Trial Objectives and Design: An Overview of Hybrid Designs

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Learning goals

- Overview of the 3 types of effectiveness-implementation hybrid trial designs and when they may be appropriate for ePCTs
- Q & A with attendees
Hybrid trial designs

- Trials with a focus on both clinical (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 adoption and fidelity?
  - How will we know this without data from both sides?
Types of hybrids

Hybrid Type 1
Test a clinical intervention, observe or gather information on implementation

Hybrid Type 2
Test a clinical intervention, test or study an implementation strategy

Hybrid Type 3
Test an implementation strategy, observe or gather information on intervention's effectiveness
Type 1

- Clinical Trial PLUS
  - Implementation-focused process evaluation
  - Usually a mixed-methods study of what worked or 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…)

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®
Interdisciplinary team-based care for patients with chronic pain on long-term opioid treatment in primary care (PPACT) – Protocol for a pragmatic cluster randomized trial

Lynn DeBar\textsuperscript{a,b,1}, Lindsay Benes\textsuperscript{a,b}, Allison Bonifay\textsuperscript{a}, Richard A. Deyo\textsuperscript{c}, Charles R. Elder\textsuperscript{a}, Francis J. Keeffe\textsuperscript{d}, Michael C. Leo\textsuperscript{a}, Carmit McMullen\textsuperscript{a}, Meghan Mayhew\textsuperscript{a}, Ashli Owen-Smith\textsuperscript{e,f}, David H. Smith\textsuperscript{a}, Connie M. Trinacty\textsuperscript{g}, William M. Vollmer\textsuperscript{a}
Type 1 example: PPACT

- Effectiveness aim: Determine effectiveness of team-based intervention for reducing pain impact
- Implementation aim: Conduct an implementation-focused process evaluation to assess reach of and fidelity to the intervention, and barriers to and facilitators of the interventions
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 2 example: STOP CRC

Using a continuum of hybrid effectiveness-implementation studies to put research-tested colorectal screening interventions into practice

Beverly B. Green¹, Gloria D. Coronado², Malaika Schwartz³, Jen Coury⁴ and Laura-Mae Baldwin³
Type 2 example: STOP CRC

- Effectiveness aim: Determine effectiveness of mailed outreach for increasing colorectal cancer screening
- Implementation aim: Determine feasibility and potential utility of an implementation strategy (training, technical support, PDSA)
Type 3

- Implementation trial!
  - Primary test is comparing implementation strategies
  - Clinical effectiveness is a secondary analysis

- Indications
  - We sometimes proceed with rollouts or implementation studies of interventions without strong effectiveness data
  - Interested in exploring how clinical effectiveness might vary by extent and/or quality of implementation?
A cluster randomized controlled trial comparing Virtual Learning Collaborative and Technical Assistance strategies to implement an early palliative care program for patients with advanced cancer and their caregivers: a study protocol

Lisa Zubkoff1,2,*, Kathleen Doyle Lyons3,4, J. Nicholas Dionne-Odom5,6,7, Gregory Hagley3, Maria Pisu1,7, Andres Azuero1,5,6, Marie Flannery8, Richard Taylor5,6, Elizabeth Carpenter-Song9, Supriya Mohile8, and Marie Anne Bakitas5,6,7,11
Concluding points

- This was a very brief summary!
- ePCTs are usually type 1 or 2, depending on how ready you are to test an implementation strategy on summative implementation outcomes
  - To describe implementation during the trial and prepare for later work on real-world implementation strategies = 1
  - To test the impact of real-world strategies on implementation outcomes like adoption and fidelity = 2
Effectiveness-implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

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An introduction to effectiveness-implementation hybrid designs

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3 If you want to learn more…