

CLINICAL EPIDEMIOLOGY

Summary of



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AN INTRODUCTION TO EFFECTIVENESS-IMPLEMENTATION HYBRID DESIGNS

Landes SJ, McBain SA, Curran GM. Psychiatry Res. 2019 Oct;280:112513. doi: 10.1016/j.psychres.2019.112513. Epub 2019 Aug 9. PMID: 31434011; PMCID: PMC6779135.

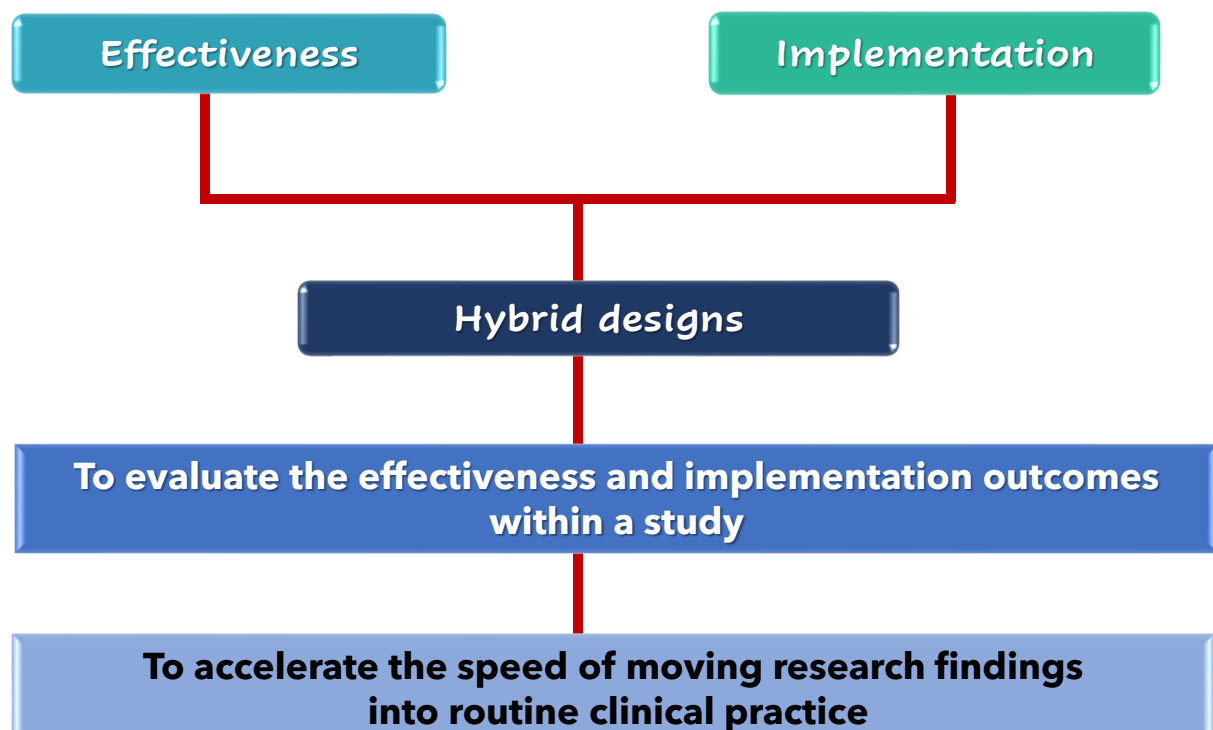
INTRODUCTION

The traditional research pipeline that encourages a stepwise approach to moving an intervention from efficacy trials to the real world could take a long time.



Figure 1. Traditional Research Pipeline

Why do hybrid effectiveness-implementation designs?



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INTRODUCTION



Hybrid designs

Relatively focusing on both the effectiveness of the clinical intervention and its implementation, but the type of trial (e.g., stepped wedge, cluster randomized, pilot), which is often referred to as a design, is not necessarily yoked to the type of hybrid.

Various types of randomized and non-randomized trial designs can be used in the context of a hybrid depending on the **specific aims**.

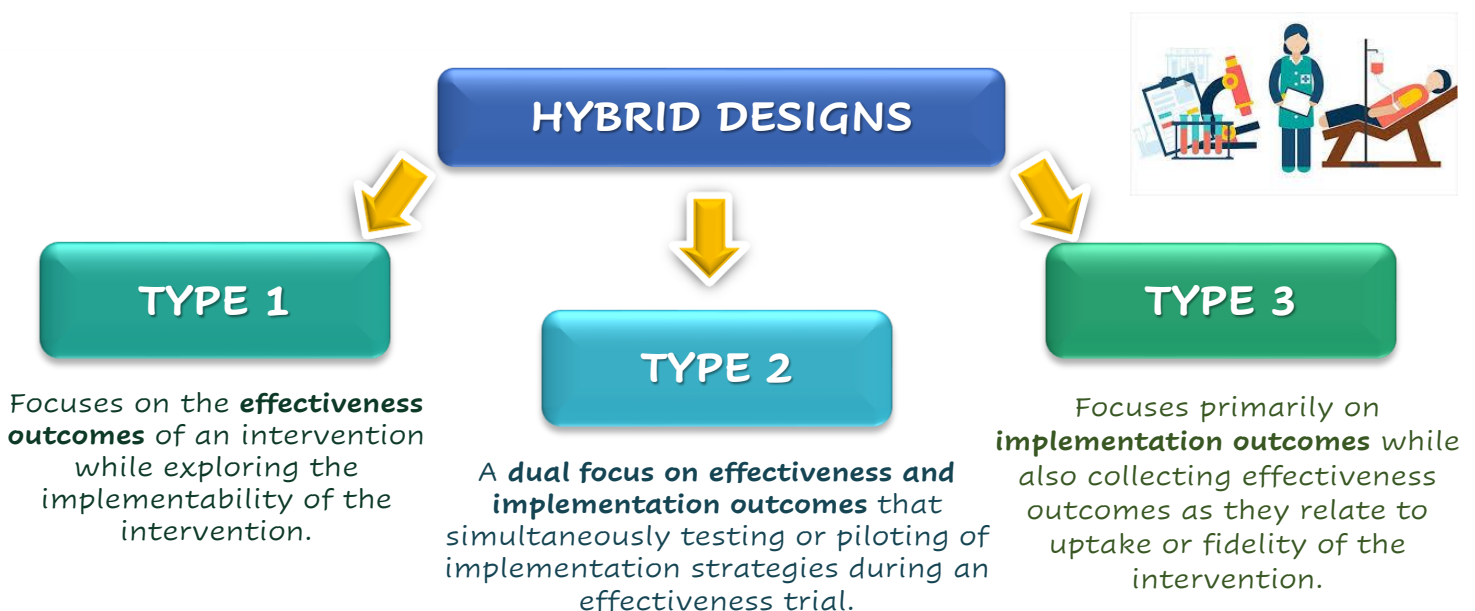
To design **any type of hybrid study**, it is important to use a **framework** (e.g., CFIR, PRECIS-2) to guide the study process and **reporting** of outcomes (e.g., RE-AIM).

Note:

- CFIR: The Consolidated Framework for Implementation Research
- PRECIS-2: The PRagmatic Explanatory Continuum Indicator Summary-2
- RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

TYPES OF HYBRID DESIGNS

There are **3 types of hybrid designs** which vary based on their primary focus and the amount of emphasis on effectiveness versus implementation outcomes.



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TYPES OF HYBRID DESIGNS

Type 1



A hybrid type 1 design focuses **primarily on the effectiveness outcomes of a clinical or prevention intervention** while exploring the "implementability" of the intervention.



This design helps to identify what is needed to support the implementation in the real-world setting - to identify barriers and facilitators of implementation that will inform the selection of appropriate implementation strategies.



This design could be a combination of **traditional effectiveness study and "process evaluation"** to describe the implementation experience, identification of how the intervention needs to be adapted for the setting, and/or what is needed to support the delivery of the intervention to the target people and place.



The implementation outcomes can be obtained via interview, survey, and/or observation of participants.



This design is indicated when the clinical effectiveness evidence remains limited, therefore studying implementation alone is premature.



It is also recommended to be adopted when effectiveness study conditions offer an ideal opportunity to explore implementation issues and plan implementation strategies for the next stage.

Type 1

- **Primary focus:** To test the effectiveness of a clinical intervention.
- **Secondary focus:** To explore implementation related factors.



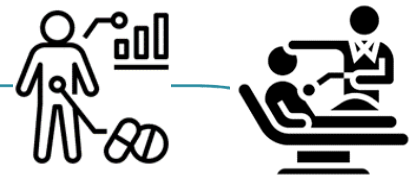
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TYPES OF HYBRID DESIGNS

Type 2



A hybrid type 2 design consisting of an **effectiveness trial paired with an implementation trial** - has a dual focus on the effectiveness of clinical intervention and its implementation outcomes.



This design allows for the **simultaneous testing or piloting of implementation strategies while conducting an effectiveness trial.**



This hybrid design is ideal when studying interventions that are supported by existing evidence of effectiveness in other settings or populations.



There is no clear designation of how each aspect should be allotted (e.g., 50/50, 60/40).



It is important to clearly define the intervention components versus the implementation strategy components. The implementation strategy should be plausible in the real world.



This design requires an explicit measurement of implementation outcome (e.g., adoption, fidelity).



Both qualitative and quantitative methods can be used in this design. The investigators will be able to corroborate, compare, and expand the findings and identify barriers to and facilitators of intervention fidelity.

Type 2

To simultaneously identify the effectiveness of the intervention and test an implementation strategy aimed at increasing the use and fidelity of the intervention.



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TYPES OF HYBRID DESIGNS

Type 3



A type 3 hybrid focuses **primarily on implementation outcomes** (e.g., testing of implementation strategies) while also identifying effectiveness outcomes as they relate to uptake or fidelity of the intervention.

This design is essentially a **combination of an implementation trial and evaluation of patient outcomes.**

This design compares implementation strategies and when a study is conducted in healthcare settings, the strategies usually target provider, clinic, and/or system levels and their impact on implementation outcomes.

The option to use this design is also appropriate when there is a high-level need or call for implementation despite a paucity of evidence base (e.g., strong momentum within a healthcare system or a formal mandate).

This type of hybrid **works best with easily accessible clinical outcomes** (e.g., those that can be passively assessed through the medical record).

It is not ideally designed for outcomes that usually require primary data collection.

- **Primary focus:** Implementation outcomes (adoption, fidelity & sustainability)
- **Secondary focus:** To observe or gather information on the intervention outcomes.



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Types of Hybrid Designs and the Associated Research Aims and Outcomes

| Hybrid design | Type 1 | Type 2 | Type 3 |
|------------------------|--|---|---|
| Research Aims | | | |
| ➤ Primary | Determine the effectiveness of an intervention | Determine the effectiveness of an intervention | Determine the impact of an implementation strategy |
| ➤ Secondary | A better understanding of the context for implementation | Co-Primary Aim: Determine feasibility and/or (potential) impact of an implementation strategy | Assess the clinical outcomes associated with implementation |
| Primary Outcome | Clinical effectiveness | Clinical effectiveness and implementation outcomes | Implementation outcomes |

Conclusion and Recommendation



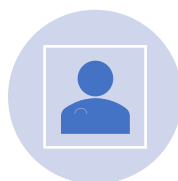
Hybrid designs can provide insight into how clinical outcomes are related to implementation outcomes (e.g. levels of adoption and fidelity).



By concurrently gathering both effectiveness and implementation data, investigators will be aware of crucial contextual factors related to the success of their interventions and the potential barriers that may affect the implementation outcomes of the interventions.



Prior to choosing an appropriate hybrid design, it is important to design the effectiveness trials with dissemination and implementation components in the first stages of study development.



It is also possible to start with an implementation study in a new effort to translate an evidence-based intervention into clinical practice.



It is not required to wait for "perfect" effectiveness data before moving to implementation research as additional effectiveness data can be gathered while testing implementation strategies.



To ensure the implementability of an effectiveness study, gathering input from stakeholders before the trial is crucial to developing culturally-adapted interventions that increase their engagement and participation.