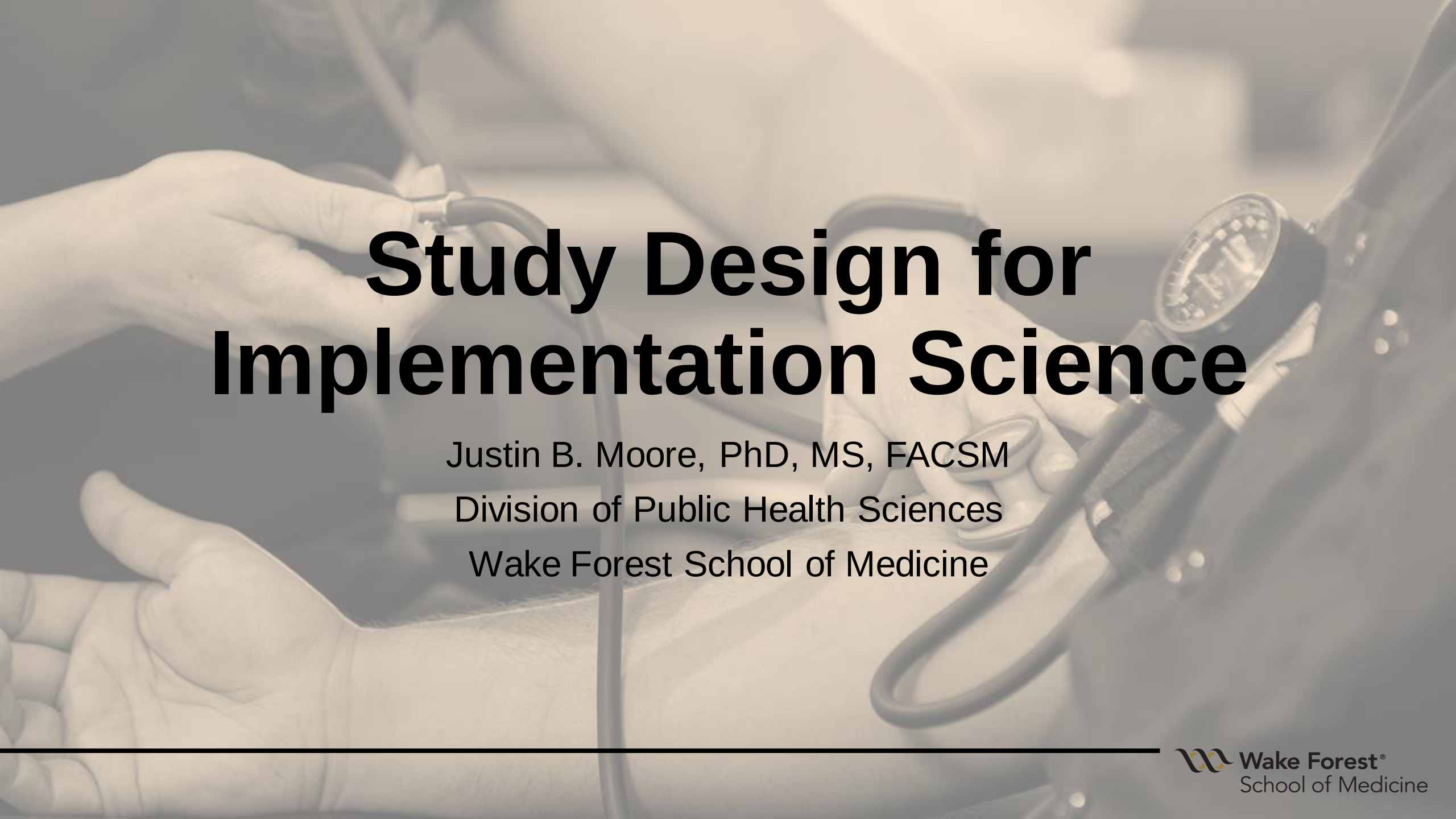

Study Design for Implementation Science

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Objectives

- By the end of the lecture, learners will be able to:
  - Describe an array of of IS study designs
  - Identify the strengths and limitation of IS study designs

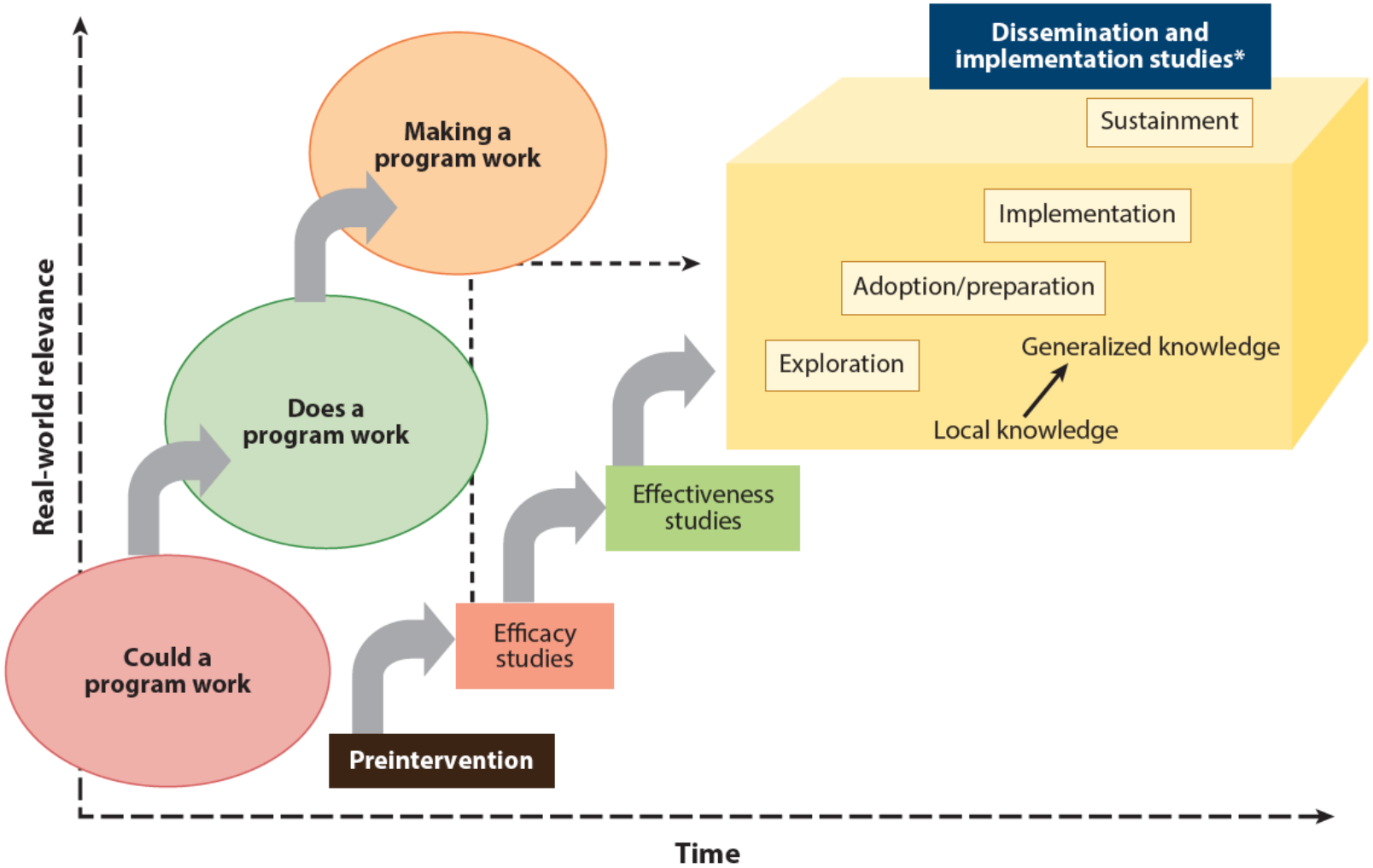

Figure 1

Traditional translational pipeline from preintervention, efficacy, effectiveness, and dissemination and implementation studies.

Brown CH, Curran G, Palinkas LA, Aarons GA, Wells KB, Jones L, Collins LM, Duan N, Mittman BS, Wallace A, Tabak RG, Ducharme L, Chambers DA, Neta G, Wiley T, Landsverk J, Cheung K, Cruden G. An Overview of Research and Evaluation Designs for Dissemination and Implementation. Annu Rev Public Health. 2017 Mar 20;38:1-22.

Study Designs

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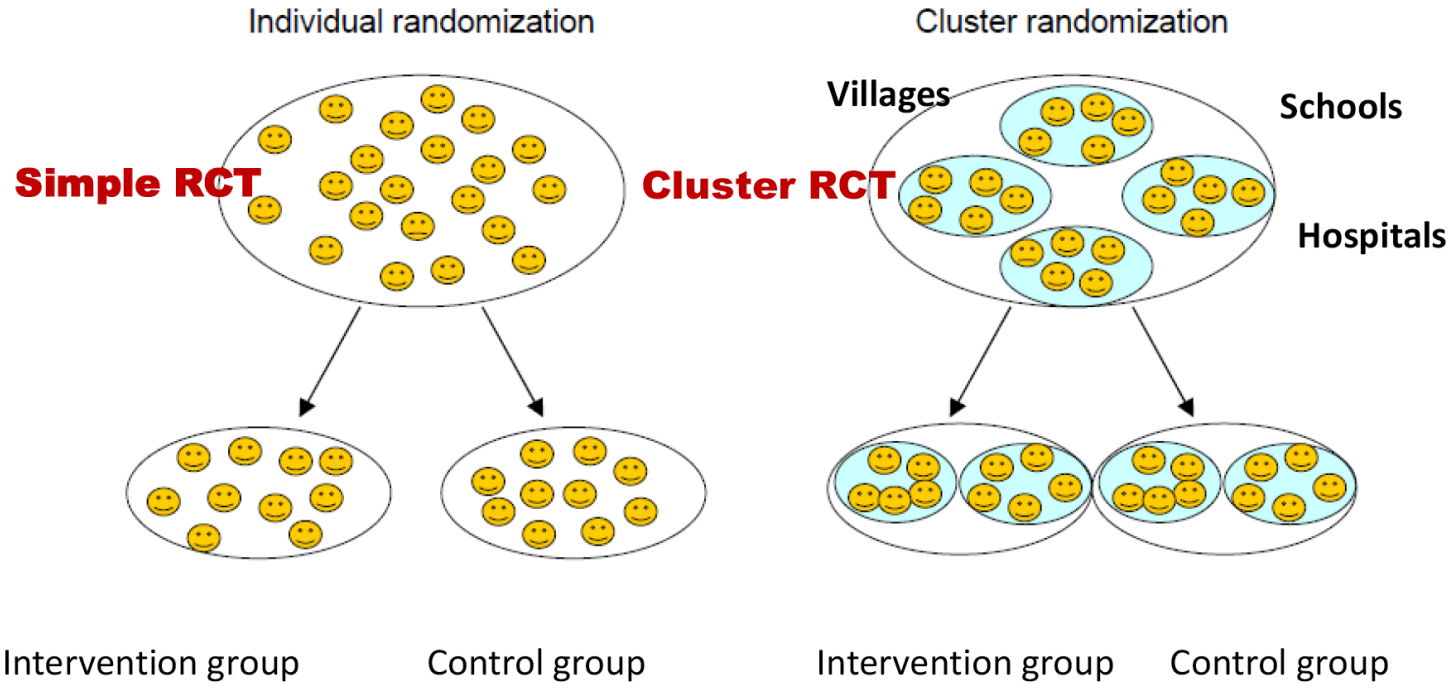
Examples of study designs

- New implementation strategy versus usual-practice implementation design
  - Cluster RCTs
- Head-to-head randomized implementation trial design
  - Hybrid designs
- Factorial designs for implementation
  - multiphase optimization strategy implementation trials
    - Sequential, Multiple Assignment, Randomized Trial (SMART)
- Within- and Between-Site Comparison Designs
  - Stepped wedge
  - Dynamic wait-listed design

Brown CH, Curran G, Palinkas LA, Aarons GA, Wells KB, Jones L, Collins LM, Duan N, Mittman BS, Wallace A, Tabak RG, Ducharme L, Chambers DA, Neta G, Wiley T, Landsverk J, Cheung K, Cruden G. An Overview of Research and Evaluation Designs for Dissemination and Implementation. Annu Rev Public Health. 2017 Mar 20;38:1-22.

New implementation strategy versus usual-practice implementation design

- Often comparing active dissemination or implementation to usual practice in naturally occurring clusters
- Employ a cluster randomized trial design



Head-to-head randomized implementation trial design

- Testing of one(or more) implementation strategy vs. another (or others)
- May employ a hybrid design

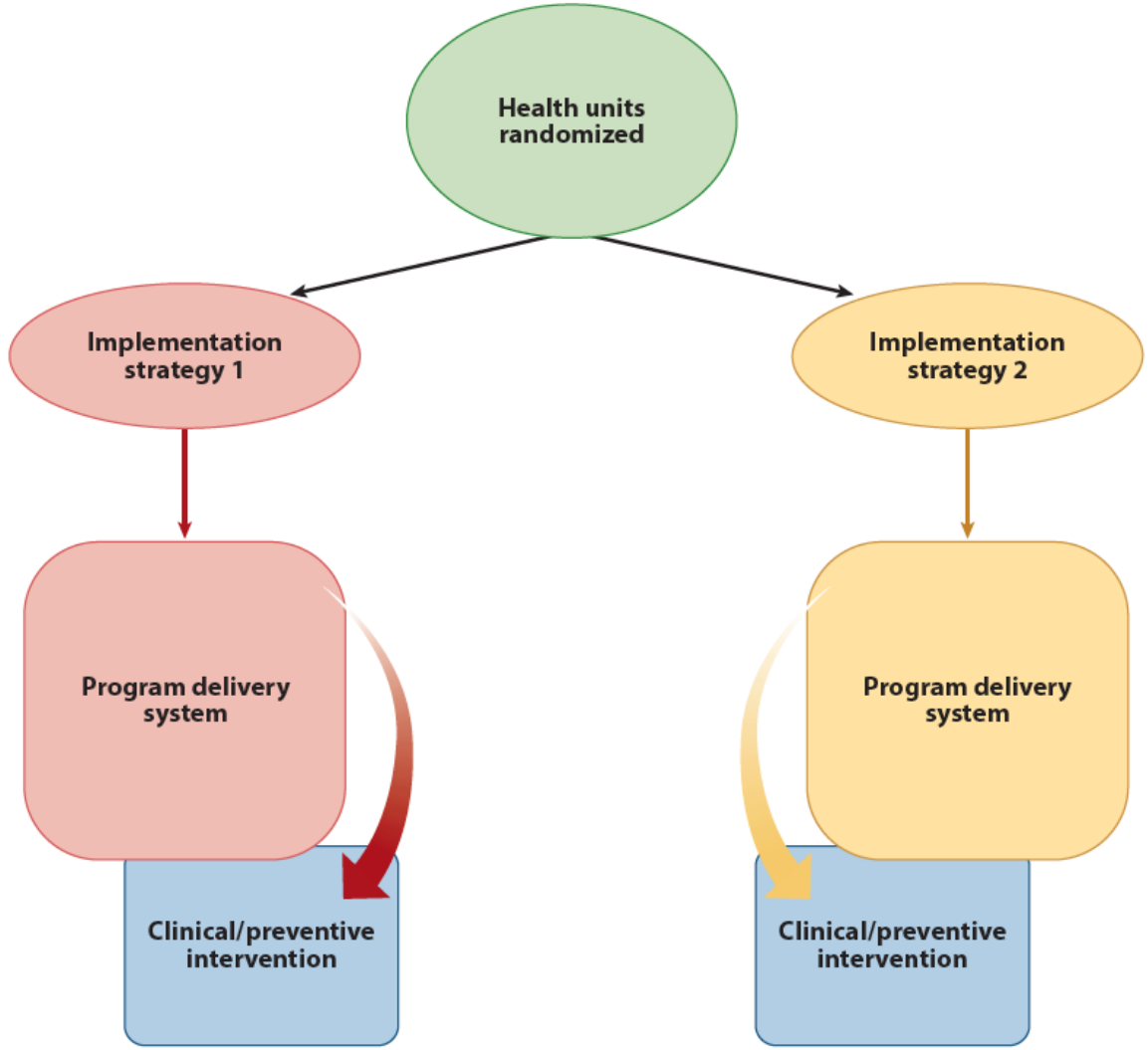


Figure 2

Focus of research in a head-to-head randomized implementation trial with identical clinical/preventive intervention and different implementation strategies.

Brown CH, Curran G, Palinkas LA, Aarons GA, Wells KB, Jones L, Collins LM, Duan N, Mittman BS, Wallace A, Tabak RG, Ducharme L, Chambers DA, Neta G, Wiley T, Landsverk J, Cheung K, Cruden G. An Overview of Research and Evaluation Designs for Dissemination and Implementation. Annu Rev Public Health. 2017 Mar 20;38:1-22.

Hybrid Implementation/Effectiveness Designs

TABLE 3. Hybrid Design Characteristics and Key Challenges

Study Characteristic	Hybrid Trial Type 1	Hybrid Trial Type 2	Hybrid Trial Type 3
Research aims	Primary aim: determine effectiveness of a clinical intervention Secondary aim: better understand context for implementation	Coprimary aim*: determine effectiveness of a clinical intervention Coprimary aim: determine feasibility and potential utility of an implementation intervention/strategy	Primary aim: determine utility of an implementation intervention/strategy Secondary aim: assess clinical outcomes associated with implementation trial
Research questions (examples)	Primary question: will a clinical treatment work in this setting/these patients? Secondary question: what are potential barriers/ facilitators to a treatment's widespread implementation?	Coprimary question*: will a clinical treatment work in this setting/these patients? Coprimary question: does the implementation method show promise (either alone or in comparison with another method) in facilitating implementation of a clinical treatment?	Primary question: which method works better in facilitating implementation of a clinical treatment? Secondary question: are clinical outcomes acceptable?

Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012 Mar;50(3):217-26.

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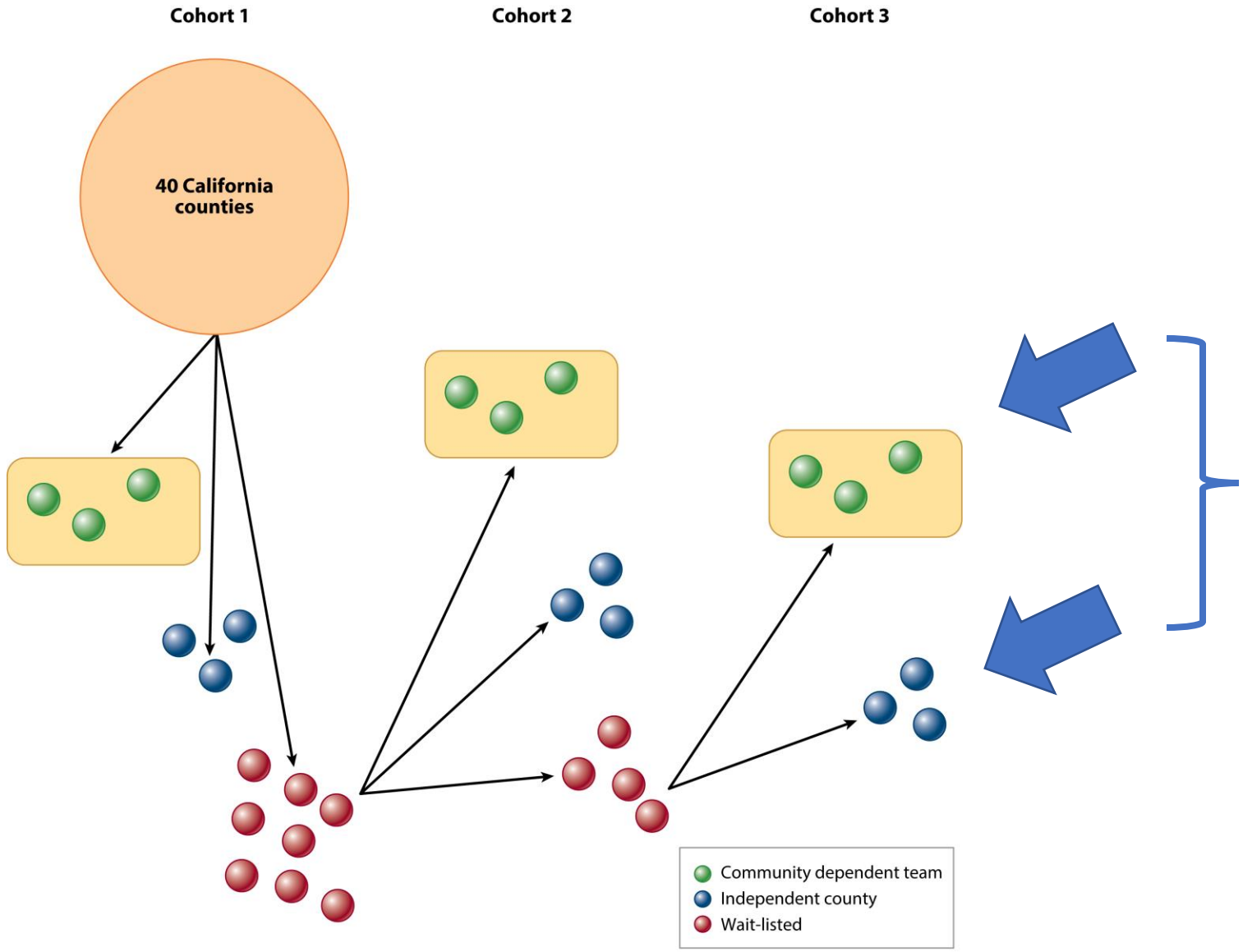


These would be different intervention strategies.

Brown CH, et al. 2017.
Annu. Rev. Public Health. 38:1–22

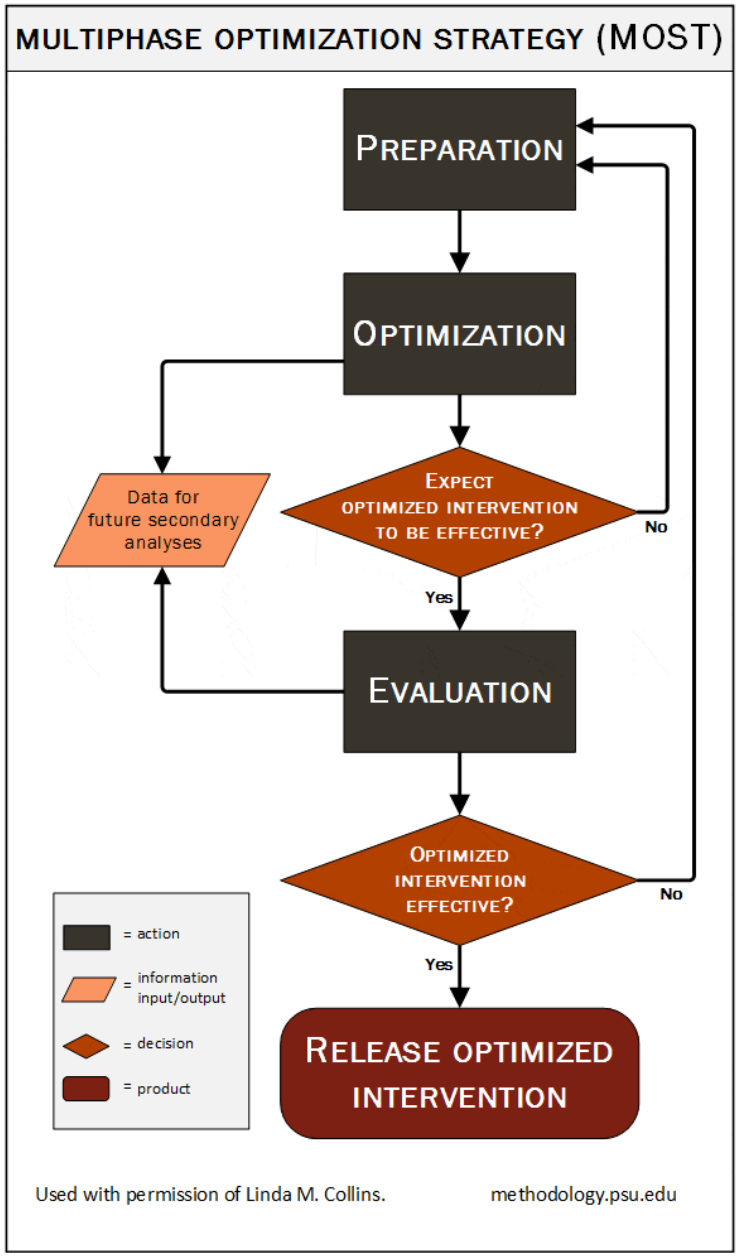
Figure 3 Design to assign 40 counties in California to an independent county or community development team implementation strategy and time (cohort) using a randomized rollout design; 11 counties in Ohio were separately randomized in a fourth cohort to the same two implementation strategies (not shown).

Factorial designs for implementation

- Multiphase optimization strategy trial (MOST)
  - An engineering-inspired framework for development, optimization, and evaluation of multicomponent behavioral, biobehavioral, and biomedical interventions.

http://www.methodology.psu.edu/

Figure 1.



Kate Guastaferro, Linda M. Collins, "Achieving the Goals of Translational Science in Public Health Intervention Research: The Multiphase Optimization Strategy (MOST)", *American Journal of Public Health* 109, no. S2 (February 1, 2019): pp. S128-S129.

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Factorial Design

	Factor		
Condition	Training	Website	Technical assistance
1	Y	Y	Y
2	Y	Y	N
3	Y	N	Y
4	Y	N	N
5	N	Y	Y
6	N	Y	N
7	N	N	Y
8	N	N	N

Factorial Design

	Factor		
Condition	Training	Website	Technical assistance
1	Y	Y	Y
2	Y	Y	N
3	Y	N	Y
4	Y	N	N
5	N	Y	Y
6	N	Y	N
7	N	N	Y
8	N	N	N

Factorial Design

	Factor		
Condition	Training	Website	Technical assistance
1	Y	Y	Y
2	Y	Y	N
3	Y	N	Y
4	Y	N	N
5	N	Y	Y
6	N	Y	N
7	N	N	Y
8	N	N	N

Factorial designs for implementation

- Sequential, Multiple Assignment, Randomized Trial (SMART)
  - Involves multistage randomizations where the site-level implementation process can be modified if unsuccessful
    - eg, re-randomizing no-responding units

Within- and Between-Site Comparison Designs

a

Time	1	2	3	4
Cohort A	0	X*	X	X
Cohort B	0	0	X*	X
Cohort C	0	0	0	X*

Stepped wedge

b

Time	1	2	3	4
Cohort A	0	X*	X	X
	0	Y*	Y	Y
Cohort B	0	0	X*	X
	0	0	Y*	Y
Cohort C	0	0	0	X*
	0	0	0	Y*

Dynamic wait-listed

0 Implementation as usual
X*, Y* Introductions on new implementation strategies
X, Y Continuation of strategies over extended periods of time

Figure 4

Schematics of three rollout randomized designs that determine the timing of changes from usual practice, startup or continuation of one or more implementation strategies.

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Brown CH, Curran G, Palinkas LA, Aarons GA, Wells KB, Jones L, Collins LM, Duan N, Mittman BS, Wallace A, Tabak RG, Ducharme L, Chambers DA, Neta G, Wiley T, Landsverk J, Cheung K, Cruden G. An Overview of Research and Evaluation Designs for Dissemination and Implementation. Annu Rev Public Health. 2017 Mar 20;38:1-22.

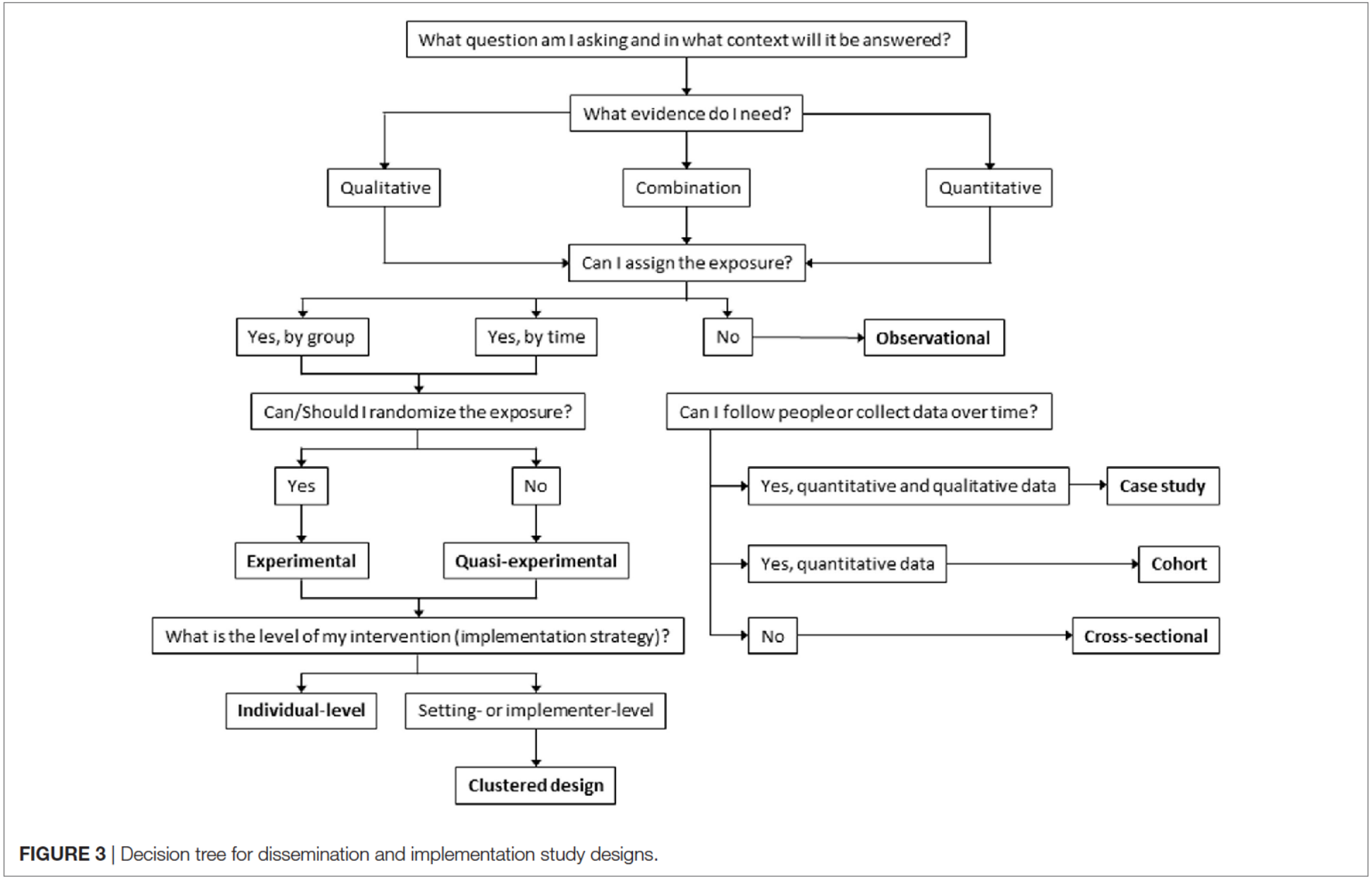

FIGURE 3 | Decision tree for dissemination and implementation study designs.

Summary

- A ***lot*** of research design options available
- Many are pragmatic by nature (or necessity)
- Models and research designs often used concurrently, “nested” within each other
- Have considerable implications for power calculations, sampling, statistical analyses, and external validity of results

Resource

https://impsciuw.org/implementation-science/research/designing-is-research/

Questions?

Thank you.