A Proposed Framework for Designing Trials Evaluating the Effectiveness and Implementation of Digital Interventions for Substance Use

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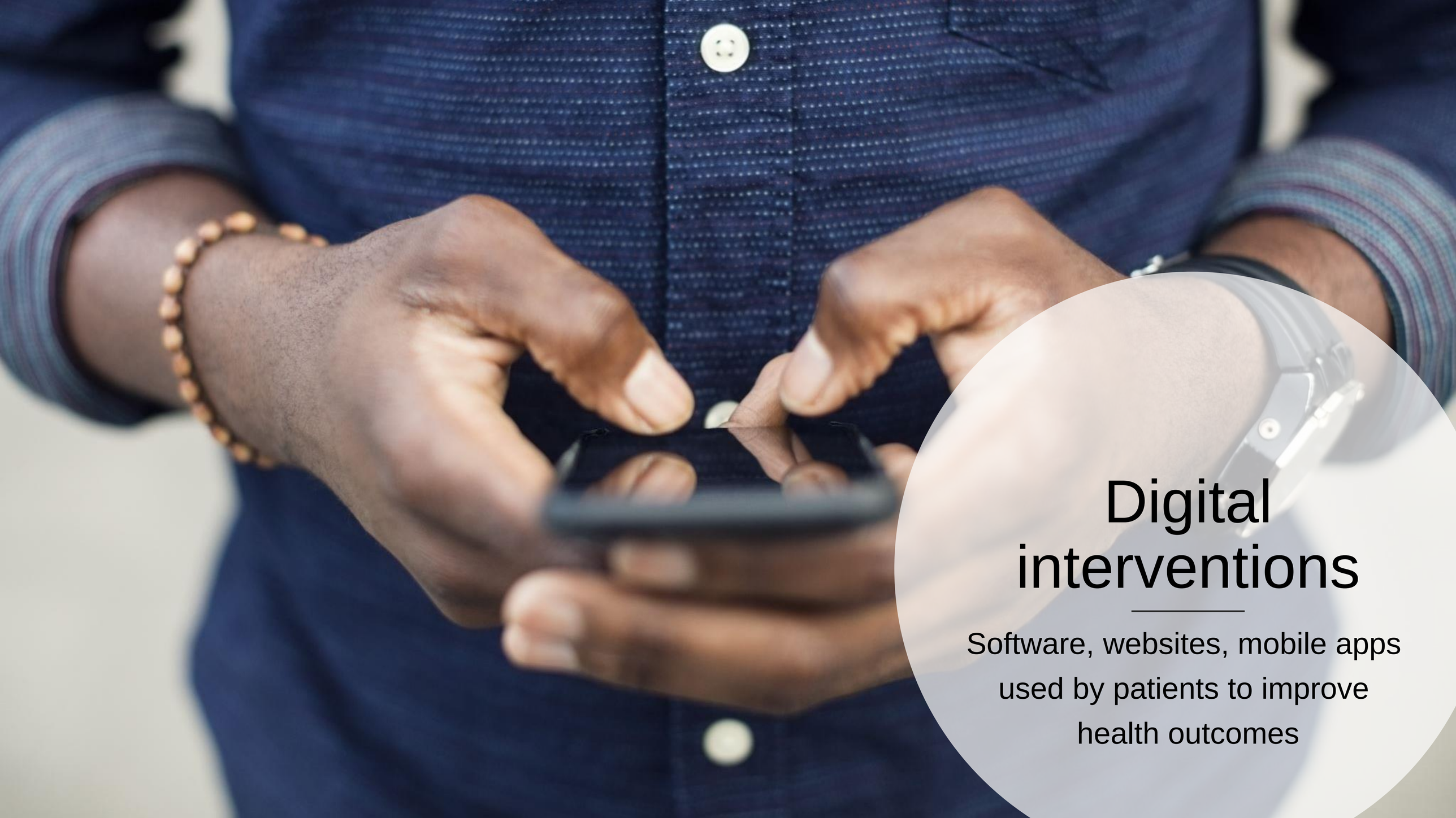


Digital interventions

Software, websites, mobile apps used by patients to improve health outcomes

Digital interventions for substance use

Used for screening, brief intervention, or to deliver evidence-based treatment

Potential to address barriers and bottlenecks to substance use treatment

Evidence of efficacy but mixed evidence of effectiveness **under** real-world **conditions**

Effectiveness of digital interventions in real-world settings may depend on its implementation

Implementation Challenges

Digital interventions have unique implementation considerations
that may not fit traditional care pathways

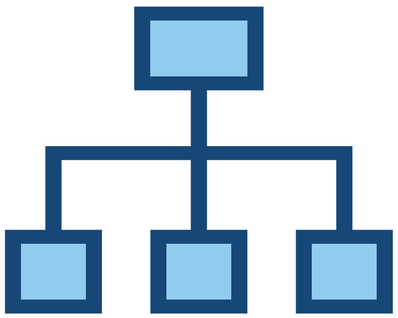
Technology infrastructure

Digital literacy

Monitoring and follow-up

Studies on delivery of digital interventions in clinical care

Clinical Workflows



Clinicians provide introduction, setup and follow-up

(Glass et al., 2021, 2022)

Staffing models

- Clinical technology specialists
  (Ben-Zeev, 2015)
- Peer specialists
  (Fortuna et al, 2019)
- Health coaches
  (Glass et al., 2023; Park et al., 2022)

Specialized Clinics

Digital clinics

(Rodriguez-Vila et al., 2020)

Implementation strategy studies

- Map implementation strategies to digital intervention barriers (Graham et al., 2020)

Implementation Strategies for Digital Mental Health Interventions in Health Care Settings

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Abstract

U.S. health care systems are tasked with alleviating the burden of mental health, but are frequently under-prepared and lack workforce and resource capacity to deliver services to all in need. Digital mental health interventions (DMHIs) can increase access to evidence-based mental health care. However, DMHIs commonly do not fit into the day-to-day activities of the people who engage with them, resulting in a research-to-practice gap for DMHI implementation. For health care settings, differences between digital and traditional mental health services make alignment and integration challenging. Specialized attention is needed to improve the implementation of DMHIs in health care settings so that these services yield high uptake, engagement, and sustainment. The purpose of this paper is to enhance efforts to integrate DMHIs in health care settings by proposing implementation strategies, selected and operationalized based on the discrete strategies established in the Expert Recommendations for Implementing Change project, that align to DMHI-specific barriers in these settings. Guidance is offered in how these strategies can be applied to DMHI implementation across four phases commonly distinguished in implementation science using the Exploration, Preparation, Implementation, Sustainment Framework. Next steps to advance research in this area and improve the research-to-practice gap for implementing DMHIs are recommended. Applying implementation strategies to DMHI implementation will enable psychologists to systematically evaluate this process, which can yield an enhanced understanding of the factors that facilitate implementation success and improve the translation of DMHIs from controlled trials to real-world settings.

Few trials testing new delivery approaches

STUDY PROTOCOL Open Access

Study protocol for a factorial-randomized controlled trial eva
costs, effectiveness
therapeutics for su
in primary care (DI

Joseph E. Glass[1*], Caitlin N. Dorsey[1], Tara
Deborah King[1], Jessica Mogk[1], Kelsey Stefa
Rosemarie Thomas[5], Angela Garza McWeth

JMIR RESEARCH PROTOCOLS Park et al

Protocol

Testing an mHealth System for Individuals With Mild to Moderate Alcohol Use Disorders: Protocol for a Type 1 Hybrid Effectiveness-Implementation Trial

Linda S Park[1], MSW, PhD; Ming-Yuan Chih[2], MHA, PhD; Christine Stephenson[3], PhD; Nicholas Schumacher[1], MS; Randall Brown[1], MD, PhD; David Gustafson[4], PhD; Bruce Barrett[1], MD, PhD; Andrew Quanbeck[1], PhD

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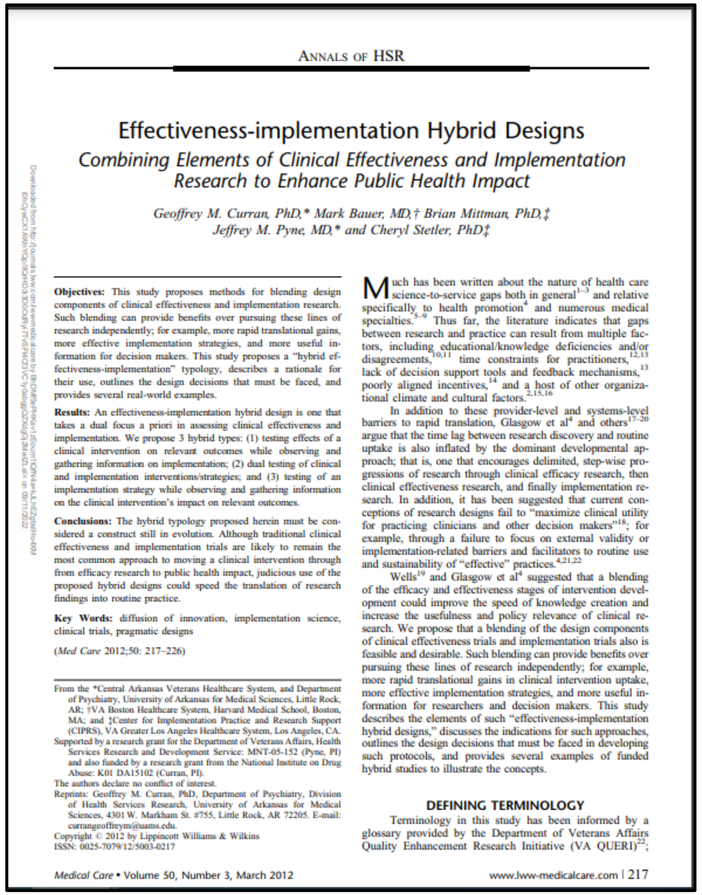
Motivation for this framework

- Few trials test these approaches in the real world
- Lack of studies that seek to answer how to deliver digital interventions
- Trials need to be harmonized

We propose a framework for designing trials that seek to address questions about the implementation and effectiveness of digital interventions in real-world care

Methods

- Draws on literature from trial design, expert perspectives, lessons learned



ANNALS OF HSR

Effectiveness-implementation Hybrid Designs

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡ Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

(*Med Care* 2012;50: 217–226)

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The authors declare no conflict of interest.

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Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to "maximize clinical utility for practicing clinicians and other decision makers"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

Wells[19] and Glasgow et al[4] suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains in clinical intervention uptake, more effective implementation strategies, and more useful information for researchers and decision makers. This study describes the elements of such "effectiveness-implementation hybrid designs," discusses the indications for such approaches, outlines the design decisions that must be faced in developing such protocols, and provides several examples of funded hybrid studies to illustrate the concepts.

DEFINING TERMINOLOGY

Terminology in this study has been informed by a glossary provided by the Department of Veterans Affairs Quality Enhancement Research Initiative (VA QUERI)[22];

Viewpoint

Measuring the Implementation of Behavioral Intervention Technologies: Recharacterization of Established Outcomes

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Abstract

Behavioral intervention technologies (BITs) are websites, software, mobile apps, and sensors designed to help users address or change behaviors, cognitions, and emotional states. BITs have the potential to transform health care delivery, and early research has produced promising findings of efficacy. BITs also favor new models of health care delivery and provide novel data sources for measurement. However, there are few examples of successful BIT implementation and a lack of consensus on as well as inadequate descriptions of BIT implementation measurement. The aim of this viewpoint paper is to provide an overview and characterization of implementation outcomes for the study of BIT use in routine practice settings. Eight outcomes for the evaluation of implementation have been previously described: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability. In a proposed recharacterization of these outcomes with respect to BIT implementation, definitions are clarified, expansions to the level of analysis are identified, and unique measurement characteristics are discussed. Differences between BIT development and implementation, an increased focus on consumer-level outcomes, the expansion of providers who support BIT use, and the blending of BITs with traditional health care services are specifically discussed. BITs have the potential to transform health care delivery. Realizing this potential, however, will hinge on high-quality research that consistently and accurately measures how well such technologies have been integrated into health services. This overview and characterization of implementation outcomes support BIT research by identifying and proposing solutions for key theoretical and practical measurement challenges.

(J Med Internet Res 2019;21(1):e11752) doi: 10.2196/11752

KEYWORDS

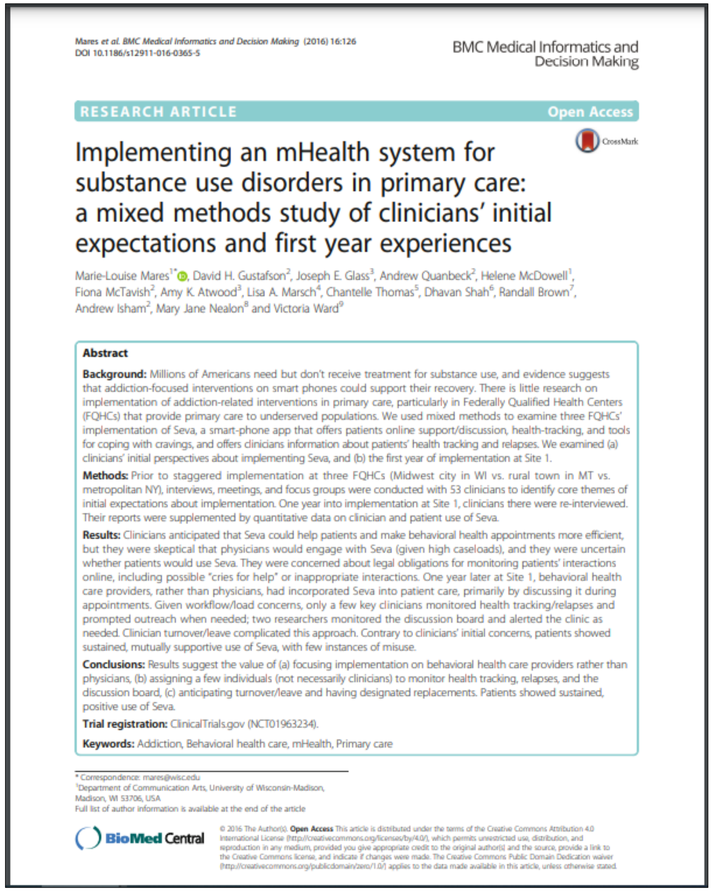
mobile applications; behavior therapy; technology; internet; telemedicine; diffusion of innovation; translational medical research; outcome assessment (health care); review; implementation; behavioral intervention technology

Introduction

Behavioral Intervention Technology

A broad range of health information technologies are increasingly used in the delivery of health care to expand access, increase the effectiveness of care, and improve the productivity of health systems [1,2]. This article focuses on a subset of health information technology developed to intervene in a wide range of behavioral, psychosocial, or chronic health conditions, termed *behavioral health* conditions, by assisting the user to change behaviors, cognitions, and emotional states [3]. The term behavioral intervention technology (BIT) is used to refer to these interventions, although alternative terms such as eHealth, mobile health, *digital treatments*, and *internet interventions* are also used [4].

BITs are interventions delivered over computer software, internet websites, mobile apps, and wearable devices [2]. Such programs present material in varied formats, including audio,



Mares et al. BMC Medical Informatics and Decision Making (2016) 16:126
DOI 10.1186/s12911-016-0365-5

BMC Medical Informatics and Decision Making

RESEARCH ARTICLE Open Access

Implementing an mHealth system for substance use disorders in primary care: a mixed methods study of clinicians' initial expectations and first year experiences

Marie-Louise Mares[1*], David H. Gustafson[2], Joseph E. Glass[3], Andrew Quanbeck[2], Helene McDowell[1], Fiona McTavish[2], Amy K. Atwood[3], Lisa A. Marsch[4], Chantelle Thomas[5], Dhavan Shah[6], Randall Brown[7], Andrew Isham[2], Mary Jane Nealon[8] and Victoria Ward[9]

Abstract

Background: Millions of Americans need but don't receive treatment for substance use, and evidence suggests that addiction-focused interventions on smart phones could support their recovery. There is little research on implementation of addiction-related interventions in primary care, particularly in Federally Qualified Health Centers (FQHCs) that provide primary care to underserved populations. We used mixed methods to examine three FQHCs' implementation of Seva, a smart-phone app that offers patients online support/discussion, health-tracking, and tools for coping with cravings, and offers clinicians information about patients' health tracking and relapses. We examined (a) clinicians' initial perspectives about implementing Seva, and (b) the first year of implementation at Site 1.

Methods: Prior to staggered implementation at three FQHCs (Midwest city in WI vs. rural town in MT vs. metropolitan NY), interviews, meetings, and focus groups were conducted with 53 clinicians to identify core themes of initial expectations about implementation. One year into implementation at Site 1, clinicians there were re-interviewed. Their reports were supplemented by quantitative data on clinician and patient use of Seva.

Results: Clinicians anticipated that Seva could help patients and make behavioral health appointments more efficient, but they were skeptical that physicians would engage with Seva (given high caseloads), and they were uncertain whether patients would use Seva. They were concerned about legal obligations for monitoring patients' interactions online, including possible "cries for help" or inappropriate interactions. One year later at Site 1, behavioral health care providers, rather than physicians, had incorporated Seva into patient care, primarily by discussing it during appointments. Given workflow/load concerns, only a few key clinicians monitored health tracking/relapses and prompted outreach when needed; two researchers monitored the discussion board and alerted the clinic as needed. Clinician turnover/leave complicated this approach. Contrary to clinicians' initial concerns, patients showed sustained, mutually supportive use of Seva, with few instances of misuse.

Conclusions: Results suggest the value of (a) focusing implementation on behavioral health care providers rather than physicians, (b) assigning a few individuals (not necessarily clinicians) to monitor health tracking, relapses, and the discussion board, (c) anticipating turnover/leave and having designated replacements. Patients showed sustained, positive use of Seva.

Trial registration: ClinicalTrials.gov (NCT01963234).

Keywords: Addiction, Behavioral health care, mHealth, Primary care

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Methods

- Draws on literature from trial design, expert perspectives, lessons learned
- We apply this framework to a working example

DIGITS Trial: Optimizing the implementation of digital therapeutics for substance use disorders in primary care

Interventions

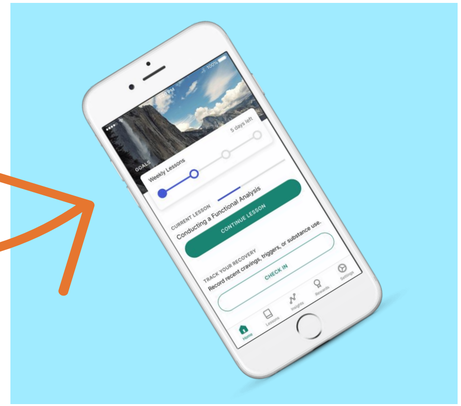
- reSET® and reSET-O®
- Practice facilitation
- Health coaching

Comparator: Standard Implementation

Population: Primary care patients with substance use disorder

Outcomes: Reach, fidelity, cost effectiveness

Timeline: 1-year active implementation and 1 year sustainment



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https://doi.org/10.1186/s13012-022-01258-9

Implementation Science

STUDY PROTOCOL Open Access

Study protocol for a factorial-randomized controlled trial evaluating the implementation, costs, effectiveness, and sustainment of digital therapeutics for substance use disorder in primary care (DIGITS Trial)

Joseph E. Glass[1*], Caitlin N. Dorsey[1], Tara Beatty[1], Jennifer F. Bobb[1], Edwin S. Wong[2,3], Lorella Palazzo[1], Deborah King[1], Jessica Mogk[1], Kelsey Stefanik-Guizlo[1], Abisola Idu[1], Dustin Key[1], John C. Fortney[3,4], Rosemarie Thomas[5], Angela Garza McWethy[5], Ryan M. Caldeiro[5] and Katharine A. Bradley[1]

Abstract

Background Experts recommend that treatment for substance use disorder (SUD) be integrated into primary care. The Digital Therapeutics for Opioids and Other SUD (DIGITS) Trial tests strategies for implementing reSET® and reSET-O®, which are prescription digital therapeutics for SUD and opioid use disorder, respectively, that include the community reinforcement approach, contingency management, and fluency training to reinforce concept mastery. This purpose of this trial is to test whether two implementation strategies improve implementation success (Aim 1) and achieve better population-level cost effectiveness (Aim 2) over a standard implementation approach.

Methods/Design The DIGITS Trial is a hybrid type III cluster-randomized trial. It examines outcomes of implementation strategies, rather than studying clinical outcomes of a digital therapeutic. It includes 22 primary care clinics from a healthcare system in Washington State and patients with unhealthy substance use who visit clinics during an active implementation period (up to one year). Primary care clinics implemented reSET and reSET-O using a multifaceted implementation strategy previously used by clinical leaders to roll-out smartphone apps ("standard implementation" including discrete strategies such as clinician training, electronic health record tools). Clinics were randomized as 21 sites in a 2x2 factorial design to receive up to two added implementation strategies: (1) practice facilitation, and/or (2) health coaching. Outcome data are derived from electronic health records and logs of digital therapeutic usage. Aim 1's primary outcomes include reach of the digital therapeutics to patients and fidelity of patients' use of the digital therapeutics to clinical recommendations. Substance use and engagement in SUD care are additional outcomes. In Aim 2, population-level cost effectiveness analysis will inform the economic benefit of the implementation strategies compared to standard implementation. Implementation is monitored using formative evaluation, and sustainment will be studied for up to one year using qualitative and quantitative research methods.

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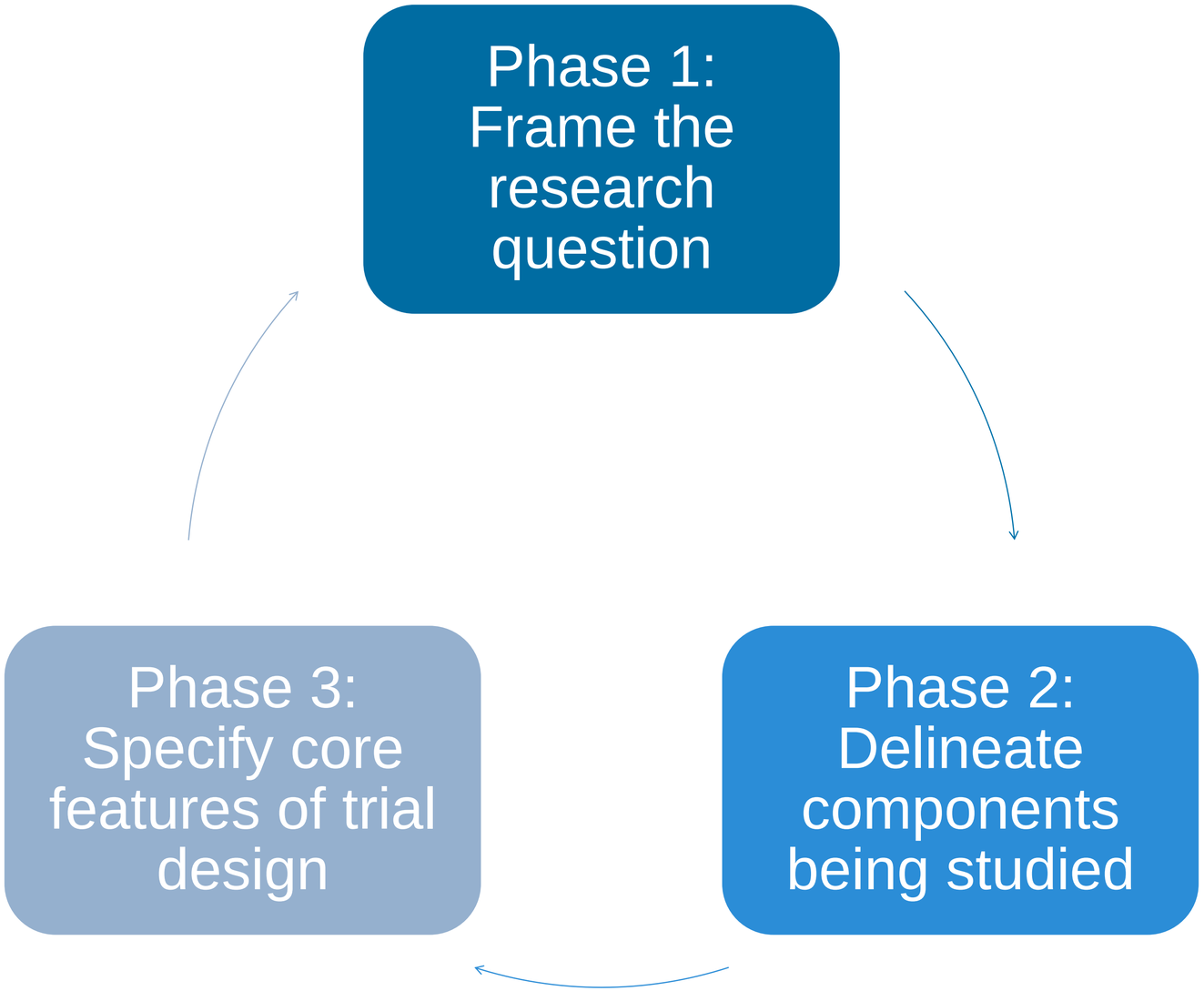
Framework

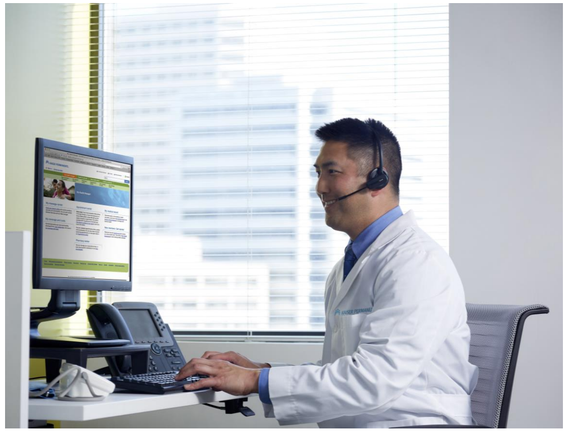


Trial Components

At each phase, consider three trial components critical to effectiveness and implementation of digital interventions

Digital Interventions

(Philippe et al., 2022; Bewick et al., 2017)



Clinical Support Services

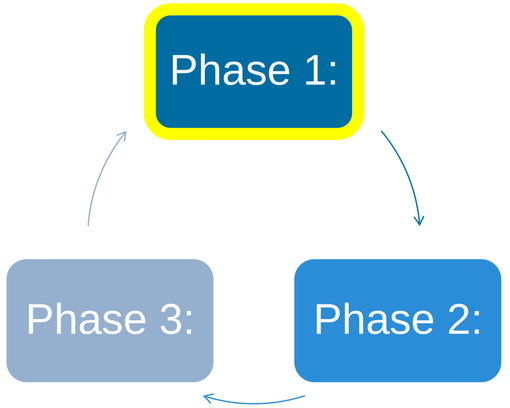
(Hermes et al., 2019)

Implementation Strategies

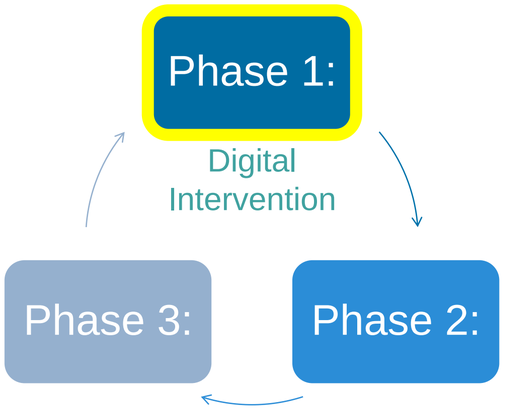
(Powell et al., 2015; Graham et al., 2021)

Phase 1: Frame the research question

- All aspects of the trial design should follow the research questions.
- Identify timely, relevant question **worthy of an experimental design**
- Frame the question in terms of the components to be tested…



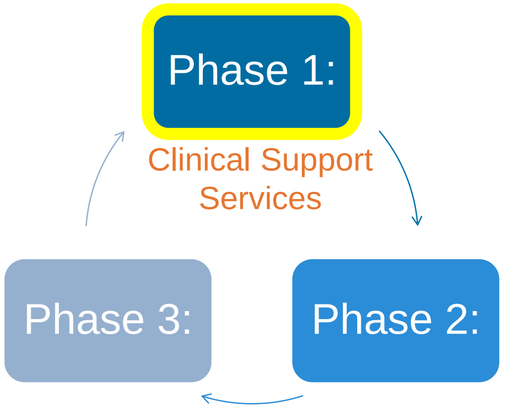
Phase 1: Frame the research question



- All aspects of the trial design should follow the research questions.
- Identify timely, relevant question **worthy of an experimental design**
- Frame the question in terms of the components to be tested…

	Digital intervention
Research question	Does the digital intervention work in this population or setting? Which digital intervention to use?
Rationale	Stakeholders want to know: • whether to invest • in which product to invest
Example	Secondary in DIGITS Trial

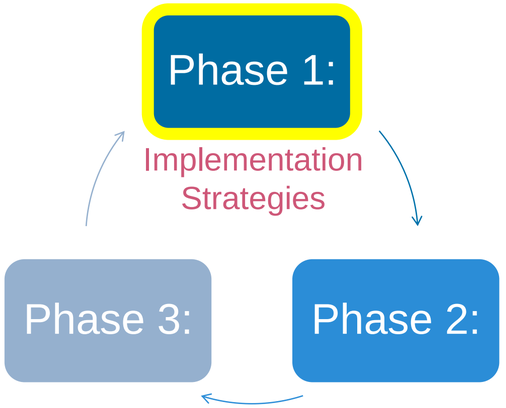
Phase 1: Frame the research question



- All aspects of the trial design should follow the research questions.
- Identify timely, relevant question **worthy of an experimental design**
- Frame the question in terms of the components to be tested…

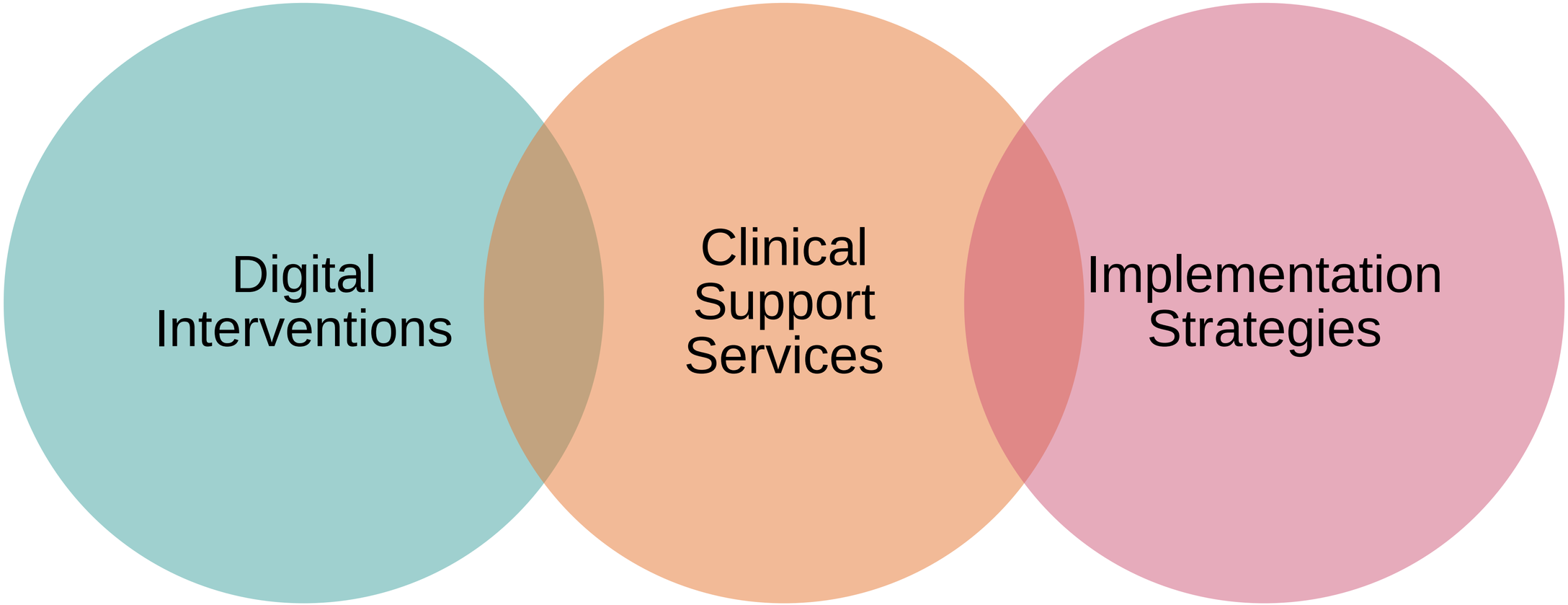
	Digital intervention	Clinical support services
Research question	Does the digital intervention work in this population or setting? Which digital intervention to use?	What approaches for offering digital interventions are needed to support delivery in real world?
Rationale	Stakeholders want to know: • whether to invest • in which product to invest	Stakeholders want to know • how to reorganize resources • hire new staff • contract out to a 3rd party
Example	Secondary in DIGITS Trial	Primary in DIGITS Trial

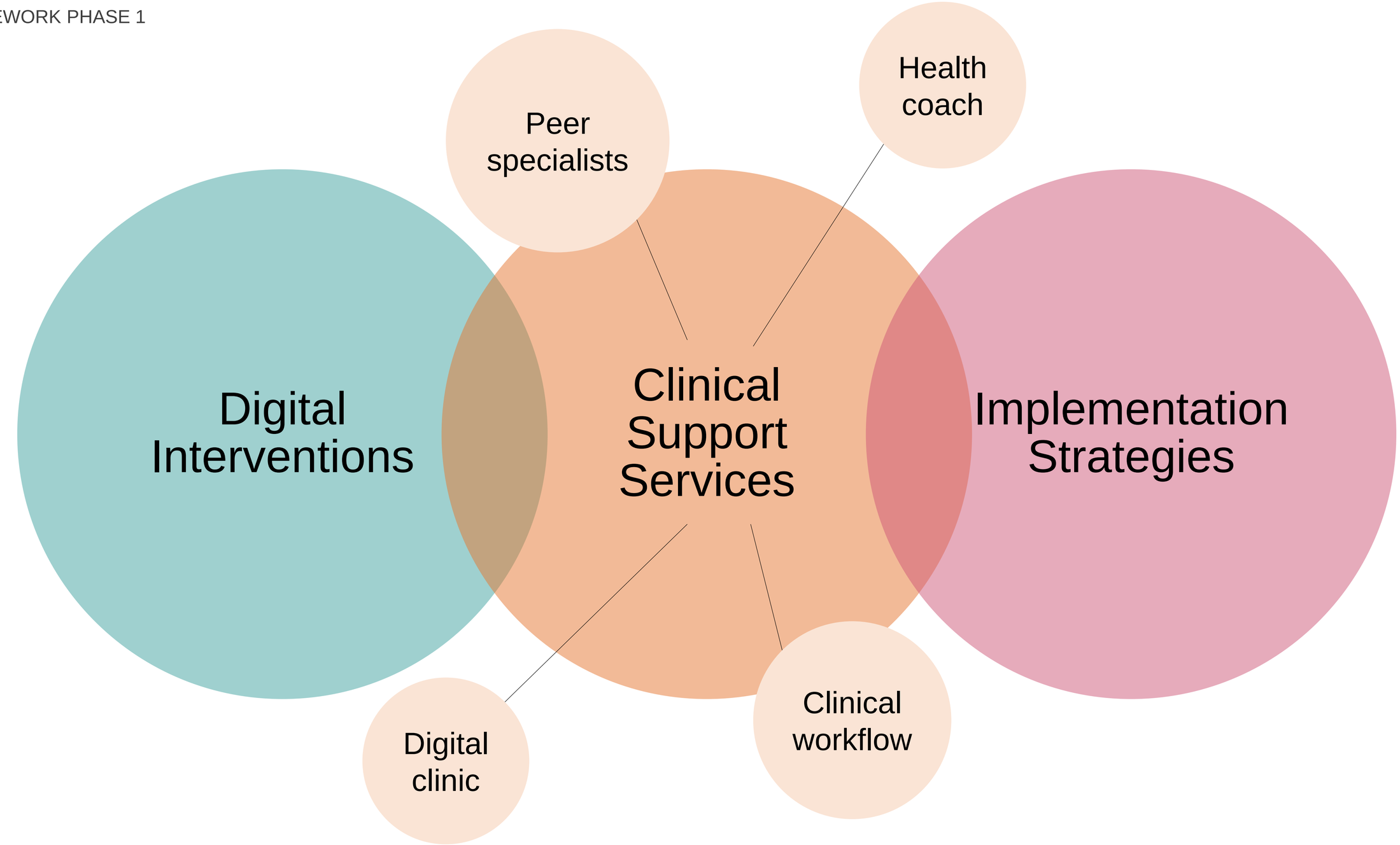
Phase 1: Frame the research question



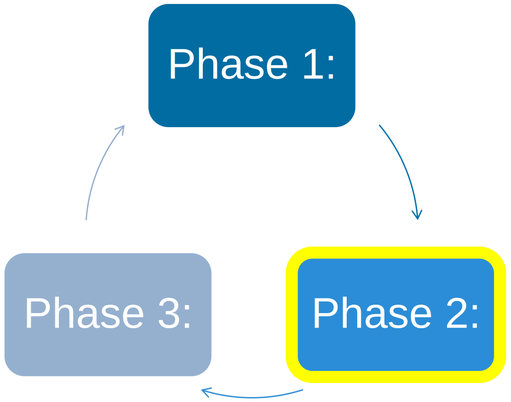
- All aspects of the trial design should follow the research questions.
- Identify timely, relevant question **worthy of an experimental design**
- Frame the question in terms of the components to be tested…

	Digital intervention	Clinical support services	Implementation strategies
Research question	Does the digital intervention work in this population or setting? Which digital intervention to use?	What approaches for offering digital interventions are needed to support delivery in real world?	How to encourage adoption, implementation, and sustainment of digital interventions in clinics?
Rationale	Stakeholders want to know: • whether to invest • in which product to invest	Stakeholders want to know • how to reorganize resources • hire new staff • contract out to a 3rd party	Stakeholders have buy-in but want to know: • How to maximize uptake of digital interventions in clinics
Example	Secondary in DIGITS Trial	Primary in DIGITS Trial	Primary in DIGITS Trial



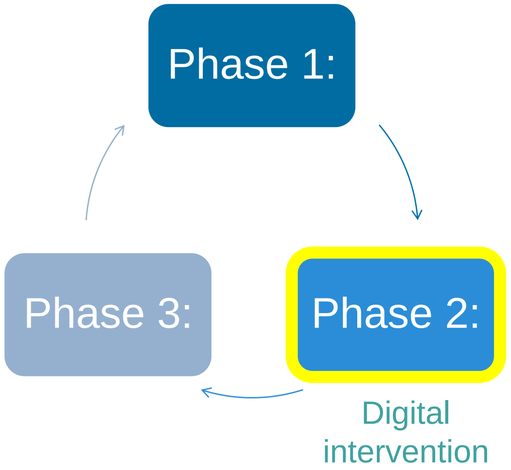


Phase 2: Delineate components under study



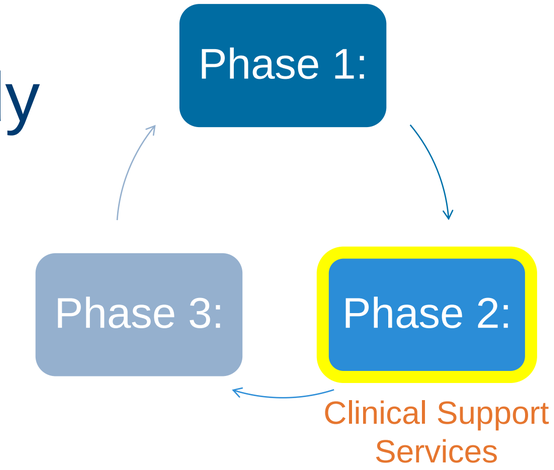
- Likely overlap between components
- Bring **clarity to the boundaries** of each for your study
- Critical to health system stakeholders
- Delineate based on four dimensions (Proctor et al., 2013)

Phase 2: Delineate digital interventions under study



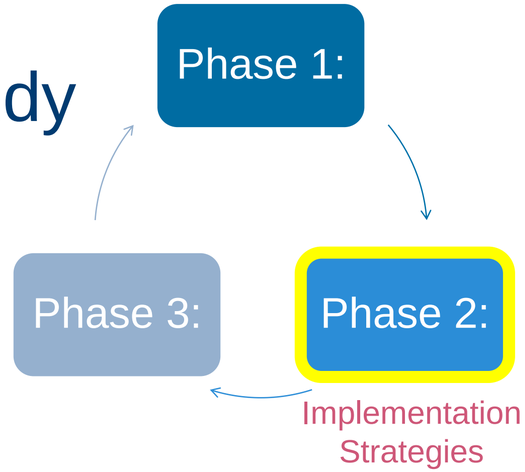
Component	Actor	Activities	Action Target	Proximal Outcome
Digital Intervention: **reSET and reSET-O**	Patients with substance use disorder	Spent time using app to engage in:		Substance use reductions
		1) Community reinforcement approach	1) Explore healthier ways to meet need	Treatment engagement
		2) Contingency management	2) Incent adherence and abstinence	
		3) Fluency training	3) Reinforce concept mastery	

Phase 2: Delineate clinical support services under study



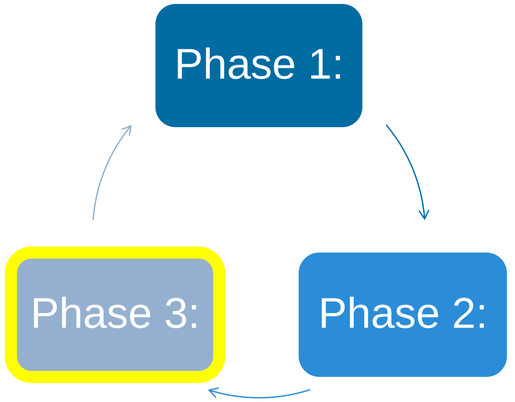
Component	Actor	Activities	Action Target	Proximal Outcome
Clinical Support Service: **Health Coaching**	"Centralized" medical assistant	1) Conduct phone outreach to patients who might benefit	1 & 2) Activate patients; reduce burden on clinicians	Fidelity Feasibility Health services outcomes
		2) Monitor and encourage engagement		
		3) Encourage practice of skills	3) Support patients' skill development	
		4) Facilitate follow-up with care team	4) Promote collaboration between patients and providers	

Phase 2: Delineate implementation strategies under study



Component	Actor	Activities	Action Target	Proximal Outcome
Implementation Strategy: **Practice Facilitation**	Practice facilitator (external)	In the context of a supportive relationship, deliver:		Reach Adoption
		1) Education	1) Create clinic-wide demand	
		2) Audit & feedback	2) Clarify measurable goals to improve performance	
		3) PDSA cycles	3) Reinforce mastery of treatment concepts	
		4) Engagement	4) Support local implementation	

Phase 3: Specify core features of the trial design



- Features of trial design should be driven by the research question
- **PICO** is a widely-known strategy for reframing research questions in a precise and testable manner
- Some applications of PICO recommend 2 additional dimensions: **PICOTS** to capture intervention complexity

Phase 3: Specify core features of the trial design using PICO

Population of Interest

Who is the trial targeting?

What are the important characteristics of this population?

Intervention

What is the experiment or thing to be tested?

- Digital intervention
- Clinical support service
- Implementation strategy

Comparator

What is the control or comparator?

How will the trial isolate the studied component

Outcome

What does the researcher hope to accomplish or improve?

Is this an effectiveness, health services, or implementation outcome?

Timing

Over what period will the trial occur?

What is the period for follow-up?

Setting

Where does the intervention occur?

In what type of healthcare setting does this trial occur?

Phase 3: Specify core features of the trial design using PICO

Population of Interest

Integrated mental health and primary care providers

Patients with a drug use disorder

Intervention

What is the experiment or thing to be tested?

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Phase 3: Specify core features of the trial design using PICO

Population of Interest

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Patients with a drug use disorder

Intervention

1) Clinical support service: Health coaching
2) Implementation strategy: Practice facilitation

Comparator

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(Freedland et al., 2019)

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Phase 3: Specify core features of the trial design using PICO

Population of Interest

Integrated mental health and primary care providers

Patients with a drug use disorder

Intervention

1) Clinical support service: Health coaching
2) Implementation strategy: Practice facilitation

Comparator

“Standard implementation”

Outcome

What does the researcher hope to accomplish or improve?

Is this an effectiveness, health services, or implementation outcome?

Timing

Over what period will the trial occur?

What is the period for follow-up?

Setting

Where does the intervention occur?

In what type of healthcare setting does this trial occur?

Phase 3: Specify core features of the trial design using PICO

Population of Interest

Integrated mental health and primary care providers

Patients with a drug use disorder

Intervention

1) Clinical support service: Health coaching
2) Implementation strategy: Practice facilitation

Comparator

“Standard implementation”

Outcome

Fidelity

Reach

Timing

Over what period will the trial occur?

What is the period for follow-up?

Setting

Where does the intervention occur?

In what type of healthcare setting does this trial occur?

Phase 3: Specify core features of the trial design using PICO

Population of Interest

Integrated mental health and primary care providers

Patients with a drug use disorder

Intervention

1) Clinical support service: Health coaching
2) Implementation strategy: Practice facilitation

Comparator

“Standard implementation”

Outcome

Fidelity

Reach

Timing

12-week intervention (fidelity)

1-year active implementation period (reach)

Setting

Where does the intervention occur?

In what type of healthcare setting does this trial occur?

Phase 3: Specify core features of the trial design using PICO

Population of Interest

Integrated mental health and primary care providers

Patients with a drug use disorder

Intervention

1) Clinical support service: Health coaching
2) Implementation strategy: Practice facilitation

Comparator

“Standard implementation”

Outcome

Fidelity

Reach

Timing

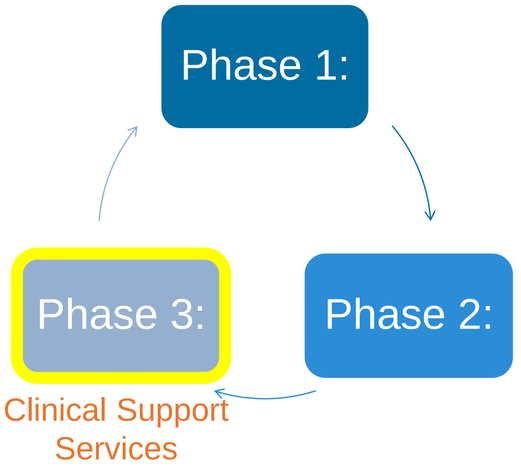
12-week intervention (fidelity)

1-year active implementation period (reach)

Setting

Integrated healthcare setting

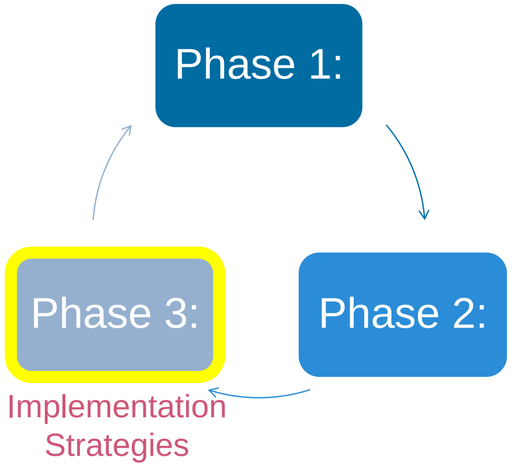
Phase 3: Specify core features of the trial design



1) HEALTH COACHING (clinical support service)

In the context of an integrated healthcare setting **(S)**, do primary care clinics randomized to health coaching **(I)** compared to standard implementation **(C)** have a higher mean number of weeks in which patients with documented drug use disorder **(P)** use reSET and reSET-O as recommended [fidelity] **(O)** over the 12-week intervention **(T)**?

Phase 3: Specify core features of the trial design



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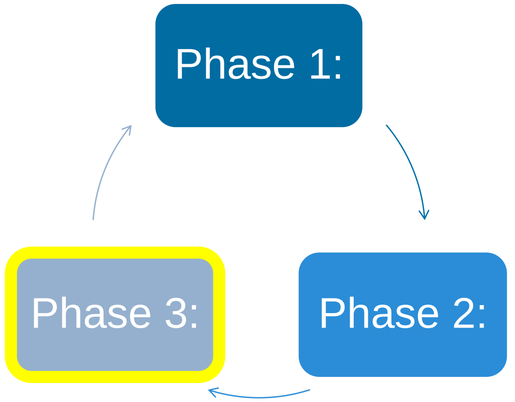
In the context of an integrated healthcare setting **(S)**, do primary care clinics randomized to health coaching **(I)** compared to standard implementation **(C)** have a higher mean number of weeks in which patients with documented drug use disorder **(P)** use reSET and reSET-O as recommended [fidelity] **(O)** over the 12-week intervention **(T)**?

2) PRACTICE FACILITATION (intervention strategy)

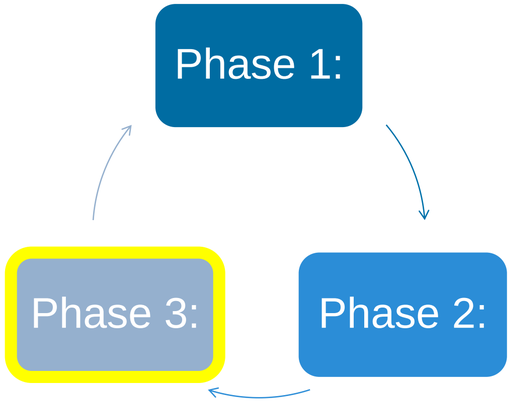
In the context of an integrated healthcare setting **(S)**, do primary care clinicians who care for patients with a drug use disorder **(P)** in clinics randomized to practice facilitation **(I)** compared to standard implementation **(C)** prescribe reSET and reSET-O to a higher proportion of eligible patients with documented drug use disorder [reach] **(O)** during a 1-year active implementation period **(T)**?

Phase 3: Specify hybrid trial design

- Hybrid trials allow the researcher to address questions related to **implementation** while gathering data on **effectiveness**



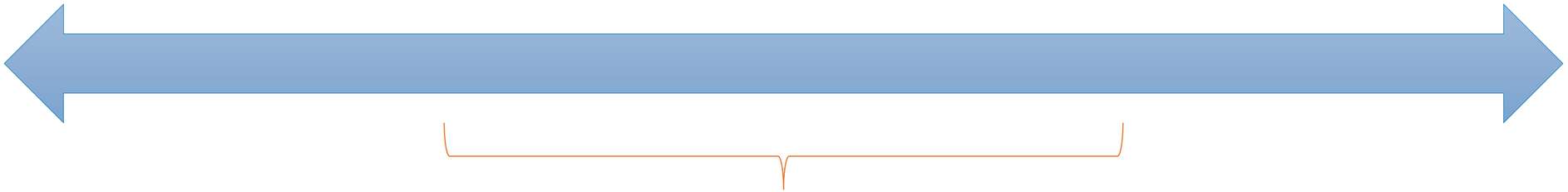
Phase 3: Specify hybrid trial design



- Hybrid trials allow the researcher to address questions related to **implementation** while gathering data on **effectiveness**

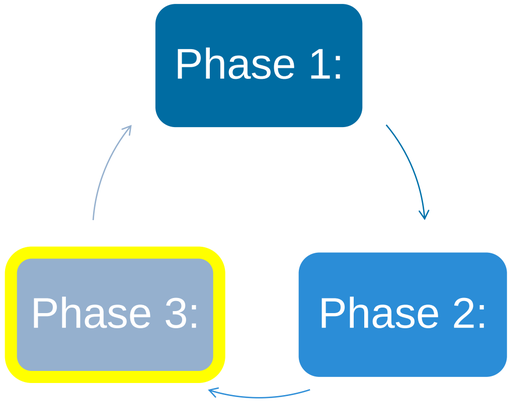
Effectiveness
patient health outcomes (typically)
real-world settings with researchers delivering interventions

Implementation
clinic/provider outcomes (typically)
real-world setting with clinicians delivering intervention



Hybrid Trials

Phase 3: Specify hybrid trial design



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- Well-suited when effectiveness is lacking/limited but there is **political will to implement**

Effectiveness
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real-world settings with researchers delivering interventions

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clinic/provider outcomes (typically)
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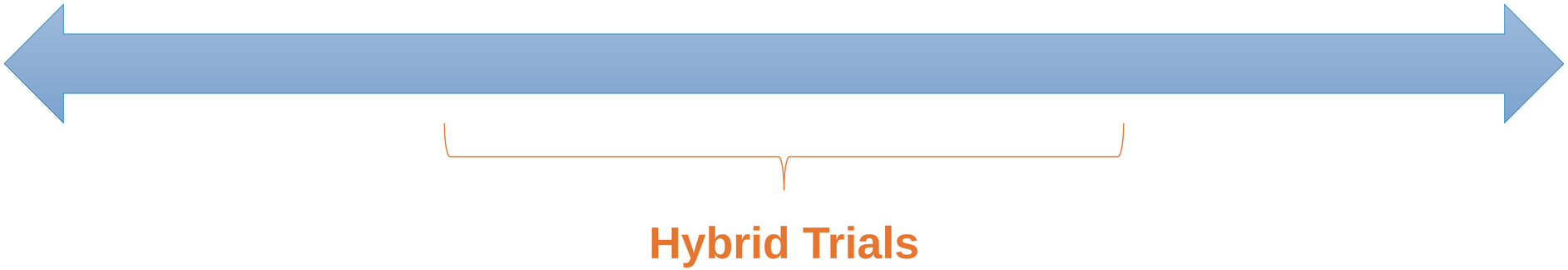


Hybrid Trials

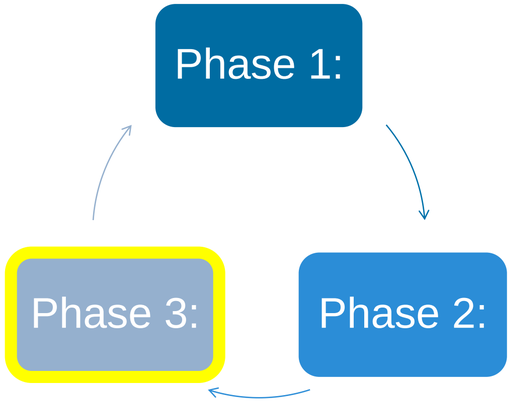
Phase 3: Specify hybrid trial design

Hybrid Type I studies have a primary research question about effectiveness and a secondary focus on implementation

Hybrid Type II studies have an equal focus on effectiveness and implementation

Hybrid Type III studies have a primary research question about implementation and a secondary focus on effectiveness

Phase 3: Specify hybrid trial design



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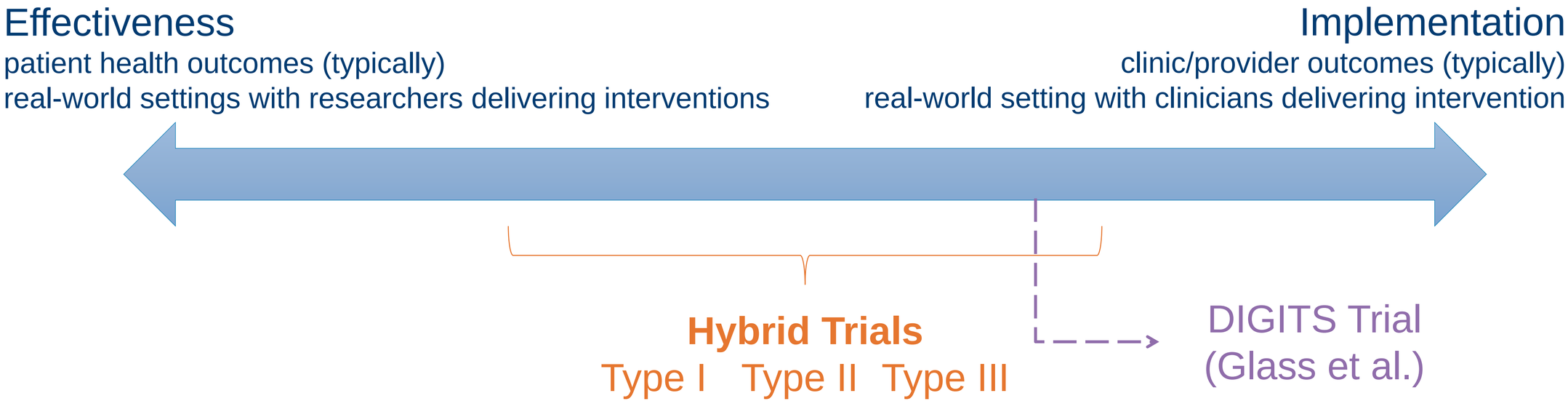
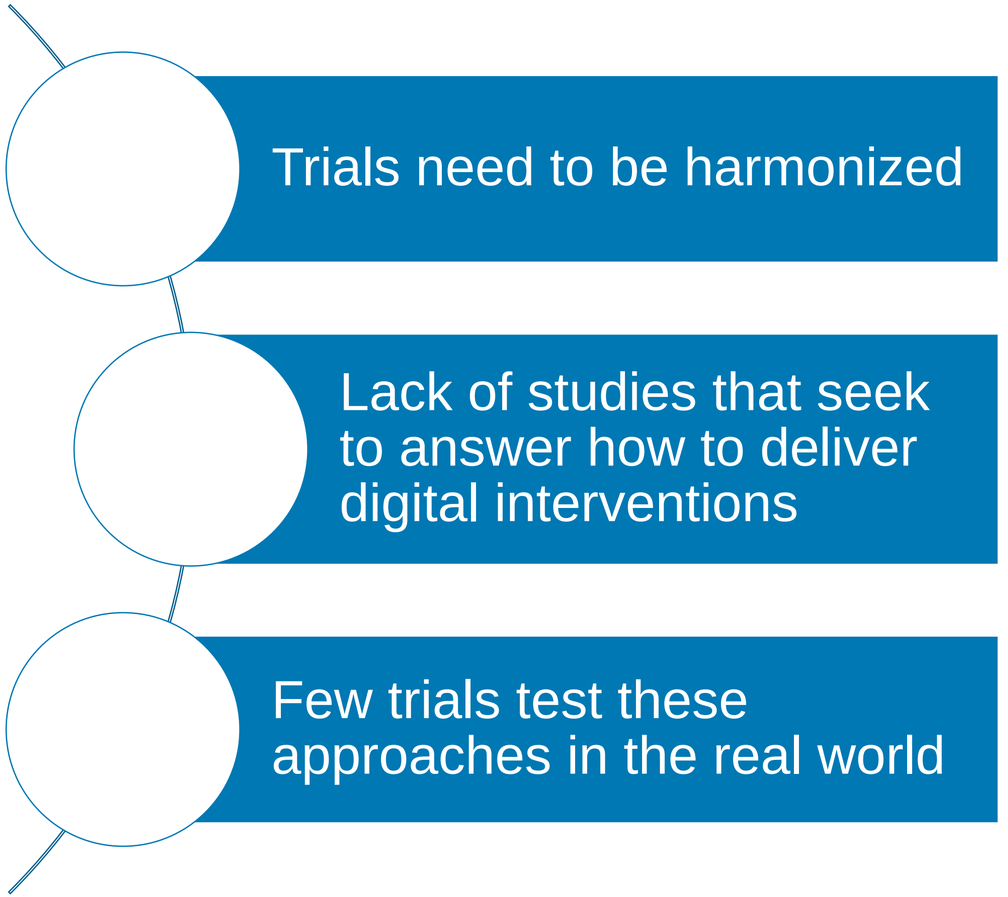


Phase 3: Specify hybrid trial design

Where do Clinical Support Services fit?

- Could be considered Type I, II, or III
- Consider **research question** and **primary outcome(s)**
- Important to clarify and report rationale

Implications



Helps researchers **design**, **review**, and **execute** trials of digital interventions; helps **communicate** to decision-makers

Considers the impact **clinical support services** have on effectiveness and implementation of digital interventions

Advocates for the use of **hybrid trials** to advance evidence-to-practice and applicability in real-world settings

KAISER PERMANENTE®

This is a working framework.
We welcome your questions, comments, and feedback!

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Tessa.e.matson@kp.org or Joseph.e.glass@kp.org

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