

# An Overview of Hybrid Effectiveness-Implementation Designs

Geoffrey M. Curran, PhD

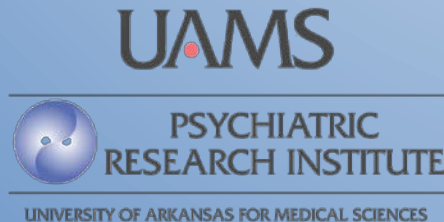
Professor, Pharmacy Practice & Psychiatry

Director, Center for Implementation Research

Research Health Scientist

University of Arkansas for Medical Sciences

Central Arkansas Veterans Healthcare System



# Goals for the session

- Discuss the concept of “hybrid designs” which combine elements of clinical/preventive effectiveness and implementation research
  - Type 1: Explore *Implementability* of an intervention while we are testing its effectiveness (towards real world implementation strategies)
  - ✓ Type 2: Test implementation strategies *during* effectiveness trials (simultaneous look at both)
  - ✓ Type 3: Test implementation strategies while also documenting clinical/prevention intervention outcomes (evaluating them as they relate to uptake and fidelity)
- Review trends in use of designs; some examples
- Present newer thinking on specification, measurement, reporting

# Some early slides cover material from this paper



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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

# Some later slides are reflected in this paper



ELSEVIER

Contents lists available at [ScienceDirect](#)

## Psychiatry Research

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



## 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*

# But, let's begin with THIS paper...

Curran *Implementation Science Communications*  
<https://doi.org/10.1186/s43058-020-00001-z>

(2020) 1:27


Implementation Science  
Communications

DEBATE

Open Access

## Implementation science made too simple: a teaching tool



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



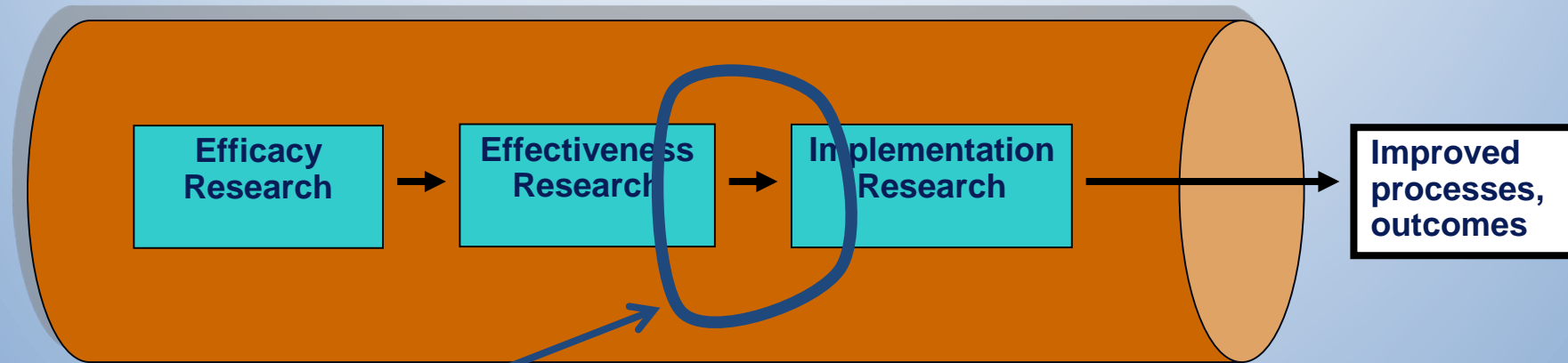
# When teaching this stuff, some very non-scientific language can also be helpful...

- The intervention/practice/innovation is **THE THING**
- Effectiveness research looks at whether **THE THING** works
- D&I 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**

# Why Hybrid Designs?

- The speed of moving research findings into routine adoption could be improved by considering *hybrid designs* that combine elements of effectiveness and implementation research
  - Or, combine research questions in both areas
- Don't wait for “perfect” effectiveness data before moving to implementation research
- We can “backfill” effectiveness data while we test implementation strategies
- How do clinical outcomes relate to levels of adoption and fidelity?
  - How will we know this without data from “both sides”?

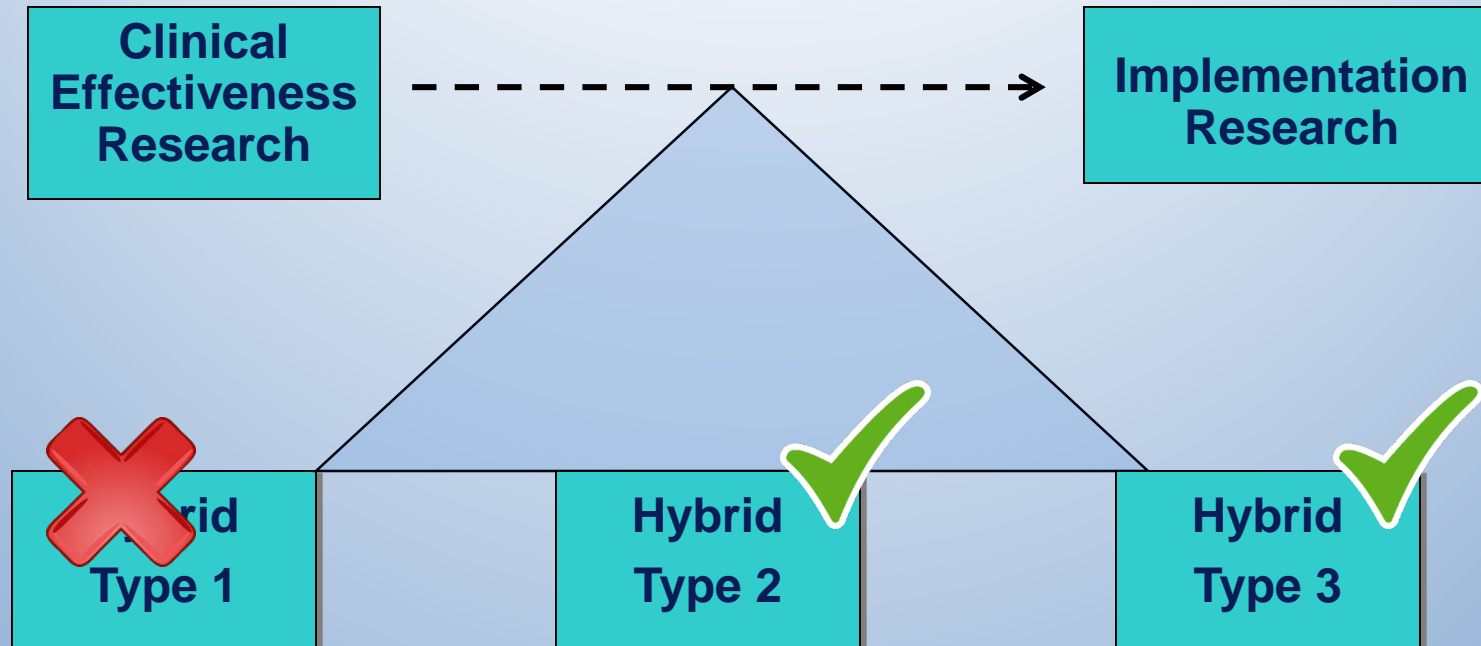
# Effectiveness-Implementation hybrid designs



*Spatially speaking, hybrids “fit” in here...*



# Types of Hybrids



**Hybrid Type 1:** test the **thing**, observe/gather information on **doing the thing**

**Hybrid Type 2:** test **thing**, test/study **do the thing**

**Hybrid Type 3:** test **do the thing**, observe/gather information on the **thing**

# Hybrid Type 1 Designs

## Definition:

- Test clinical intervention and explore implementation-related factors (80%/20%?)

## Description:

- Conventional effectiveness 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?

## Design:

- Often qualitative or mixed method “implementation-focused” process evaluation
- Focused on locations where the trial took place; or also adding “naïve” sites
- Common to see frameworks like CFIR guide analysis (interview guides, coding)
- Sites visits, interviews, surveys (e.g., feasibility, acceptability, appropriateness)

# Hybrid Type 3 Designs

## Definition:

- test implementation strategy, observe/gather information on clinical intervention and outcomes

## Description:

- Largely focused on trial of implementation strategies
- Randomization usually at level of provider, clinic, or system
- Clinical outcomes are “secondary”

## Indications (circa 2012):

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

# More Design Considerations: Type 3

- How much power you got? (same issue with non-hybrid implementation trials)
- Important to use outcomes framework
  - RE-AIM
  - Proctor et al., 2011
- What's your evidence for implementation strategies selected?
- What about *mechanisms of action* of the strategies?
- What about cost of the strategies?
  - Mechanisms and Cost 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?

# Smelson et al., 2015

- **Mission-Vet is an evidence-based treatment for co-occurring SUD and MH disorders among homeless Veterans**
- **Compare “implementation as usual” of Mission-Vet to IAU plus Getting To Outcomes (GTO)**
  - IAU = Standard training plus access to Mission-Vet manual
  - GTO = planning, implementation facilitation (supervision, monitoring...), self evaluation (audit and feedback)
- **3 large VAMCs**
  - Case managers (69) randomized to IAU or IAU+GTO
  - 1500-2000 Veterans
- **RE-AIM measures**
  - Adoption = 50% of eligible Veterans involved in intervention
  - Effectiveness = SUD, MH symptoms, functioning, housing



# More Type 3 examples

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

Implementation Science

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

## 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>

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

 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

## 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 Designs

## Definition:

- Test clinical intervention and test/study implementation strategy (50/50? 60/40? 72/28?)

## Description:

- Dual-focus study:
  - Clinical Effectiveness trial within either:
    - Implementation trial of 2+ strategies/packages
    - Pilot (non-randomized) study of single implementation strategy/package

## Indications (circa 2012):

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

# More Design Considerations: Type 2

- The original definition of a type 2 described possibilities of dual focused, dual randomized designs & randomized effectiveness trials nested in pilots of an implementation strategy
  - Majority of currently published Type 2s are the latter
  - Some dual randomized designs (see example soon)
- When looking at the aims or hypotheses of existing studies, most have primary aim on *intervention outcomes*

# More Design 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
  - Existing papers sometimes not clear here
  - This isn't always easy to decide or describe
  - E.g., *delivery format...*
    - *Is delivering an intervention over the telephone an intervention component or an implementation strategy?*

# Still More Design 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....



# Example 1: Cully et al., 2012, 2014+


- **Clinical trial of brief cognitive behavioral therapy in treating depression and anxiety; 1 “pilot” implementation strategy**
  - Patient randomization only; Pilot study of implementation strategy (online training, audit and feedback, facilitation) in 2 large VAMCs
  - Intent-to-treat analysis of clinical outcomes (N=320)
  - Feasibility, acceptability, and “preliminary effectiveness” data collected on implementation strategy
    - Measured knowledge acquisition, fidelity to model
    - Qualitative data on implementability, time spent, etc.
  - Measured sustainability of provision of brief CBT after trial
  - Preparatory to implementation trial of strategy

# Example 2: Garner et al., 2017; 2020

- **Aim 1**: effectiveness of a motivational interviewing-based brief intervention (MIBI) for substance use as an adjunct to usual care (referral) within AIDS service organizations (ASOs)
- **Aim 2**: effectiveness of implementation and sustainment facilitation (ISF) as an adjunct to the Addiction Technology Transfer Center (ATTC) model for training staff in MI
  - Patients randomized within ASOs (N=1872)
    - SUD outcomes
  - ASOs randomized to ACCT or ACCT+ISF (N=39)
    - Proctor et al (2011) measures (*pretty much all of them...!*)

# More Type 2 examples

**TBM** ORIGINAL RESEARCH

 CrossMark

**Evaluating the effectiveness of physician counseling to promote physical activity in Mexico: an effectiveness-implementation hybrid study**

Karla I. Galaviz,<sup>1</sup> Paul A. Estabrooks,<sup>2</sup> Edna Jauregui Ulloa,<sup>3</sup> Rebecca E. Lee,<sup>4</sup> Ian Janssen,<sup>5</sup> Juan López y Taylor,<sup>6</sup> Luis Ortiz-Hernández,<sup>7</sup> Lucie Lévesque<sup>8</sup>

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

BMC Public Health

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

Protocol

**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>

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



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>

# Newish thinking on hybrid designs

- Changing thinking on “lack of fixed-ness” of interventions contributing to changing views on when and why of hybrid-type designs
- Hybrid type 1 less of a “special case” but more routine?
  - If effectiveness research is the “last step” before trying to get people to do the thing... why not also focus on implementation questions?
- Some folks doing hybrid 1 type work in efficacy research, pilots
- Type 2 designs need to be fully justified and include “failsafe”
  - Make scientific premise argument based on evidence of intervention *and* strategies
  - Clarity around intervention/strategy components essential
- Hybrid type 3 less of a “special case” also?
  - When wouldn’t we want patient-level outcomes data?
    - Clearly some tho... like perhaps uptake of vaccines
  - Shouldn’t we PROVE how much fidelity is important and under what circumstances?



# What problems do people run into in trying to get hybrid studies funded?

- Disagreements over “how much evidence is enough” to begin including implementation focus
  - “But, we have no trials among people with green eyes...”
  - “Enough already! Get people to do the darn thing.”
- What if interventionist and/or context is REALLY different than in the effectiveness trials?
  - LMIC research
  - How different is *too* different for hybrid?
- Not enough data on barriers/facilitators to uptake to ground selection of proposed implementation strategies
- No pilot data on implementation strategy (type 3)



# Worksheet to help decide: Q1

Effectiveness-Implementation Hybrid Designs D&I Workshop 2019

Geoffrey M. Curran, Sara J. Landes

## Workshopping your idea: Questions to consider

- What is the nature of the effectiveness data on “the thing”?
  - “Very/pretty darn strong”, especially if not a lot of intervention adaptation needs to take place? Consider type 3 or type 2 depending on how much you also know about implementation factors (see below).
  - Mixed results? Missing (strong) effectiveness data? Consider Types 1 and 2.

# Q2 and Q3

- How much do you expect “the thing” will need to be adapted for where you want to study/use it?
  - A little? Consider including adaptation process as a step in an implementation-focused project (so, more type 2 or 3).
  - A lot? Consider focusing on effectiveness in a type 1 or type 2 “pilot of implementation strategy” version.
- How much do you already know about the barriers/facilitators to the implementation of the thing in your context of interest?
  - Not much? If you also need to focus on effectiveness data right now, consider type 1.
  - Do you know enough already to develop and pilot test a “new” implementation strategy (or package)? Consider type 2 to “pilot” strategy.

# Q4 and Q5

- Have you or someone else already tried an implementation strategy (or package) with your intervention and you know it didn't work very well?
  - If your intervention already has strong effectiveness data, this could be a great place to start for a type 3 or type 2 “pilot” for a new strategy (or package).
- Do you already have pilot data on a strategy (or package) that you want to test in a comparative study?
  - If your intervention effectiveness data are strong, consider a type 3.
  - If your intervention effectiveness data are mixed, consider a dual-randomized type 2.

# Q6

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# Q6

- After answering all of the above questions, do you still want to consider a hybrid design at all?
  - No? Feel free to run screaming from the room. We understand.
  - Yes? Seek out and learn from published protocol papers and other 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.



# Thanks to these great folks for their thoughts and contributions to the work:

- Brian Mittman, PhD
- Mark Bauer, MD
- Jeff Pyne, MD
- Cheryl Stetler, PhD, RN
- David Chambers, DPhil
- Ross Brownson, PhD
- Alison Hamilton, PhD
- Sacha McBain, PhD
- JD Smith, PhD
- Amy Kilbourne, PhD
- Rick Owen, MD
- Jeff Cully, PhD
- JoAnn Kirchner, MD
- John Fortney, PhD

# Question, comments, heckling...



# 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!

# More Design Considerations: Type 1

- The original definition of a type 1 emphasized secondary aims/questions and exploratory data collection and analysis preparatory to a greater focus on implementation activity
  - Review indicates that this is the common model of type 1
- However, some type 1 studies are doing more intense focus on “implementability” in developing/adapting intervention before effectiveness trial
  - i.e., “(re-)design for dissemination/implementation” step first
- What if you have a small number of sites?
  - Expand data collection to *naïve* sites (clinics not yet doing the thing)



# Example of Type 1: CALM study

- **Curran et al., 2012, *Implementation Science***
- **Large effectiveness trial of anxiety intervention in primary care**
  - 4 cities, 17 clinics, 1004 patients
  - Care managers using software tool with patients to navigate Tx manual
  - Care managers were local nurses/social workers already working in the clinics
  - Intervention was designed with “future implementation in mind”
- **Qualitative process evaluation alongside trial**
  - 47 interviews with providers, nurses, front office, and anxiety care managers
  - Most interviews done on the phone
  - Interview guide informed by an implementation framework (PARIHS)
    - (these days, that link needs to be very explicit...)



# CALM study process evaluation

- **Interview Guide**

1. What worked and what didn't work?
2. How did CALM operate in your clinic? Adaptations?
3. How did CALM affect workload, burden, and space?
4. How was CALM received by you and others in your site and how did that change over time?
5. Were there "champions" or "opinion leaders" for CALM and if so, what happened with them?
6. How did the communication between the care manager, the external psychiatrist, and local PCPs work?
7. What outcomes are/were you seeing?
8. What changes should be made to CALM?
9. What are the prospects for CALM being sustained in your clinic and why/why not?

# What did we learn?

- Lots of stuff...
- But, I'll share one important piece of data that illustrates the value of this kind of evaluation
  - Many of the providers in the participating clinics DID NOT refer a lot of patients for the trial. Some referred NOBODY.
  - Those who referred a lot were *already* interested in MH
  - Those who didn't were not persuaded during the site trainings that this was a good enough idea to actually take part
  - So, “uptake” and “reach” were not great in the trial, even though the researchers tried to get all providers to refer
  - So, key barrier to future implementation was provider buy-in and engagement. “Standard” strategies to entice them didn't work.
  - We would have learned this about this barrier about 2+ years later if we had done this sequentially.

# More Type 1 examples

Contemporary Clinical Trials 43 (2015) 260–278


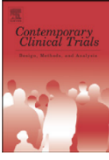

Contents lists available at ScienceDirect

**Contemporary Clinical Trials**

journal homepage: [www.elsevier.com/locate/conclintrial](http://www.elsevier.com/locate/conclintrial)

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.ascpjournals.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>

