ORIGINAL RESEARCH

Prompting Patients with Poorly Controlled Diabetes to Identify Visit Priorities Before Primary Care Visits: a Pragmatic Cluster Randomized Trial

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BACKGROUND: Most patients with diabetes do not meet all evidence-based goals of care, and many patients report poor communication and lack of involvement in decision-making during primary care visits.

OBJECTIVE: To test the hypothesis that a "Pre-Visit Prioritization" secure email message could improve visit communication and glycemic control among patients with type 2 diabetes.

DESIGN: We conducted a pragmatic, provider-randomized, multi-site clinical trial from March 2015 to October 2016 across 30 primary care practices within Kaiser Permanente Northern California (KPNC), a large integrated care delivery system.

PARTICIPANTS: Eligible patients had at least 1 year of KPNC membership, type 2 diabetes with most recently measured hemoglobin A1c (HbA1c) >= 8.0%, and were registered users of the KPNC online patient portal.

INTERVENTIONS: Patients in the intervention arm, upon booking an appointment, received a secure email through the KPNC online portal with a link to the EHR allowing them to submit their top one or two priorities prior to the visit. Control patients received usual care.

MAIN MEASURES: Glycemic control; change in HbA1c 6 and 12 months after the initial visit; patient-reported outcomes related to patient-provider communication and patient care experiences.

KEY RESULTS: During the study period, 1276 patients had at least one eligible visit. In post-visit surveys (n = 457), more intervention arm patients reported preparing questions for their visit (72% vs 63%, p = 0.048) and being given treatment choices to consider (81% vs 73%, p = 0.041). Patients in both arms had similar reductions in HbA1c over the 12-month study period (0.56% ± 1.45%), with no significant differences between arms.

CONCLUSIONS: A "light touch" email-based pre-visit intervention resulted in improved measures of visit interaction but did not significantly improve glycemic control relative to usual care. Improving diabetes clinical outcomes through more effective primary care visits may require more intensive approaches to patient visit preparation.

TRIAL REGISTRY: NCT02375932

KEY WORDS: clinical trials; doctor-patient relationships; diabetes; primary care; health information technology.

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INTRODUCTION

Over 30 million people in the USA have diabetes, representing an annual health care cost of over $245 billion dollars.[1] A robust evidence base from clinical trials and large cohort studies provides clear guidelines for the clinical management of diabetes and associated risk factors.[2] Despite gains in the quality of diabetes care in past decades, however, the majority of patients with diabetes still do not reach all goals of evidence-based management.[3] Indeed, evidence suggests that improvements in the overall quality of diabetes care have now plateaued.[4]

Most patients with type 2 diabetes are managed in the primary care setting. Providing effective diabetes care during brief and complicated primary care visits remains an important challenge.[5] Prior research has shown that there is insufficient time to address all preventative and chronic disease management care tasks.[6–8] With too many tasks in too little time, patients and providers must inevitably prioritize how to use their time together.[9] This prioritization can be a challenging task, particularly because some patients may be reluctant to voice relevant concerns (such as those related to mental or social health),[10–12] or do so near the end of the visit.[13]

Recent research has focused on improving patient-provider communication and facilitating more effective shared decision-

making.[14,15] Patient-centered efforts to improve visit interactions are seen as important avenues to improving care but have often had limited dissemination due to the increased resources and cost needed to implement.[16–18] We tested the hypothesis that providing a simple and inexpensive means for patients with inadequately controlled type 2 diabetes to identify and then notify their primary care physician (PCP) of their top one or two concerns prior to their primary care visit would lead to more effective visit interactions. We further hypothesized that improved shared decision-making and alignment of patient and provider priorities during these visits could, in turn, facilitate the necessary changes to improve diabetes control.

METHODS

Study Design and Randomization

We conducted the Pre-Visit Prioritization Study (ClinicalTrial.gov NCT02375932) from March 15, 2015, to October 30, 2016, with 1 year of clinical follow-up ending October 30, 2017. This pragmatic, two-arm, cluster-randomized trial was implemented with 1:1 random number sequence randomization at the provider level stratified by practice. We enrolled 146 PCPs from 30 primary care practices within Kaiser Permanente Northern California (KPNC), a non-profit integrated care delivery system providing care for over 260,000 members with diabetes. The distribution of member demographic and socioeconomic factors is diverse and similar to that of the area population.[19]

Each PCP provided informed consent. Prior to randomization, physicians reviewed and approved patients from a list of their potentially eligible patients (lists ranged from 5 to 52 patients). Patient eligibility criteria consisted of KPNC membership for at least 1 year, type 2 diabetes with most recently measured hemoglobin A1c (HbA1c) >= 8.0%, age 20 to 80 years, and registered user of the KPNC online patient portal used for secure electronic communication with physicians and other members of their health care team. During the study period, 73% of KPNC members with type 2 diabetes were registered users of the portal.

The Kaiser Foundation Research Institute Institutional Review Board (IRB) approved the waiver for written informed consent from patients of providers enrolled in our study. The rationale was twofold: (1) the intervention itself posed minimal patient risk (secure electronic messaging is a standard clinical practice, message recipients and content were approved by participating PCPs, and all clinical decision-making remained solely the responsibility of the patient's PCP) and (2) this pragmatic approach would improve generalizability of results by including a minimally selected population of "real-world" primary care patients.

Intervention Design

The rationale and design for the study have been described in detail elsewhere.[20,21] Briefly, our premise was that patients with type 2 diabetes are increasingly complex and often have multiple medical and social concerns apart from their diabetes. For these patients, competing demands and lack of visit preparation may lead to less effective visit encounters.[12,22] Our goal was to facilitate communication between a prepared patient who has had time before the visit to identify his/her priorities and an informed provider who is aware of the patient's care priorities at the beginning of the visit.[23] Improved visit communication, in turn, would ultimately lead to better diabetes management due to addressing barriers to care and greater adherence to collaborative care plans.

Intervention Implementation

Eligible intervention arm patients received a "Pre-Visit Prioritization (PVP)" secure electronic email message sent by study staff soon after scheduling a primary care appointment. Most PVP email messages were sent within 24 h of the appointment being scheduled. Appointments were not restricted by visit type as long as they were with the patient's own PCP. The message thanked the patient for making the appointment, emphasized the importance of identifying concerns to discuss at the visit, and provided an embedded hyperlink to a form for the patient to select one or two priorities (see Table 1 for choices provided). Once the patient completed and submitted this electronic form, his or her chosen visit priorities (and a small amount of allowed free text) were stored within the electronic health record (Epic®). These priorities became visible to the PCP on the day of the visit by being automatically uploaded into the provider's visit encounter form when opened during (or just prior to) the visit. For appointments scheduled more than 2 weeks in advance, a reminder email was sent the week prior to the visit to those patients who had not yet submitted their visit priorities. Control arm patients continued with usual care, which included a coordinated diabetes disease management program and as needed primary care visits.

Study Outcomes

Our primary clinical outcome was proportion of patients achieving HbA1c goal at 1 year comparing all patients in the

Table 1 Five Visit Priority Options and Examples Provided

Priority	Examples provided in the PVP secure message
Diabetes-related concerns	Making lifestyle changes, blood sugar levels too high or too low, numbness or pain in your feet, diet or exercise goals
Important changes in life	Important changes at home or work, financial problems, illness involving family or friends
Medication concerns	Side effects, cost of medicines, not filling a prescription, or any changes you have made
Mood/motivation	Difficulty getting motivated to take care of yourself, feeling anxious or depressed, problems with alcohol or addiction
New/important health issues	Pain, poor sleep, sexual issues, trouble with your usual activities.

intervention and control arms. We also investigated change in HbA1c levels. Eligible baseline HbA1c was defined as an HbA1c ≥ 8.0% measured most recently prior to a visit during the study period. Follow-up HbA1c results were collected over the 12 months post-visit. We used any results within 3 months (before or after) the 6-month and 12-month end points after the index visit for outcome assessment. By definition, providers could not be blinded to randomization status; however, collection and assembly of data for post-visit telephone surveys and analysis were masked to randomization status.

Our primary patient-reported outcomes were assessed using post-visit telephone surveys conducted in a subset of patients during the final 6-month period of the clinical trial. With IRB approval, we obtained patient informed consent for this portion of the study before administering a 15-min post-visit survey that included questions related to patient-provider communication and patient care experiences.[24–29] We purposefully sampled intervention and control patients in a 2:1 ratio so that we could gather additional qualitative data from intervention patients after respondents completed the post-visit survey. Response rate was 58%.

Statistical Methods

In our analysis of the post-visit surveys, ordinal responses were re-grouped into dichotomous responses and analyzed using χ^2 tests. We examined change in HbA1c both as a continuous outcome and as a dichotomous outcome (improvement vs no improvement). Our target study size was based on 80% power to detect a difference of 0.25% in HbA1c between study arms, a cluster size of 10 patients per provider, an intra-cluster correlation co-efficient of 0.01, and less than 5% missing outcome data. Continuous outcomes were analyzed using linear mixed models with a random intercept for PCP to account for the correlation induced by the cluster randomized design. Dichotomous outcomes were analyzed using generalized linear mixed models with a logit link and a random intercept for PCP. We also examined differences between study arms in time to HbA1c control, defined as HbA1c < 8.0%, using the Kaplan-Meier analysis (SAS version 9.3, SAS Institute, Cary, NC). All primary analyses were based on "intention to treat" randomization status where the significance level was 0.05 and hypothesis testing was two-sided.

We conducted pre-planned sensitivity analyses of change in HbA1c stratified by pre-visit HbA1c level and by "on-treatment" use of the PVP secure message among intervention patients compared to controls. We also conducted exploratory analyses examining differences between treatment arms based on level of prior year secure electronic messaging and, at the physician level, years of practice. Within the treatment arm, we also explored changes in HbA1c stratified by whether or not the patient chose diabetes as a top priority for the visit.

RESULTS

Recruitment and Enrollment

Primary care physicians and their patients were recruited over a 12-week period (March 2015–June 2015) from 30 primary care practices at 13 different medical facilities across four Northern California counties. The study was presented during routine physician practice meetings attended by 162 primary care physicians, of whom 146 consented to enroll (90% physician recruitment success rate). Enrolled providers excluded very few potentially eligible patients (60 of 2556, < 2%; Fig. 1).

Provider Baseline Characteristics and Survey Results

Enrolled PCPs had a mean age of 50.0 ± 8.2 years and had practiced for an average of 22.2 ± 8.6 years. More than half were women (89/146, 61%) and 14 (10%) had joined KPNC within the past 5 years. Physician characteristics were similar between study arms (Table 2). Of the 146 PCPs enrolled in our study, 141 PCPs (97%) completed a baseline five-question survey about their patients with elevated HbA1c. This survey showed that the majority of PCPs (118/141, 84%) reported "sometimes," "rarely," or "never" having enough time during visits with their diabetes patients with elevated HbA1c. Although most PCPs (117/141, 83%) reported that they "usually" or "always" elicited patients' one or two top concerns, only 57% (81/141) reported that their patients "usually" or "always" came prepared with one or two topics to discuss during their visit, and 39% (55/141) reported that patients "usually" or "always" raised their concerns near the end of the visit.

Patient Baseline Characteristics

In total, 1276 unique patients (673 intervention patients; 603 control patients) attended at least one visit during the study period and were eligible for analysis. Patients had 2.0 ± 1.5 visits with their primary care physician during the study period (2513 total visits; 1309 intervention visits; 1204 control visits). The patient study cohort was 56% male, 38% non-White race/ethnicity, with a mean age of 61.2 (± 10.3) years and last measured HbA1c of 9.3% (± 1.3%). Patient characteristics were similar between study arms (Table 2).

Uptake of the Intervention

A pre-visit email was successfully sent by research staff for 1204 of 1309 (92%) attended visits within the intervention arm. The primary reason for not sending a pre-visit email was insufficient time between booking and appointment (median = 10 h for visits without PVP emails sent).

Intervention patients opened 62% of pre-visit emails (746/1204). For one-third (34%, 254/746) of opened emails, intervention patients submitted their visit priorities (21% of pre-visit emails, 254/1204). Patients most frequently chose "New/important health issues" and "Diabetes-related concerns" as their visit

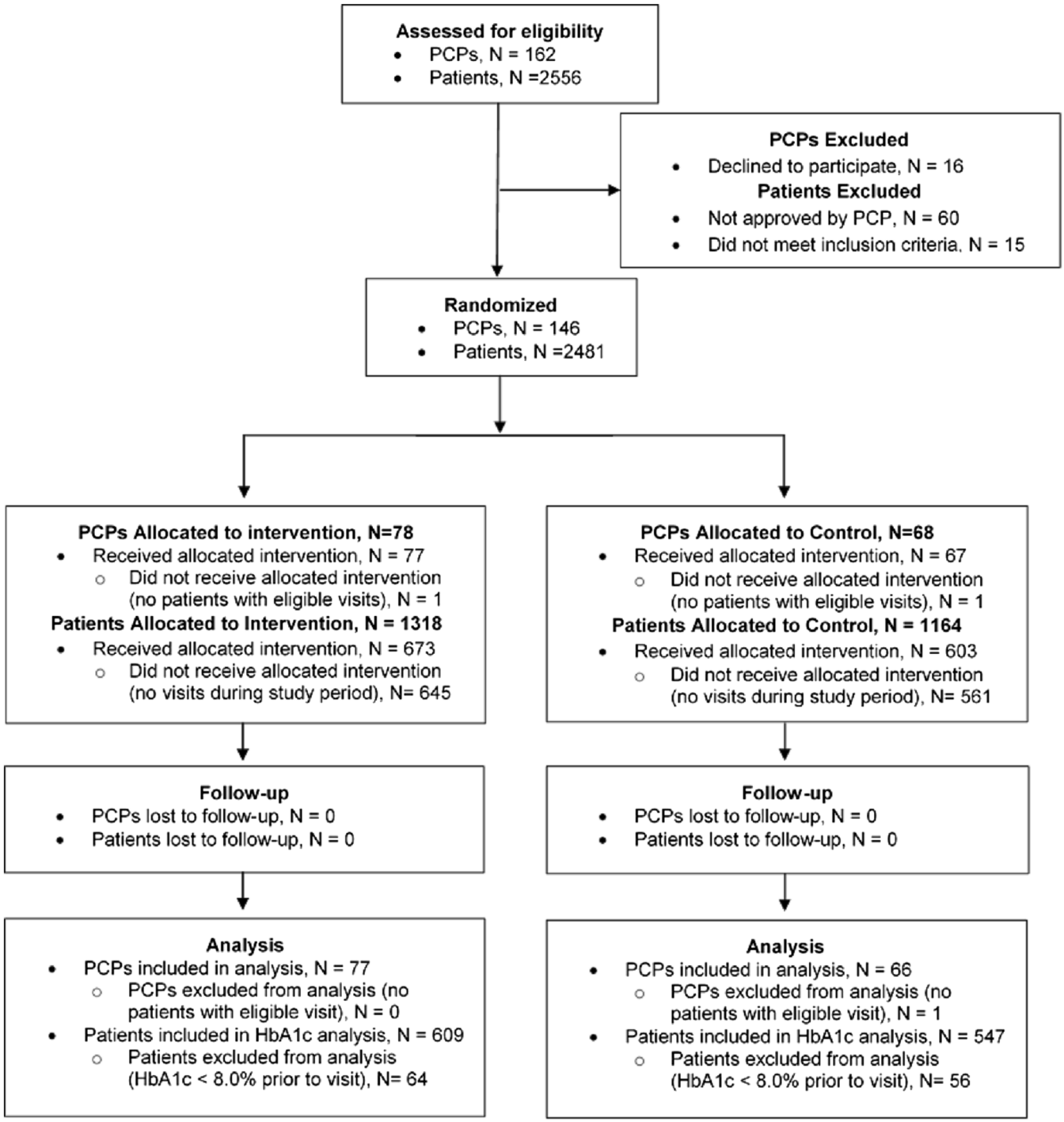

Figure 1 CONSORT diagram of patient and PCP flow.

priority (Online Appendix Table 1). Among patients submitting their visit priorities, nearly one-third (64/205, 31%) included concerns related to mood, motivation, or important life events.

Effects on Visit Communication and Visit Interactions

Post-visit patient surveys were administered over the final 6 months of the clinical trial, with 457 surveys completed (58% response rate). Compared to control patients, patients who received the intervention were more likely to report preparing a list of questions for their doctor (72% to 63%, $p = 0.048$). They were also more likely to report being given choices about their treatment to think about compared to control patients (81% to 73%, $p = 0.041$). Patients in both study arms rated their physicians very highly, with almost all respondents reporting that their physicians spent enough time with them (96.9%) and listened carefully to their concerns (99.7%) (Table 3). There were no other significant differences in other survey items between study arms.

Table 2 Baseline Characteristics of Study Physicians and Their Eligible Randomized Patients ($n = 1276$)

Study physicians	All PCPs ($n = 146$)	Control ($n = 68$)	Intervention ($n = 78$)	*P*
Age, years (SD)	50.0 (8.2)	50.9 (8.4)	49.2 (8.0)	0.21
Women, *n* (%)	89 (61.0)	41 (60.3)	48 (61.5)	0.88
Years in practice (SD)	22.2 (8.6)	23.3 (8.7)	21.2 (8.4)	0.13
*Baseline survey responses (*n*, %)	$n = 141$	$n = 66$	$n = 75$	
Enough time during your visits	23 (16.3)	12 (18.2)	11 (14.7)	0.57
Patients typically prepared with 1 or 2 topics	81 (57.4)	39 (59.1)	42 (56.0)	0.71
Able to get through all the items on your agenda	82 (58.6)	36 (54.5)	46 (62.2)	0.36
Patients raising their concerns near the end of the visit	55 (39.0)	23 (34.8)	32 (42.7)	0.34
Study patients	**All patients ($N = 1276$)**	**Control ($N = 603$)**	**Intervention ($N = 673$)**	***P***
Women, *n* (%)	564 (44.2)	268 (44.4)	296 (44.0)	0.87
Race/ethnicity, *n* (%)				0.09
African-American	131 (10.3)	49 (8.1)	82 (12.2)	
Asian	192 (15.0)	88 (14.6)	104 (15.5)	
Hispanic	128 (10.0)	56 (9.3)	72 (10.7)	
Other	39 (3.1)	18 (3.0)	21 (3.1)	
White	786 (61.6)	392 (65.0)	394 (58.5)	
Age, mean (SD)	61.2 (10.3)	61.2 (10.4)	61.2 (10.3)	0.94
Prescribed medicines, mean (SD)	5.6 (3.5)	5.6 (3.5)	5.6 (3.5)	0.85
Baseline HbA1c, mean (SD)	9.3 (1.3)	9.3 (1.3)	9.3 (1.2)	0.78
Baseline SBP, mean (SD)	129.9 (11.3)	129.5 (11.3)	130.1 (11.0)	0.38
Baseline LDL, mean (SD)	87.9 (33.8)	86.7 (33.4)	88.1 (34.2)	0.24

PCP primary care physician
**Proportions are PCPs answering "usually" or "always" (choices were "never," "rarely," "sometimes," "usually," and "always") when considering a typical visit with patients with diabetes and elevated HbA1c*

Effects on Diabetes Control

Study participants experienced an overall mean decrease in HbA1c of 0.56% ± 1.45% from baseline to 12-month follow-up, and one-third of patients (502/1156, 43%) achieved HbA1c control (defined as < 8%) with mean time to control of 147 ± 100 days. We found no statistically significant differences in changes in HbA1c at 6 or 12 months or in time to HbA1c < 8.0% between study arms (Table 4, Online Appendix Fig. 1). Differences between arms remained non-significant after stratifying by pre-visit HbA1c, frequency of prior year secure messaging, and after limiting intervention patients to those opening the Pre-Visit Prioritization secure message (Online Appendix Tables 2 and 3). In Cox proportional hazards models, time to control was significantly related to pre-visit HbA1c level (hazard ratio 0.60, 95% CI 0.54–0.66, $p < 0.01$) but demographic characteristics known to be associated with glycemic control (gender, race/ethnicity, age) and intervention arm were not (Table 5, Online Appendix Fig. 1).

Analyses of Patients in the Intervention Arm

Intervention arm patients who opened their PVP secure messages had sent more electronic secure messages of any kind to KPNC in the prior year (13.4 vs 8.5, $p < 0.01$) compared to intervention patients who did not open their PVP secure messages. There were no differences between PVP secure message openers and non-openers in age, gender, or race/-ethnicity. Opening the PVP secure message was associated with more days between scheduling and attending the appointment (7.4 vs 3.3 days, $p < 0.01$). Patients were also more likely to open emails sent by physician study staff than non-physician study staff (70% vs 54% opened, $p < 0.01$). Among intervention arm patients submitting visit priorities, we found no significant differences in HbA1c comparing patients who listed diabetes as a top visit priority vs patients who did not (Online Appendix Table 4).

DISCUSSION

A major challenge to the primary care of patients with type 2 diabetes is the limited amount of time available during visits to address the many competing demands faced by both patients and providers.[6,30,31] Time limitations can lead to a lack of shared decision-making and lack of alignment between patient and physician priorities for the visit, with patient priorities often not being addressed. We conducted a pragmatic, physician-randomized, controlled trial to test the impact of a simple

Table 3 Patient Post-visit ($n = 457$) Survey Responses

	Freq. (%) answering "Yes"		
Patient post-visit survey questions	**Intervention ($n = 291$)**	**Control ($n = 166$)**	***P* value**
Did you prepare a list of questions for your doctor?	210 (72.2)	105 (63.3)	0.05
Were you given choices about treatment to think about?	236 (81.1)	121 (72.9)	0.04
Were you asked about any problems with medicines or their effects?	232 (79.7)	120 (72.3)	0.07
Did your doctor spend enough time with you?	282 (96.9)	158 (95.2)	0.35
Did your doctor listen carefully to you?	290 (99.7)	164 (99.8)	0.27

Table 4 Hemoglobin A1c Outcome

	N	Overall	*N*	Control	*N*	Treatment	*P*
HbA1c							
Mean ± SD							
Pre-visit	1156	9.39 ± 1.32	547	9.39 ± 1.32	609	9.40 ± 1.32	0.91
6-month	1052	8.91 ± 1.48	510	8.86 ± 1.53	542	8.96 ± 1.43	0.26
12-month	712	8.78 ± 1.42	340	8.80 ± 1.47	372	8.76 ± 1.37	0.69
Change in HbA1c							
Mean ± SD							
6-month	1052	− 0.44 ± 1.38	510	− 0.48 ± 1.48	542	− 0.39 ± 1.28	0.31
12-month	712	− 0.56 ± 1.45	340	− 0.53 ± 1.47	372	− 0.59 ± 1.43	0.59
Any decline in HbA1c (%)							
6-month	1052	644 (61.2)	510	313 (61.4)	542	331 (61.1)	0.92
12-month	712	473 (66.4)	340	221 (65.0)	372	252 (67.7)	0.44

online tool to help patients prepare for their visits. This "light touch" intervention strategy improved several key patient-reported measures related to the visit but did not lead to better glycemic control compared to control arm patients.

There are several possible explanations for the lack of impact of our intervention on the clinical endpoint of HbA1c control. Glycemic control reflects a wide array of factors, including disease severity, medication intensity, and patient adherence to medicines and lifestyle changes. Helping patients and providers begin the visit knowing the patient's top concerns is likely an important first step towards improved diabetes control but, by itself, this strategy appears insufficient to ensure the timely cascade of steps necessary to lower HbA1c levels. Future efforts to improve glycemic control through pre-visit patient preparation may need to go beyond this first step of prioritization and onto empowering patients to more effectively raise and address concerns related to medication intensification and adherence, lifestyle changes, and other barriers or competing demands.

A second explanation is that many patients may already engage in pre-visit preparation and thus did not need the tool tested in this intervention. Indeed, in this insured population, we found in our post-visit phone surveys that many patients reported that they already prepared for visits. By conducting a pragmatic trial that optimized real-world applicability, we were unable to "screen out" patients who already prepared for visits. Other patients made appointments for acute concerns rather than to address diabetes care (as suggested by the high prevalence of "New/important health issues" as the top visit priority). Finding ways to identify and focus on the subset of patients in most need of pre-visit preparation might lead to more successful outcomes.

A third factor is that in modern health care systems, diabetes management is increasingly conducted by a team of health care providers that may include diabetes educators, pharmacists, nurses, and care managers.[32] Focusing solely on primary care visits, while clearly a foundation of care, may not have taken full advantage of the opportunity to help patients in their interactions with other care team members. Moreover, the patient was given the opportunity to identify both diabetes-related and diabetes-unrelated priorities. A more diabetes-centric intervention may have had a greater impact on HbA1c control.

Finally, our intervention used online secure messages, an inexpensive and wide-reaching approach to patient contact. However, we found that many patients reported technical

Table 5 Cox Proportional Hazard of Achieving HbA1c < 8% During Study Period

	Univariate HR (95% CI)	*P*	Multivariate HR (95% CI)	*P*
Study arm				
Control	1			
Treatment	0.90 (0.74–1.09)	0.29	0.91 (0.76–1.10)	0.34
Pre-visit a1c	0.58 (0.52–0.63)	< 0.01	0.60 (0.54–0.66)	< 0.01
Race				
White	1			
Asian	0.65 (0.49–0.86)	< 0.01	0.75 (0.56–0.99)	0.05
African-American	0.69 (0.50–0.95)	0.02	0.91 (0.66–1.26)	0.58
Hispanic	0.82 (0.60–1.11)	0.20	1.16 (0.85–1.60)	0.36
Other	1.07 (0.66–1.75)	0.79	1.36 (0.83–2.24)	0.22
Gender				
Female	1			
Male	1.15 (0.96–1.38)	0.13	1.09 (0.91–1.31)	0.33
Age (years)				
< 40	1			
40–49	0.66 (0.31–1.42)	0.28	0.63 (0.29–1.35)	0.23
50–59	1.41 (0.71–2.80)	0.32	1.25 (0.63–2.49)	0.53
60–69	2.21 (1.13–4.32)	0.02	1.65 (0.84–3.27)	0.15
≥ 70	2.28 (1.16–4.50)	0.02	1.51 (0.76–3.02)	0.24

difficulties with their computers or tended to ignore our study message because of the volume of other emails received from KPNC. To the extent that these issues contributed to our null findings, these results demonstrate the potential value of combining technology with human interactions to achieve more robust impacts on patient care.

Results from patient and provider surveys partially confirmed key elements of our hypotheses for the intervention model. Provider baseline surveys clearly supported our premise that providers are pressed for time and perceive that their patients are often unprepared or leave important concerns to the end of the visit. Similarly, many of our patient respondents endorsed the value of tools to prepare for their primary care visits. Among patients submitting their priorities, nearly one-third included "non-medical" concerns related to mood, motivation, or important life events—issues that are often perceived as competing demands that may complicate standard diabetes management and directly impact diabetes care.

While prior research has shown the value of pre-visit preparation,[33,34] these interventions have rarely been widely adopted in "real-world" settings despite promising initial results. We chose to implement a large pragmatic trial rather than a smaller more intensive intervention to more closely approximate the type of change that can be implemented across a broad range of practices and systems. Pragmatic trials maintain the rigor of randomization but seek to have broadly inclusive eligibility criteria and to measure outcomes of relevance to patients.[35–37] By taking a less resource-intensive approach, our strategy had the potential to be more widely adopted by care systems and to benefit a larger segment of the patient population without imposing undue burdens on clinicians or care systems. The limitation of this approach is that greater patient inclusiveness came at the cost of less restrictive patient selection. Another study limitation was our setting in a highly functioning integrated delivery system with multiple programs targeting patients with poor glycemic control. KPNC leverages population-based team care and routinely achieves nation-leading success in managing patients with diabetes, as shown in the improvements in HbA1c achieved by patients in both arms in our study. Incremental improvement in such a highly functioning system is often more difficult than in settings where diabetes care is less well organized.

Our pragmatic randomized trial demonstrated that a light touch intervention directed towards patients before their primary care visits has the potential to improve visit interactions by helping patients identify and communicate their top visit priorities at the start of the visit. Further work is needed to translate this model into one that can directly improve clinical outcomes. Incremental advances could include using the pre-visit period to also help patients define care goals and articulate addressable barriers to making changes in care. More dramatic improvements in the current quality of diabetes care may require radical changes beyond incremental improvements at the margins of existing care.

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Compliance with Ethical Standards:

The Kaiser Foundation Research Institute Institutional Review Board (IRB) approved the waiver for written informed consent from patients of providers enrolled in our study.

Conflict of Interest: *The authors declare that they do not have a conflict of interest.*

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