

What Are Embedded Pragmatic Clinical Trials (ePCTs) and How do They Intersect With D&I Research?

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Learning goals

- Recognize key considerations in the design and conduct of ePCTs
- Review relevant concepts and terms in D&I research
- Identify key areas of convergence between ePCTs and D&I research



ePCTs: Important things to know

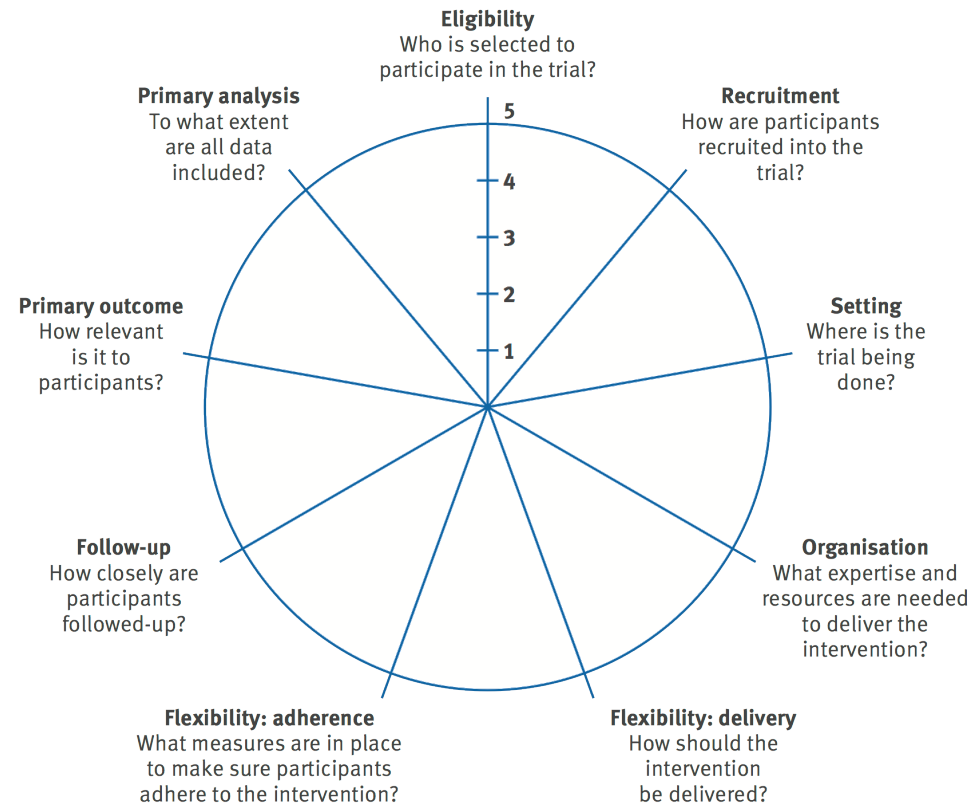
- ePCTs are designed to answer important, real-world clinical questions
- Broad stakeholder engagement and support are essential from beginning to end
- Trade-offs in flexibility, adherence, and generalizability are inevitable

ePCT characteristics

- Conducted within healthcare systems
- Use streamlined procedures and existing infrastructure
- Answer important medical questions



Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) Wheel

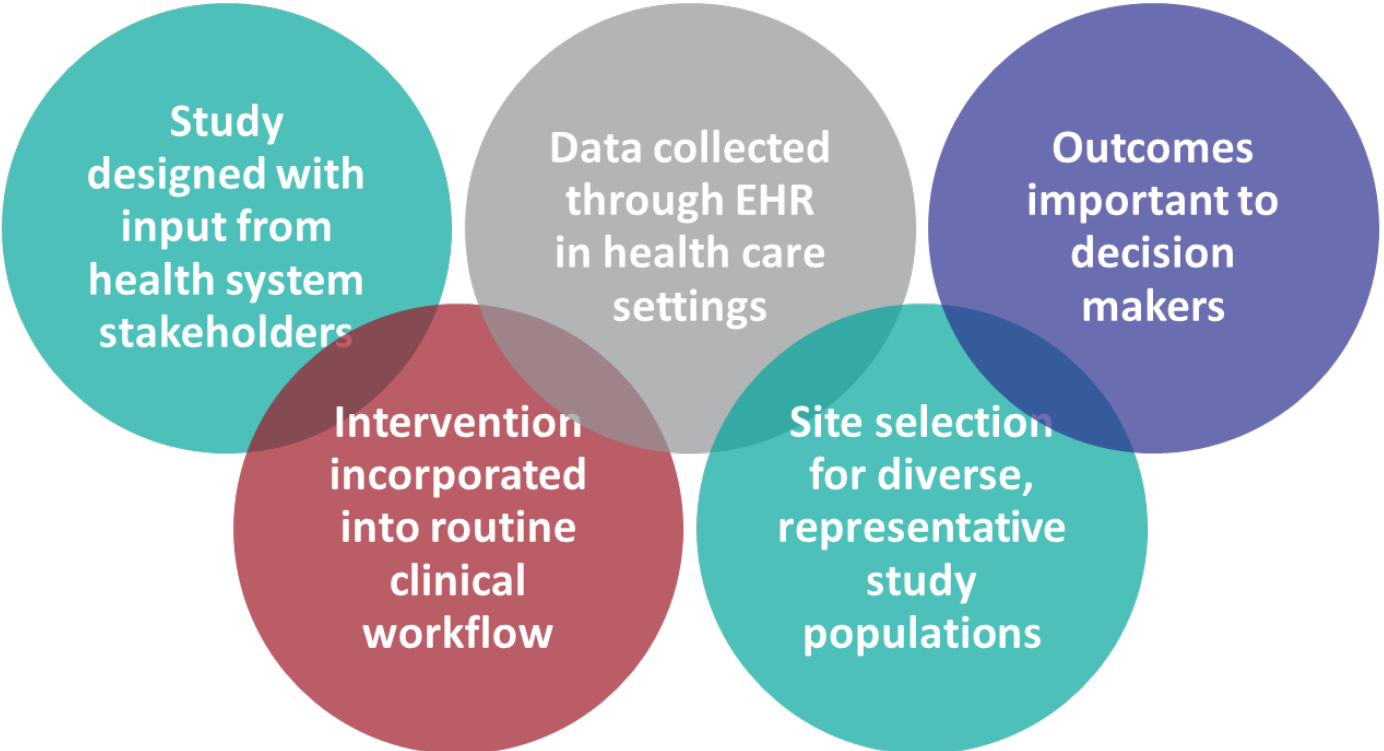


Why conduct ePCTs?



ePCTs have the potential to inform policy and practice with high-quality evidence at reduced cost and increased efficiency compared with traditional clinical trials

ePCTs bridge clinical care into research



What is a Pragmatic Clinical Trial?

There is a need for “a different context to clinical research that could speed the discovery and implementation of evidence-based advancements to healthcare delivery. Pragmatic clinical trials (PCTs) are a promising type of trial conducted within real-world health care delivery systems”
(Tuzzio and Larson 2019).

Relevant D&I concepts: Dissemination Research

- “Scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to communicate and integrate knowledge and the associated evidence-based interventions.”
- How, when, by whom, and under what circumstances does evidence spread?
- How do we package and share evidence to increase adoption and use?

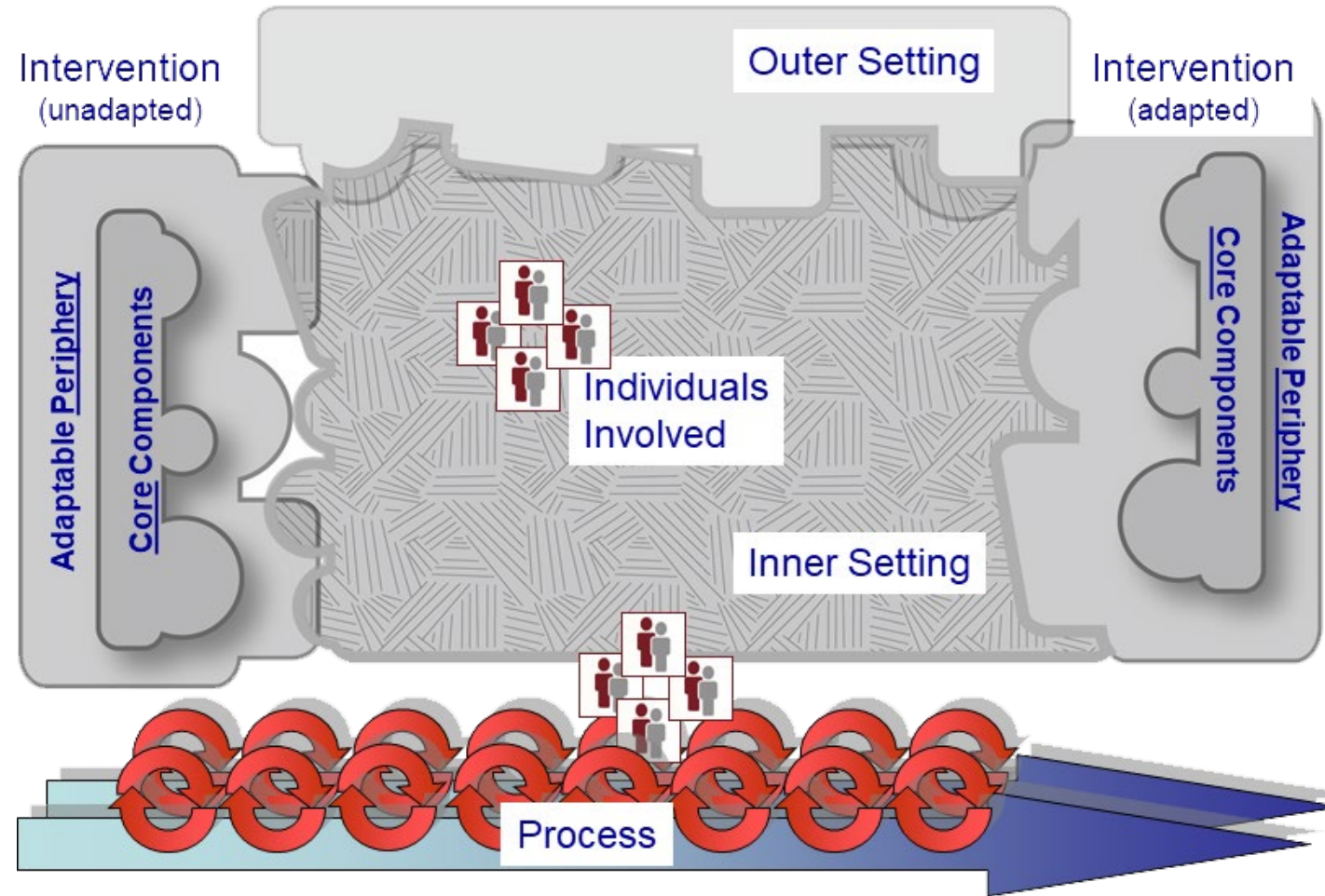
Relevant D&I concepts: Implementation Research

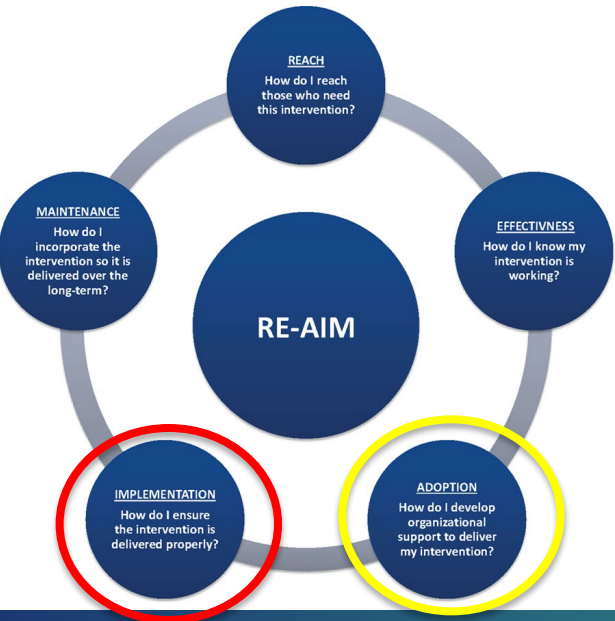
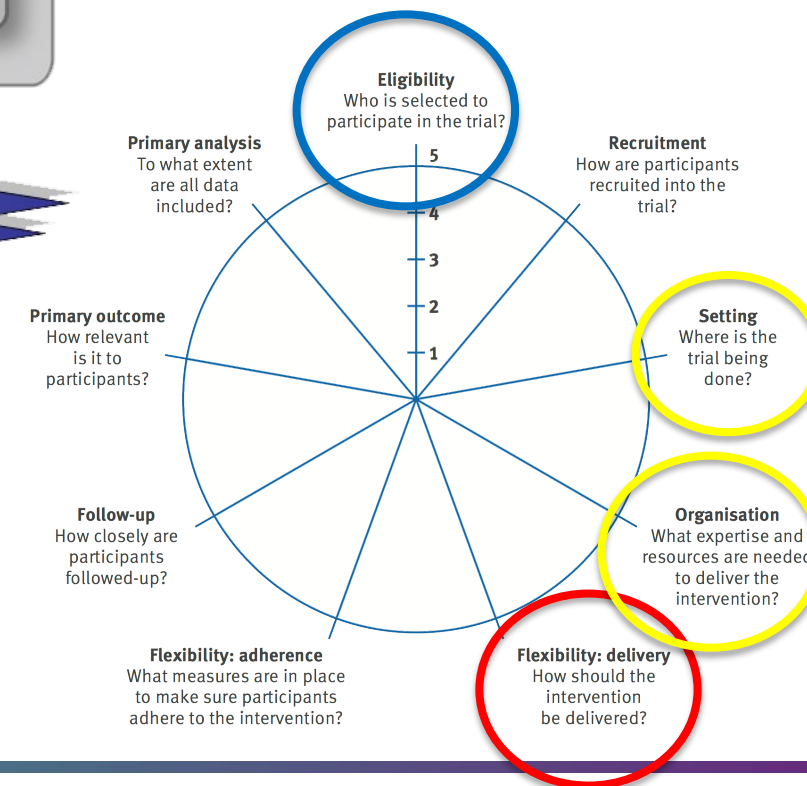
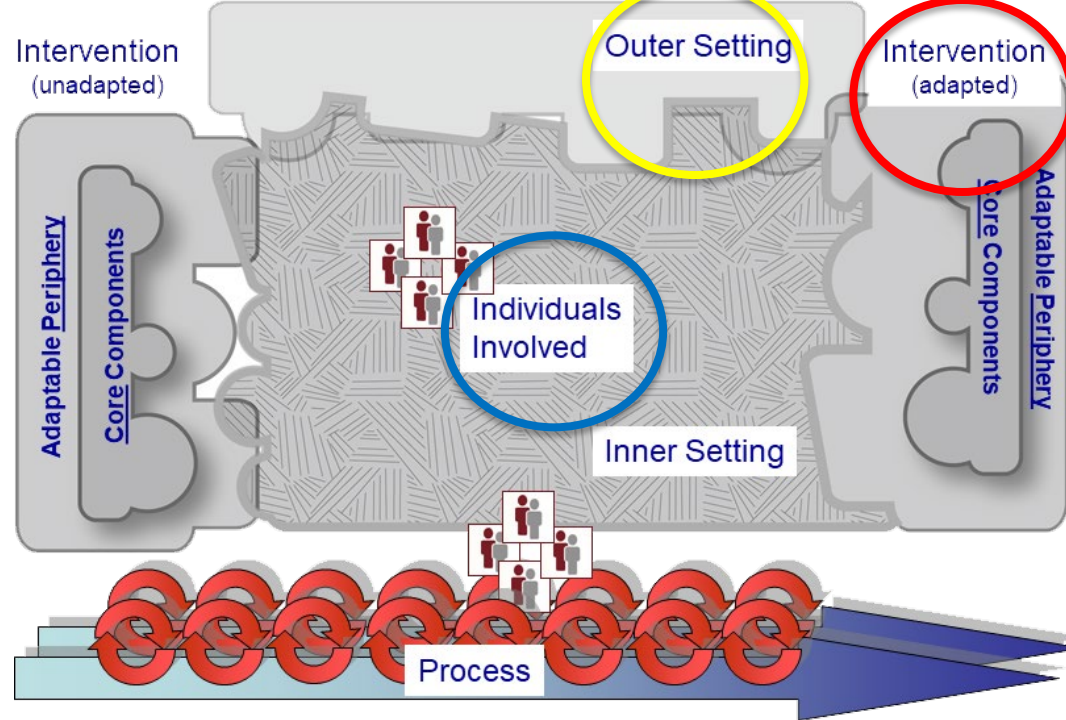
- “Scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.”
- How do we best implement evidence-based interventions, practices, and programs in routine, real-world settings?
- What approaches are needed to facilitate integration, adaptation, and sustainability of evidence in delivery settings?

Frameworks



Consolidated Framework for Implementation Research





Key areas of convergence with ePCTs

- Pragmatic/stakeholder-engaged *intervention* design
- Study design that considers implementation
- Regulatory concerns

Opportunities

- Pragmatic trials can be improved by including implementation strategies
- Hybrid designs offer the opportunity to evaluate effectiveness and implementation strategies
- Multidisciplinary teams improve pragmatic research and dissemination/implementation research

Resources

Visit the Living Textbook of Pragmatic Clinical Trials at

www.rethinkingclinicaltrials.org

IMPACT Training Modules ePCT Video Learning Library

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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Training Videos

Learn more about how to conduct ePCTs for people living with dementia

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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