McMaster University

Family Medicine

David Braley Primary Care Research Collaborative

@McMasterFamMed

Basic and Advanced Research Designs for Primary Care Research

Watch a recording of the session here

Ric Angeles

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Michael G. DeGroote SCHOOL OF MEDICINE

Basic and Advanced Research Designs for Primary Care Research

Ric Angeles

What is the best research design?

A. Randomized Controlled Trials (Ofcourse!!!)
B. It depends on the Research Question (according to my research prof)
C. It depends on how much money we have (the Research, not Us)
D. It depends on how much time we have (to finish the Research, not on Earth)
E. It depends on who's checking it (the meana reviewers)
F. It depends on who's doing it (the research team, are you still reading this…)
G. It depends on what I ate this morning

A few basic intro points

- Research Design refers to the overall strategy that you choose to integrate the different components of the study in a coherent and logical way, thereby, ensuring you will effectively address the research problem… blah blah blah
- In short: it is your plan to prove your hypothesis or answer your research question
    - What is your question and/or theory/hypothesis/conceptual framework?
- Do you need to follow the standard research designs for your research?
    - No. Go crazy and use your imagination… but many, many… many of smart (old) people already did it for you…
        - *Why learn from your own mistakes when you can learn it from the mistakes of others.*

Basic Research Designs

a

Observational:

1. Cross-sectional
2. Case-Control
3. Cohort

Interventional/Experimental:

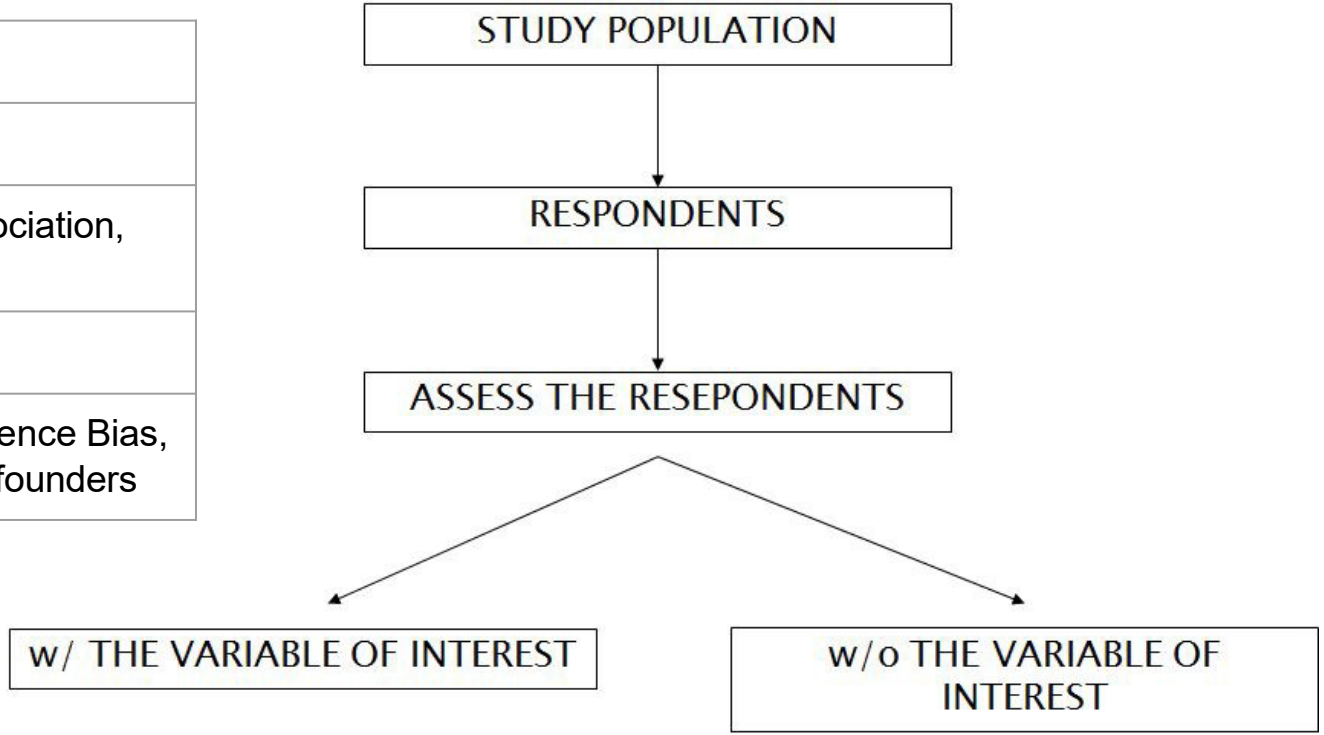
4. Pre-post interventional
5. Quasi-Experimental
6. True Experimental/RCT

Advanced Research Designs

1. Cross-sectional
2. Case-Control
3. Cohort
4. Pre-post interventional
5. Quasi-Experimental/Non-Equivalent Group
   a. Double Pretest
   b. Regression Discontinuity
6. True Experimental/RCT
   a. Cluster Randomized
   b. Factorial
   c. Cross-over
   d. Delayed Intervention
   e. Stepped Wedge Design

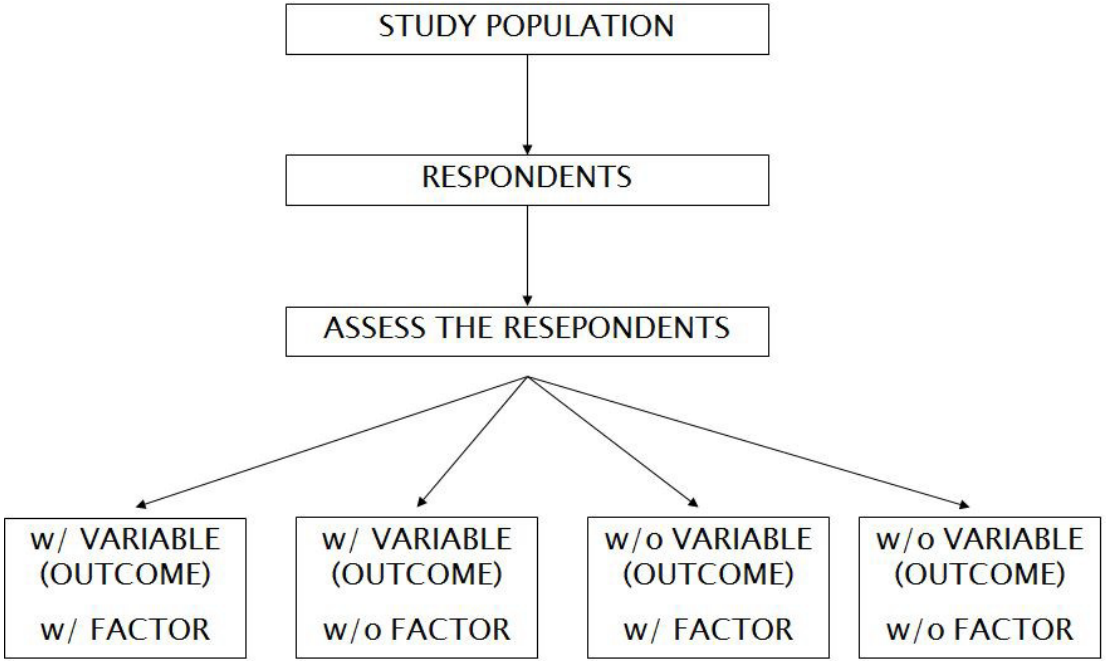
Cross-sectional study (Descriptive)

Cost	Cheap
Time	Quick
Research Question	Prevalence, Association, NOT causation
Viewed as	Weak study
Other info	Incidence-Prevalence Bias, Recall Bias, Confounders



Cross-sectional study (Analytical)

Cost	Cheap
Time	Quick
Research Question	Prevalence, Association, NOT causation
Viewed as	Weak study
Other info	Incidence-Prevalence Bias, Recall Bias, Confounders



Cross-sectional examples

Cross-sectional examples

Descriptive:

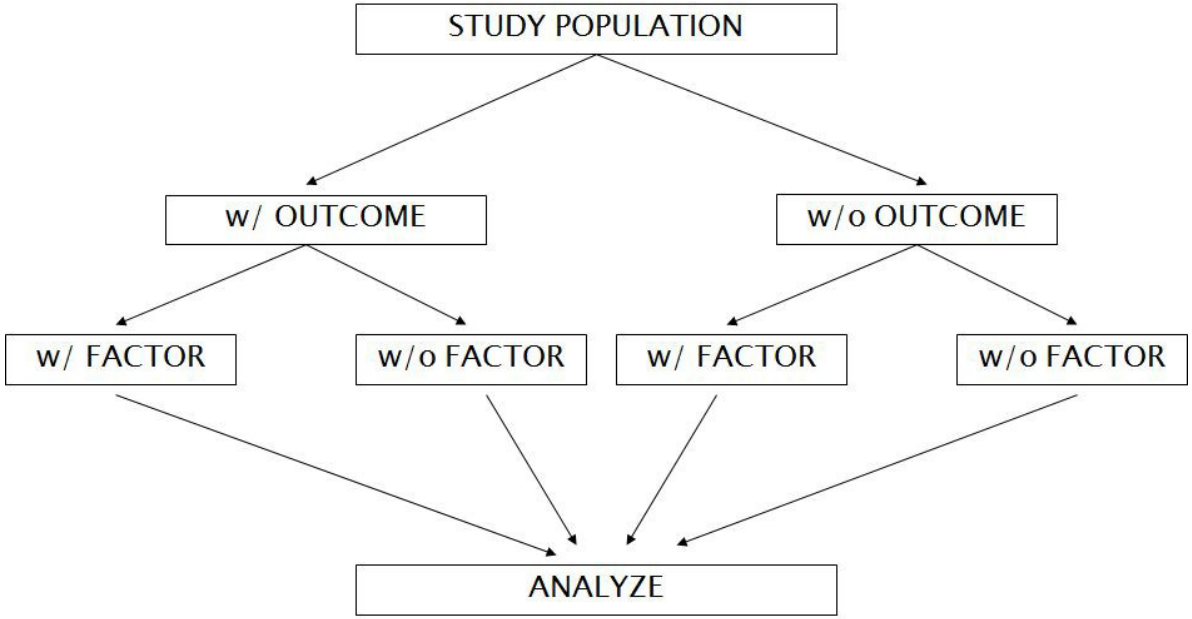
- Why high-users call 911

Analytical:

- Perceptions of MFP patients regarding advanced directives
    - Secondary objective: factors associated with having advanced directives

Case-Control

Cost	Cheap
Time	Quick
Research Question	Association, NOT causation
Viewed as	Hmmm… Depends who's on the panel
Other Info	Requires less samples than Cross-sectional Recall Bias, Confounders



Case-control examples

Validity of the FINDRISC tool in measuring risk of diabetes in the Philippines

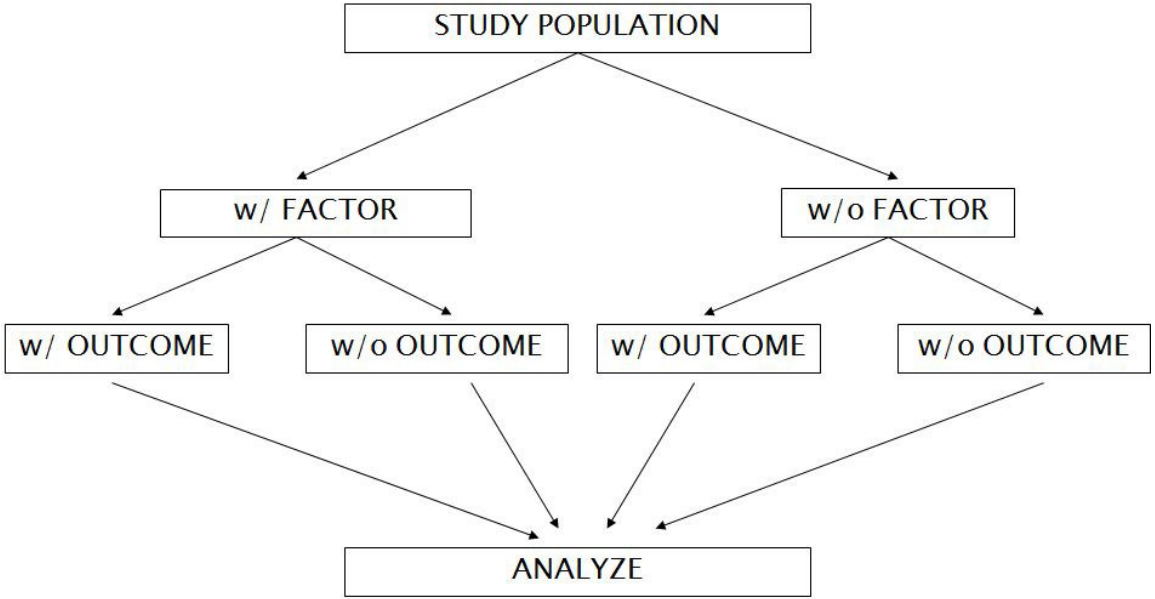
	With Risk Factor	Without Risk Factor
With Diabetes	a	b
Without Diabetes	c	d

ODDS (RATIO) of Having Diabetes = (a*d)/(c*b)

Sensitivity, Specificity, PPV, NPV, AUC, LR, MLB, NHL, NBA...

Cohort study (Prospective/Retrospective)

Cost	Generally more expensive
Time	Varies, tend to be longer
Research Question	Can establish causation When randomization is not ethical
Viewed as	Potentially strong study if done well
Other Info	Can be difficult to find matched controls Confounders



Cohort Example

Framingham Heart Study - Smoking and CVD

	With CVD	Without CVD
Smoking	a	b
Not smoking	c	d

Relative Risk of having CVD = (a/(a+b))/(c/(c+d))

PPV, NPV, AUC, Sensitivity, Specificity, LR...

Variations of observational studies

Panel Study

- Repeated cross-sectional/cohort

Ecological Study

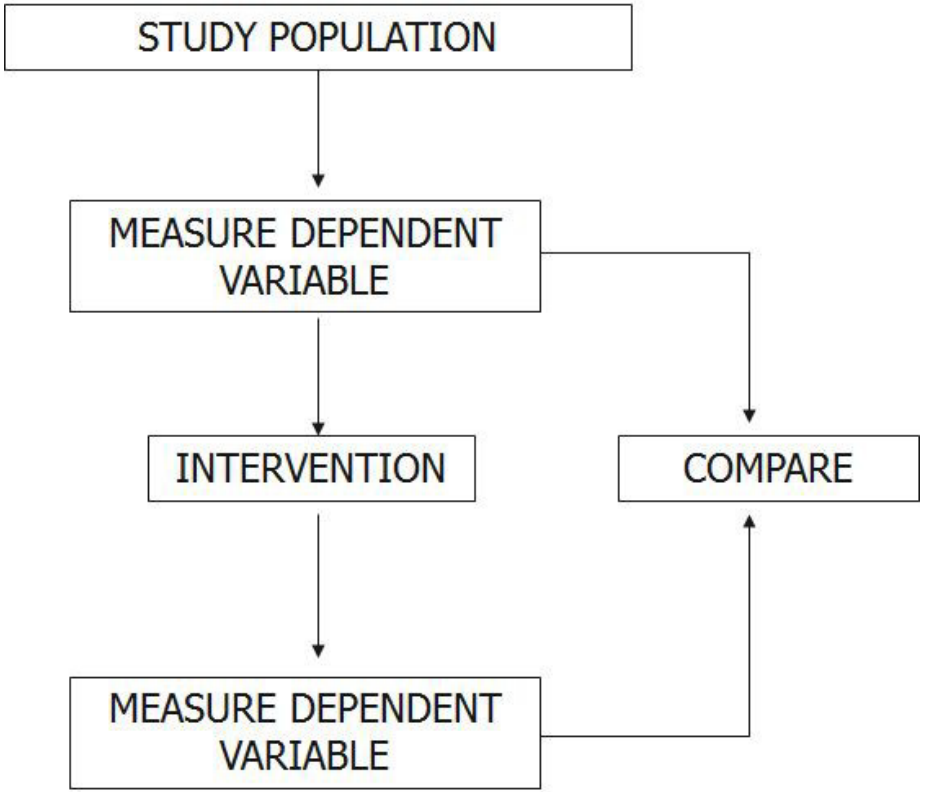
- Unit of analysis is an aggregate

Nested studies (Cohort)

- Case-Control
- Case-Cohort

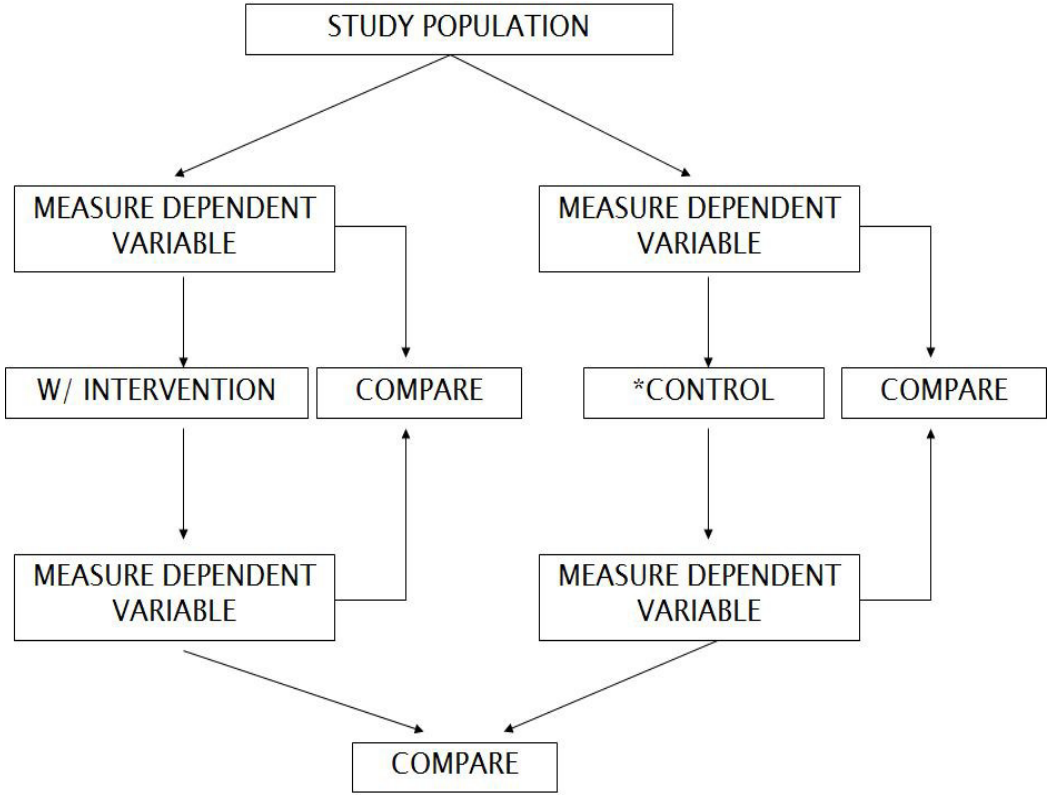
Pre-post interventional research design

Cost	Can be expensive
Time	Varies (Relatively short)
Research Question	Test an intervention (pilot) When you have a small target population
Viewed as	Generally weak especially if effect is minimal
Variant	Double pretest design
Examples	CHAP-EMS pilot study



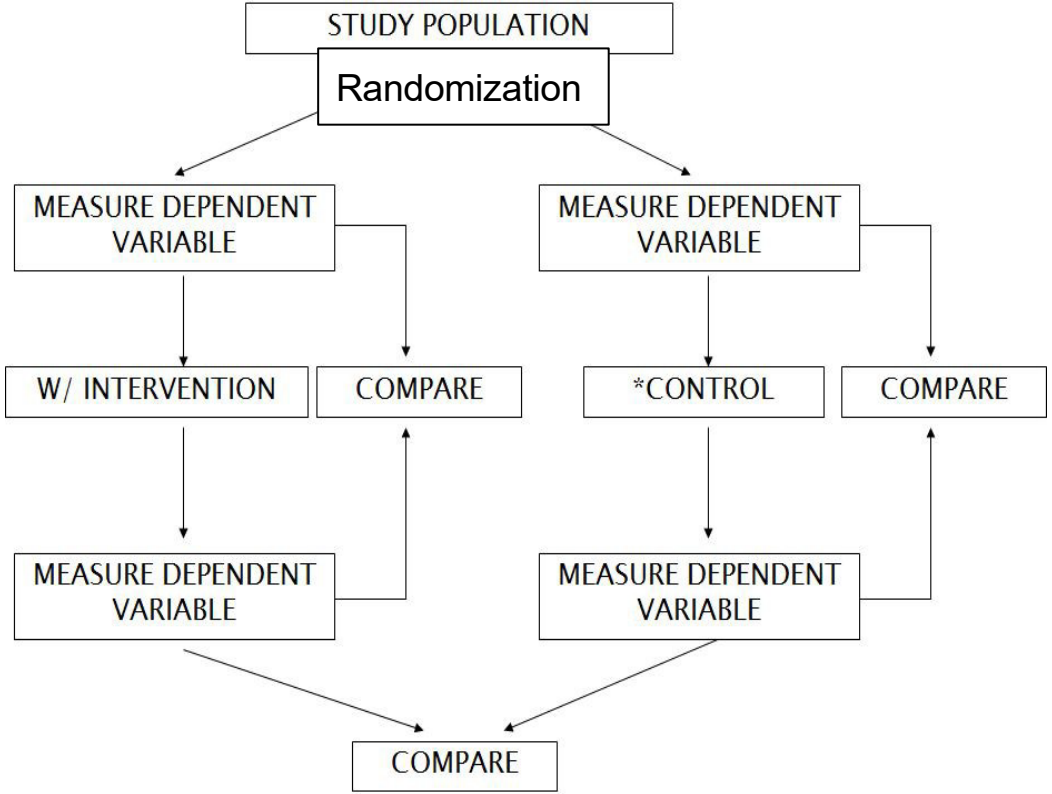
Quasi-Experimental/Non-Equivalent Group Designs(NEGD)

Cost	Can be expensive
Time	Same as an RCT
Research Question	Test an intervention
Viewed as	Better than one-group design
Other Info	Just missing random assignment Compensate by matching
Variant	Double pretest design Dummy Control
Examples	Lecture vs. Counselling vs. Video vs. Pamphlet...



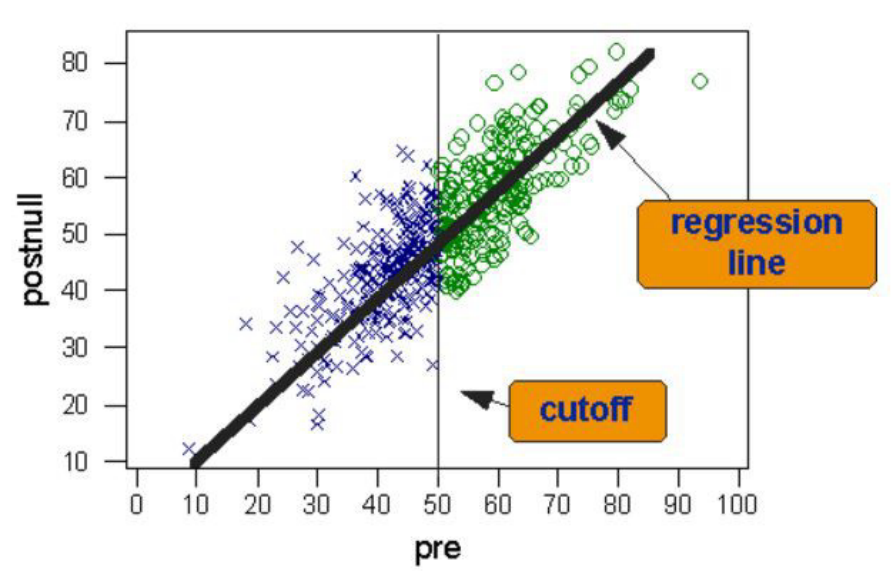
True-Experimental Study/RCT

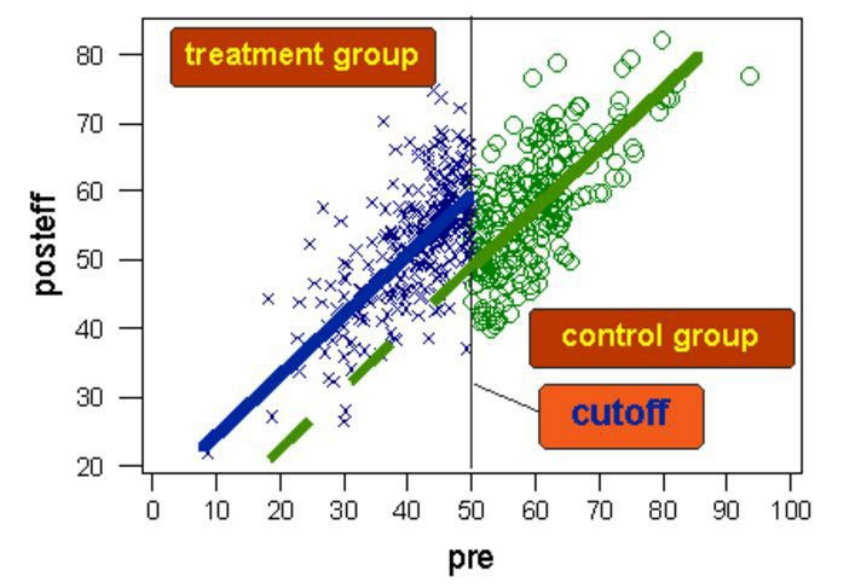
Cost	Can be expensive
Time	Varies (Relatively short)
Research Question	Test an intervention
Viewed as	Best
Other Info	Stronger if with Blinding
Example	Equivalence study: IV vs. Rectal Midazolam in preventing seizures



Regression Discontinuity Design

- Like a traditional NEGD with one difference: Participants are assigned to intervention based on a cut-off score





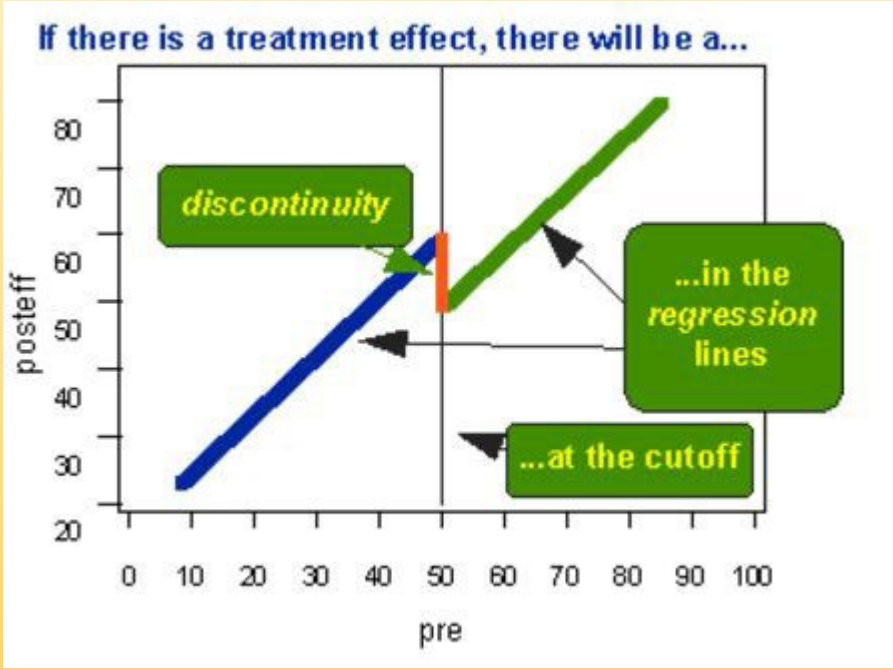
Regression Discontinuity Design

Strength:

- Appropriate when we wish to target a program or treatment to those who most need or deserve it.
- Causal...
- Ethical…

Threats to Validity

- Selection maturation
- Regression towards the mean



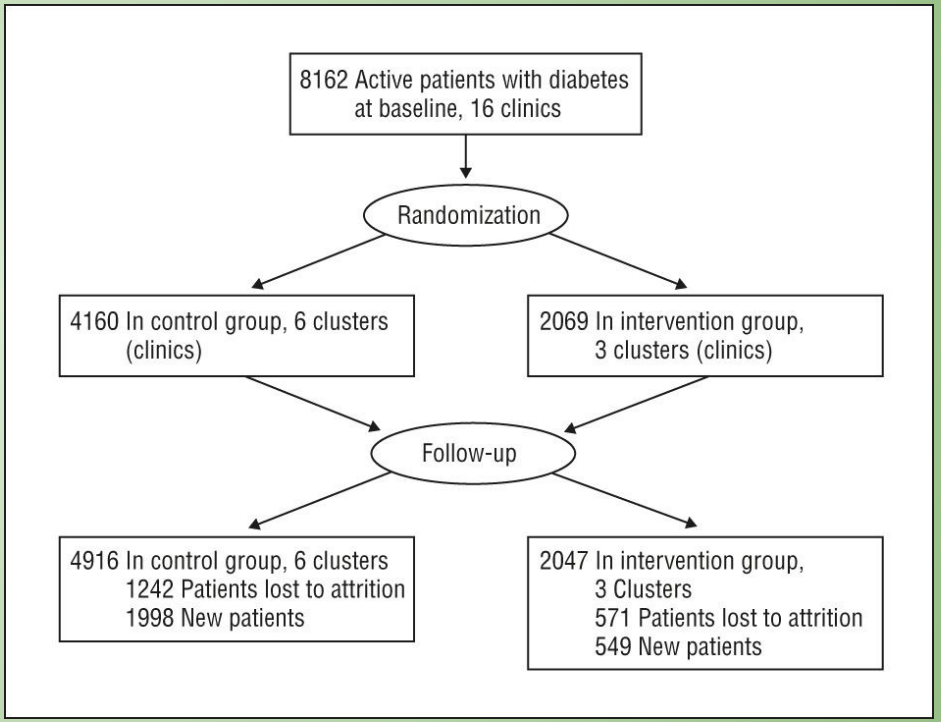
Regression Discontinuity Design

Cost	Can be expensive - It requires 2.75 more participants than a traditional RCT
Time	Same as traditional RCT
Research Question	Test an intervention, alternative to RCT
Viewed as	Generally strong
Other Info	Why the heck use it??? To be fair to those who really needs the intervention
Examples	Never tried it… Any takers… (Commonly used in Education studies)

Reference: https://www.socialresearchmethods.net/kb/index.php

Cluster Randomized Trial

- Randomization Unit: Cluster
- Very common in Family Medicine Research
- Common in community research
- Advantage:
  - Pragmatic
  - Easier for participating clusters

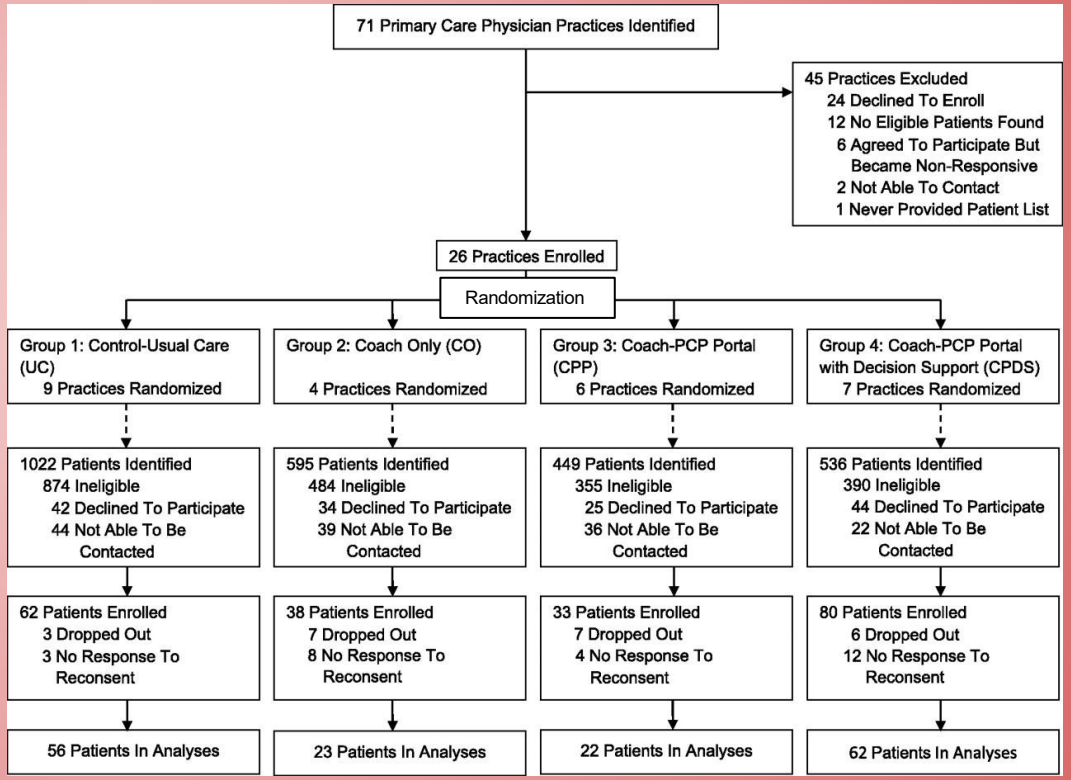


Cluster Randomized Trial

Cost	Probably the same as a traditional RCT
Time	Same as traditional RCT
Research Question	Test an intervention, when potential participants are naturally clustered
Viewed as	Depends on who reviews it… Some studies suggests many pitfalls, others suggest it's better since it's pragmatic
Other Info	Potentially more individual samples because of the natural clusters but requires more samples because of the Intracluster Correlation Coefficient (ICC)… Makes sense?
Examples	CHAP Study (20 intervention/19 control Communities) CP@Clinic Study (18 intervention/15 control buildings)

Factorial Design

- Can be a traditional/cluster RCT where interventions are combined
- Same advantage and disadvantage as traditional/cluster RCT
- Main use: Testing additive effects of combining intervention



Factorial Design

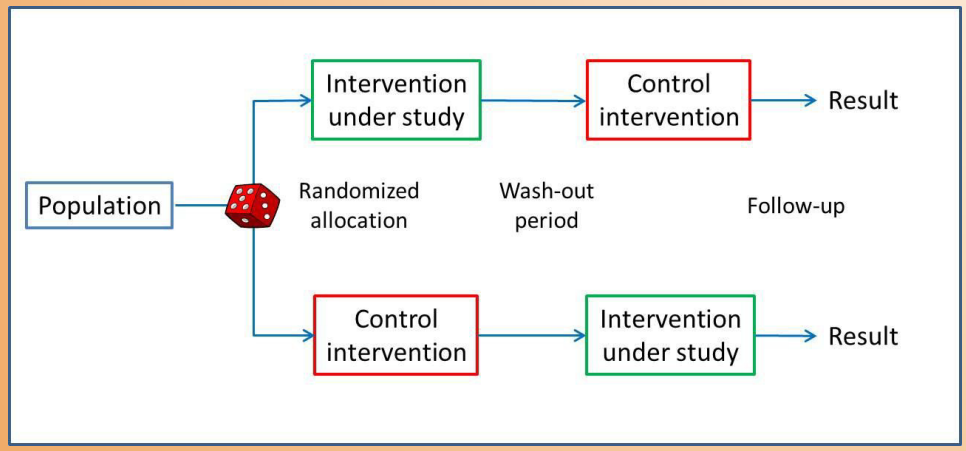
Examples:

- MFP QA Project - Comparing the effectiveness of Letters vs. Phone call vs. Letters + Phone call in increasing booster immunization rates for TDap immunization among teenagers

- Hospital study - Comparing Vit A+ Placebo, Zinc +Placebo, Vit A+ Zinc, Placebo + Placebo in improving hospital course of childhood diarrhea

Cross-over Design

- All participants are assigned to intervention/control at a point in time
- Participants serves as their control
- Cool but uncommon



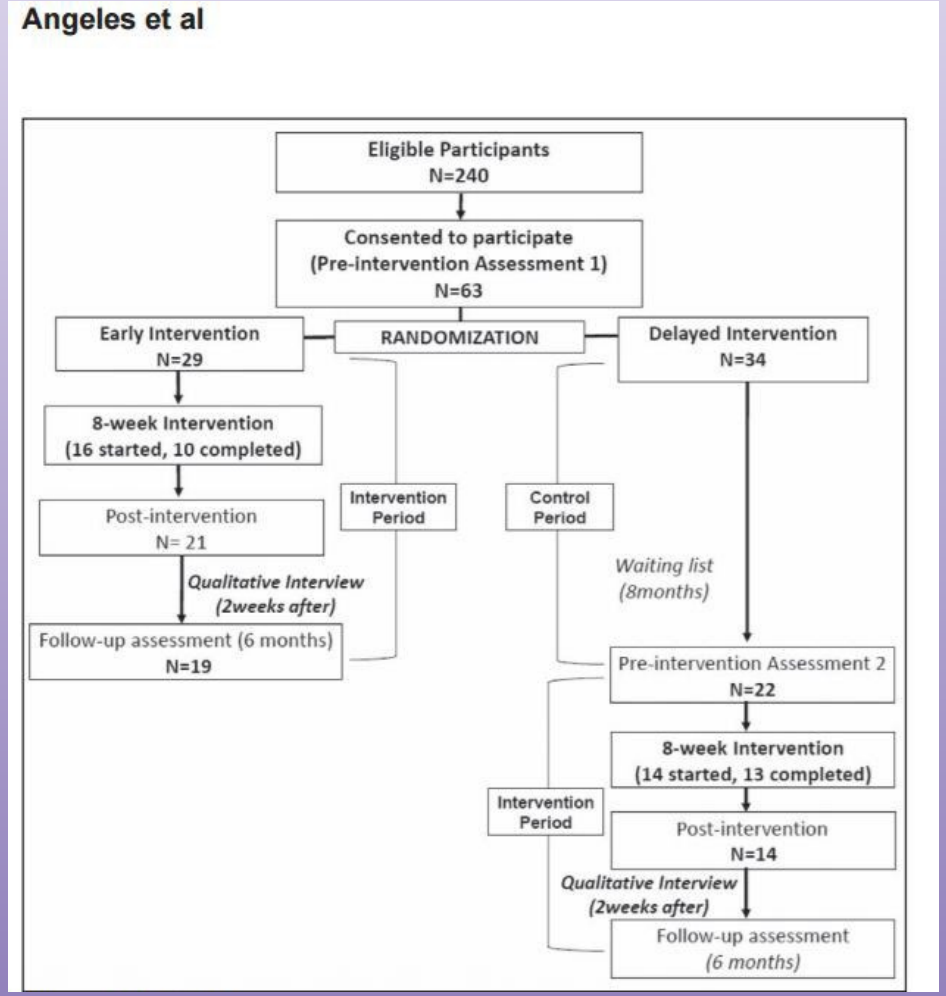
- Condition should be chronic and stable
- Treatment should not cure the participant

Cross-over Design

- Full cross-over may be limited in Family Practice/Primary care (Diabetes, HTN)
- Example:
  - Cross-over trial on chayote plant in decreasing HTN among community residents with stage 1 HTN

Delayed Intervention Design

- Variant of the cross-over study
- Just a single cross-over
- Advantage:
  - Everyone gets the intervention (Ethical)
  - Follows a natural course in the Health System
  - For paired analysis, sample is doubled

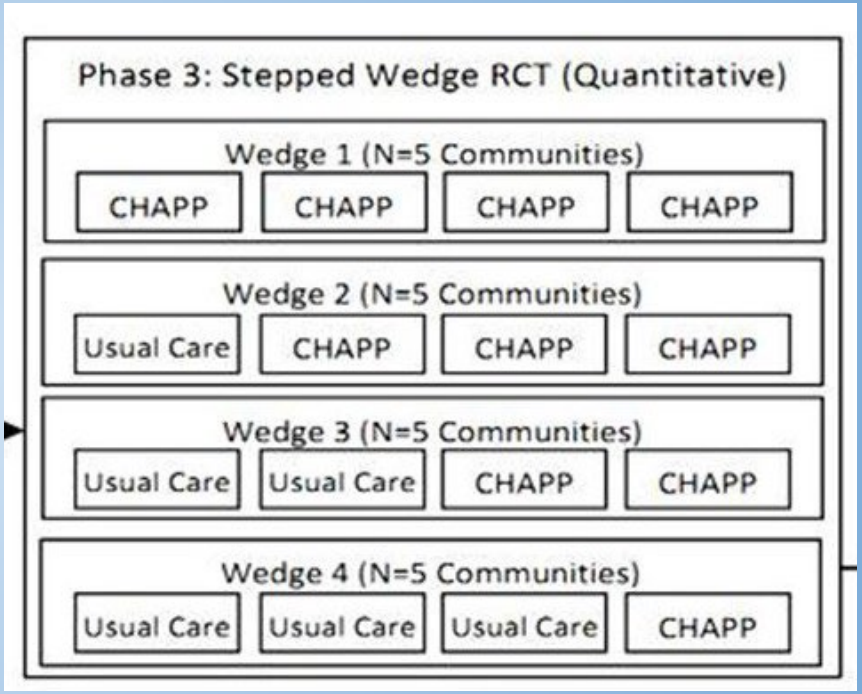


Delayed Intervention Design

Cost	More expensive than a traditional RCT
Time	Longer than traditional RCT
Research Question	Test an intervention, when you want all participants to get the intervention When you want to measure the effect of wait times
Viewed as	Same as an RCT
Other Info	Easier to recruit participants, easier to justify than no intervention Lost to follow-up can be problematic in the delayed intervention group
Examples	Group interprofessional chronic pain management in the primary care setting: a pilot study of feasibility and effectiveness in a family health team in Ontario

Stepped Wedge Design

- Further extension of the Delayed Intervention (DI) design
- Generally cluster randomized trials but can also be for traditional RCT
- Has all the advantages of the DI Design, less samples needed
- Challenges:
  - Matching
  - This is relatively new
    - Types (2015)
    - Sample size (2015)



Stepped Wedge Design

Wedge	Pre-intervention	Post/Pre	Post/Pre	Post/Pre	Post-intervention	Parallel Comparison	Pairwise Comparison	Duration	Equipment Cost
1	5	5				15 (20)	20	2 years	$ 66,209.00
2		5	5						
3			5	5					
4				5	5				
Wedge									
1	10	10				20 (30)	30	1.5 years	$ 95,392.00
2		10	10						
3			10	10					
RCT									
Intervention	20	20				20 (20)	20	<1 year	$ 114,068.00
Control	20	20							

Stepped Wedge Design

Cost	Similar or about the same as a traditional RCT
Time	Longer than traditional RCT
Research Question	Test an intervention, when you want all participants to get the intervention
Viewed as	Same as an RCT
Other Info	Divides implementation of intervention and evaluation of outcome into more manageable chunks Everybody gets the intervention, less ethical dilemma
Examples	CHAP-Philippines study

Questions???