risk  
● Chi square  
● multivariate analysis |
| **Case-control Study** | ● 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 | ● Is outcome associated with presence of factor?  
● What are risk factors?  
● What are protective factors?  
● Is there a dose response? | ● sample representative of reference population  
● good match between cases and controls/bias  
● recall bias  
● ability to find exposure data  
● blinded data collectors | ● proportion (%) with exposure to factor in each group  
● stratified by subgroups  
● adjusted for confounders | ● OR odds ratio  
● multivariate analysis  
● multivariate analysis |
| **Cross-sectional Study** | ● Group identified by some characteristic (outcome)  
● Look once, exposure and outcome collected at same time  
● No investigator manipulation  
● Association only | ● Is outcome associated with presence of factor?  
● What factors are correlated?  
● Are there clues to suggested a more rigorous study is indicated? | ● sample representative of reference population  
● biologically plausible  
● recall bias  
● blinded data collectors | ● % with factor in each group  
● stratified by subgroups  
● adjusted for confounders | ● OR odds ratio  
● multivariate analysis  
● multivariate analysis |
| **Case Series** | ● Patients defined by diagnosis or treatment  
● Followed prospectively  
● Observational study, no investigator manipulation | ● What is the experience of a set of patients with a disease in common?  
● What are the details of care provided? | ● not representative of reference population  
● all cases in time period  
● inclusion/exclusion criteria  
● consistent measurement  
● investigator bias  
● data for each subject shown on table  
● quantitative  
● qualitative/subjective | | ● simple descriptive statistics  
● means, std deviation  
● range  
● frequency  
● percent |