

OBJECTIVE

To investigate if physician attention to medication management was augmented among the patients in the intervention group of the Mobile Diabetes Intervention System (MDIS).

RESEARCH DESIGN AND METHODS

- Cluster-randomized clinical trial.
- 26 primary care practices assigned to one of three stepped treatment groups or control group (usual care).
- 163 patients included in analysis.
- Medications records from patient's charts were abstracted at baseline and for changes over 1 year.
- The primary outcome-change in HbA1c levels over one-year treatment period.
- Secondary outcomes-changes in patient-reported diabetes symptoms, diabetes distress, depression, blood pressure, and lipids.
- Post-hoc analysis of medication physician prescribing behavior to determine if medications alone explained change in HbA1c.

INTERVENTIONS

- Reports included an analysis of patient's glycemic control, diabetes medication management, lifestyle behaviors, and evidence-based treatment recommendations (clinical decision support).
- Patients received automated, real-time educational and behavioral messaging.
- Response to individually analyzed blood glucose (BG) values, diabetes medications, lifestyle behaviors communicated by mobile phone.
- Providers received quarterly reports.
- Reports summarized patient's glycemic control, diabetes medication management, lifestyle behaviors, treatment options.

Figure 1.

Primary Outcome and Baseline HbA1c Stratified Analyses.

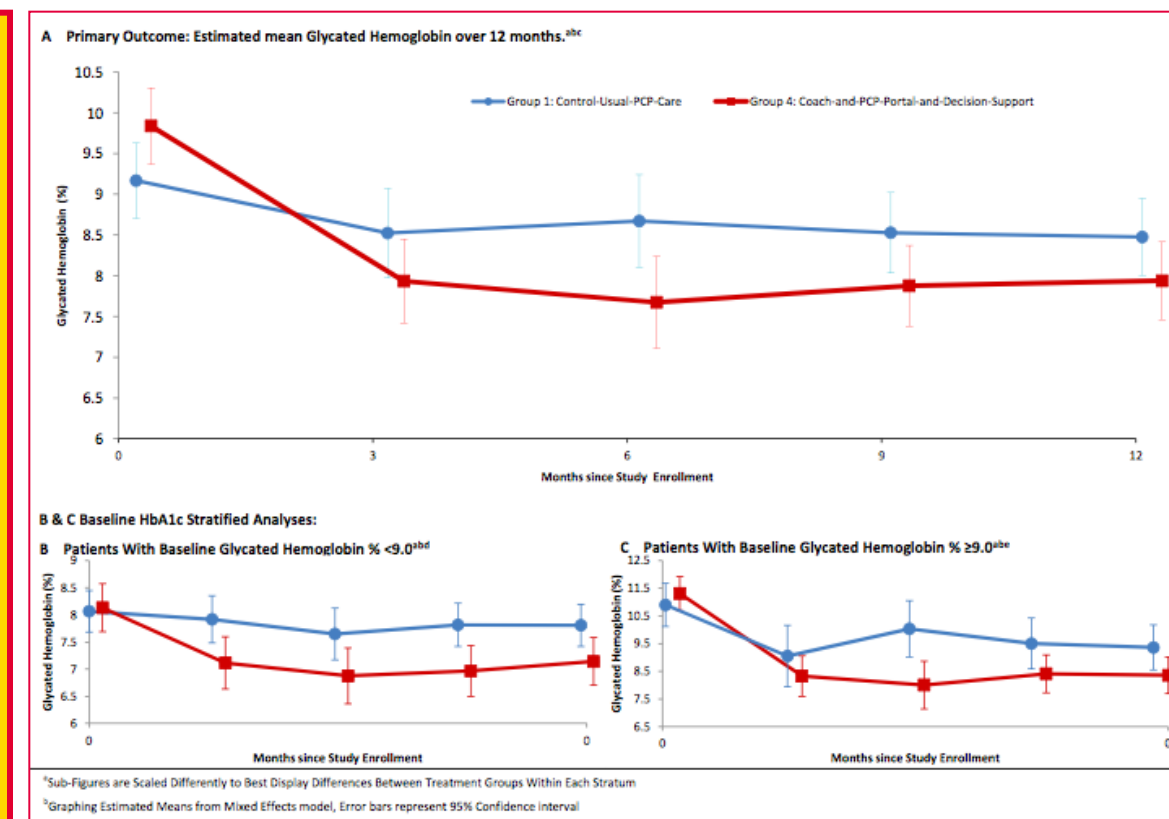


Table 1. Baseline Characteristics of Patients

Characteristics	Usual care Control (n=55)		Intervention (n=62)	
	n	% or M (SD)	n	% or M (SD)
Glycated Hemoglobin (%) — M (SD)	55	9.1 (1.7)	62	9.9 (2.1)
7.5-8.9% — no. (%)	35	63.6%	28	45.2%
≥9% — no. (%)	20	36.4%	34	54.8%
Age (yr) — M (SD)	55	53.3 (8.4)	62	52.0 (8.0)
Sex — no. (%)				
Male	28	50.9%	31	50.0%
Female	27	49.1%	31	50.0%
Race — no. (%)				
Black (Non-Hispanic)	26	47.3%	17	27.4%
White (Non-Hispanic)	26	47.3%	39	62.9%
Other	3	5.5%	6	9.7%
Body Mass Index (kg/m²) — M (SD)	55	34.4 (6.3)	62	35.8 (7.1)
Underweight (16.5-18.4) — no. (%)	1	1.8%	0	0.0%
Normal (18.5-24.9) — no. (%)	0	0.0%	1	1.6%
Pre-obese (25-29.9) — no. (%)	11	20.0%	12	19.4%
Obese class 1 (30-34.9) — no. (%)	21	38.2%	18	29.0%
Obese class 2 (35-39.9) — no. (%)	10	18.2%	17	27.4%
Obese class 3 (≥ 40) — no. (%)	12	21.8%	14	22.6%
Laboratory Values — M (SD)				
Systolic Blood Pressure — mmHg	55	131 (22)	62	130 (14)
Diastolic Blood Pressure — mmHg	55	78 (12)	62	79 (14.5)
LDL — mg/dL	50	100 (34)	55	106 (33)
HDL — mg/dL	55	45 (11)	59	43 (11)
Triglycerides — mg/dL	55	186 (168)	59	187 (145)
Total Cholesterol — mg/dL	55	180 (50)	59	184 (41)
Urine Microalbumin — mg/dL	17	44 (95)	26	55 (100)
Kidney Creatinine — mg/dL	54	0.94 (0.22)	33	0.96 (0.45)

Table 2. Baseline Characteristics of Practices and Physicians

Practice Characteristics	Usual care Control (n=9)		Intervention (n=7)	
	n	% or M (SD)	n	% or M (SD)
Practice Type				
Private Group Practice	4	44.4%	6	85.7%
Solo Practice	5	55.6%	1	14.3%
Number of Patients — M (SD)				
Total Patients in Practice	8	6613 (6389)	6	7850 (1375)
Patients in Practice with Diabetes	6	2187 (2895)	2	1375 (530)
Study Patients per Practice — M (SD)	9	6.2 (2.9)	7	8.9 (7.9)
Physician Characteristics	Usual care Control (n=11)		Intervention (n=11)	
	n	% or M (SD)	n	% or M (SD)
Age				
25-44	2	18.2%	7	63.6%
45-54	4	36.4%	2	18.2%
55-64	2	18.2%	2	18.2%
65-74	3	27.3%	0	0.0%
Gender				
Male	10	90.9%	4	36.4%
Female	1	9.1%	7	63.6%
Race				
White	10	90.9%	5	45.5%
Black	0	0.0%	1	9.1%
Asian	1	9.1%	3	27.3%
No Response	0	0.0%	2	18.2%
Full time/Part time				
Full time	10	90.9%	10	90.9%
Part time	1	9.1%	1	9.1%
Years practicing medicine				
Up to 10 years	2	18.2%	6	54.5%
11-20 years	3	27.3%	2	18.2%
20 Years or More	6	54.5%	2	18.2%
No Response	0	0.0%	1	9.1%
Hours in clinical practice per week — M (SD)	10	51.2 (6.5)	8	43 (15.1)
Degree				
M.D.	10	90.9%	10	90.9%
D.O.	1	9.1%	0	0.0%
Nurse Practitioner	0	0.0%	1	9.1%

Table 3. Prescription Behavior

Prescription Characteristics	Usual care Control (n=55)		Intervention (n=62)		Usual care vs Intervention p-value	
	n	%	n	%	Baseline	Any Change Intensified
No change to medications throughout study	35	63.6%	27	43.5%		0.1211
Insulin or non-Insulin Antihyperglycemics						
On Oral Antihyperglycemic or Insulin at baseline	50	90.9%	61	98.4%	0.2747 ^a	
Any change in Insulin or non-Insulin	15	27.3%	29	46.8%		0.0941
Intensification of Insulin or non-Insulin	14	25.5%	27	43.5%		0.0995
Oral Antihyperglycemic Medications						
On Oral Antihyperglycemic meds at baseline	48	87.3%	56	90.3%	0.6022	
Any change in Oral Antihyperglycemic	13	23.6%	24	38.7%		0.1344
Intensification of Oral Antihyperglycemic	9	16.4%	23	37.1%		0.0527
Antihyperglycemic Subclasses						
Sulfonylureas						
On Sulfonylureas at baseline	24	43.6%	20	32.3%	0.2247	
Any change in Sulfonylureas	6	10.9%	5	8.1%		0.8402
Intensification of Sulfonylureas	4	7.3%	1	1.6%		0.2353 ^a
Thiazolidinediones						
On Thiazolidinediones at baseline	21	38.2%	11	17.7%	0.1034	
Any change in Thiazolidinediones	6	10.9%	5	8.1%		0.7095
Intensification of Thiazolidinediones	4	7.3%	5	8.1%		0.6816 ^a
Biguanide						
On Biguanide at baseline	41	74.5%	45	72.6%	0.8104	
Any change in Biguanides	4	7.3%	15	24.2%		0.0325
Intensification of Biguanide	4	7.3%	15	24.2%		0.0332
Incretin Mimetics						
On Incretin Mimetics at baseline	3	5.5%	11	17.7%	0.0628	
Any change in Incretin Mimetics	0	0.0%	6	9.7%		0.0082^a
Intensification of Incretin Mimetics	0	0.0%	5	8.1%		0.0082^a
DPP4 Inhibitors						
On DPP4 Inhibitors at baseline	8	14.5%	23	37.1%	0.0248	
Any change in DPP4 Inhibitors	1	1.8%	5	8.1%		0.4286 ^a
Intensification of DPP4 Inhibitors	1	1.8%	5	8.1%		0.4286 ^a
Insulin						
On Insulin at baseline	16	29.1%	29	46.8%	0.1943	
Any change in Insulin	2	3.6%	7	11.3%		0.0957 ^a
Intensification of Insulin	2	3.6%	6	9.7%		0.2747 ^a
Insulin Subgroups						
Mealtime Insulins						
On Mealtime Insulin at baseline	6	10.9%	8	12.9%	0.7409	
Any change in Mealtime Insulins	1	1.8%	2	3.2%		0.4286 ^a
Intensification of Mealtime Insulins	1	1.8%	1	1.6%		0.7500 ^a
Basal Insulins						
On Basal Insulins at baseline	15	27.3%	29	46.8%	0.137	
Any change in Basal Insulins	2	3.6%	7	11.3%		0.0957 ^a
Intensification of Basal Insulins	2	3.6%	6	9.7%		0.2747 ^a
Antihypertensive Medications						
On HBP meds at baseline	38	69.1%	48	77.4%	0.8818	
Any change in Oral Antihypertensive	7	12.7%	10	16.1%		0.6884
Intensification of Oral Antihypertensive	7	12.7%	10	16.1%		0.6884
Antilipemic Medications						
On Antilipemic Agent(s) at baseline	36	65.5%	40	64.5%	0.9316	
Any change in Oral Antilipemic	3	5.5%	10	16.1%		0.1434
Intensification of Oral Antilipemic	3	5.5%	9	14.5%		0.1675

^a Due to small cell sizes these tests were performed at the Practice level using Wilcoxon Rank Sum

RESULTS

- Overall, 36.4 % control patients and 66.5% intervention patients had changes in medications during the study period (p=0.12) (Table 3).
- Mobile diabetes intervention reduced HbA1c on average over one year by 1.9% compared to 0.7% A1c reduction for control group (Figure 1).
- Results were consistent for persons with low and high HbA1c at baseline (Figure 1).
- Intervention physicians were more likely to be younger, female*, and a practicing provider for 10 years or less (*p=0.008) (Table 2).
- Examining by antihyperglycemic subclasses, intervention patients had more change and intensification in Biguanides (metformin)(p=0.03); and more likely to have Incretin mimetics added (p=0.008) .
- More intervention (47%) than control patients (27%) had Insulin and Oral antihyperglycemic medications adjusted (dose changes or medications dropped).
- No difference in prescribing behavior for antihypertensive or antilipemic medications.

CONCLUSIONS

- Although not statistically significant, patients with any changes in medications may be clinically significant (Figure 1-parent study). Lack of significance may be related to inclusion criteria that all patients had to be on an antihyperglycemic medication.
- Mobile diabetes intervention giving providers analyzed patient self-management data and treatment recommendations impacted provider behavior to adjust medication dosages or change medications..
- Additional analyses to understand the role of patient and diabetes educator messaging behaviors and mHealth usage may provide insight into other factors contributing to patient outcomes.

REFERENCES

Quinn CC, Shardell MD, Terrin ML, et al. Cluster-Randomized Trial of a Mobile Phone Personalized Behavioral Intervention for Blood Glucose Control. Diabetes Care. 2011;34(9):1934 –1942. PMID: 21788632

Errors in consent form completion were found on audit after study enrollment was complete. Our Institutional Review Board (IRB) asked us to repeat consent procedures to assure we had obtained proper signatures from all parties. We completed repeat consent procedures for 163 patient participants and 39 physician participants for whom we have permission from our IRB for human subjects research