



Atrium Health

Wake Forest Baptist

Study Designs for Implementation Science

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About the series

- **Description**

- This series provides an introduction to dissemination and implementation (D&I) science and a theoretical foundation to translate evidence into clinical practice, health policy, or public health.

- **Sessions**

- Wed, 9/15: Study Designs in Implementation Science
- Wed, 9/29: Integrating Implementation Science Frameworks and Behavioral Theory into Implementation Research
- Wed, 10/13: Process Evaluation and Implementation Monitoring

A little about me...



- A faculty member in the Departments of Implementation Science (primary), Epidemiology & Prevention, and Family & Community Medicine.
- I have formal training in exercise science, health behavior, epidemiology, & implementation science.
- I've been conducting implementation science research since 2003.
- The primary focus of my research has been the epidemiology of health behaviors related to obesity and the design, delivery, and evaluation of interventions to promote physical activity and healthy eating prevent or treat obesity or related comorbidities.

DISSEMINATION AND
IMPLEMENTATION
RESEARCH
IN HEALTH

TRANSLATING
SCIENCE TO
PRACTICE

SECOND EDITION

EDITED BY
ROSS C. BROWNSON
GRAHAM A. COLDITZ
ENOLA K. PROCTOR

Recommended Texts

- **Dissemination and Implementation Research in Health: Translating Science to Practice (2nd Edition)**
 - Ross C. Brownson, Graham A. Colditz, Enola K. Proctor
- **Handbook on Implementation Science**
 - Per Nilsen & Sarah A. Birken

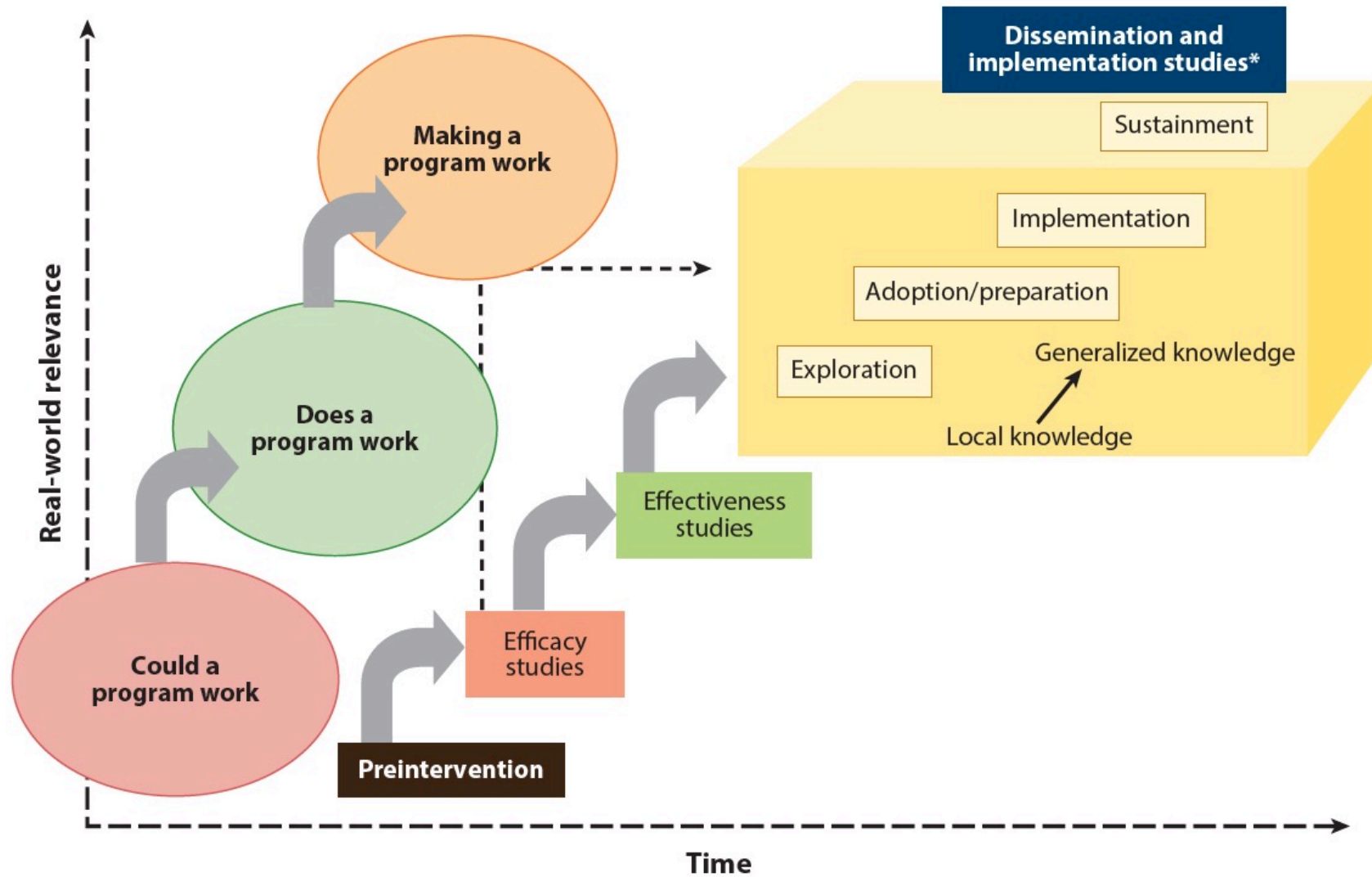

HANDBOOK ON
Implementation Science

Edited by
Per Nilsen • Sarah A. Birken



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



*These dissemination and implementation stages include systematic monitoring, evaluation, and adaptation as required.

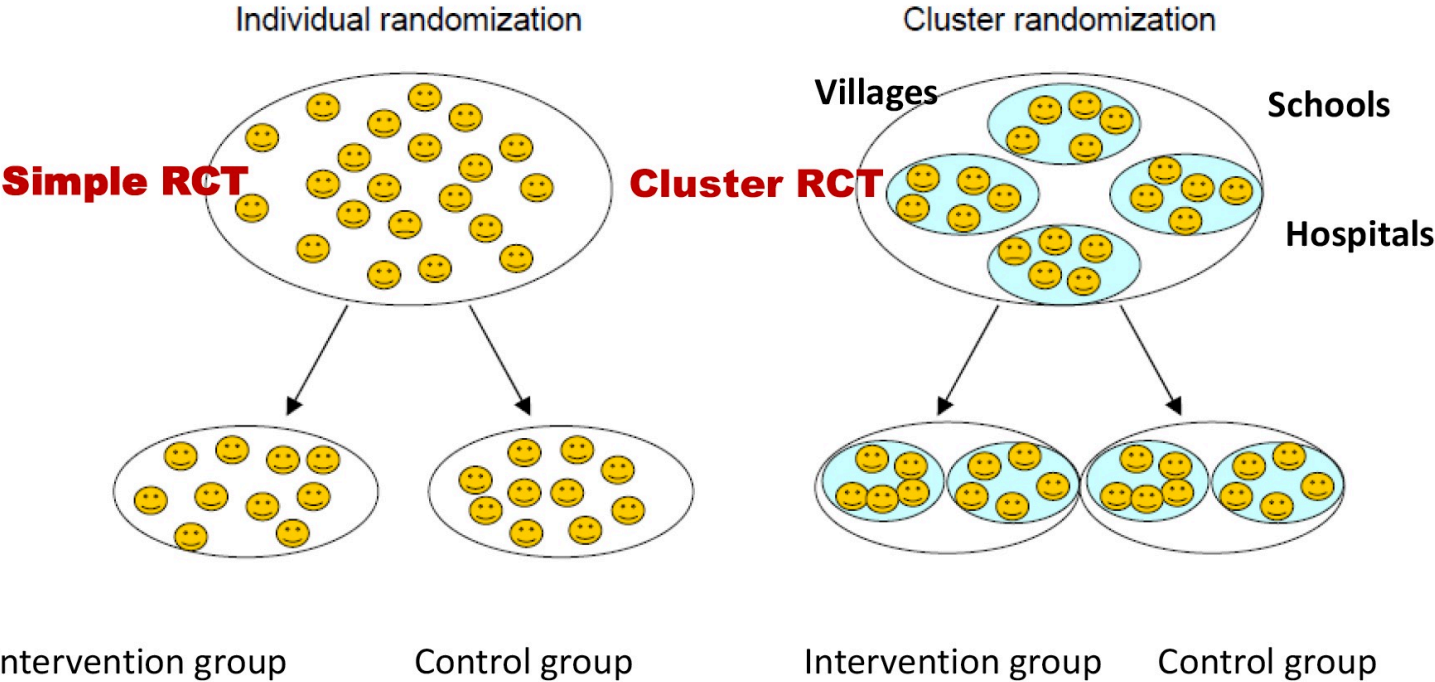
Study Designs

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

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

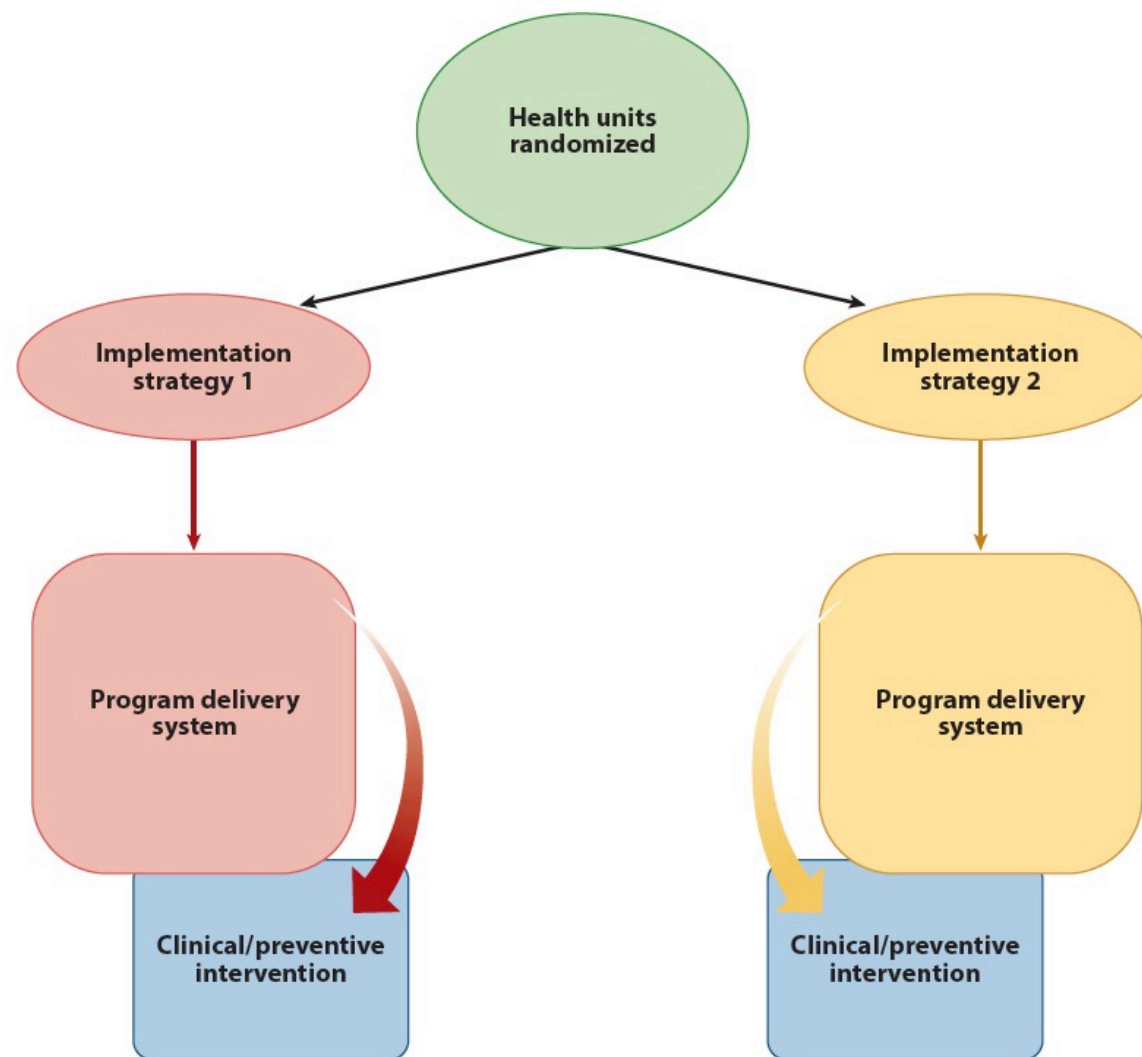


Figure 2

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

Hybrid Implementation/Effectiveness Designs

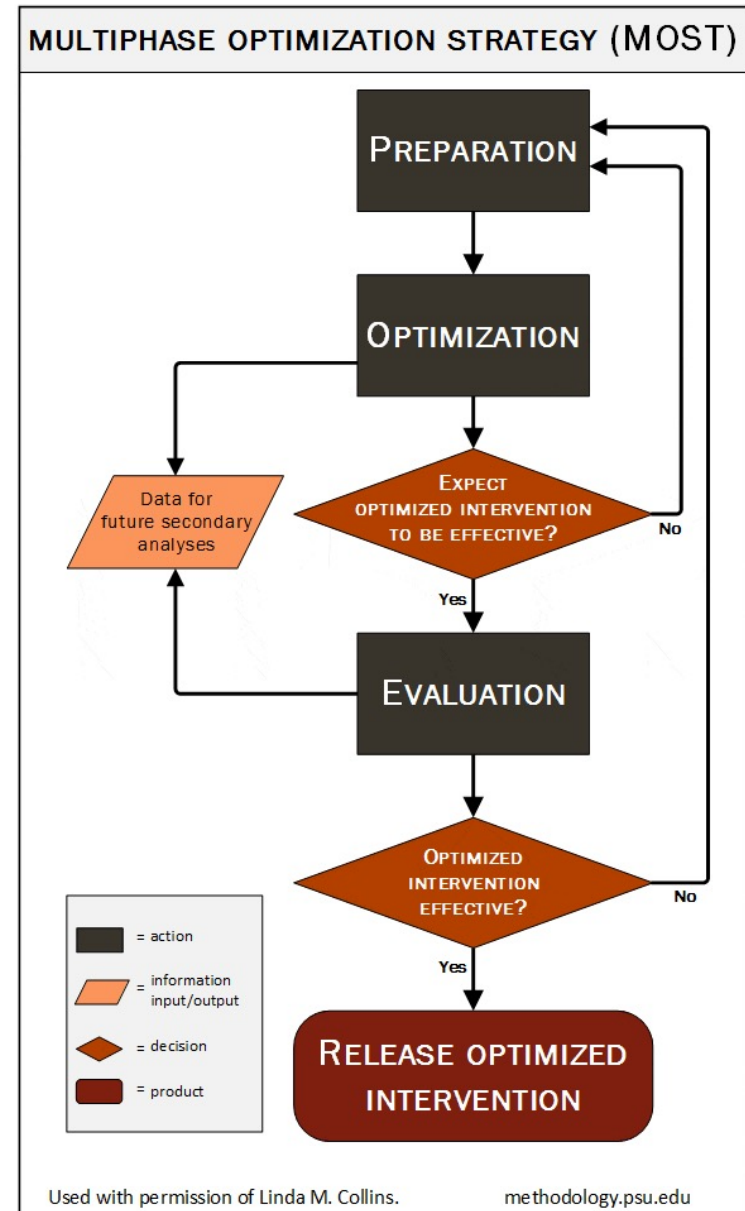
TABLE 3. Hybrid Design Characteristics and Key Challenges

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

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/>



Factorial Design

Condition	Factor		
	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

Condition	Factor		
	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

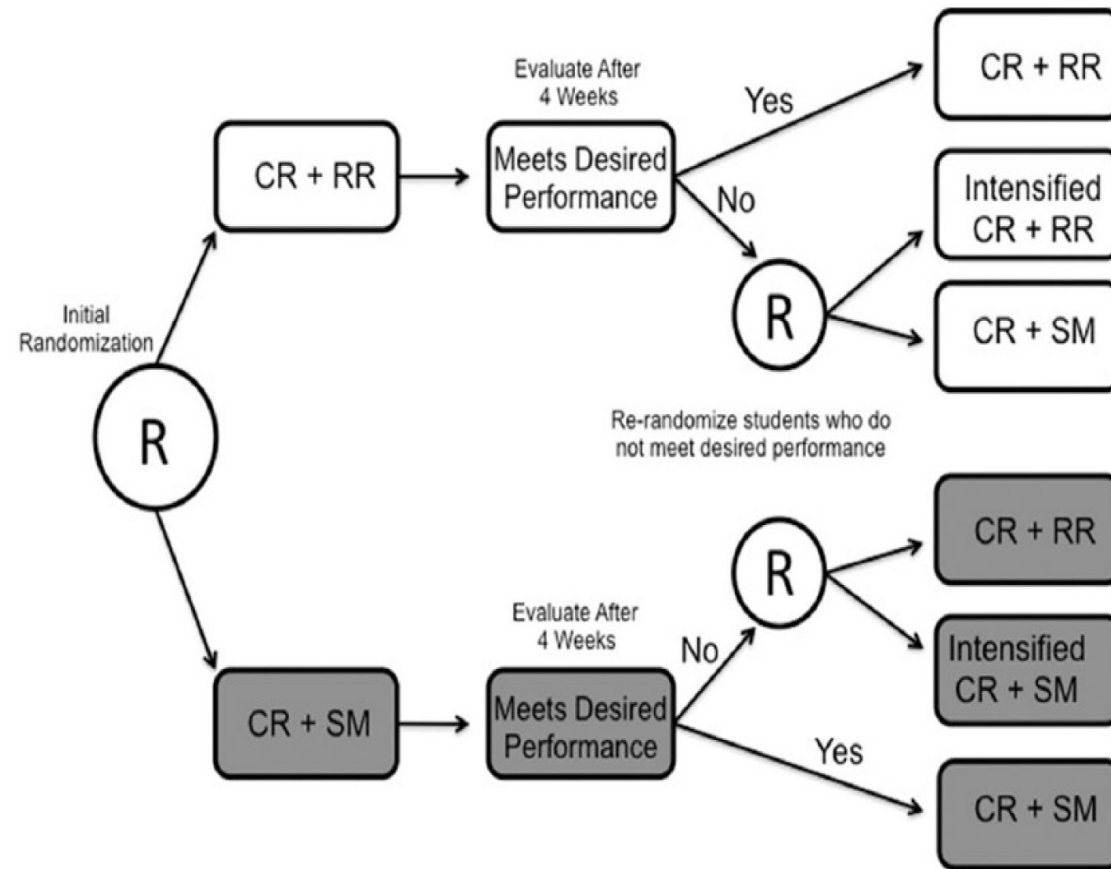
Factorial Design

	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

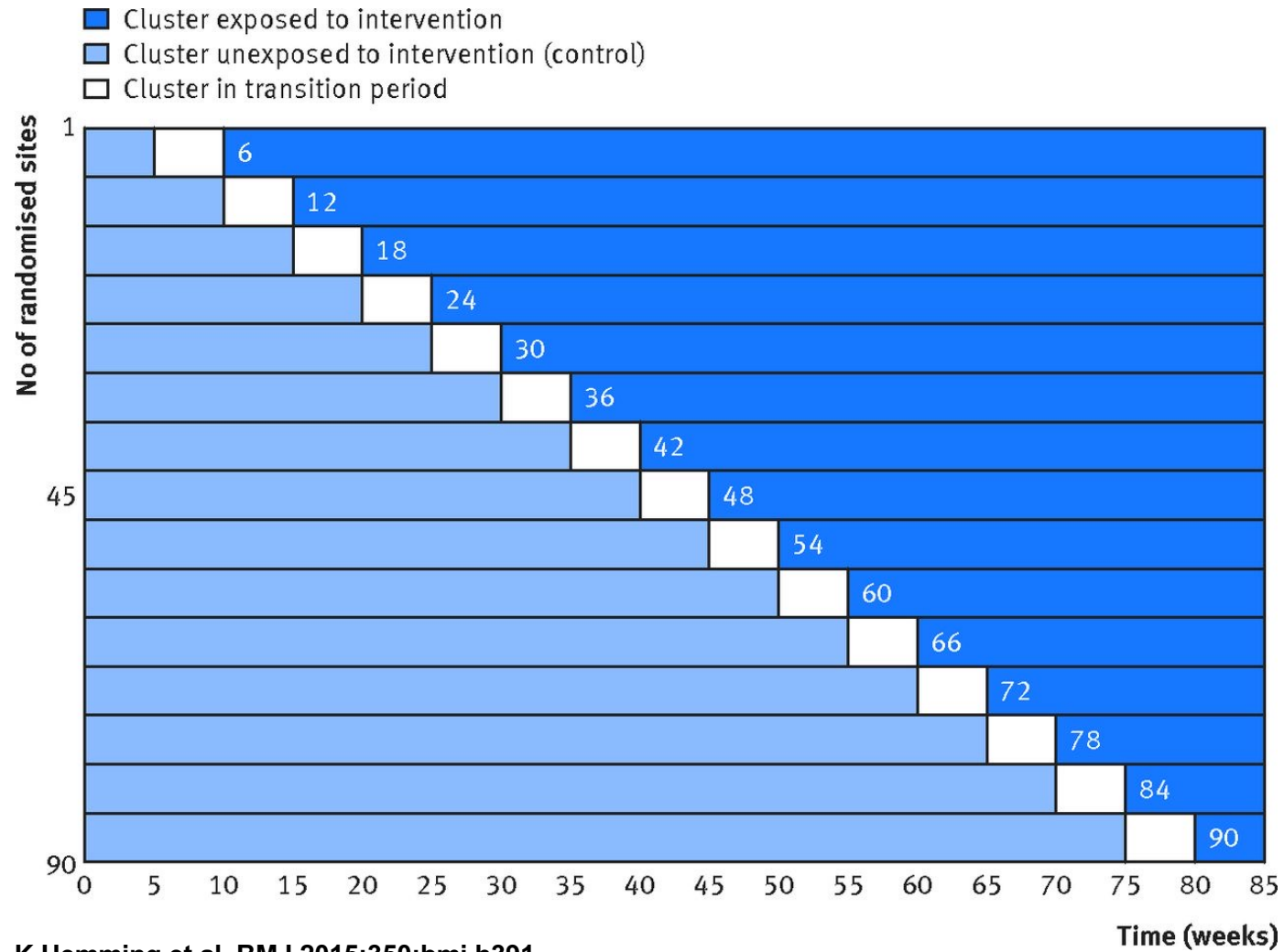
Factorial designs for implementation

- 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

Example SMART design used to develop an adaptive intervention



Schematic representation of the EPOCH stepped wedge study



K Hemming et al. BMJ 2015;350:bmj.h391

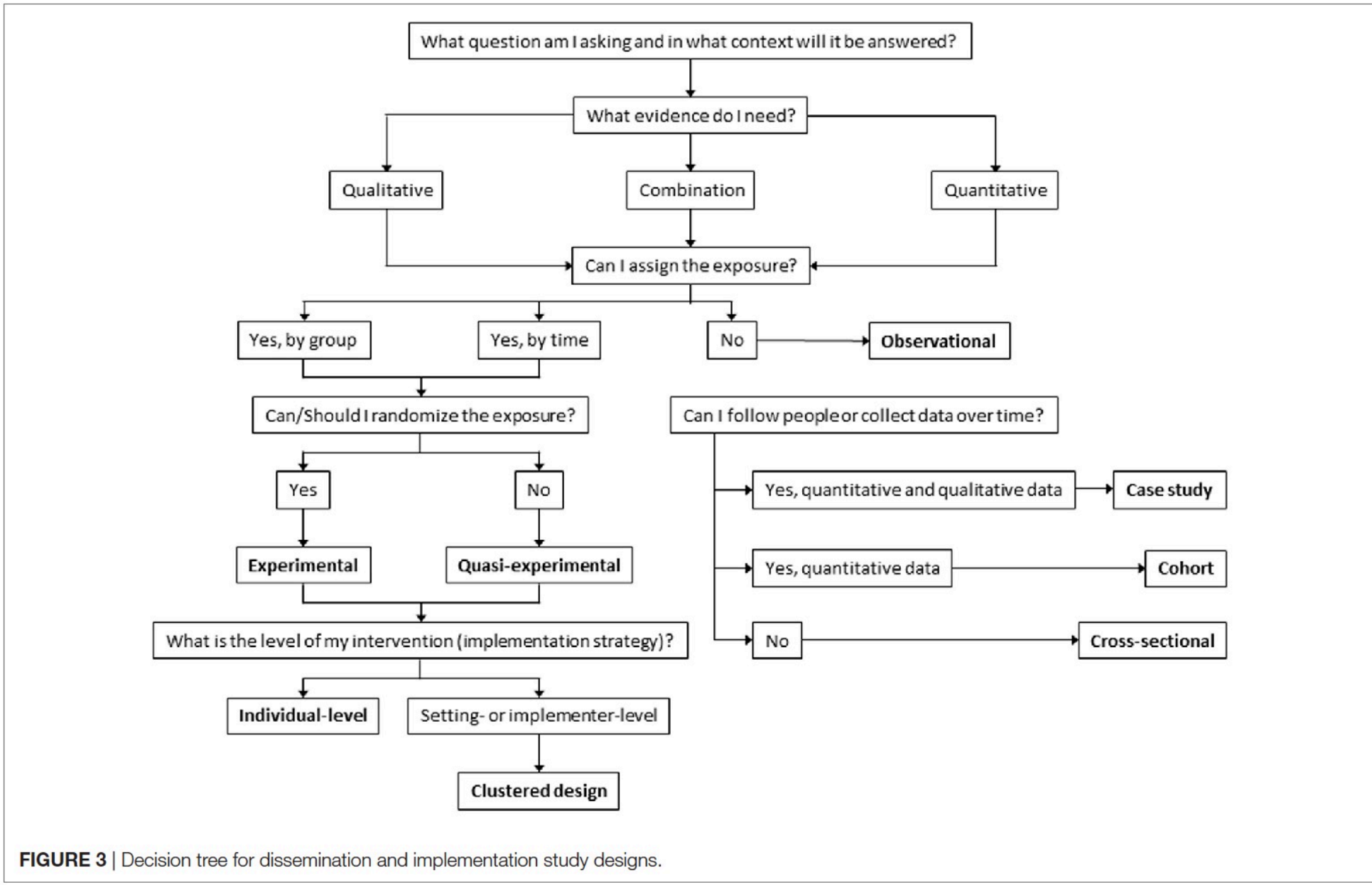


FIGURE 3 | Decision tree for dissemination and implementation study designs.

Summary

- A *lot* of models, trial types, and 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



Overview of Study Designs in Implementation Science

Implementation science seeks to improve the adoption, adaptation, delivery and sustainment of evidence-based interventions in healthcare, and central to this goal is understanding how interventions are delivered effectively in the context of the 7 P's.



Research designed to evaluate the impact of these contexts takes many forms, and design selection is critical to capturing data in a manner that appropriately addresses your research question or questions.

Implementation research largely attends to external validity, whereas most randomized efficacy and effectiveness research designs emphasize internal validity.

Given these differing focal points, a debate exists in the field as to the role of randomized design in implementation research and the relative merit of quantitative, qualitative, and mixed methods designs.

Doing Research

- Frame Your Question
- Pick a Theory, Model, or Framework
- Identify Implementation Strategies
- Select Research Method
- Select Study Design
- Choose Measures
- Get Funding
- Report Results

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

Questions?