

# Hybrid Effectiveness- Implementation Approaches

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(RCC-RD-MCD) Investigator Skills Development Unit (ISDU)

December 8, 2022



# Funding Acknowledgements & Disclaimer

- Dr. Landes' time is supported by Quality Enhancement Research Initiative (QUERI) grants (PII 19-462, QUE 20-026, EBP 22-104), the South Central MIRECC, and the Translational Research Institute (TRI), UL1 TR003107, through the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH).
- Disclaimer: The views expressed in this presentation are those of the author and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States Government.

# Hello from Little Rock!





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# Special shout out!



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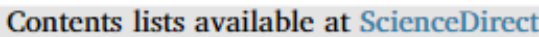

# Today's Topic: Hybrid ~~Designs~~ Approaches


**NIH Public Access**  
**Author Manuscript**  
*Med Care. Author manuscript; available in PMC 2013 August 01.*

Published in final edit  
*Med Care. 2012 Mar*

**Effectiveness**  
**Combining Element**  
**Public Health Impa**

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**Psychiatry Research**  
journal homepage: [www.elsevier.com/locate/psychres](http://www.elsevier.com/locate/psychres)



**An introduction to effectiveness-implementation hybrid designs**


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[Curran et al., 2012](#)  
[Landes et al., 2019](#)


But first, let's start with this paper


Curran *Implementation Science Communications* (2020) 1:27  
<https://doi.org/10.1186/s43058-020-00001-z>

Implementation Science Communications

**DEBATE** **Open Access**

# Implementation science made too simple: a teaching tool

Geoffrey M. Curran<sup>1,2</sup> 

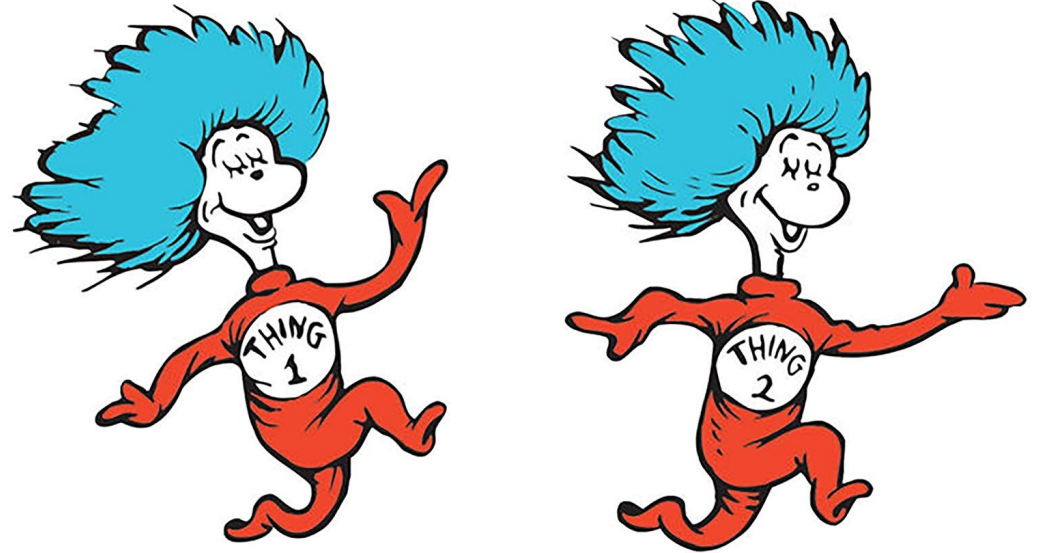


# When discussing hybrids, some very non-scientific language can be helpful

- The intervention/practice/innovation is **THE THING**
- *Effectiveness* research looks at whether **THE THING** works
- *Implementation* research looks at how best to help people/places **DO THE THING**
- Implementation strategies are the stuff we do to try to help people/places **DO THE THING**
- Main implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

# Using that language...

- Hybrid approaches look at *both*
  - The thing
  - Doing the thing
- There are “types” of hybrid approaches which tend to emphasize either or
- In the chat:
  - Does your project focus on the thing, doing the thing, or both in some way?



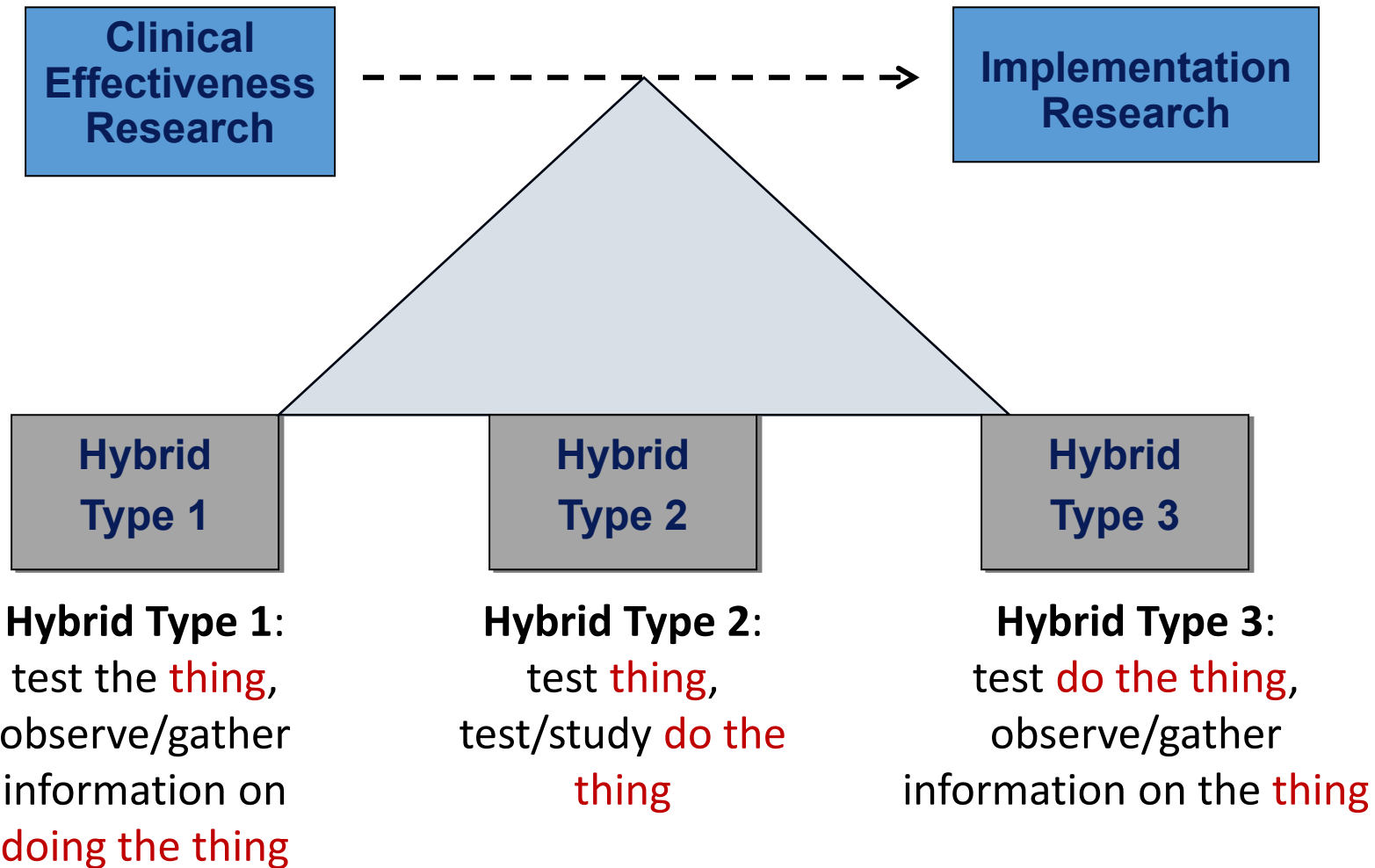
# Why should we consider hybrid approaches?

- Maybe we can speed this up a little?
  - Sequential examination can be slow
  - Don't wait for "perfect" intervention effectiveness data before moving to implementation research
  - We can "backfill" effectiveness data while we test/evaluate implementation strategies
- How do intervention/innovation outcomes relate to levels of adoption and fidelity?
  - How will we know this without data from "both sides"?

# Some intro thoughts about hybrids

- The original paper in 2012 tried to bring some attention to the issues surrounding such combinations, along with some direction, examples, and recommendations
- We started from a clinical orientation, but seems to work for other types of interventions (e.g., policies)
- Original paper focused on trials but the *hybrid idea* is being used in lots of research designs
  - *It's more about combining research questions*
- We are now calling them hybrid approaches or hybrid studies

# Types of hybrid approaches



# Research aims by hybrid types

Study Characteristic	Hybrid Type 1	Hybrid Type 2	Hybrid Type 3
Research Aims	<p><b>Primary Aim:</b> Determine effectiveness of an intervention</p> <p><b>Secondary Aim:</b> Better understand context for implementation</p> <p>And/or</p> <p>Assess “implementability” of intervention/determine necessary adaptations</p>	<p><b>Primary Aim:</b> Determine effectiveness of an intervention</p> <p><b>Co-Primary* Aim:</b> Determine feasibility and/or (potential) impact of an implementation strategy</p> <p>*or “secondary”...</p>	<p><b>Primary Aim:</b> Determine <i>impact</i> of an implementation strategy</p> <p><b>Secondary Aim:</b> Assess clinical outcomes associated with implementation of intervention</p>

# Hybrid Type 1

## Definition:

- Test intervention/innovation and explore implementation-related factors

## Description:

- Conventional effectiveness trial/study “plus”:
  - Describe implementation experience (worked/didn’t; barriers/facilitators)
  - How might the intervention need to be adapted going forward?
  - What is needed to support people/places to do THE THING in the real world?

## Indications:

- Clinical effectiveness evidence remains limited, so intensive focus on implementation might be premature...BUT
- Effectiveness study conditions offer ideal opportunity to explore implementation issues, plan implementation strategies for next stage

# Remember...

- All effectiveness trials use “implementation strategies” to support the delivery of the intervention, we just usually don’t call them that...
- They are normally resource-intensive
  - Paying clinics, paying interventionists, paying for care, frequent fidelity checks and intervening when it goes south...
- We “know” that some/many the strategies used in effectiveness trials are not feasible for supporting wide-spread adoption
- BUT, we can learn from the use of those strategies during the trial!

# Type 1 examples



Research aimed at improving both mood and weight (RAINBOW) in primary care: A type 1 hybrid design randomized controlled trial☆

Jun Ma<sup>a,b,\*</sup>, Veronica Yank<sup>b</sup>, Nan Lv<sup>a</sup>, Jeremy D. Goldhaber-Fiebert<sup>c</sup>, Megan A. Lewis<sup>d</sup>, M. Kaye Kramer<sup>e</sup>, Mark B. Snowden<sup>f</sup>, Lisa G. Rosas<sup>a,b</sup>, Lan Xiao<sup>a</sup>, Andrea C. Blonstein<sup>a</sup>

Lane-Fall et al. *BMC Surgery* 2014, **14**:96  
<http://www.biomedcentral.com/1471-2482/14/96>



## STUDY PROTOCOL

Open Access

Handoffs and transitions in critical care (HATRICC): protocol for a mixed methods study of operating room to intensive care unit handoffs

Meghan B Lane-Fall<sup>1,2,3\*</sup>, Rinad S Beidas<sup>3,4</sup>, Jose L Pascual<sup>5,6</sup>, Meredith L Collard<sup>1</sup>, Hannah G Peifer<sup>7</sup>, Tyler J Chavez<sup>8</sup>, Mark E Barry<sup>2</sup>, Jacob T Gutsche<sup>1</sup>, Scott D Halpern<sup>3,9,10</sup>, Lee A Fleisher<sup>1,3,10</sup> and Frances K Barg<sup>11,12</sup>

Hagedorn et al. *Addiction Science & Clinical Practice* 2014, **9**:12  
<http://www.ascpjournal.org/content/9/1/12>



## RESEARCH

Open Access

An implementation-focused process evaluation of an incentive intervention effectiveness trial in substance use disorders clinics at two Veterans Health Administration medical centers

Hildi J Hagedorn<sup>1,2,3\*</sup>, Cheryl B Stetler<sup>4</sup>, Ann Bangerter<sup>2</sup>, Siamak Noorbaloochi<sup>2,3</sup>, Maxine L Stitzer<sup>5</sup> and Daniel Kivlahan<sup>6,7</sup>

Bramoweth et al. *Trials* (2018) 19:73  
DOI 10.1186/s13063-017-2437-y

Trials

## STUDY PROTOCOL

Open Access

A hybrid type I trial to increase Veterans' access to insomnia care: study protocol for a randomized controlled trial

Adam D. Bramoweth<sup>1,2\*</sup>, Anne Germain<sup>3</sup>, Ada O. Youk<sup>1,4</sup>, Keri L. Rodriguez<sup>1,5</sup> and Matthew J. Chinman<sup>1,2,6</sup>



# Questions to ponder in the chat...

- How soon is “too soon” to start to look at implementation questions?
  - Can we do a type 1 efficacy study?
- Can we do hybrid type 1 pilot effectiveness studies?
  - Meaning a pilot of the intervention/practice/innovation

# Hybrid Type 3

## Definition:

- Test implementation strategy, observe/gather information on intervention/innovation and outcomes

## Description:

- Largely focused on study of implementation strategies
- Intervention/innovation outcomes are “secondary”

## Indications (circa 2012):

- We sometimes proceed with implementation studies without completing a “full portfolio” of effectiveness studies
  - Strong momentum in a system, e.g., “We are rolling this out!”
- Interested in exploring how intervention effectiveness might vary by level/quality of implementation?

# More Considerations: Type 3

- Similar for any implementation trial really...
  - How much power do you have?
  - What's your evidence for implementation strategies selected?
  - What about *mechanisms of action* of the strategies?
  - What about *cost* of the strategies?
    - *Cost* and *Mechanisms* will likely become essential parts of type 3 studies
- Clinical outcomes data collection
  - Do you really need them? **What interventions might we NOT need to do a hybrid 3 study for?**
  - Measures available in existing data?
  - Primary data collection? (*Mental health outcomes not routinely available...*)
    - Sub-sample?

# Type 3 examples

Bauer et al. *Implementation Science* (2016) 11:22  
DOI 10.1186/s13012-016-0385-7

Implementation Science

Kilbourne et al. *Implementation Science* 2014, 9:132  
<http://www.implementationscience.com/content/9/1/132>



## STUDY PROTOCOL

Open Access

### Partnering with health system operations leadership to develop a controlled implementation trial



Mark S. Bauer<sup>1\*</sup> , Christopher Miller<sup>1</sup>, Bo Kim<sup>1</sup>, Robert Lew<sup>2</sup>, Kendra Weaver<sup>3</sup>, Craig Coldwell<sup>4</sup>, Kathy Henderson<sup>5</sup>, Sally Holmes<sup>6</sup>, Marjorie Nealon Seibert<sup>6</sup>, Kelly Stolzmann<sup>6</sup>, A. Rani Elwy<sup>6</sup> and JoAnn Kirchner<sup>5</sup>

Swindle et al. *Implementation Science* (2017) 12:90  
DOI 10.1186/s13012-017-0624-6

Implementation Science

## STUDY PROTOCOL

Open Access

### Protocol: Adaptive Implementation of Effective Programs Trial (ADEPT): cluster randomized SMART trial comparing a standard versus enhanced implementation strategy to improve outcomes of a mood disorders program

Amy M Kilbourne<sup>1,2\*</sup>, Daniel Almirall<sup>3</sup>, Daniel Eisenberg<sup>4</sup>, Jeanette Waxmonsky<sup>5,6</sup>, David E Goodrich<sup>1,2</sup>, John C Fortney<sup>7</sup>, JoAnn E Kirchner<sup>8,9</sup>, Leif I Solberg<sup>10</sup>, Deborah Main<sup>11</sup>, Mark S Bauer<sup>12</sup>, Julia Kyle<sup>1,2</sup>, Susan A Murphy<sup>3,3</sup>, Kristina M Nord<sup>1,2</sup> and Marshall R Thomas<sup>5,6</sup>

Cucciare et al. *Implementation Science* (2016) 11:65  
DOI 10.1186/s13012-016-0432-4

Implementation Science

## STUDY PROTOCOL

Open Access

### A mixed methods protocol for developing and testing implementation strategies for evidence-based obesity prevention in childcare: a cluster randomized hybrid type III trial



Taren Swindle<sup>1\*</sup> , Susan L. Johnson<sup>2</sup>, Leanne Whiteside-Mansell<sup>3</sup> and Geoffrey M. Curran<sup>3</sup>

## STUDY PROTOCOL

Open Access

### Assessing fidelity of cognitive behavioral therapy in rural VA clinics: design of a randomized implementation effectiveness (hybrid type III) trial



Michael A. Cucciare<sup>1,2,3,4\*</sup>, Geoffrey M. Curran<sup>1,2,5</sup>, Michelle G. Craske<sup>6</sup>, Traci Abraham<sup>1</sup>, Michael B. McCarthur<sup>1</sup>, Kathy Marchant-Miros<sup>1</sup>, Jan A. Lindsay<sup>3,4,7,8</sup>, Michael R. Kauth<sup>3,4,7,8</sup>, Sara J. Landes<sup>1,2,3,4</sup> and Greer Sullivan<sup>9</sup>

# Hybrid Type 2

## Definition:

- Test intervention and test/study implementation strategy

## Description:

- Dual-focus study:
  - Intervention Effectiveness study within either:
    - Implementation study of 2+ strategies (“dual randomized”)
    - Single arm (“pilot”) study of 1 implementation strategy (or *package of...*)

## Indications:

- Clinical effectiveness data available, though perhaps not for context/population of interest for this study
- Data on barriers and facilitators to implementation available
- Implementation momentum in terms of system/policy demands?

# More Considerations: Type 2

- Important to have an explicitly described implementation strategy that is thought to be plausible in the real world
  - Clear distinction from type 1
- Explicit measurement of adoption, fidelity...
  - Always happens in type 2
- Important to be clear about intervention components versus implementation strategy components
  - This isn't always easy to decide or describe
  - E.g., *delivery format...*
    - *Is delivering an intervention over the telephone an implementation strategy or a component of the intervention? (or neither...?)*

# Still More Considerations: Type 2

- What if the implementation strategy leads to poor adoption and poor fidelity?
  - Effectiveness trial gets compromised
- What to do about this?
  - Use implementation strategies with relevant evidence base
  - Build in adoption/fidelity benchmarks
  - Build in measurement and plans to address poor adoption and/or fidelity
  - Build in time to deal with this possibility
  - Anyone getting queasy over this?? Understandable....

# Type 2 examples

Garner et al. *Addict Sci Clin Pract* (2017) 12:32  
DOI 10.1186/s13722-017-0096-7

Addiction Science &  
Clinical Practice

Open Access

Protocol

STUDY PROTOCOL

Open Access



Testing the implementation and sustainment facilitation (ISF) strategy as an effective adjunct to the Addiction Technology Transfer Center (ATTC) strategy: study protocol for a cluster randomized trial

Bryan R. Garner<sup>1\*</sup> , Mark Zehner<sup>2</sup>, Mathew R. Roosa<sup>3</sup>, Steve Martino<sup>4</sup>, Heather J. Gotham<sup>5</sup>, Elizabeth L. Ball<sup>1</sup>, Patricia Stilen<sup>5</sup>, Kathryn Speck<sup>6</sup>, Denna Vandersloot<sup>7</sup>, Traci R. Rieckmann<sup>8</sup>, Michael Chaple<sup>9</sup>, Erika G. Martin<sup>10,11</sup>, David Kaiser<sup>1</sup> and James H. Ford II<sup>2</sup>

Rich et al. *BMC Public Health* (2018) 18:29  
DOI 10.1186/s12889-017-4584-1

BMC Public Health

Rogers et al. *Addiction Science & Clinical Practice* 2013, **8**:7  
<http://www.ascpjournals.org/content/8/1/7>

STUDY PROTOCOL

Open Access



Implementation-effectiveness trial of an ecological intervention for physical activity in ethnically diverse low income senior centers

Porchia Rich<sup>1\*</sup> , Gregory A. Aarons<sup>2</sup>, Michelle Takemoto<sup>1</sup>, Veronica Cardenas<sup>3</sup>, Katie Crist<sup>1</sup>, Khalisa Bolling<sup>1</sup>, Brittany Lewars<sup>1</sup>, Cynthia Castro Sweet<sup>4</sup>, Loki Natarajan<sup>1,3</sup>, Yuyan Shi<sup>1</sup>, Kelsie M. Full<sup>1</sup>, Eileen Johnson<sup>1</sup>, Dori E. Rosenberg<sup>5</sup>, Melicia Whitt-Glover<sup>6</sup>, Bess Marcus<sup>1</sup> and Jacqueline Kerr<sup>1,3</sup>

Open Access

**BMJ Open** Effectiveness of implementing a best practice primary healthcare model for low back pain (BetterBack) compared with current routine care in the Swedish context: an internal pilot study informed protocol for an effectiveness-implementation hybrid type 2 trial

Allan Abbott,<sup>1</sup> Karin Schröder,<sup>1</sup> Paul Enthoven,<sup>1</sup> Per Nilsen,<sup>2</sup> Birgitta Öberg<sup>1</sup>



ADDICTION SCIENCE &  
CLINICAL PRACTICE

STUDY PROTOCOL

Open Access

Telephone care coordination for smokers in VA mental health clinics: protocol for a hybrid type-2 effectiveness-implementation trial

Erin Rogers<sup>1,2\*</sup>, Senaida Fernandez<sup>8</sup>, Colleen Gillespie<sup>2</sup>, David Smelson<sup>4,5</sup>, Hildi J Hagedorn<sup>6,7</sup>, Brian Elbel<sup>3</sup>, David Kalman<sup>4,5</sup>, Alfredo Axtmayer<sup>1</sup>, Karishma Kurowski<sup>1,2</sup> and Scott E Sherman<sup>1,2</sup>

# Need more support or tools?

- We are working on tools to help people select a hybrid
  - ~~Not published yet, but we are distributing~~
  - Building a web tool also (U of Texas and WHO)

# Published TODAY!

 **frontiers** | Frontiers in Health Services

TYPE Perspective  
PUBLISHED 08 December 2022  
DOI 10.3389/frhs.2022.1053496

 Check for updates

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SPECIALTY SECTION  
This article was submitted to  
Implementation Science,  
a section of the journal  
Frontiers in Health Services

## Reflections on 10 years of effectiveness-implementation hybrid studies

Geoffrey M. Curran<sup>1,2†</sup>, Sara J. Landes<sup>3,4\*†</sup>, Sacha A. McBain<sup>4</sup>, Jeffrey M. Pyne<sup>2,4</sup>, Justin D. Smith<sup>5</sup>, Maria E. Fernandez<sup>6</sup>, David A. Chambers<sup>7</sup> and Brian S. Mittman<sup>8</sup>

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# Reflections across 5 conceptual and methodological areas

1. Recommendation to replace the term “design” in favor of “study”
2. Guidance on selecting a hybrid study type based on evidentiary and contextual information and stakeholder concerns/preferences via a series of questions
3. Critique on the hybrid 1-2-3 typology and offers reflections on when and how to use the typology moving forward
4. Recommendations on research designs that align with each hybrid study type
5. Thoughts on how to integrate costs analyses into hybrid studies

# Figure 1. Four questions to consider when selecting a hybrid study type.

1. What is the nature of the effectiveness data on your intervention of interest?
  - Very-to-moderately strong, especially if not a lot of intervention adaptation needs to take place? Consider type 3 or type 2 depending on how much you expect the intervention will need to be adapted (Question 2).
  - Mixed results? Missing (strong) effectiveness data? Consider types 1 or 2.
2. How much do you expect the intervention will need to be adapted for where you want to study/use it?
  - A little? Consider type 2 or 3, including adaptation process as a step in an implementation-focused project.
  - A lot? Consider focusing on effectiveness in a type 1 or type 2.
3. How much do you already know about implementation determinants for the intervention in your context of interest?
  - Not much? If you also need to focus on effectiveness data, consider type 1.
  - If the effectiveness data are strong, and you know enough already to develop/select a strategy or package of strategies to evaluate? Consider type 2 or 3.
4. How ready are you to evaluate a "real world" implementation strategy or package of strategies?
  - Not ready? A type 1 is indicated, where you collect information on implementation determinants to help you prepare for developing strategies later.
  - Ready, and you need to focus as well on effectiveness of the intervention (Question 1)? Consider a type 2.
  - Ready, and your effectiveness data are strong (Question 1) and you don't need to adapt a lot (Question 2)? Consider a type 3.

# Four questions to consider when selecting a hybrid study type

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  - Very-to-moderately strong, especially if not a lot of intervention adaptation needs to take place? Consider type 3 or type 2 depending on how much you expect the intervention will need to be adapted (Question 2).
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2. How much do you expect the intervention will need to be adapted for where you want to study/use it?
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3. How much do you already know about implementation determinants for the intervention in your context of interest?
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# Four questions to consider when selecting a hybrid study type

4. How ready are you to evaluate a "real world" implementation strategy or package of strategies?
- Not ready? A type 1 is indicated, where you collect information on implementation determinants to help you prepare for developing strategies later.
  - Ready, and you need to focus as well on effectiveness of the intervention (Question 1)? Consider a type 2.
  - Ready, and your effectiveness data are strong (Question 1) and you don't need to adapt a lot (Question 2)? Consider a type 3.

# Bonus question

- After answering all of the above questions, do you still want to consider a hybrid study?
  - **No?** Feel free to run screaming from the room. We understand.
  - **Yes?** Seek out and learn from published protocol papers and manuscripts describing studies that seem to be like what you want to do. Talk with people already funded to do the type of study you want to do. Talk with project officers/portfolio managers. Give us a call.

# Equity and hybrid designs

- So how does equity efforts fit into hybrids?
  - Can look at equity in intervention/health outcomes
  - Can look at equitable delivery of interventions
  - Can target equity with implementation strategies designed to increase equity and address systematic racism

# Questions?

