ORIGINAL RESEARCH

Adapting Diabetes Shared Medical Appointments to Fit Context for Practice-Based Research (PBR)

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Introduction: Complex behavioral interventions such as diabetes shared medical appointments (SMAs) should be tested in pragmatic trials. Partnerships between dissemination and implementation scientists and practice-based research networks can support adaptation and implementation to ensure such interventions fit the context. This article describes adaptations to and implementation of the Targeted Training in Illness Management (TTIM) intervention to fit the primary care diabetes context.

Methods: The Invested in Diabetes pragmatic trial engaged 22 practice-based research network practices to compare 2 models of diabetes SMAs, based on TTIM. We used surveys, interviews, and observation to assess practice contextual factors, such as practice size, location, payer mix, change and work culture, motivation to participate, and clinical and administrative capacity. The enhanced Replicating Effective Programs framework was used to guide adaptations to TTIM and implementation in participating practices.

Results: Practices varied in size and patient demographics. All practices had integrated behavioral health, but limited health educators or prescribing providers. Adaptations to SMA delivery accommodated the need for flexibility in personnel and reduced scheduling burden. Adaptations to TTIM content were designed to fit general primary care diabetes and Spanish-speaking patients.

Conclusion: Enhanced Replicating Effective Programs is a useful process framework for adaptation, implementation, and testing of diabetes SMAs in primary care. Adapting intervention content, delivery, and training to fit context can help ensure pragmatic trials have both internal and external validity. Attention to intervention fit to context can support continued practice engagement in research and sustainability of evidence-based interventions. (J Am Board Fam Med 2020;33:716–727.)

Keywords: Comparative Effectiveness Research, Diabetes Mellitus, Evidence-Based Medicine, Implementation Science, Mental Health, Motivation, Patient Care Team, Practice-Based Research, Primary Health Care, Shared Medical Appointments, Stakeholder Participation, Surveys and Questionnaires

Introduction

Calls for conducting pragmatic research emphasize generating evidence that can be readily adopted and sustained in real-world care settings.[1,2] In contrast to traditional randomized controlled trials, pragmatic trials are "undertaken in the 'real world' and with usual care and [are] intended to help support a

decision on whether to deliver an intervention."[3] Pragmatic research methods have grown in use and acceptability.[4–6] Pragmatic trials should be designed to closely approximate existing resources, systems, and processes in diverse usual care settings and patient populations.[3] Pragmatic trials for complex behavioral interventions in primary care are still emerging, and methods are needed to minimize practice burden while maintaining fidelity to research protocols.[7,8]

One challenge is ensuring intervention fit for the primary care context in terms of feasibility and sustainability (using existing staff, resources, and payment mechanisms), acceptability, and responsiveness to the needs of patients, practice members, and organizational leaders. Here, we describe our approach to ensuring intervention fit to context for the Invested in Diabetes pragmatic trial, including support for intervention adoption and implementation. Invested in Diabetes is testing the comparative effectiveness of 2 models of diabetes shared medical appointments (SMAs) in primary care.[9] The study compares "patient-driven" to "standardized" diabetes SMAs. Both behavioral intervention models include diabetes self-management education and support (DSME/S) using the evidence-based Targeted Training in Illness Management (TTIM) curriculum.[10–13] The setting is 2 practice-based research networks (PBRNs): the State Networks of Colorado Ambulatory Practices and Partners and the American Academy of Family Physicians National Research Network. PBRNs are an important resource for conducting pragmatic trials,[14] connecting researchers with practices that are both open to innovation and research and tolerant of balancing fidelity needs with local customization.[15,16]

PBRNs provide infrastructure for identification of relevant settings, practice recruitment and engagement, and methods for randomization that account for practice context and variation.[17]

Heintzman et al[14] noted that PBRNs benefit from using dissemination and implementation (D&I) frameworks and collaborating with D&I scientists and called for studies that highlight these mutually beneficial partnerships. D&I frameworks inform the processes by which interventions are adapted and implemented in the primary care context and subsequent reporting and evaluation.[18] The enhanced Replicating Effective Programs (REP) framework supports intervention uptake through adaptation to local practice settings, while retaining sufficient fidelity to core elements. Enhanced REP consists of 5 phases: preconditions, preimplementation, implementation, maintenance and evolution, and facilitation.[19–21] Facilitation within enhanced REP is a collaborative process in which practice coaches and local stakeholders work together to implement and sustain new interventions by encouraging organizational buy-in and support.[22] Here, we describe application of the enhanced REP framework for adapting diabetes SMAs to fit PBRN practice context in the Invested in Diabetes pragmatic trial. Specifically, we describe (1) use of PBRNs to recruit practices for pragmatic research, (2) use of the enhanced REP framework to adapt the TTIM intervention to the primary care context before implementation, and (3) use of practice facilitation and mixed methods to refine intervention adaptations and uptake.

Methods
Study Design
Invested in Diabetes is a cluster randomized pragmatic trial testing the comparative effectiveness of patient-driven versus standardized models of diabetes SMAs.[9] We used quantitative and qualitative methods to assess practice contextual factors relevant to intervention adaptation and implementation. We used the enhanced REP framework to adapt interventions for fit within this context, while retaining core elements needed to address research questions. Core elements included (1) use of TTIM curriculum materials, (2) a closed group setting (2+ patients, ideally 8 to 10 per cohort), (3) a set number of sessions with equal duration (12 total hours of instruction), (4) a standardized condition (content delivered by a health educator with topics in a set order) versus the addition of a behavioral health provider (BHP) who delivers TTIM mental and behavioral health content (in 1 to 2+ sessions) and a peer mentor (in all sessions) with topic order selected by each group (patient-driven condition), and (5) patients meeting individually with prescribing providers for medical management.

Setting and Participants
Twenty-two practices were randomized to deliver patient-driven or standardized diabetes SMAs (11 per condition) using existing clinical staff and payment mechanisms. Eligible practices were required to have existing health education staff and BHPs, defined as licensed clinical social workers and/or licensed clinical

psychologists who worked in primary care (note that we did not restrict participation to or formally assess level or type of integrated care model for this project; practices endorsed a range of colocated to fully integrated models). As part of usual processes of care, patients could be referred to BHPs in both study conditions for behavioral health concerns; for the patient-driven condition, BHPs were intentionally included in the delivery of the TTIM content, thus actively integrating the BHPs into diabetes education and self-management support. Covariate constrained randomization ensured balance in practice characteristics across conditions.[17]

Quantitative Measures and Data Collection

A practice representative (eg, practice manager) first completed a baseline practice characteristics survey, including 20 items assessing practice size and type, types and numbers of providers in the practice (including clinicians with prescribing privileges and those eligible to serve as health educators), patient demographics, payer mix, and prior experience with SMAs and quality improvement (QI) initiatives. This survey also included several subscales from the Patient-Centered Medical Home Practice Monitor, consisting of 33 items addressing QI processes, data capacity, team-based care, and population management subscales.[23,24] All practice staff and clinicians were invited to complete the Practice Culture Assessment, a 22-item survey of organizational change culture, work culture, and practice chaos.[25]

Qualitative Data Collection

Individual interviews were conducted with specific care team members from each practice, including 27 medical providers, 19 BHPs, 23 health educators, 27 SMA coordinators, and 14 practice managers. A semistructured interview guide focused on experience and understanding of SMAs, perceived importance of SMAs, sustainability factors, and expected patient response to the SMAs. A demographic form assessed interviewee practice role, background, and credentials.

Quantitative Analysis

Baseline practice characteristics and culture surveys were analyzed with descriptive statistics and compared across conditions. Categorical variables were analyzed via the Fisher's exact test due to the small sample size. Medians were compared via the Wilcoxon rank-sum test. Practice Culture Assessment scores were compared using linear regression with a fixed term for study arm and random facility effect to account for correlation among responses from the same practice.

Qualitative Analysis

Interview transcripts were analyzed using thematic analysis (data triangulation and a constant comparative technique). Using immersion crystallization with repeated phases of reading, reviewing, and refining themes and codes,[26] a team of 3 qualitative researchers developed a master code list using *a priori* codes based on the underlying project theory and *de novo* codes developed through an iterative, collaborative process.[27] The team then independently coded the same documents and compared them until a high degree of conceptual interrater reliability was established, at which point documents were independently coded by 1 team member. We used a matrix approach to summarize qualitative data across themes for each practice.[28] Corroborating/legitimizing (ie, determining validity of qualitative themes) was conducted to ensure accuracy of themes and as an approach to member checking.[26] This includes a process of reviewing interviews after analysis, reviewing the literature to confirm/disconfirm themes, and seeking input from the research team. The qualitative interview findings were intended to complement and triangulate with quantitative data and stakeholder discussions; insights were consistent across sources. We intentionally interviewed specific care team members from each practice to ensure representation of perspectives from each practice and, therefore, continued interviews even after thematic saturation was achieved.

Enhanced REP Implementation Process

Figure 1 shows the application of enhanced REP to the Invested in Diabetes study.

Preconditions Phase

During this phase, an evidence-based intervention for a targeted patient population that fits with local clinical settings is selected. Intervention materials are adapted based on local stakeholder input. Intervention training, implementation, and outcome measures are refined and "packaged" in a user-friendly way.[19,22,29] Before this study, we engaged patients with diabetes, family members, and health care providers in the Boot Camp

Figure 1. The enhanced Replicating Effective Programs framework for Invested in Diabetes Study planning and adaptations. Abbreviation: SMAs, shared medical appointments.
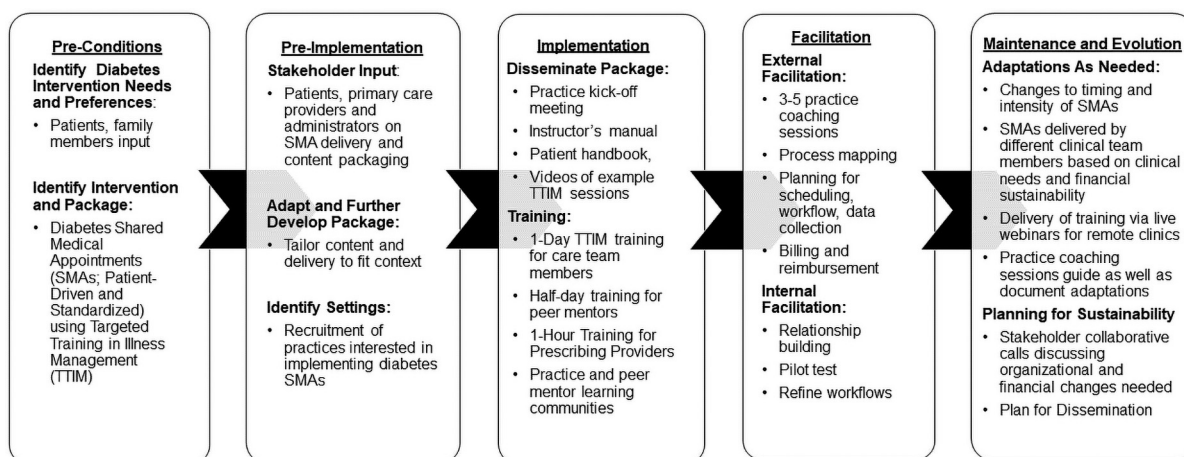
Translation (BCT) community engagement process.[30,31] The BCT objective was to identify preferences about DSME/S in primary care.[32] Based on BCT, the study team (including patient stakeholders) identified TTIM as an evidenced-based DSME/S curriculum that fit stakeholder preferences for addressing concurrent medical and mental health needs. The TTIM version selected for Invested in Diabetes was developed for diabetes and co-occurring serious mental illness.[10–13] Diabetes distress was selected as the primary patient-centered outcome and glycohemoglobin (HbA1c) as the primary clinical outcome. Cost and sustainability were prioritized as practice-level outcomes.

Preimplementation Phase

The next step is to identify and engage practices in preparing for implementation. After orientation to core elements of the intervention, participating practices identify staff to deliver the intervention. Communication protocols are established between practices and researchers to create dialog regarding further adaptations needed to fit local context. In this study, PBRNs recruited practices with interest and capacity to implement diabetes SMAs. We elicited local stakeholder input to refine the protocol and clarify potential payment mechanisms for diabetes SMAs. We assessed practice context and resources and negotiated adaptations to intervention materials and delivery protocols for fit while retaining fidelity to core elements. Practice staff roles were also determined for intervention delivery as well as operational support.

Implementation Phase

The next phase involves dissemination of the packaged intervention, training in intervention delivery, ongoing technical assistance, resolving implementation barriers, and evaluation and fidelity monitoring. For this study, the research team disseminated the packaged intervention to practice members, including training and recruitment materials (with additional guidance for recruiting peer mentors in the patient-driven condition) and electronic health record templates for documentation. Practice coaches met with practice staff to facilitate implementation tailoring. Practice facilitators assisted in process mapping and identifying potential implementation barriers and adaptations. Communication strategies such as quarterly practice stakeholder calls and scheduled practice coach check-ins were established. Practice coaches scheduled at least 4 facilitation sessions per practice, plus more outreach as needed.

Iterative Process of Adaptations

Adaptations are deliberate modifications made to intervention design or delivery to fit the context or address implementation barriers.[33] Informed by preimplementation data and insights from practice coaching sessions, and in collaboration with stakeholder groups, the study team discussed and approved adaptations needed to fit practice capacity, culture, workflows, resources, and systems, without compromising fidelity. We used the Framework for Reporting Adaptations and Modifications-Expanded (FRAME) by Stirman

Table 1. Baseline Practice Contextual Characteristics

Contextual Characteristics	Overall (n = 22)	Patient-Driven Condition (n = 11)	Standardized Condition (n = 11)	Difference across Conditions*
Practice type, N (%) federally qualified health centers	12 (54)	5 (45)	5 (45)	P = 1.00
Practice location, N (%)				P = 1.00
Urban	17 (77)	9 (82)	8 (73)	
Rural	3 (14)	1 (9)	2 (18)	
Suburban	2 (9)	1 (9)	1 (9)	
Estimated no. of diabetes patients, median (range)	549 (90–4000)	500 (90–4000)	576 (214–2112)	P = .48
Latino patients > 10%, N (%) of practices	10 (67)	5 (63)	5 (71)	P = 1.00
Minority patients > 20%, N (%) of practices	13 (87)	5 (71)	8 (100)	P = .20
Payer mix, median (range)				
Private insurance FFS or preferred provider organization	11 (3–70)	12 (3–64)	10 (5–70)	
Private managed care	11 (5–35)	15 (10–20)	10 (5–35)	
Medicare	19 (2–60)	20 (9–30)	14 (2–60)	
Medicaid	40 (2–63)	30 (5–60)	55 (2–63)	
Other public insurance	3 (0–5)	3 (0–5)	3 (0–5)	
Self-pay or uninsured	10 (0–92)	6 (0–92)	10 (3–36)	
Unknown	0 (0–10)	0 (0–10)	0 (0–5)	
Other	4 (0–100)	0 (0-0)	9 (0–100)	
Private (FFS + managed care) > (Medicare + Medicaid + other pub)	3 (19%)	2 (29%)	1 (11%)	P = .55
No. of clinicians with prescribing privileges, median (range)	8 (2–65)	7 (2–39)	8 (3–65)	P = .39
No. of staff eligible to be health educator, median (range)	2 (1–6)	2 (1–6)	3 (1–6)	P = .79
No. of behavioral health providers by level of training (interviewees)	Doctorate level: 3; Master's level: 10; other: 4; unknown: 2	Doctorate level: 2; Master's level: 5; other: 3; unknown: 1	Doctorate level: 1; Master's level: 5; other: 1; unknown: 1	
Previous experience with SMAs, N (%)	10 (45)	5 (45)	5 (45)	P = 1.00
PCMH PM†, median (range)				
PM data capacity	79 (39–100)	89 (50–100)	77 (39–96)	P = .26
PM team-based care	75 (35–100)	80 (50–100)	75 (35–95)	P = .27
PM quality improvement processes	82 (7–100)	82 (50–100)	82 (7–100)	P = 1.00
PM population management	70 (0–100)	70 (50–100)	73 (0–90)	P = .62

FFS, fee for service; PM, Patient-Centered Medical Home Practice Monitor; SMAs, shared medical appointments.

*P values reported for comparisons across conditions.

†Possible scores range from 0–100.

et al.[33,34] to codify the type of intervention adaptation, organized by intervention content (curriculum and materials), context (format, setting, population, and personnel), training, and evaluation.

Results

Practice Contextual Characteristics

Practice contextual characteristics are shown in Table 1 (practice-level measures) and Table 2

Table 2. Baseline Practice Culture Assessment Scores among All Clinicians and Staff in Participating Practices

	PCA Scores*			
PCA Category	Overall	Patient-Driven Practices	Standardized Practices	Difference between Conditions†
Work culture, mean ± SD	70.4 ± 14.6 (n = 432)	70.2 ± 15.1	70.8 ± 13.9	P = .66
Change culture, mean ± SD	71.5 ± 15.5 (n = 433)	72.0 ± 14.5	70.8 ± 16.8	P = .44
Chaos, mean ± SD	35.1 ± 16.9 (n = 432)	34.6 ± 16.0	35.8 ± 18.1	P = .46

PCA, Practice Culture Assessment; SD, standard deviation.
*Possible scores range from 0–100.
†The P value seen in the table is derived from the fixed effect for study arm in the linear regression model.

(provider and staff-level measures). Practices varied along several dimensions related to practice type, size, location, culture, staffing, health information systems, patient demographics and language, and payer mix. Twelve federally qualified health centers and 10 non-federally qualified health centers enrolled. Most practices self-identified as urban/suburban and 3 were rural. Most practices had experience with SMAs (77%), whereas half had experience with diabetes-specific SMAs (50%). All practices had an existing QI team and used an electronic health record. Half of the practices served a Latino population and 1 served a Native American population. There were no differences between study conditions.

Baseline Practice Interviews

Thematic analysis revealed perceived opportunities and barriers to address in preparing for SMA implementation. Practices saw value in opportunities to improve diabetes care using SMAs, as most interviewees reported QI efforts had not adequately improved diabetes metrics. Practices recognized that a team-based approach including behavioral health and other practice resources was especially important:

"I think somehow figuring out how to intertwine behavioral health more in with diabetics because…it can be a very stressful condition for people. As I mentioned earlier, stress contributing to higher cortisol levels, higher blood sugars, generally being unwell" [physician]

"…improve diabetes management and health literacy of patients, empowerment of patients and yeah, the ability for patients to feel able to do these things, like confidence and compassion." [BHP]

Practices with previous experience delivering SMAs described several past challenges but also interest in trying again, with Invested in Diabetes project implementation support. Patient recruitment

and retention was one challenge to address: "The variable attendance, trying to get that buy-in [from patients] and that follow-through…people would be really motivated at first, and then quickly taper off after [initial sessions]." [prescribing provider]

Involving prescribing providers in SMAs—needed to ensure reimbursement but also logistically difficult—was also an anticipated challenge. "We've learned a lot about how to make the SMA structure easier on providers, which I think is challenging, especially when you are dealing with issues of productivity, which is always important, and then, of course, sustainability. Our program—we've pushed the limits of productivity, and we're still not yet sustainable." [SMA coordinator].

Adaptations to Fit Context

Table 3 shows key differences in personnel, setting, population, and format between the original versus adapted delivery of TTIM to fit context while retaining core elements. TTIM was not originally designed for delivery by a multidisciplinary care team, including a prescribing provider, or for patients to select topic order. Training, facilitation, and intervention materials provided guidance for these features. Table 4 summarizes adaptations made during enhanced REP phases to intervention content, delivery (personnel, format, and setting/population), and trainings. One major adaptation was condensing TTIM from 12 1-hour modules to 6 2-hour modules, given challenges of coordinating visits and patient burden. As many practices prioritized education on stress management (vs serious mental illness), we added an alternative general stress and coping module based on a related intervention.[13] Table 5 shows how practice contextual characteristics informed adaptation decision making. The study team also at times negotiated with

Table 3. High-Level Intervention Adaptations to Targeted Training in Illness Management Intervention Content and Context for Delivery in Primary Care

Intervention	Content	Personnel	Format	Setting and Population
Original TTIM	Twelve 1-hour sessions with content focused on skills building and self-management of diabetes and SMI	Delivered by study nurses and peer educators	Group-format with standardized topic order	Research setting for patients with diabetes and SMI
Adapted TTIM	Six 2-hour sessions with content focused on skills building, stress and coping, and self-management of diabetes, with optional SMI content	Delivered by practice staff: health educators, behavioral health providers, and peer mentors (differs by condition)	Group-format with standardized topic order or topic order selected by patients; 1:1 visits with prescribing provider for medication management	Primary care setting for patients with diabetes (± co-occurring mental health conditions)

SMI, serious mental illness; TTIM, Targeted Training in Illness Management.

individual practices based on their specific needs and circumstances to ensure the project's success. Figure 2 provides case vignettes describing how the intervention was adapted in consideration of diverse practice contexts.

Significant adaptations involved personnel delivering SMAs. Several practices had concerns about involving prescribing providers at every session given scheduling challenges and patient copay burden. Not all practices determined they needed reimbursement from prescribing provider encounters. The resulting adaptation was to support practices in determining how many and in which sessions to include prescribing providers, while recommending their involvement at minimum during the first and last sessions. Similarly, the health educator role was expanded based on staffing needs to include nutritionists, medical assistants, and community health workers (with adequate supervision), whereas our initial protocol called for a registered nurse, health educator, or certified diabetes educator. BHPs were ineligible for the health educator role, despite some requests for this adaptation, as BHP involvement is a core distinguishing element of the patient-driven condition. BHP eligibility for the patient-driven condition also expanded. Although people filling the BHP role were predominantly masters-level licensed clinical social workers and doctoral-level licensed clinical psychologists, some had a Bachelor's degree in social work and psychology, were licensed family therapists, or were going through training to be a BHP, either through education or on-the-job training. As the patient-driven condition also includes a peer mentor, the study's patient stakeholders developed peer mentor selection criteria and recruitment materials for use by practices.

We adapted practice training for diabetes SMAs. For health educators, training first includes a comprehensive review of the TTIM instructor's manual, as with prior TTIM training, but was modified to further cover group facilitation skills, how to involve the peer mentor and BHP (for the patient-driven condition), and role playing sessions. To reduce time and travel burden based on feedback from initial training sessions, we shortened training from 8 to 6 hours and offered choices of in-person locations or video conferencing and the option to complete training on a single day or split over 2 days. For prescribing providers, a 1-hour training provides

Table 4. Intervention Content and Delivery Adaptations across the Replicating Effective Programs Phases

Intervention Content and Delivery Adaptations	Replicating Effective Programs Phases		
	Preconditions Phase		
Selection of intervention content	Stakeholder input prioritizes mental and physical health content		Selected TTIM curriculum based on inclusion of diabetes self-management and mental health focus
Specification of core elements for delivery of SMAs	Stakeholder input prioritizes patients selecting topics, peer mentors, and involvement of behavioral health professionals		Selected TTIM based on inclusion of peer educators
	Pre-implementation Phase		
Content adaptations: reordering elements and adjusting timing	Repackaged and reordered content into 6 2-hour modules (vs original 12, 1-hour modules) In patient-driven condition, provided instructions for reordering content to fit cohort-specific preferences	Divided content and training material for standardized versus patient-driven SMA conditions.	Adjusted timing to fit experience of interventionists In standardized condition, manual provides instructions on duration of each topic; patient-driven manual provides suggested time only
Content adaptations: removing elements	Removed ongoing TTIM illness management phase	Changed TTIM manual language to focus more on a primary care population rather than SMI population	Less focus on serious mental illness, with now-optional mental health elements
Content adaptations: adding and substituting elements	General stress and coping module substituted for primary care population in lieu of Diabetes and Serious Mental Illness module Emphasized medical management of diabetes	PROs and instructions for addressing PROs as part of tailoring content to patients added	Translation of TTIM instructor's manual and patient handbook to Spanish Updated stress management tips with infographic from the American Heart Association "Fight Stress with Healthy Habits"
Delivery adaptations: personnel	Added 1:1 visits with prescribing provider for medical management	In patient-driven condition, behavioral health provider and peer mentor instructions added Delivered by practice staff: health educators, behavioral health providers, peer mentors (differs by condition)	Up-to-date diabetes management, nutrition, and physical activity content substituted Added PharmD as eligible for prescribing provider
	Implementation Phase		
Content adaptations: packaging and visual appeal	Use of icons and text formatting to guide reader through use of the instructor's manual	Professional graphic design for visuals for patient handbook and PowerPoint slides	Developed two versions of instructor manual based on study condition (standardized vs patient-driven SMA)
Practice facilitation adaptations	Expanded beyond initial 5 planned sessions to meet practices' needs for additional support		Developed system to prioritized practice facilitation outreach based on practice implementation progress
Training adaptations	Offered remote and multiday trainings in addition to full-day in person trainings	Incorporated role play into trainings	Group facilitation instructions added

PRO, patient-reported outcomes; SMA, shared medical appointments; TTIM, targeted training in illness management; SMI, serious mental illness.

Table 5. Intervention Content, Delivery, and Training: Adaptations Fit to Context

Contextual Factors	Invested in Diabetes Practice Characteristics	Corresponding Adaptations
Data capabilities and population management	All practices had electronic health records Some had registries to help identify eligible patients Varied experience with PRO collection and use	Simplified eligibility criteria for patients (any adult with Type II diabetes, no exclusion criteria) for ease of identification Ensured PROs were relevant to clinical care and SMA discussions
Payer mix	Practices vary in payer mix, with different billing and reimbursement practices	Informed guidelines for frequency of prescribing provider visits (at every session/1st/last only etc) Provided documentation templates and common billing codes used for diabetes SMAs
Prior experience with SMAs	Some practices had prior experience delivering and billing for diabetes SMAs	Informed intensity of technical assistance, plans for process mapping; practice coaches spent more time with helping practices determine SMA workflows and staffing
Team-based care	Practice all had behavioral health Some were fully integrated with behavioral health providers and experienced with integrated team-based care; others had collocated care where the behavioral health provider operated independently of the primary care provider	Influenced plans to include behavioral health providers in trainings alongside health educators (in patient-driven condition) and adaptations to mental health and stress and coping content
Patient populations	Practices delivering care to >10% Hispanic/Latino patients opted to provide SMAs in Spanish Patients vary in prior diabetes education, resources, and literacy	Spanish language TTIM materials and Spanish-speaking peer mentors and health educators made available Optional TTIM content with basic vs more advanced information and skills, with instructions to practices for selecting content most appropriate for their patients (e.g., basic carb counting vs glycemic index content)
Practice culture	Practices had moderate-to-high chaos and moderate-to-strong change culture; high chaos practices more sensitive to burden and resources	Influenced decisions about how to reduce burden to practices and how much technical assistance was required from the coach
Practice location and size	Practices vary in size, urban, suburban, and rural Native American population that travels ≥50 miles for primary care services	Informed flexibility/adaptations around frequency/duration of sessions, expected size of cohorts, and number of sessions
Practice clinician and staff availability	Practices vary in number and type of clinicians and staff available to deliver SMAs	Influenced adaptations to health educator and prescribing provider eligibility criteria, frequency of prescribing provider visits

PRO, patient-reported outcomes; SMA, shared medical appointments; TTIM, targeted training in illness management.

a brief review of the TTIM curriculum and guidance on documentation to support reimbursement. Peer mentors receive a 5-hour training that focuses on the peer support role, with materials adapted from Peers for Progress[35] and TTIM skill-building exercises for goal setting, action planning, glucose monitoring, problem solving, and communication skills to prepare peer mentors for demonstrations to SMA patients.

Discussion

Prior research has often overlooked how to best adapt interventions for real-world health care settings, resulting in a limited uptake of evidence-based practices.[36] Furthermore, external validity limitations have often resulted in evidence-based interventions lacking alignment with practice needs and priorities, such as yielding a return on

Figure 2. Case vignettes of adaptations to fit practice characteristics. Abbreviations: SMA, shared medical appointments; FQHCs, federally qualified health centers.

Adapting SMA Timing for Specific Population Needs

Context	Adaptation
One practice is the only urban Indian health program providing culturally appropriate care for American Indian and Alaskan Native adults, children, and families. During the pre-implementation phase, this practice determined that they would provide SMAs once a month.	During implementation, the practice determined that they needed to provide SMAs once a week. Meeting once a month was too far between appointments and so provider visits were taking longer than anticipated during the SMAs. Also, the practice found it difficult to retain patients when they met once a month as patients were traveling and following the pow wow circuit, school vacation schedules were causing disruptions, and patients were forgetting about the groups.

Adapting for Existing Clinic Staff and Sustainability

Context	Adaptation
Many Family Medicine practice teams also offer support to patients by way of 1:1 access to specialized roles (pharmacists and nutritionist, for example) and classes focused on living with chronic conditions. With an eye on sustainability, a physician-owned system with multiple practice sites wanted to expand services offered to patients by adding shared medical appointments to patients and families.	During implementation, the leadership and staff determined that having SMAs with PharmDs, rather than MDs, was the most viable plan for sustainability without impacting patient satisfaction. Patient feedback on the focused visit on medication management and reinforcement of nutrition, lifestyle and stress curriculum with the PharmD paved the way to the adaptation. PharmDs are able to bill for the visits and have more structured time for SMAs. Patient pays a copay for PharmD visit and this has not been prohibitive for their patients or model.

Adapting for a Rural Setting/Population with Integrated Behavioral Health Care

Context	Adaptation
A rural FQHC practice invites patients to SMAs to meet patients' ongoing education and management needs for Type 2 diabetes. Additionally, patients are seen by the medical provider and behavioral health provider at each visit.	The medical and behavioral provider team co-visit with the patient allows for a comprehensive approach to focus on aspects of their diabetes care and management plans as well as their diabetes distress or other mental/behavioral factors. The model adds to the sustainability of the SMAs as each professional can bill for services on the same day.

investment and minimizing burden.[36] Pragmatic trials can address these limitations, balancing equally important external and internal validity concerns.[37] In turn, pragmatic trials should report contextual factors that may influence replication and relevance of research findings[36]—for which D&I frameworks may be useful toward "designing for dissemination and sustainability." In a pragmatic trial among PBRN-affiliated primary care practices, we used the enhanced REP framework[22] to guide the process of engaging practices in identifying and negotiating a variety of adaptations needed to fit practice contextual factors expected to influence adoption, implementation, and sustainability of diabetes SMAs.

Our findings showed considerable practice context variability across several dimensions, and corresponding adaptations were made to intervention content (eg, general stress and coping), delivery (eg, fewer sessions), training (eg, group facilitation techniques), and facilitation (eg, tailored technical assistance depending on prior SMA experience). Similar adaptations to reduce patient barriers and encourage practice-level buy in were reported by Kowalski et al.[8] Adaptations were made through an iterative process in which patient and practice stakeholders informed intervention content, format, and delivery before and during initial implementation. Practice coaches also identified opportunities for adaptations at individual practices, jointly maintaining fidelity to protocols and supporting implementation and sustainability for each practice—an important function of practice facilitation.[38,39] Concurrently, planned adaptations and explicit discussions and decisions relative to core elements of the study protocol helped to ensure fidelity and rigor (ie, adaptations were intended to be "fidelity consistent").[40,41] FRAME was a useful framework for codifying and categorizing the type of adaptations.[33,34] Practices are likely to make additional unplanned, fidelity-inconsistent adaptations and will be evaluated separately.[33,42]

Limitations and Conclusions

The specific adaptations made to SMAs for this project may not generalize to other contexts, as the practices that participated in this project are PBRN members with existing behavioral health and health education resources. However, the primary contribution of this article concerns the process for adaptation to context—whatever that context may be. In summary, this project illustrates the use of mixed methods and D&I frameworks, namely, the REP framework to guide the process of adaptation of an intervention to fit context and FRAME to describe and categorize adaptations—expected to simultaneously advance science and support potential for future uptake—as is the goal of pragmatic trials.[43]

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