

Study Designs

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-smoking status, amount of fats ingested, new surgery tool

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Outcome-response event

-weight, presence of cancer, recovery time

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Outcome-response event

-weight, presence of cancer, recovery time

Confounder-variable that may influence the outcome

-age, gender, education level

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-weight, presence of cancer, recovery time

Confounder-variable that may influence the outcome

-age, gender, education level

Bias-a systematic difference between results of a study and true measure

-recall, psychological, selection

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Outcome-response event

-weight, presence of cancer, recovery time

Confounder-variable that may influence the outcome

-age, gender, education level

Bias-a systematic difference between results of a study and true measure

-recall, psychological, selection

Relative Risk-ratio of the probability of the event occurring in the exposed group versus a control group

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Prevalence-the proportion of a population found to have a condition

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Prevalence-the proportion of a population found to have a condition

Populations-group of individuals who share a common set of characteristic

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Prevalence-the proportion of a population found to have a condition

Populations-group of individuals who share a common set of characteristic

-location: neighborhood, country, desert

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Prevalence-the proportion of a population found to have a condition

Populations-group of individuals who share a common set of characteristic

-location: neighborhood, country, desert

-biological factors: age, race, genetic condition

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Key terms

Prevalence-the proportion of a population found to have a condition

Populations-group of individuals who share a common set of characteristic

-location: neighborhood, country, desert

-biological factors: age, race, genetic condition

-social factors: income level, education, religion

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Three main types of study designs

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Three main types of study designs

Observational- researcher does not intervene

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Experimental- participants are randomization to specific treatment groups

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Experimental- participants are randomization to specific treatment groups

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Three main types of study designs

Observational- researcher does not intervene

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Experimental- participants are randomization to specific treatment groups

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Goal: detail the aspects of the patient's medical situation

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Lowest level of study design

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Consists of a single case

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Goal: detail the aspects of the patient's medical situation

Lowest level of study design

Consists of a single case

Common topic of case reports:

- An unexpected association between diseases or symptoms

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Lowest level of study design

Consists of a single case

Common topic of case reports:

- An unexpected association between diseases or symptoms
- An unexpected event in the course of observing or treating a patient

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Lowest level of study design

Consists of a single case

Common topic of case reports:

- An unexpected association between diseases or symptoms
- An unexpected event in the course of observing or treating a patient
- Unique or rare features of a disease

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Goal: detail the aspects of the patient's medical situation

Lowest level of study design

Consists of a single case

Common topic of case reports:

- An unexpected association between diseases or symptoms
- An unexpected event in the course of observing or treating a patient
- Unique or rare features of a disease
- A variation of anatomical structures

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Dr. Rivers treats a young and otherwise healthy patient suffering from numbness over the patient's body.

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Dr. Rivers treats a young and otherwise healthy patient suffering from numbness over the patient's body.

After an exhaustive history, Dr. Rivers believes that the numbness occurred because of a new type of sunscreen the patient used

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Example

Dr. Rivers treats a young and otherwise healthy patient suffering from numbness over the patient's body.

After an exhaustive history, Dr. Rivers believes that the numbness occurred because of a new type of sunscreen the patient used

Dr. Rivers writes up a case report describing how the numbness presented, how and why she concluded it was the sunscreen, and how she treated the patient.

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- Requires only one patient
- Details many different aspects of the patient's medical situation
- Quickly inform the medical community of new trends

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Advantages

- Requires only one patient
- Details many different aspects of the patient's medical situation
- Quickly inform the medical community of new trends

Disadvantages

- Case may not be generalizable
- May emphasize the bizarre or focus on misleading elements

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Goal: detail a medical condition in a collection of people that is rare or otherwise unknown

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Goal: detail a medical condition in a collection of people that is rare or otherwise unknown

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Goal: detail a medical condition in a collection of people that is rare or otherwise unknown

Expands on case report by investigating several cases

Example

Dr. Rivers examines the original patient's friends that also used the same sunscreen.

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Goal: detail a medical condition in a collection of people that is rare or otherwise unknown

Expands on case report by investigating several cases

Example

Dr. Rivers examines the original patient's friends that also used the same sunscreen.

Two of the six patients also present with similar symptoms.

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Goal: detail a medical condition in a collection of people that is rare or otherwise unknown

Expands on case report by investigating several cases

Example

Dr. Rivers examines the original patient's friends that also used the same sunscreen.

Two of the six patients also present with similar symptoms.

Dr. Rivers writes a case series for the three patients that presented with the numbness.

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- Requires a small number of patients
- Details many different aspects of the patient's medical situation
- Informs the medical community of new trends quickly

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- Requires a small number of patients
- Details many different aspects of the patient's medical situation
- Informs the medical community of new trends quickly

Disadvantages

- Selection bias
- Unknown causality

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Goal: determine if exposure and outcome are associated.

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Goal: determine if exposure and outcome are associated.

Compares patients who have the outcome of interest (cases) with patients who do not have the outcome (controls)

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Goal: determine if exposure and outcome are associated.

Compares patients who have the outcome of interest (cases) with patients who do not have the outcome (controls)

Subjects are selected by outcome status and afterward exposure status is assessed

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Goal: determine if exposure and outcome are associated.

Compares patients who have the outcome of interest (cases) with patients who do not have the outcome (controls)

Subjects are selected by outcome status and afterward exposure status is assessed

Controls must be carefully chosen to match the population the cases are from

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Dr. Washburne has read about Dr. Rivers' studies and wants to find out if the numbness and the sunscreen are associated.

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Dr. Washburne has read about Dr. Rivers' studies and wants to find out if the numbness and the sunscreen are associated.

He finds 20 people that have experienced numbness (cases) and 20 people that have not (controls).

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Example

Dr. Washburne has read about Dr. Rivers' studies and wants to find out if the numbness and the sunscreen are associated.

He finds 20 people that have experienced numbness (cases) and 20 people that have not (controls).

Dr. Washburne interviewed all the people to find if they used the sunscreen and finds that 16 of the people with numbness used the sunscreen while only 2 people who did not experience numbness used it.

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Advantages

- Require only a moderate amount of time to complete
- Relatively inexpensive to carry out
- Useful when outcomes are rare

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Advantages

- Require only a moderate amount of time to complete
- Relatively inexpensive to carry out
- Useful when outcomes are rare

Disadvantages

- Subject to several biases
- May be difficult to find an appropriate control group
- Unknown causality

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Goal: determine prevalence of outcome for entire population

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Goal: determine prevalence of outcome for entire population

Sample is based on the entire population, not just cases and controls

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Goal: determine prevalence of outcome for entire population

Sample is based on the entire population, not just cases and controls

Sample taken at one specific point in time

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Goal: determine prevalence of outcome for entire population

Sample is based on the entire population, not just cases and controls

Sample taken at one specific point in time

Surveys are example of cross-sectional studies

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Dr. Jayne has heard that the new sunscreen and numbness are associated and wants to know if this condition is wide spread

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Dr. Jayne has heard that the new sunscreen and numbness are associated and wants to know if this condition is wide spread

Dr. Jayne collects information on a random sample of people across the state

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Example

Dr. Jayne has heard that the new sunscreen and numbness are associated and wants to know if this condition is wide spread

Dr. Jayne collects information on a random sample of people across the state

He finds that the risk of numbness is low for the general state population, but high for people between the ages of 13 and 18

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- Results can be applied to the population
- Relatively low cost

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Advantages

- Results can be applied to the population
- Relatively low cost

Disadvantages

- Does not work well for rare outcomes
- Unknown causality
- Recall bias

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Goal: determine if the exposure precedes the outcome

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Goal: determine if the exposure precedes the outcome

Also call longitudinal studies or prospective studies

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Goal: determine if the exposure precedes the outcome

Also call longitudinal studies or prospective studies

Cohort is identified before the appearance of the outcome

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Goal: determine if the exposure precedes the outcome

Also call longitudinal studies or prospective studies

Cohort is identified before the appearance of the outcome

Exposure is assessed and then participants are followed for a set amount of time

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After seeing the findings from Dr. Jayne, Drs. Kay and Lee want to know if the sunscreen precedes the numbness

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After seeing the findings from Dr. Jayne, Drs. Kay and Lee want to know if the sunscreen precedes the numbness

Focusing on people between the ages 13 and 18, the doctors finds 500 participants and follow them for two years

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After seeing the findings from Dr. Jayne, Drs. Kay and Lee want to know if the sunscreen precedes the numbness

Focusing on people between the ages 13 and 18, the doctors finds 500 participants and follow them for two years

Over the course of the two years, 60% of the participants who use the sunscreen experienced numbness

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- Risk can be assessed
- Accurate collection of information
- Less expensive than randomized trials

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Advantages

- Risk can be assessed
- Accurate collection of information
- Less expensive than randomized trials

Disadvantages

- More expensive than previous studies
- Confounding caused by no randomization
- Outcome may require a long time until it occurs

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Goal: determine the efficacy or effectiveness of a exposure or treatment

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Goal: determine the efficacy or effectiveness of a exposure or treatment

Also called Randomized Control Trail or Randomized Clinical Trail

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Goal: determine the efficacy or effectiveness of a exposure or treatment

Also called Randomized Control Trail or Randomized Clinical Trail

Subjects are randomly assigned to a treatment group

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Goal: determine the efficacy or effectiveness of a exposure or treatment

Also called Randomized Control Trail or Randomized Clinical Trail

Subjects are randomly assigned to a treatment group

Subjects are followed for a set amount of time

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Goal: determine the efficacy or effectiveness of a exposure or treatment

Also called Randomized Control Trail or Randomized Clinical Trail

Subjects are randomly assigned to a treatment group

Subjects are followed for a set amount of time

Various outcomes can be investigated

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5 phases of clinical trials

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5 phases of clinical trials

- Phase 0-Pharmacodynamics and Pharmacokinetics (10-15 subjects)

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5 phases of clinical trials

- Phase 0-Pharmacodynamics and Pharmacokinetics (10-15 subjects)
- Phase 1-Screening for safety (20-100 subjects)

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5 phases of clinical trials

- Phase 0-Pharmacodynamics and Pharmacokinetics (10-15 subjects)
- Phase 1-Screening for safety (20-100 subjects)
- Phase 2-Establishing the efficacy of the drug (100-300 subjects)

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5 phases of clinical trials

- Phase 0-Pharmacodynamics and Pharmacokinetics (10-15 subjects)
- Phase 1-Screening for safety (20-100 subjects)
- Phase 2-Establishing the efficacy of the drug (100-300 subjects)
- Phase 3-Final confirmation of safety and efficacy (300+ subjects)

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5 phases of clinical trials

- Phase 0-Pharmacodynamics and Pharmacokinetics (10-15 subjects)
- Phase 1-Screening for safety (20-100 subjects)
- Phase 2-Establishing the efficacy of the drug (100-300 subjects)
- Phase 3-Final confirmation of safety and efficacy (300+ subjects)
- Phase 4-Postmarketing surveillance (number of subjects varies)

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Dr. Simon is part of a Phase 4 trial to determine how much the sunscreen is effecting the risk of numbness

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Example

Dr. Simon is part of a Phase 4 trial to determine how much the sunscreen is effecting the risk of numbness

Focusing on subjects between the ages of 13-18, Dr. Simon follows 200 subjects who are using the sunscreen over the course of a year

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Example

Dr. Simon is part of a Phase 4 trial to determine how much the sunscreen is effecting the risk of numbness

Focusing on subjects between the ages of 13-18, Dr. Simon follows 200 subjects who are using the sunscreen over the course of a year

Initial results appear inconclusive with only 50% of the subjects experiencing numbness

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Example

Dr. Simon is part of a Phase 4 trial to determine how much the sunscreen is effecting the risk of numbness

Focusing on subjects between the ages of 13-18, Dr. Simon follows 200 subjects who are using the sunscreen over the course of a year

Initial results appear inconclusive with only 50% of the subjects experiencing numbness

After adjusting for confounding variables, it appears that 90% of the subjects on a particular acne medication experience numbness

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- Strong cause and effect association
- Can adjust for confounding
- Easier to remove biases than observational studies

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Advantages

- Strong cause and effect association
- Can adjust for confounding
- Easier to remove biases than observational studies

Disadvantages

- Usually the most expensive study design
- Volunteer bias

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Goal: comprehensive review of all relevant studies on a particular topic

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Goal: comprehensive review of all relevant studies on a particular topic

Highest level of analysis

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Goal: comprehensive review of all relevant studies on a particular topic

Highest level of analysis

Can employ meta-analysis

- contrasting and combining results from different studies

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Goal: comprehensive review of all relevant studies on a particular topic

Highest level of analysis

Can employ meta-analysis

- contrasting and combining results from different studies

Based on both published and unpublished results

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Example

Dr. Reynolds reviews all the literature on the connection between sunscreen and numbness

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Example

Dr. Reynolds reviews all the literature on the connection between sunscreen and numbness

Based on the finding from the RCT, he goes back to get data from previous studies

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Example

Dr. Reynolds reviews all the literature on the connection between sunscreen and numbness

Based on the finding from the RCT, he goes back to get data from previous studies

He finds that 87% of the patients that experienced numbness were on the same acne medication

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Example

Dr. Reynolds reviews all the literature on the connection between sunscreen and numbness

Based on the finding from the RCT, he goes back to get data from previous studies

He finds that 87% of the patients that experienced numbness were on the same acne medication

Dr. Reynolds makes a recommendation to the FDA to inform them about the interaction between the two items

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Advantages

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Advantages

- Strongest form of medical evidence
- Less time and cost than conducting a new RCT or cohort study
- More reliable and accurate than individual studies

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Advantages

- Strongest form of medical evidence
- Less time and cost than conducting a new RCT or cohort study
- More reliable and accurate than individual studies

Disadvantages

- Difficult to determine if studies could be combined
- Requires using results from other researchers

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The lowest level of study design is what type of study?

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The lowest level of study design is what type of study?

- case study

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The lowest level of study design is what type of study?

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Which type of study assess outcome first?

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The lowest level of study design is what type of study?

- case study

Which type of study assess outcome first?

- case-control study

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The lowest level of study design is what type of study?

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Which type of study assess outcome first?

- case-control study

What type of study follows subjects for a set amount of time?

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The lowest level of study design is what type of study?

- case study

Which type of study assess outcome first?

- case-control study

What type of study follows subjects for a set amount of time?

- cohort and randomized trial

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Which type of study assess outcome first?

- case-control study

What type of study follows subjects for a set amount of time?

- cohort and randomized trial

What type involves no new subject?

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Which studies are not affected by recall bias?

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What phase of a clinical trial focuses on determining safe levels?

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What phase of a clinical trial focuses on determining safe levels?

- Phase 1 and Phase 3

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What phase of a clinical trial focuses on determining safe levels?

- Phase 1 and Phase 3

T/F: Subjects are randomized into treatment groups for a cohort study.

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What phase of a clinical trial focuses on determining safe levels?

- Phase 1 and Phase 3

T/F: Subjects are randomized into treatment groups for a cohort study.

- False

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What phase of a clinical trial focuses on determining safe levels?

- Phase 1 and Phase 3

T/F: Subjects are randomized into treatment groups for a cohort study.

- False

What study design is used to measure prevalence?

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What phase of a clinical trial focuses on determining safe levels?

- Phase 1 and Phase 3

T/F: Subjects are randomized into treatment groups for a cohort study.

- False

What study design is used to measure prevalence?

- Cross-sectional

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What phase of a clinical trial focuses on determining safe levels?

- Phase 1 and Phase 3

T/F: Subjects are randomized into treatment groups for a cohort study.

- False

What study design is used to measure prevalence?

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What study requires the fewest number of subjects?

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What phase of a clinical trial focuses on determining safe levels?

- Phase 1 and Phase 3

T/F: Subjects are randomized into treatment groups for a cohort study.

- False

What study design is used to measure prevalence?

- Cross-sectional

What study requires the fewest number of subjects?

- Case study

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A research team wants to know if there is an association between artificial sweeteners and urinary tract cancers. The prevalence of urinary tract cancers is low.

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A research team wants to know if there is an association between artificial sweeteners and urinary tract cancers. The prevalence of urinary tract cancers is low.

- case control study

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A research team wants to know if there is an association between artificial sweeteners and urinary tract cancers. The prevalence of urinary tract cancers is low.

- case control study

A doctor examines an extended family of 20 people who all have Heterochromia. 5 otherwise healthy family members also suffer from vision loss in one eye.

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A research team wants to know if there is an association between artificial sweeteners and urinary tract cancers. The prevalence of urinary tract cancers is low.

- case control study

A doctor examines an extended family of 20 people who all have Heterochromia. 5 otherwise healthy family members also suffer from vision loss in one eye.

- case series

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Questions

A research team is interested in whether a new medication reduces the risk of strokes. They ask the drug manufacturer for the number of annual prescriptions in the US and obtain data from death certificates to assess the number of death due to strokes.

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A research team is interested in whether a new medication reduces the risk of strokes. They ask the drug manufacturer for the number of annual prescriptions in the US and obtain data from death certificates to assess the number of death due to strokes.

- cross-sectional study

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A research team is interested in whether a new medication reduces the risk of strokes. They ask the drug manufacturer for the number of annual prescriptions in the US and obtain data from death certificates to assess the number of death due to strokes.

- cross-sectional study

A research group is interested in determining the relationship between the Atkins diet and heart disease. They sample 150 people that have heart disease and 200 people without heart disease.

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A research team is interested in whether a new medication reduces the risk of strokes. They ask the drug manufacturer for the number of annual prescriptions in the US and obtain data from death certificates to assess the number of death due to strokes.

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- case control study

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Questions

Researchers want to know if the number of plants in a patient's room impacts recovery time. The researchers randomly select 300 patients entering the ICU. Measurements are taken on the number of plants in the room and the number of days until they leave the ICU.

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Researchers want to know if the number of plants in a patient's room impacts recovery time. The researchers randomly select 300 patients entering the ICU. Measurements are taken on the number of plants in the room and the number of days until they leave the ICU.

- cohort study

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Researchers want to know if the number of plants in a patient's room impacts recovery time. The researchers randomly select 300 patients entering the ICU. Measurements are taken on the number of plants in the room and the number of days until they leave the ICU.

- cohort study

Researchers want to know if the number of plants in a patient's room impacts recovery time. The researcher select 500 patients entering the ICU and place either 0, 1, 4, or 8 plants in their rooms and measure the number of days until they leave the ICU.

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Researchers want to know if the number of plants in a patient's room impacts recovery time. The researchers randomly select 300 patients entering the ICU. Measurements are taken on the number of plants in the room and the number of days until they leave the ICU.

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- randomized trial

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- Andresen, Elena and Erin DeFries Bouldin eds. (2010) **Public Health Foundations: Concepts and Practices**. John Wiley & Sons.
- DeMets, D., Friedman, L., and Furberg, C., (2010). **Fundamentals of Clinical Trials**. Springer 4th Edition
- Himmelfarb Health Sciences Library Study Design 101. (2011) <http://www.gwumc.edu/library/tutorials/studydesign101/index.html>