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← Training Institute for  
← Dissemination and  
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Westin Pasadena | Pasadena, California

# Designs for Dissemination & Implementation Research

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Selected content adapted from presentations by:

Amy M. Kilbourne, PhD, MPH, & Karen M. Emmons,  
Ph.D.- TIDIRH, July, 2015, Pasadena, CA

Maureen Smith, Ph.D., Introduction to Translational  
Outcomes Research, Sept 2017, Madison, WI



# Declaration

I have a shareholder interest in CHESS Mobile Health, a web-based health care technology company that has developed software for patients and family members struggling with addiction.

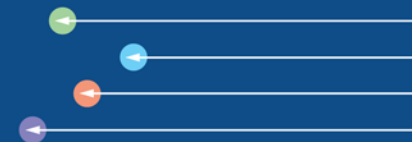
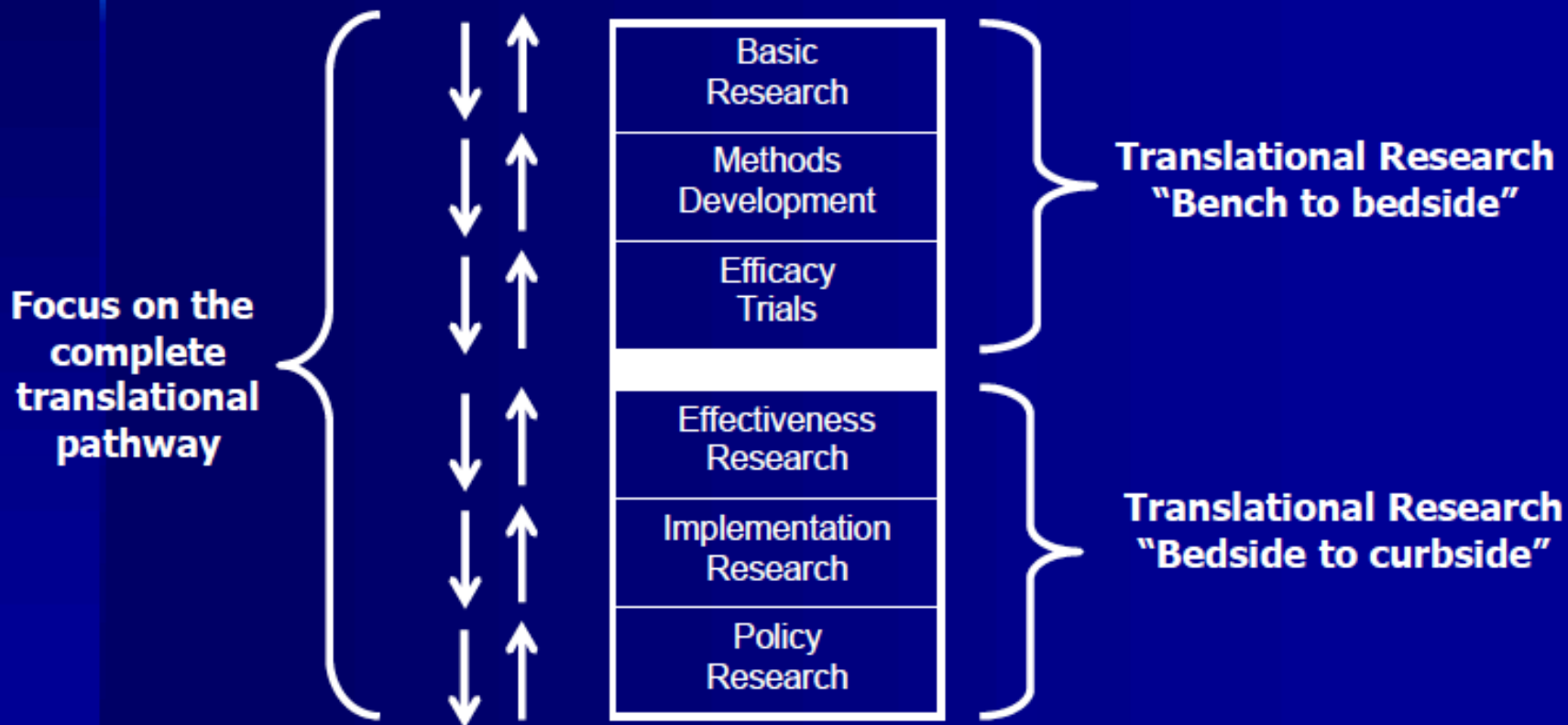


# Overview

- Translational research spectrum
- Designs for D&I research
- Group exercise- asking the right questions to get started with study design



# The Continuum of Translational Research



# Randomized Clinical Trials

- Conducted to obtain safety and efficacy data on new treatments
- ClinicalTrials.gov currently has 198,792 trials with locations in 190 countries
- Application of scientific method to understand human biology
  - Test causality
  - Rigorously monitor and assess
  - Randomize assignment into groups
- Gold standard...for what conclusions?



# Effectiveness Research

- Examine the gap between knowledge and usual community practice
- Includes reasons for and impact of the gap
- Presumption that having a gap may be fine...depends on impact



# Implementation Research

- Develop, evaluate, disseminate behavioral interventions to improve practice and outcomes
- Strategies to close the gap
- Presumption that having a gap is bad



# Commonly Used Designs

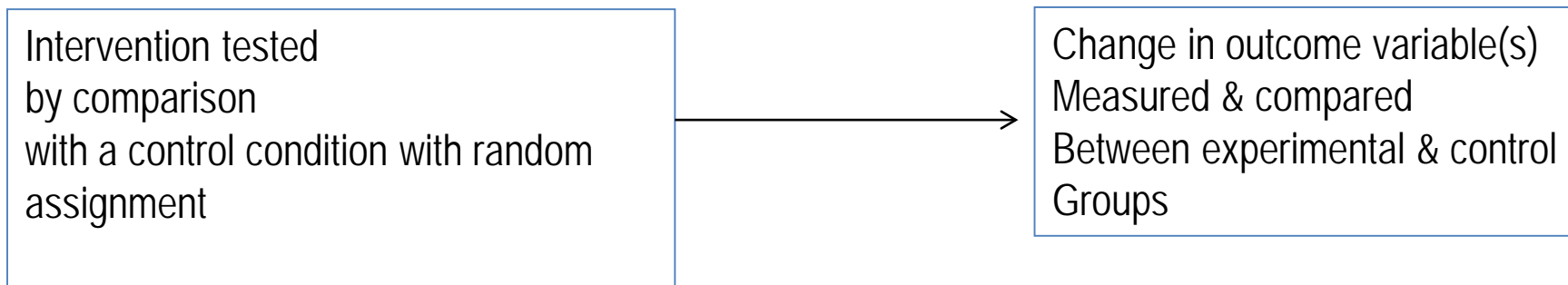
- Randomized controlled trial (RCT)
- Parallel assignment cluster RCT
- Stepped-wedge design
- Interrupted time series (ITS)
- Mixed-methods designs
- Hybrid/Implementation Effectiveness Designs

Mercer SL, DeVinney BJ, Fine LJ, Green LW, Dougherty D.. Am J Prev Med. 2007 Aug;33(2):139-154.





# The Historically Prevailing Standard of Evidence: The Randomized Controlled Trial

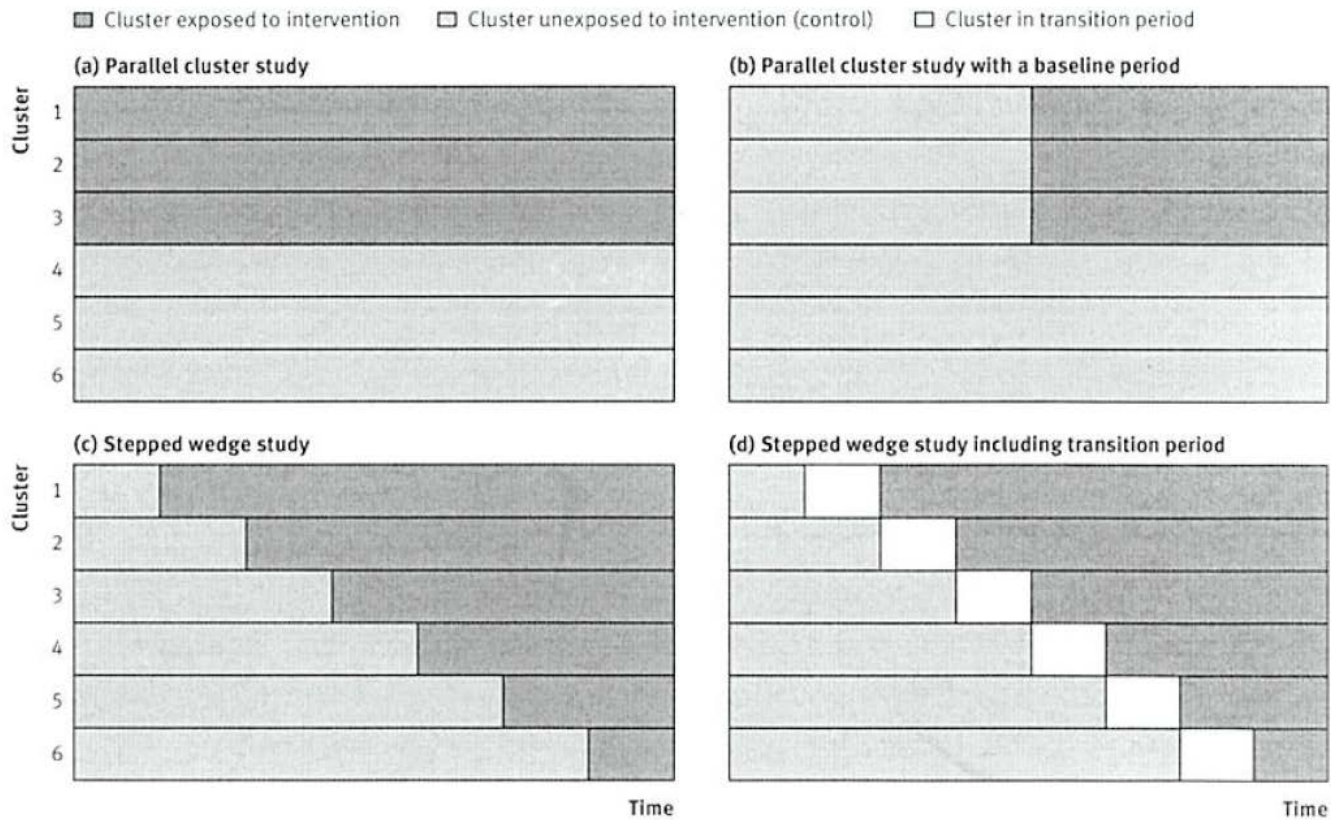


- Interventions highly standardized
- All else held constant
- Clients randomized, no choice
- Comparison based on average change for each group
- Subgroup analysis discouraged/limited
- Dropouts discounted, ignored

Green TIDIRH, 2013



# Parallel Cluster vs. Stepped Wedge Designs

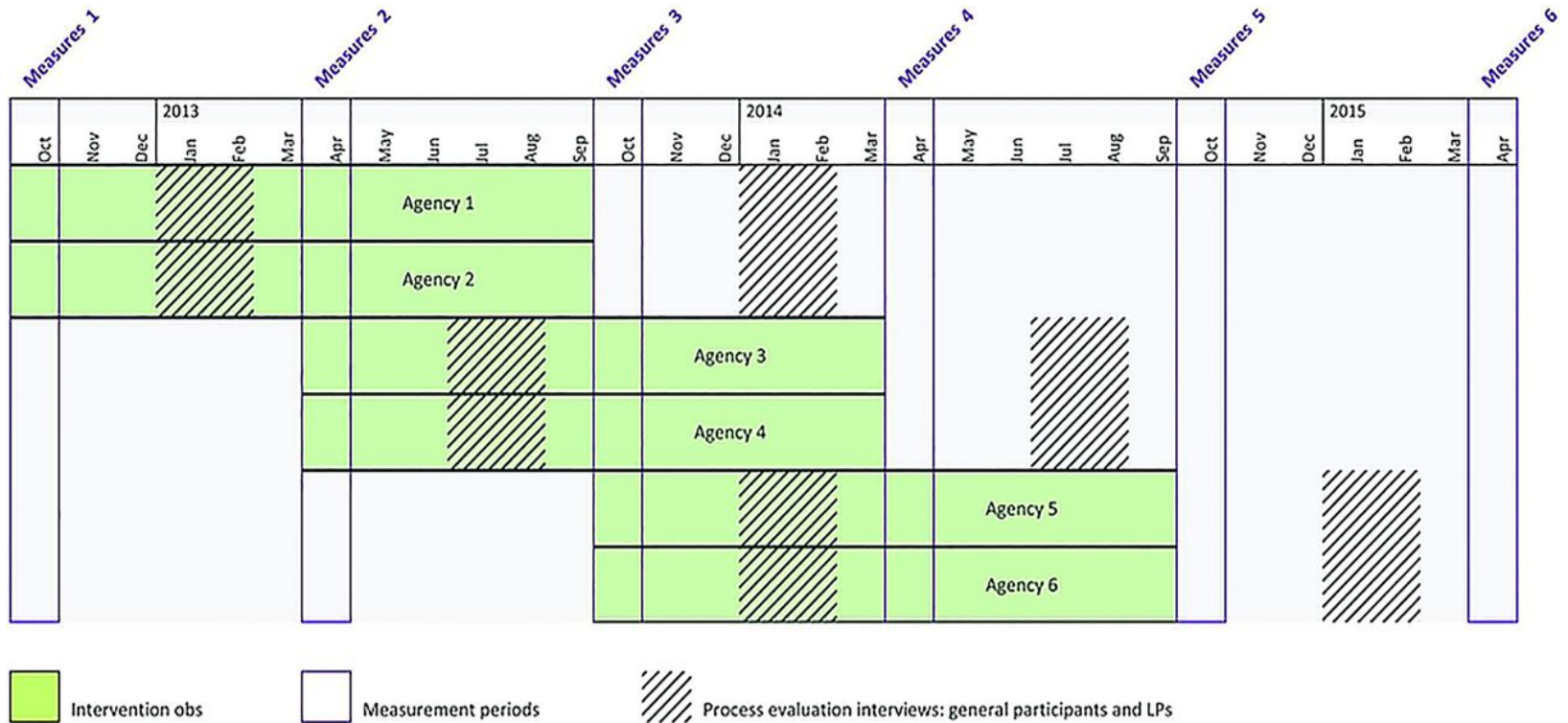


# Stepped Wedge Design Benefits/Cautions

- Preferable when:
  - There is evidence in support of the intervention, or resistance to a parallel design where half receive the Ix
  - The Tx is service delivery or policy change that does not need participant consent.
  - Logistical concerns mean that implementation must be staggered
- Deserves caution when:
  - Methods for calculating power are murky
  - Clusters may not be able to follow randomization schedule



# Stepped Wedge Design Example: Supporting Policy In Health with Research (SPIRIT)



The CIPHER Investigators *BMJ Open* 2014;4:e005293

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# Interrupted Time Series Example: Coordinated Approach to Cancer Screening

Interventions: Interactive Voice Response Reminder System  
Preventive Care Coach

	Baseline (6 months)	Intervention (18 months)	
Site 1	oooooooooooo	IVR + PCC oooooooooooooooooooooooooooooooooooo	IVR + PCC oooooooooooooooooooo
Site 2	oooooooooooo	IVR oooooooooooooooooooooooooooooooooooo	IVR oooooooooooooooooooo
Site 3	oooooooooooo	oooooooooooooooooooooooooooooooooooo	IVR + PCC oooooooooooooooooooo
Site 4	oooooooooooo	oooooooooooooooooooooooooooooooooooo	IVR oooooooooooooooooooo

Emmons, et al, 2013



# Mixed methods

Counts as “Mixed” when:

1. At least one QUAL and one QUANT method used
2. Each method is used rigorously
3. Data collection &/or analysis &/or results are integrated

- What
  - Focus groups, structured interviews, ethnographic field techniques, etc.
- When & where
  - Throughout research process
- Why
  - To inform development and refinement of interventions and implementation strategies
  - To identify barriers and facilitators
  - To illustrate context

Johnson, et al., 2007; Pluye & Hong, 2014



# Hybrid Effectiveness/ Implementation Designs

- Address limits of step-wise research (speed research → practice)
- Promote external validity
- Blended ability to test both intervention effectiveness and effectiveness of implementation strategies

Curran, et. al. Effectiveness-Implementation Hybrid Designs. Med Care 2012



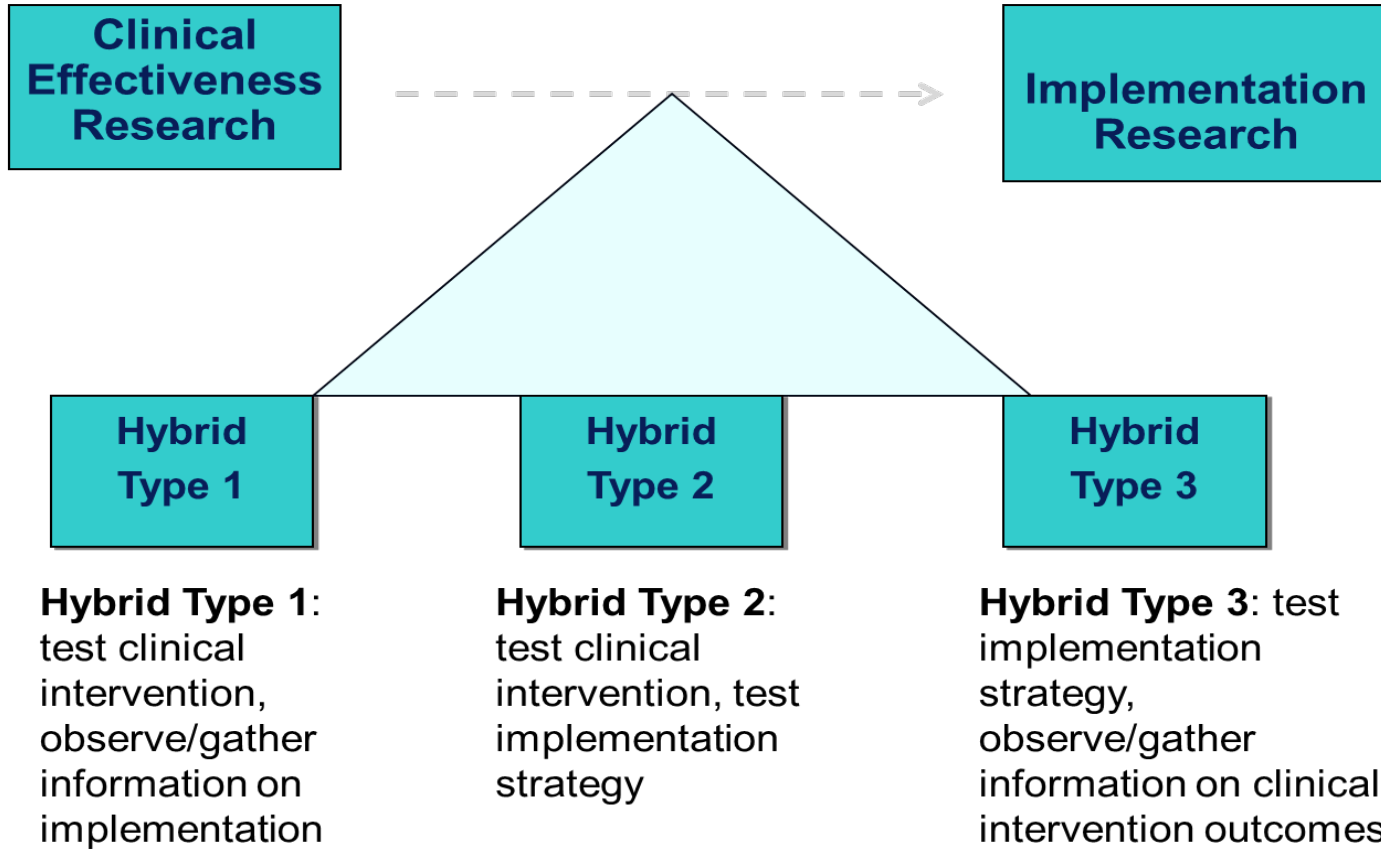
# *Some important questions to address in hybrid designs*

- What implementation strategies are most effective in improving the uptake of effective practices?
- What implementation barriers or problems emerge?
- What changes to implementation strategy, or clinical intervention, could be made to improve uptake?





# Types of Hybrid Designs



# Sequential Multiple Assignment Randomized Trial (SMART) Designs

- Usually 2-3 critical decisions to address, e.g.,
  - Sequencing decisions: Which treatment to try first? Which treatment to try if sign of nonresponse?
  - Which treatment to try if subject doing well?
  - Timing decisions: How soon do we declare nonresponse? How soon do we declare response?
- Which decisions are most controversial or need investigation?
- Which decisions are likely to have the biggest impact on the outcome?

***The goal of a SMART is to inform development of adaptive intervention strategies***



# ADEPT Design

## Study Start

**Run-In Phase**  
All sites offered REP to implement EBP;  
Patients start EBP by **Month 3**

**Month 6 Assessment**

## Phase 2

**Month 12 Assessment**

## Follow Up

**Month 18 and 24 Assessments**

**REP**  
k=80 sites

**Non-Responders**  
(<10 out of 20 enrolled patients receiving EBP or <75% sessions completed)  
k=60 sites



Add External Facilitation  
**REP+EF**  
k=30 sites  
N=600 patients

Add Internal & External Facilitation  
**REP+EF/IF**  
k=30 sites  
N=600 patients

**Responders**

**Non-responders**

**Responders**

**Non-responders**



Continue follow-up assessments

Continue **REP+EF**

Add IF (**REP+EF/IF**)

Continue follow-up assessments

Continue **REP+EF/IF**

Continue follow-up assessments (A)

Continue **REP+EF** (B)

Continue **REP+EF/IF** (C)

Continue follow-up assessments (D)

Continue **REP+EF/IF** (E)

**Responders**  
k=20 sites

6 Month follow-up assessment

Continue follow-up assessments

Continue follow-up assessments (F)

# Why SMART Designs → Adaptive Interventions for Implementation Research?

- Heterogeneity of practices/providers
- Not all barriers/facilitators observable
- React to non-responsiveness/limited uptake
- Reduce implementation burden; use only what is necessary (“Chevy vs. Cadillac”)



# Pilot/feasibility research

- Arain, M., Campbell, M. J., Cooper, C. L., & Lancaster, G. A. (2010). What is a pilot or feasibility study? A review of current practice and editorial policy. BMC medical research methodology, 10(1), 67.

	Pilot n = 6	Feasibility n = 5
<i>Methods related</i>		
Miniature RCT	4	3
Testing recruitment	4	1
Determining sample size/numbers available	3	0
Resources	1	0
Randomization	4	1
Outcome measures	2	4
Data collection	1	0
Follow up/dropout	2	0
<i>Intervention related</i>		
Clinical outcomes	3	1
Dose/efficacy/safety	0	1
Acceptability	2	0
Feasibility	3	0



## Pilot/feasibility research (cont.)

- Suggestion- ALWAYS include qualitative component in pilot-level research (since small studies will rarely provide convincing evidence of efficacy)
- Devil's advocate- do you need to develop, test, and implement your own intervention?



## Takeaway thoughts

- Mixing and matching terms is OK (i.e., your study could be described as a mixed-methods, Type III hybrid, cluster RCT design with an adaptive implementation strategy)
- Designs should seamlessly integrate implementation models/frameworks
- Find a way to build in qualitative components
- Hybrid designs seem to be winning the day in D&I research



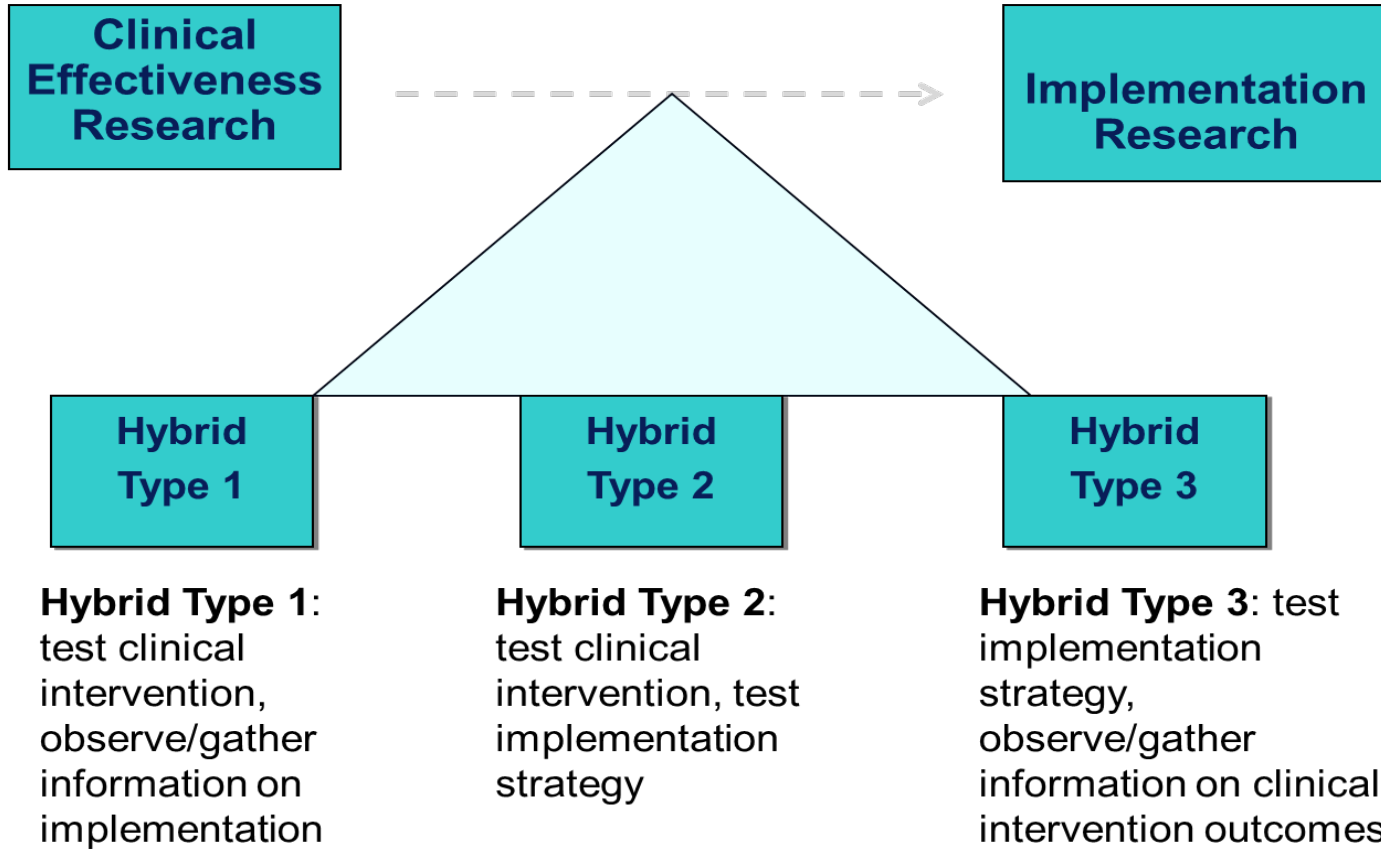
## Group exercise – introduction & example

- Basic building blocks of a D&I project:
  - Intervention (WHAT you are implementing)
  - Implementation strategy (HOW you are implementing the intervention)
  - Outcomes (your outcomes place you on the spectrum from efficacy research to implementation research)
  - Study design (how you will assess the effectiveness of the intervention and/or the implementation strategy)





# Types of Hybrid Designs



## Group exercise

- At your table, please spend 20 minutes working through the 6 questions on the worksheet
- Afterwards, we will spend time reporting out and discussing



# Selecting your intervention – key considerations

Is there evidence of efficacy of the intervention?

- Yes- Consider Type III hybrid
- No- conduct pilot efficacy research on the intervention before proceeding to implementation research, or consider Type I hybrid



# If there's no evidence of efficacy for your intervention-what about conducting a type II hybrid?

- Make sure your study design allows you to do simultaneous testing
- Avoid conflating the intervention and the implementation strategy
- Get feedback on your design (early and often)



# Question: is there evidence of effectiveness of your implementation strategy?

- “Getting to Yes”: consult Powell’s taxonomy of implementation strategies; pick one or bundle them
  - Powell, B. J., Waltz, T. J., Chinman, M. J., Damschroder, L. J., Smith, J. L., Matthieu, M. M., ... & Kirchner, J. E. (2015). A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science*, 10(1), 21.
- Conduct Type III hybrid trial?
- No: conduct pilot research of a novel implementation strategy, or consider type II hybrid



Thank you!

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