

1. Title:

Maximizing hybrid designs for implementation research: Non-experimental approaches

2. Author(s):

Arno Parolini, Aron Shlonsky,

3. Key words:

Implementation, Evaluation, Effectiveness, Hybrid designs

4. Abstract text:

a. Background and aims

Implementation of interventions in real world environments often encompasses multiple components, each contributing to the overall treatment effect. The possibility of imperfect implementation, resulting in variable program fidelity, complicates the investigation of intervention and implementation effects via randomised experiments. Acknowledging these challenges, there has been a push to accommodate the duality of clinical effects and implementation through the development of effectiveness-implementation hybrid designs (Curran et al., 2012). However, complexity of implementing these designs and increased costs pose significant evaluation challenges.

Expanding current thinking in this field, we propose a series of non-experimental study designs as flexible, cost-effective alternatives to existing hybrid designs for measuring implementation and intervention effectiveness.

b. Methods

First, we will provide a general introduction to non-experimental study designs for evaluating interventions with dual foci on effectiveness and uptake of interventions. We will then illustrate the conditions under which well-planned, non-experimental approaches can be used to model the extent to which overall implementation and individual implementation components influence the effectiveness of treatment. Finally, we will explore the strengths and weaknesses of non-experimental designs compared with randomised controlled trials (RCTs), elaborating a set of potential research questions that are best answered using each approach.

c. Conclusion

Non-experimental studies are attractive extensions to existing evaluation approaches when there is a focus on intervention effectiveness as well as uptake and implementation components. Like RCTs, however, these methods rely on the presence of certain conditions and a well-planned study requires in-depth knowledge of the intervention, the context in which it is being implemented, and methodological expertise.