Fidelity Observations of Diabetes Shared Medical Appointments for the Invested in Diabetes Pragmatic Trial

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RESEARCH OBJECTIVE

Assess fidelity to the conceptual framework and protocol for the Invested in Diabetes study, a **pragmatic cluster-randomized comparative effectiveness trial** comparing two diabetes shared medical appointments (SMAs) delivery models (Kwan et al 2020).

Compare Standardized (STD) vs Patient-Driven (PTD) diabetes SMAs –

- Same 6-session skills-building curriculum (Targeted Training in Illness Management; TTIM)
- PTD includes multidisciplinary team delivering SMAs (peer mentors and behavioral health providers (BHPs))
- PTD allows patients to select topic order and emphasis

We expected PTD SMAs would show:

- Greater fidelity behavioral health components
- Less overall fidelity to protocol
- Increased autonomy and relatedness needs support as defined by **self-determination theory** (SDT; Ryan & Deci, 2000)
- Increased patient attendance

METHODS

Trained observers used a structured guide to evaluate ~8% of randomly selected SMA sessions, observed in-person or virtually, depending on session format (pre- and post-Covid-19). Attendance sheets were maintained by practices.

Structured fidelity observation guide:

- Session number and duration
- Patients and facilitators in attendance
- TTIM curriculum content covered
- # of patients completing prescribing provider visits
- Group facilitation style and skills (5-point bipolar scale)
  - Following the TTIM **script** verbatim vs paraphrasing
  - **Balance** of didactic vs group discussion
  - Demonstration of effective group facilitation **techniques**
  - Demonstration of SDT psychological needs support: **autonomy, competence, relatedness**

Practice attendance sheets

- Patient attendance records
- Staff personnel scheduled

Analysis:

- Descriptive statistics to assess fidelity elements, retention rates, and ratings
- T-tests to compare differences between PTD and STD

RESULTS

Table 1: Select Fidelity Observation and Attendance Data

	PTD	STD	P-diff
Fidelity Observation Data	N=30	N=38	
N(%) of classes observed with all topics covered	26 (87%)	32 (84%)	0.78
Mean (SD) time spent on observed session (out of 120min)	94 (24)	81 (21)	0.45
N(%) observed sessions with peer mentor present (PTD only)	16 (53%)	1 (2%)	--
Attendance Data			
	N=75	N=72	
N(%) peer mentor assigned to cohort (PTD only)	71 (95%)	0	--
N (%) BHP assigned to cohort (PTD only)	60 (80%)	0	--
N(%) evidence of topic selection present (PTD only)	57 (76%)	0	--
Average #(SD) sessions patients attended (out of 6)	3.90 (1.76)	3.96 (1.80)	0.58

Table 2. Ratings of diabetes SMA facilitation style overall and by study arm

	PTD arm M (STD)	**STD** arm M (STD)	P-diff
Script*	2.71 (0.81)	3.02 (1.01)	0.19
Balance†	2.86 (0.59)	2.61 (0.72)	0.16
Techniques‡	3.75 (1.08)	3.95 (1.05)	0.46

Table 3. Ratings of SDT needs supportiveness overall and by study arm

	PTD arm M (STD)	**STD** arm M (STD)	P-diff
Autonomy‡	4.18 (1.06)	4.41 (0.98)	0.38
Competence‡	4.57 (0.57)	4.51 (0.61)	0.70
Relatedness‡	4.52 (0.80)	4.64 (0.80)	0.56

*1=verbatim; 5=paraphrasing †1=didactic; 5=group discussion ‡1=low support; 5=high support

POPULATION STUDIED

Participating practices: 22 primary care sites (12 federally qualified health centers, 10 family and internal medicine commercial payer practices) with integrated behavioral health serving patients with Type II diabetes (20 sites included in this analysis).

PRINCIPAL FINDINGS

The distinguishing features of the PTD model (e.g., presence of peer mentor and BHP, topic selection) were inconsistently present, specifically peer mentor presence, suggesting challenges in maintaining fidelity to the PTD approach.

Existing primary care personnel delivered diabetes SMAs using a skills-building curriculum demonstrated excellent support for psychological needs for autonomy, competence, and relatedness – with little observed difference in facilitation style or needs support between SMA delivery models.

Attendance to classes was the same between conditions, indicating equal amount of patient engagement.

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