Table 3.6 Study Design, Distinguishing Characteristics and Important Considerations

Study Design Type	Class	Distinguishing Characteristics	Most Important Quality Considerations (from Quality Checklist)
EXPERIMENTAL & QUASI-EXPERIMENTAL TRIALS		**Investigator managed independent variable (the intervention)**	
Randomized Controlled Trial Cluster Randomized Trial	A A	Randomization (at individual or site [a cluster of individuals] level) used to assign subjects to two or more groups	2.1, 3.1, 3.2, 4.3, 5.1, 5.2, 6.3, 6.4, 7.4
Randomized Crossover Trial Non-randomized Crossover Trial	A C	Subjects receive two interventions in a random or non-random sequence, with a washout period between them	2.1, 4.3, 5.1, 5.2, 6.3, 6.4, 7.4
Non-randomized Controlled Trial	C	Subjects assigned to two or more groups using a non-random method	2.1 - 2.3, 3.2, 4.2 - 4.4, 5.1, 5.2, 6.3, 6.4, 7.4, 7.6, 8.5
Non Controlled Trial	D	Only one group studied, no comparison group	2.1, 2.3, 4.3, 5.2, 6.3 - 6.6, 7.4, 7.6, 8.5
DESCRIPTIVE STUDIES		**No comparison, no intervention, describes "what is"**	
Case Study or Case Report Case Series	D D	Detailed description of the unfolding course of events for one or a few subjects, including treatments, intervening factors and outcomes	2.1, 2.4, 4.3, 7.4 3 – Not applicable
Other Descriptive Studies	D	In depth quantitative and/or qualitative description	1.3, 2.1, 2.4, 7.4 3 – Not applicable
OBSERVATIONAL STUDIES		**Investigation of procedure, experience or event with no researcher intervention**	
Before-After Study	D	Data collected at baseline and one or more times after a therapeutic or preventive procedure, experience or event	2.1, 2.3, 2.4, 4.2, 6.2 - 6.6, 7.3, 7.4, 7.6, 8.5 3 – NA if only one group
Time Series	C	Data from the same subjects at a series of points over time, including prior to, during, and following the introduction of a therapeutic or preventive procedure, event, or natural exposure	2.1, 2.3, 2.4, 4.2, 6.2, 6.4 - 6.6, 7.4, 7.6 3 – NA if only one group
EPIDEMIOLOGICAL ANALYTIC STUDIES		**Comparisons constructed analytically, no researcher intervention, examines relationship among exposure factors and outcomes**	
Prospective Cohort	B	Enrollment based on defining characteristic or factor and screening to verify absence of outcome of interest Large number of subjects tracked for long period of time Repeated data collection on "exposures" and status regarding outcomes of interest	2.1, 3.4, 4.2, 5.3, 6.3, 6.4, 7.1, 7.3, 7.4, 7.6, 8.5

Table 3.6 Study Design, Distinguishing Characteristics and Important Considerations

Retrospective Cohort	B	Existing database used to create a cohort and look back for a temporal relationship between exposure factors and development of the outcome	2.1, 2.4, 3.4, 5.3, 6.3 - 6.6, 7.1, 7.3, 7.4, 7.6, 8.5
Case Control Study	C	"Cases" with the outcome are identified then matched with non-case ("controls") from the same population Looks back to determine if exposures differ between cases and controls	2.1, 3.5, 4.2, 5.4, 7.4, 7.6, 7.7, 8.5 6.7 consider role of recall bias
Cross-Sectional Study	D	One round of data collection where exposure factors and outcome status is measured at the same time Statistical tests used to examine association among variables	2.1, 2.4, 3.4, 4.2, 4.3, 5.3, 6.4, 7.4, 7.6
Trend Study	D	Same data collected in different samples from the same population over time Like a series of cross-sectional studies	2.1, 2.4, 3.4, 4.2, 5.3, 6.4, 7.4, 7.6, 7.7, 8.5
DIAGNOSTIC, VALIDITY, OR RELIABILITY STUDIES		**Comparison made with reference standard**	
Diagnostic Study Validity Study Reliability Study	C C C	Used to determine the sensitivity or specificity of a diagnostic or assessment method Used to determine the "truthfulness" or accuracy of a test, tool or procedure used to measure or classify Comparisons made to determine consistency and reproducibility of results from a test, tool or procedure	1.3, 2.4, 3.6, 4.5, 6.8 5.5—Diagnostic Study only