Evidence Based Dentistry

Study designs and their power to answer research question

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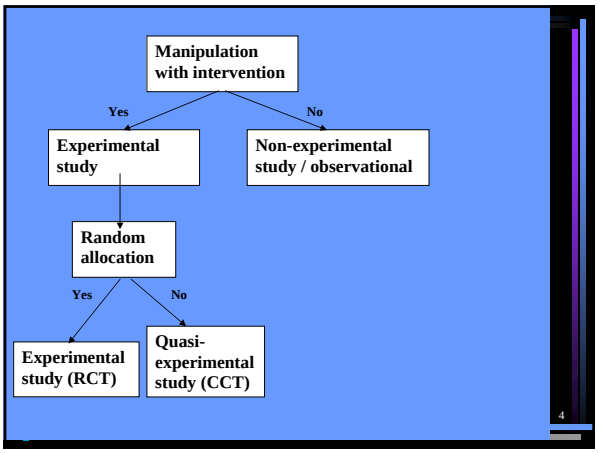
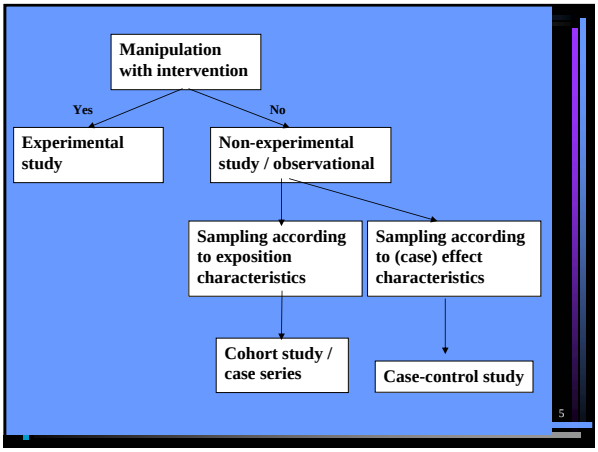
Clinical study designs (MESH terms):

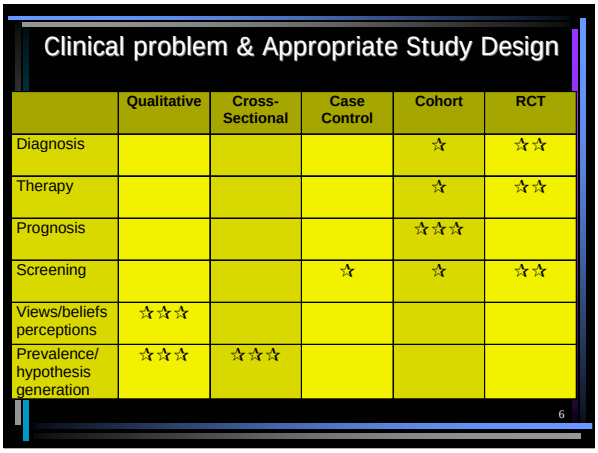
- Randomised Controlled Trial
- Cohort Study
- Case-Control Study
- Cross-Sectional Survey
- Case study/ case series

Clinical trial terminology - tower of Bable?

analytical study	ecological study	prospective cohort study
case control study (89)	etiological study	prospective follow-up study,
case serie	experimental study	observational or experimental
case study, case report	explorative study	prospective study (67)
cause-effect study	feasibility study (79)	quasi-experimental study
clinical trial (79)	follow-up study (67)	randomized clinical trial, RTC
cohort study (89)	historical cohort study	randomized controlled trial, RCT (89)
cohort study with historical	incidence study	retrospective cohort study
controls	intervention study	retrospective follow-up study
controlled clinical trial (95)	longitudinal study (79)	retrospective study (67)
cross-sectional study (89)	N=1 trial	surveillance study
descriptive study	non-randomized trial with	survey, descriptive survey
diagnostic meta-analysis	contemporaneous controls	therapeutic meta-analysis
diagnostic study	non-randomized trial with	trohoc study
double blind randomized	historical controls	
therapeutical trial with cross-over design	observational study	

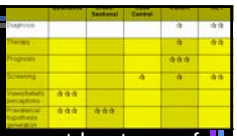






	Qualitative	Cross-Sectional	Case Control	Cohort	RCT
Diagnosis				☆	☆☆
Therapy				☆	☆☆
Prognosis				☆☆☆	
Screening			☆	☆	☆☆
Views/beliefs perceptions	☆☆☆				
Prevalence/ hypothesis generation	☆☆☆	☆☆☆			

Diagnostic tests, Differential diagnosis



- Clearly identified comparison groups, at least one of which is free of the target disorder
- Either an objective diagnostic standard/contemporary clinical diagnostic standard with reproducible criteria for any objectively interpreted component
- Interpretation of the test without knowledge of the diagnostic standard result
- Interpretation of the diagnostic standard without knowledge of the test result
- A statistical analysis consistent with study design

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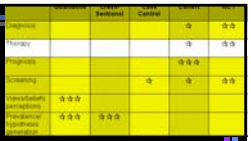
Therapy / Prevention / Education



- Random allocation of the participants to the different interventions
- Outcome measures of known or probably clinical importance for at least 80 per cent of participants who entered the investigation
- A statistical analysis consistent with the study design.

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Appropriate Study Designs to address the implementation of a therapeutic intervention

	Qualitative research	Survey	Case Control	Cohort	RCT	Non-exper	Systematic review
Effectiveness Does it work?				☆	☆☆	☆	☆☆☆
Process of intervention delivery How does it work?	☆☆	☆				☆	☆☆☆
Salience Does it matter?	☆☆	☆☆					☆☆☆
Safety Will it do more good than harm?	☆		☆	☆	☆☆	☆	☆☆☆
Acceptability Will the patient accept the intervention?	☆☆	☆			☆	☆	☆☆☆
Cost effectiveness Is it worth paying for the intervention?					☆☆		☆☆☆
Appropriateness Is this the right intervention for this patient?	☆☆	☆☆					☆☆
Satisfaction with the intervention Are users, providers and other stakeholders satisfied?	☆☆	☆☆	☆	☆			☆

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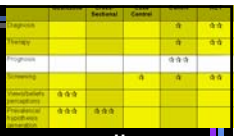
Prognosis



- An inception cohort of persons, all initially free of the outcome of interest
- Follow-up of at least 80 per cent of patients until the occurrence of either a major study criteria or the end of the study
- A statistical analysis consistent with the study design.

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Etiology - Harm - Causation

- Clearly identified comparison group for those at risk for, or having, the outcome of interest
- Masking of observers of outcomes to exposures
- Observers of exposures masked to outcomes for case-control studies and individuals masked to exposure for all other study designs
- A statistical analysis consistent with the study design.

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Cross-Sectional Survey

Advantages

1. Cheap and simple
2. Ethically safe

Disadvantages

1. Establishes association at most, not causality
2. Recall bias susceptibility
3. Confounders may be unequally distributed
4. Group sizes may be unequal

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Case-Control Studies

Advantages:

1. Quick and cheap
2. Only feasible method for very rare disorders or those with long lag between exposure and outcome
3. Fewer individuals needed than cross-sectional studies

Disadvantages:

1. Rely on recall or records to determine exposure status
2. Confounders
3. selection of control groups is difficult
4. Potential bias: recall, selection

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Questions to ask:

- How were cases defined and selected?
- How were controls defined and selected?
- Does the study adequately control for demographic characteristics and important potential confounders in the design or analysis?
- Was measurement of exposure to the factor of interest (eg the new intervention) adequate and kept blinded to case/control status?
- Were all selected subjects included in the analysis?

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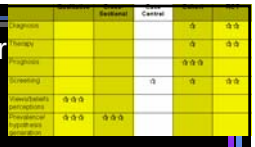
Characteristics of a poor case-control study:



Fail to:

- clearly define comparison groups
- and/or fail to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls
- and/or fail to identify or appropriately control known confounders.

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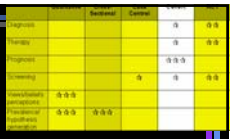
Cohort Study



Advantages:

1. Ethically safe
2. individuals can be matched
3. Can establish timing and directionality of events
4. Eligibility criteria and outcome assessments can be standardised
5. Administratively easier and cheaper than RCT

Disadvantages:

1. Controls may be difficult to identify
2. Exposure may be linked to a hidden confounder
3. Blinding is difficult
4. Randomisation not present
5. For rare disease, large sample sizes or long follow-up necessary

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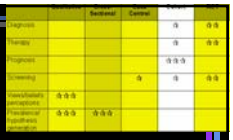
Questions to ask:

- How were subjects selected for the cohort?
- How were subjects selected for the comparison or control group?
- Does the study adequately control for demographic characteristics, clinical features and other potential confounding variables in the design or analysis?
- Was the measurement of outcomes unbiased (ie blinded to treatment group and comparable across groups)?
- Was follow-up long enough for outcomes to occur?
- Was follow-up complete and were there exclusions from the analysis?

Characteristics of a poor cohort study:



Fail to :

- clearly define comparison groups and/or
- measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or
- identify or appropriately control known confounders and/or
- carry out a sufficiently long and complete follow-up of patients.

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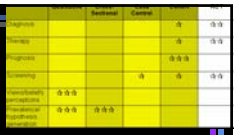
Randomised Controlled Trial - RCT



Advantages

1. Unbiased distribution of confounders
2. Blinding more likely
3. Randomisation facilitates statistical analysis

Disadvantages

1. Size, time and money - Expensive!
2. Volunteer bias
3. Ethically problematic at times

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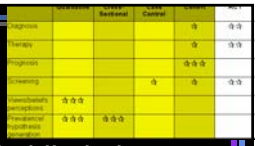
Questions to ask:



- Was the study double blinded?
- Was allocation to treatment groups concealed from those responsible for recruiting the subjects?
- Were all randomised participants included in the analysis?

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Cohort & RCT Crossover Design

Advantages

1. All individuals serve as own controls -> error variance is reduced -> reduced need of large sample size
2. All individuals receive treatment (at least some of the time)
3. Statistical tests assuming randomisation can be used
4. Blinding can be maintained

Disadvantages

1. All individuals receive placebo or alternative treatment at some point
2. Washout period lengthy or unknown
3. Cannot be used for treatments with permanent effects

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