Adaptation and Implementation of the Invested in Diabetes Study: A Pragmatic Trial of the Targeted Training in Illness Management Curriculum

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Background

- Diabetes Shared Medical Appointments (SMAs) are historically challenging to implement in primary care.
- Pragmatic trials optimally use existing staff to deliver interventions that allow for flexibility in adherence and are implemented in real-world settings.
- Invested in Diabetes[1] is an ongoing cluster-randomized comparative effectiveness trial testing two diabetes SMA models to deliver the Targeted Training in Illness Management (TTIM) curriculum in primary care.

Objectives

1. To describe use of the Enhanced Replicating Effective Programs (REP)[2] framework for adapting and implementing an evidence-based intervention for use in real-world care settings.
2. To describe methods for establishing fidelity and adaptations to a study protocol to ensure rigor and feasibility of the conduct of a pragmatic trial.

Methods

- Invested in Diabetes: Primary care practices (Federally Qualified Health Centers [FQHC] and non-FQHC) in Colorado and Kansas City delivered diabetes SMAs using the TTIM curriculum in two approaches:
  - Standardized (STD) approach– 1 health educator delivers TTIM in a preset order, plus a prescribing provider.
  - Patient-driven (PTD) approach– Multi-disciplinary healthcare team, including peer mentor, deliver TTIM in an order selected by patients.
  - Components of both approaches are detailed in Table 1.
  - Implementation planning and delivery was based on the Enhanced REP implementation framework plus intensive practice facilitation. Practice staff were supported via an trainings, quarterly practice-wide calls, curriculum and accompanying practice and patient materials, and a dedicated practice facilitator.
- Protocol Refinement and Adaptations: Patient and practice stakeholder input was used to modify study protocol and outcome measures before and during implementation using Enhanced REP (Figure 1). Practice facilitation notes, fidelity observation, and interviews measured adaptations post-implementation (Figure 3).
  - Invested study team completed PRECIS-2 ratings[3] to determine overall pragmatism of trial (Figure 2).

Table 1. Features of Comparator SMA Models

	Standardized SMAs	Patient-Driven SMAs
Same for both groups		
No. of sessions	6 (consisting of diabetes and mental health sessions)	
Educational components	Diabetes and mental health with goal setting and psychosocial support topics (TTIM curriculum)	
SMA coordinator	Scheduling and documentation	
Medical provider	Medication management by a prescribing provider (Physician Assistant, Nurse Practitioner, or MD/DO); Answer patient-specific medical questions with group present	
Distinguishing features		
Patient topic choice	Order of and time spent on TTIM topics are set for all SMA cohorts	Patients in each SMA cohort select order of and time spent on TTIM topics
Health educator role	Lead instructor for all educational components	Lead instructor for non-mental health topics
Behavioral health provider role	Not involved in SMAs	Co-instructor for mental health topics
Peer mentor role	Not involved in SMAs	Co-instructor for all topics; 1x1 peer access encouraged

Figure 1: Enhanced REP Stages

Pre-Conditions

Identify Diabetes Intervention Needs and Preferences:
- Patient and other stakeholder engagement through Boot Camp Translation[4]

Identify Effective Intervention:
- Targeted Training in Illness Management (TTIM)

Draft Package of Intervention:
- Patient-Driven and Standardized Diabetes Shared Medical Appointments (SMAs) using TTIM

Pre-Implementation

Identify and Engage Settings:
- Recruit Practice-Based Research Network practices interested in implementing diabetes SMAs

Project Orientation:
- Explain core elements of Invested in Diabetes objectives and comparator models
- Determine logistics for local delivery

Test and Finalize Package:
- Customize content and delivery to fit practice context while adhering to core elements

Implementation

Disseminate Package:
- Practice kick-off meeting
- Website with example TTIM session videos, patient and practice materials

Training and Ongoing Support:
- 1-day training for instructors (half-day for peer mentors)
- 1-hour training for prescribing providers
- Convene ongoing practice stakeholder and peer mentor learning communities

Facilitation

External Facilitation:
- 3-5 practice coaching sessions
- Process mapping
- Planning for scheduling, workflow, data collection
- Plan for billing and reimbursement as needed

Internal Facilitation:
- Relationship building
- Pilot testing encouraged
- Refine workflows

Maintenance and Evolution

Adaptations As Needed:
- Adjusted timing and intensity of SMAs
- SMA delivery by different practice members based on care/resource needs, plus remote delivery option added
- Remotely-delivered training option added for non-local clinics
- Practice coaching sessions guide as well as document adaptations

Planning for Sustainability
- Stakeholder collaborative calls discussing organizational and financial challenges faced and potential solutions

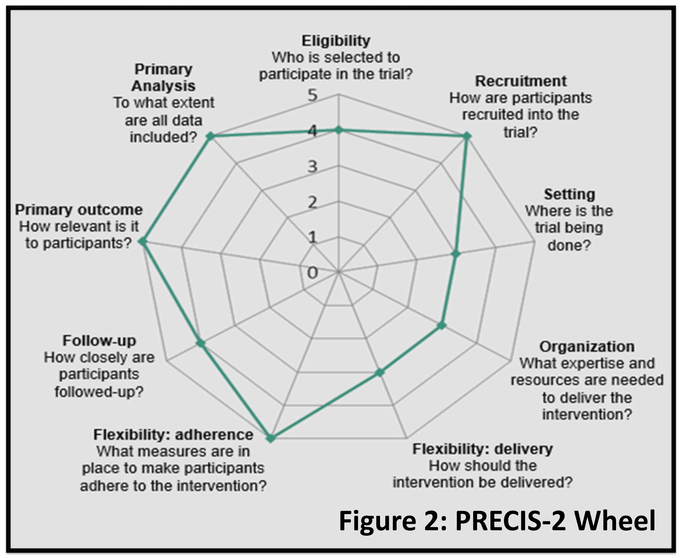

Figure 2: PRECIS-2 Wheel

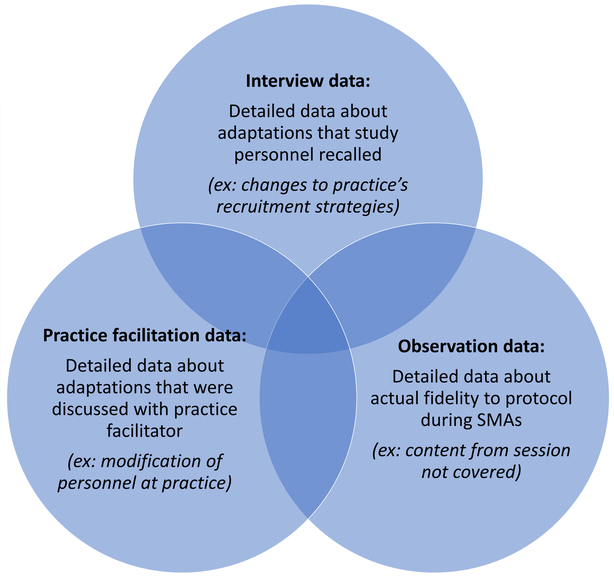

Figure 3: Adaptations post-implementation: What we learned from different data sources

Discussion

- To retain study rigor, the use of Enhanced REP framework[2] allowed for pre-implementation adaptations to context at the practice level for insuring feasible real-world delivery of the two SMA approaches while establishing and maintaining core elements (e.g., TTIM curriculum content, STD and PTD core features in Table 1) needed for hypothesis testing.
- Similar to other studies, we used practice facilitation to enhance SMA implementation by making further adaptations (post-implementation) based on practice and patient stakeholder feedback while able to maintain fidelity to core components of the intervention.
- We used the PRECIS-2 framework[3] and ratings wheel to illustrate the highly pragmatic nature of the study.
- Both the Enhanced REP and PRECIS-2 frameworks are helpful in refining study protocols to be more pragmatic, and also showcasing areas of ongoing adaptations required by practices to remain involved. Particularly, we found them helpful to observe adaptations related to implementation during the time of COVID-19 (e.g., converting to a virtual SMA format, providing virtual trainings, and assisting practices as they revised clinical workflows/processes via additional practice facilitation.

References

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Invested in Diabetes