

# An Overview of Hybrid Designs

Geoffrey Curran, PhD

Director, Center for Implementation Research

Professor, Pharmacy Practice & Psychiatry

University of Arkansas for Medical Sciences

Research Health Scientist

Central Arkansas Veterans Healthcare System





# Learning goals

- Review 3 types of effectiveness-implementation hybrid trial designs and when they may be appropriate for ePCTs

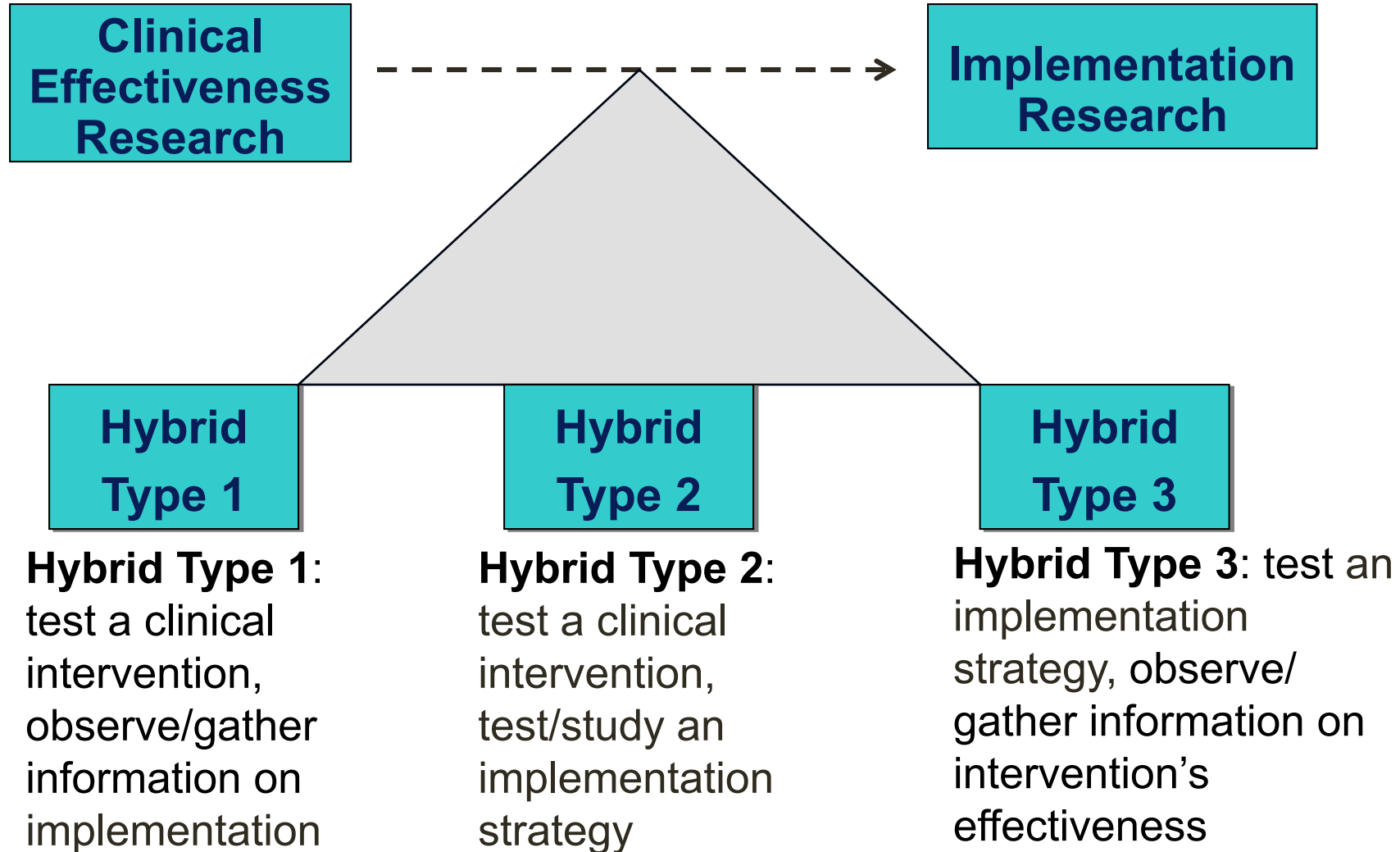
# Hybrid trial design

Trials with a focus on both patient and implementation outcomes

# Why Hybrid Trial Designs?

- Let's go faster!
  - Sequential looks at effectiveness and implementation are slower
- Don't wait for “perfect” effectiveness data before moving to implementation research
- We can “backfill” effectiveness data while we test/evaluate implementation strategies
- How do clinical outcomes relate to levels of adoption and fidelity?
  - How will we know this without data from “both sides”?

# Types of Hybrids



# Type 1

- Clinical Trial PLUS

- Implementation-focused process evaluation
- Usually mixed method study of “what worked/didn’t”
- Revise intervention? Implementation strategies needed?

- Indications

- Clinical effectiveness data remain limited, so “too early” for intensive focus on implementation, but...
- Ideal opportunity to explore implementation issues, learn what’s needed for future focus on implementation (*study or do...*)

# Type 2

- Clinical trial nested within
  - Implementation trial of competing strategies
  - “Pilot” (one arm) study of single implementation strategy
- Indications
  - Clinical effectiveness data available, though perhaps not for your population or context of interest
  - Have data on barriers and facilitators to implementation
  - “Implementation momentum” within healthcare system

# Type 3

- Implementation trial!
  - Primary test is comparing implementation strategies
  - Clinical effectiveness is a secondary analysis
- Indications
  - We sometimes proceed with roll-outs/implementation studies of interventions without strong effectiveness data
  - Interested in exploring how clinical effectiveness might vary by extent and/or quality of implementation?



# Concluding points

- 1 This was a VERY brief summary!
- 2 ePCTs would usually be type 1 or 2, depending on
  - How ready you are to “test” an implementation strategy or strategies on “summative” implementation outcomes
    - “Just” want to describe implementation during the trial and prepare for more work later on “real world” implementation strategies = 1
    - Ready to test the impact of “real world” strategies on implementation outcomes like adoption or fidelity = 2

# Concluding points

## ■ 3 If you want to learn more...



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### Effectiveness-implementation Hybrid Designs:

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD<sup>\*</sup>, Mark Bauer, MD<sup>†</sup>, Brian Mittman, PhD<sup>‡</sup>, Jeffrey M. Pyne, MD<sup>\*</sup>, and Cheryl Stetler, PhD<sup>‡</sup>

<sup>\*</sup>Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR

<sup>†</sup>VA Boston Healthcare System, Harvard Medical School, Boston, MA

<sup>‡</sup>Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA



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### An introduction to effectiveness-implementation hybrid designs

Sara J. Landes<sup>a,b,c,\*</sup>, Sacha A. McBain<sup>b,c</sup>, Geoffrey M. Curran<sup>b,c,d</sup>

<sup>a</sup> The Department of Veterans Affairs Quality Enhancement Research Initiative (QUERI) for Team-Based Behavioral Health, 2200 Fort Roots Drive, North Little Rock, AR 72114, USA

<sup>b</sup> South Central Mental Illness Research Education and Clinical Center (MIRECC), Central Arkansas Veterans Healthcare System, 2200 Fort Roots Drive, North Little Rock, AR 72114, USA

<sup>c</sup> University of Arkansas for Medical Sciences, Department of Psychiatry, 4301 W. Markham St, Little Rock, AR 72205, USA

<sup>d</sup> University of Arkansas for Medical Sciences, Department of Pharmacy Practice, 4301 W. Markham St, Little Rock, AR 72205, USA



# What about METRicAL?

- Consistent with hybrid type 2 (pilot version)
- Trial of competing music therapy approaches
  - Personalized music selections (favorite songs)
  - Preferred genre music selection
- Consistent use of 3 implementation strategies
  - Training(s)
  - Implementation guide
  - coaching

# Resources

Visit the Living Textbook of Pragmatic Clinical Trials at

[www.rethinkingclinicaltrials.org](http://www.rethinkingclinicaltrials.org)

IMPACT Training Modules ePCT Video Learning Library

[www.impactcollaboratory.org](http://www.impactcollaboratory.org)



## Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials



WATCH THE VIDEO

Welcome to the Living Textbook of pragmatic clinical trials, a collection of knowledge from the NIH Health Care Systems Research Collaboratory. Pragmatic clinical trials present an opportunity to efficiently generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than traditional clinical trials. The Living Textbook reflects a collection of special considerations and best practices in the design, conduct, and reporting of pragmatic clinical trials.

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The NIA IMPACT Training Modules are short videos designed to introduce the important components and considerations related to embedded pragmatic clinical trials (ePCTs) for people living with dementia and their care partners. These videos are appropriate for investigators, health systems leaders, research staff and others who want to learn about the design and conduct of ePCTs.

Training modules are organized by topics/cores. Each tile below opens up into a series of relevant modules. [Sign up here](#) to be included on the mailing list to be informed about new and upcoming training content and opportunities.

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