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Comparison of community health worker-led diabetes medication decision-making support for low-income Latino and African American adults with diabetes using e-Health tools versus print materials: A randomized controlled trial

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Data: Available to interested readers by contacting Dr. Heisler at mheisler@med.umich.edu

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Abstract

Background—Health care centers serving low-income communities have scarce resources to support medication decision-making among patients with poorly controlled diabetes.

Objective—We compared outcomes between community health worker (CHW) use of a tailored, interactive web-based tablet-delivered tool (iDecide) versus use of print educational materials.

Design—A randomized two-arm trial from 2011-2013. Trial Registration NCT01427660.

Setting—Community health center in Detroit serving a Latino and African American low-income population.

Participants—188 adults with a hemoglobinA1c >7.5% (55%) or who reported questions, concerns, or difficulty taking diabetes medications

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Measurements—Primary outcomes were changes in knowledge about anti-hyperglycemic medications, patient-reported medication decisional conflict, and satisfaction with anti-hyperglycemic medication information. We also examined changes in diabetes distress, self-efficacy, medication adherence, and A1c.

Intervention—Participants were randomized to receive a 1-2 hour session with a CHW using either iDecide or printed educational materials and two follow-up calls.

Results—94% of participants completed three-month follow-up. Both groups improved across most measures. iDecide participants reported greater improvements in satisfaction with medication information (helpfulness, $p=.007$; clarity, $p=.03$) and in diabetes distress compared to the print materials group ($p<.001$). There were no differences between groups in other outcomes.

Limitations—The study was conducted at one health center over a short period, and the CHWs were experienced in behavioral counseling, thus possibly mitigating the need for additional support tools.

Conclusions—Most outcomes were similarly improved among participants receiving both types of diabetes medication decision-making support. Longer-term evaluations are necessary to determine whether the greater improvements in satisfaction with medication information and diabetes distress achieved in the iDecide group at three months translate into better longer-term diabetes outcomes.

Keywords

diabetes; anti-hyperglycemic medications; randomized controlled trial; glycemic control; self-management; community health worker; tailored; e-health

Introduction

Adults with type 2 diabetes often struggle with their anti-hyperglycemic medication regimes. To improve medication management, providers need to ensure that their patients understand potential benefits, harms, and burdens of available options and to elicit patients'

preferences and barriers to taking medications. Patients who are actively involved in treatment decision-making tend to be more satisfied with their health care, more adherent to treatment, and have improved clinical outcomes (1-3). Such discussions, however, can be too time-consuming for clinic visits. For inner-city low-income African American and Latino adults, low health literacy and limited English proficiency are often additional barriers (4) that reduce the exchange of information and decrease patient participation during primary care visits (5-8). This contributes to less optimal treatment decisions and lower patient satisfaction, leading to poor medication adherence and outcomes (3, 9-11).

There is thus an urgent need for cost-effective approaches to enable low-resource health systems to help these high-risk populations gain information and decision support to more actively participate in and have increased satisfaction with their treatment decision-making. The REACH (“Racial and Ethnic Approaches to Community Health 2010”) Detroit Partnership, a coalition of community, health system, and academic partners, since 2000 has used community-based participatory research (CBPR) principles to guide development, implementation, and evaluation of interventions to meet this need among African American and Latino adults with diabetes in Detroit. These interventions have built on evidence that community health workers (CHWs) are effective in improving diabetes outcomes, particularly among racial and ethnic minority communities (12). CHW interventions train community members who work as bridges between their ethnic, cultural, and/or geographic communities and health care providers (13). Two cohorts of participants in our prior CHW-led diabetes self-management support interventions improved A1c levels and diabetes distress compared to usual care (14, 15). An important next step in increasing the potential impact of CHWs and other lay healthcare workers is to develop and test effective tools they can use to better present evidence-based information to patients and to help patients make better self-management decisions (16).

Little is known about the effectiveness of different approaches for nontraditional care providers such as CHWs to deliver health information to ethnic minority and low-literacy populations (17). By definition, CHWs and other lay workers do not have medical expertise and thus rely on effectively sharing printed educational and support materials with patients in their coaching and counseling efforts. Decision aids can increase satisfaction with treatment decisions and result in treatments that better reflect patients’ preferences (18,19). There is also evidence that ‘tailored’ health messages are more effective than generic group messages (20,21), including for patients with diabetes (22, 23). Tailoring individualizes “information and behavior change strategies to reach each person based on characteristics unique to that person derived from an individual assessment and related to the outcome of interest (24).” With the development of software programs automatically embedding tailored content into portable e-Health web applications, these tools show promise in improving health behaviors and outcomes (25,26). To date, however, most e-Health applications have been designed for use by patients with relatively high literacy and the skills to navigate them (27). Do more sophisticated tailored, interactive e-Health tools increase the effectiveness of CHW outreach with underserved patients compared to when they rely on printed educational materials alone?

We addressed this question by developing and evaluating a personally tailored, interactive diabetes medication decision aid (iDecide in English, or *iDecido* in Spanish) designed for CHWs to deliver on tablet computers with 3G access to African American and Latino adults with diabetes and low health literacy. We then evaluated the effectiveness of iDecide in improving key diabetes outcomes compared to delivery by CHWs of the same evidence-based information without tailoring using print consumer booklets developed by the Agency of Health Research and Quality (AHRQ).

Methods

Setting

This study was developed and implemented using CBPR principles (28) in partnership with the REACH Detroit Partnership and the Community Health and Social Services Center (CHASS), a federally qualified health center in Southwest Detroit serving over 13,000 patients with 47,099 visits in 2012 (29). The University of Michigan and CHASS Institutional Review Boards approved the study.

Content of AHRQ Consumer Guides

The AHRQ Guides (“Pills for Type 2 Diabetes” and “Premixed Insulin for Type 2 Diabetes”) (30, 31) provide information on diabetes and summarize the effectiveness of currently available medication classes (oral and insulin) on A1c. They also provide information on administration methods, costs, medication side effects, risks of diabetes complications, suggested questions to discuss with health care providers and prompts to make notes of any questions for the doctor. The booklets include pictures of patients and tables and graphs summarizing information.

Content of iDecide

The development process and content of the iDecide program have been described in detail elsewhere (32). Briefly, we used CBPR and User Centered Design (UCD) (33, 34) principles to iteratively develop and refine the iDecide tool. iDecide is available in English and Spanish, can be delivered via tablet computers, and enables navigation by the CHW and participant to selectively explore issues most important to the participant.

The iDecide program is organized in four main sections and includes the same content as the AHRQ Consumer Guides though presented in a more graphical style suited to patients with low literacy. Key differences between the presentation of information in iDecide and the printed materials are summarized in Table 1. The first section illustrates through animations how diabetes affects how glucose is processed in the body and how different medication classes, foods, and physical activity affect blood sugar. The second section includes pictographs showing participants’ own risk of diabetes complications (tailored based upon their baseline A1c) and enabling participants to explore how their risk of different complications changes with their A1c levels. In the third section, participants review their current diabetes medications and barriers to taking medications they had reported on the baseline survey. This section includes an interactive “issue card” approach to help elicit patient preferences and priorities about different medication characteristics (e.g. cost, side-

effects, effect on weight, dosing schedules)(22, 35). The fourth section prompts participants to set goals and develop specific action plans to address identified barriers or other concerns and identify specific questions and concerns to discuss with their doctor about their medications or making lifestyle changes. Personal information from the baseline assessment is interwoven throughout the program (i.e., high-depth tailoring within sentences). Motivational Interviewing-based, tailored discussion prompts encourage autonomy-supportive CHW-patient interactions at key points with open-ended questions and values exploration to help participants uncover their motivation, solve barriers to change, and develop an action plan (36).

Recruitment and Randomization of Patients

From September 2011 to August 2012, potentially eligible participants were identified from a computer-generated list of CHASS patients with physician-diagnosed type 2 diabetes. Inclusion criteria required A1c of $>7.5\%$ in the prior six months or expressed concerns about current diabetes medications during the screening assessment. Exclusion criteria were age less than 21 years, terminal health conditions, self-reported alcohol or drug abuse, and conditions (e.g., blindness, dementia) that would impede meaningful participation. Pregnant women and individuals who reported that they could not be contacted by phone were also excluded.

Introductory letters were sent in timed batches. Research staff then telephoned patients and screened them for eligibility. Interested eligible patients met with research staff who completed written informed consent, administered baseline surveys in English or Spanish, and measured A1c and blood pressure. Participants received a stipend of \$20 after each assessment. Participants were scheduled within 1-14 days for a visit with a CHW (at home, clinic, or other agreed upon place). At the beginning of the CHW visits, participants were registered into the iDecide program and randomized by the computer program using a random sequence algorithm into one of two study arms. There were no differences between the steps to participate in either study arm. Patients, research staff, and CHWs were blinded to randomization results through completion of all baseline measures up to the start of the intervention. Data assessors remained blinded to group assignment throughout the study.

CHW Intervention for Both Study Groups

All participants received an initial one-on-one, face-to-face session with a CHW and a copy of the printed materials to take home. The iDecide sessions lasted approximately 2 hours, while the sessions using printed materials lasted approximately 1.5 hours. All four project CHWs were employed by CHASS, had received 80 hours of initial training in Motivational Interviewing-based communication approaches and diabetes self-management support, with 4-8 hours of booster training annually. The CHWs had an average of six years experience leading diabetes self-management training programs with adult diabetes patients (14, 37). The CHWs reviewed the content (either through iDecide or the printed AHRQ guides) with participants, elicited questions, and helped patients develop a list of questions and concerns to raise with their health care provider at their next clinic visit. They also asked participants about current barriers to taking medications and helped develop action steps (an action plan) to address any identified barriers. If participants set a specific medication change goal or

identified a concern or question for their health care provider, CHWs helped schedule a follow-up clinic visit. CHWs contacted participants twice after the session by phone to address any additional questions, to discuss whether they had had a follow-up clinic visit and if so how the visit went, and to follow up on any specific goals/action steps the participant made during the session. These telephone contacts were 3 and 6 weeks after the initial face-to-face session.

Outcome Measures

Self-report outcomes were measured via survey at baseline and 3 months. We designed both interventions to improve anti-hyperglycemic medication decisional conflict (38), knowledge and beliefs about anti-hyperglycemic medications (39), and satisfaction with medication information (clarity and helpfulness)(22). We thus chose these as our primary outcomes. In prior interventions, improvements in diabetes care self-efficacy (40), diabetes distress (41), and medication adherence (42), as measured by the validated scales we used, are associated with subsequent improvements in A1c and other clinical outcomes (43-49). We therefore examined these as exploratory secondary outcomes. All measures were scaled from 0 to 100, with higher numbers indicating more positive outcomes (e.g., better medication adherence, lower diabetes distress).

We calculated the sample size to provide 80% power to detect a small to moderate between-arm effect size of 0.3-0.40 in our primary outcome measures, assuming a two-tailed α of 0.05, which would require a final sample size of 84 in each group (50). We estimated we would have an attrition rate of 20% in this very low-income population, but our attrition rate was only 6%. Because of the short study period of three months from randomization, we did not consider A1c a study outcome and did not power the study to detect between-group differences in A1c of less than 0.5%. As we needed to collect baseline A1cs to provide tailored information in the iDecide program and for the CHW-patient discussions in both groups on risks of diabetes complications, current anti-hyperglycemic medications, and possible medication changes, we decided to also collect A1c at three months. That would enable us to assess whether there was a trend toward lower A1cs in either group for developing longer-term interventions with A1c as a primary outcome. Baseline and three-month A1cs were measured with a Bayer DCA 2000+ point-of-care analyzer (51). The assay has a test coefficient of variation <5% as required by the National Diabetes Data Group.

Statistical Analysis

We followed international guidelines for analysis and reporting of clinical trials (52). Two-sided tests were used to assess differences in variables between iDecide and the print materials group. Continuous variables from the two study arms were compared using t-tests for normally distributed scales and Wilcoxon rank-sum tests for non-normally distributed scales. We used Person's chi-square statistics to assess whether each binary/categorical variable was independent of the study group indicators. To test group differences in continuous measures of our outcomes in each time point, we used t-tests without baseline covariate adjustments. To assess group differences in changes in each outcome between baseline and 3-month follow-up, we used linear mixed-effects model for repeated measures over time, with effects for time as a categorical variable, study group, time-by-group

interaction and co-variates of health literacy. Because education and health literacy measures were highly correlated, and the education measure had more missing responses, we used the health literacy measures for the adjustments. There were no differences in results in sensitivity analyses substituting education for health literacy. Within the mixed-effects model, we estimated 95% CIs and p-values.

Twelve of the 188 study subjects, 6 from each of the two arms, were lost to follow-up. We conducted three sensitivity analyses to assess the possible impact of missing values. First, we repeated analyses by using a balanced sample of subjects who had data for all data points (N=176). Second, we used multiple imputation with 10 replications using linear multivariate regressions to impute for missing values in outcomes (53-54). Third, we assumed there were no improvements in any outcomes among participants missing data, using their baseline values as their three-month follow-up values. In another sensitivity analysis, we assessed statistical significance using a Bonferroni adjusted p-value to account for multiple testing. Analyses were conducted using STATA 13.

Role of Funding Source

The funding sources had no role in study design, conduct, analysis or decision to publish findings.

Results

Participant flow and baseline data

The CONSORT diagram in Figure 1 shows participant flow. Of 391 contacted patients, 188 (48%) were enrolled, 93 allocated to iDecide and 95 to the printed materials group. Participants' baseline characteristics are reported in Table 2. The ethnic and income distribution of participants is representative of CHASS's clinic population. 60% of the community served by CHASS are Spanish-speaking Latinos with an annual median household income of approximately \$20,000 and high rates of diabetes and obesity. 35% are African Americans of similar conditions. More participants randomized to iDecide had completed high school (61%) than those randomized to the printed materials group (35 %, $p<0.001$). Patients in the iDecide group were also less likely to have difficulty with written healthcare information ($p=0.03$) and were more likely to be confident filling out medical paperwork ($p=0.003$). We had complete outcome data on 176 participants (94%).

Three-month outcomes

As Table 3 shows, participants in both groups had significant within-group improvements between baseline and three months in all our primary outcomes: decisional conflict about anti-hyperglycemic medications; knowledge about anti-hyperglycemic medications; and satisfaction with both the clarity and helpfulness of the information they received about their anti-hyperglycemic medications. Significant within-group improvements were also observed in both groups for most secondary outcomes: diabetes care self-efficacy; medication adherence; and A1c. Participants in the iDecide group achieved within-group improvements in diabetes distress, (14.1, within-group $p<.001$) while there were no improvements in the print materials group (-1.6, within-group $p=0.555$).

Among primary outcomes, the mean improvements in clarity and helpfulness of information were significantly greater for participants in the iDecide arm (between-group $p=0.028$, $p=0.007$, respectively). No significant between-group differences were found in improvements in decisional conflict or in knowledge. Among secondary outcomes, significantly greater improvements in mean diabetes distress scores were achieved by participants in the iDecide arm (between-group difference of 15.7, $p<.001$).

In sensitivity analyses, we repeated main analyses using the three described approaches for addressing missing values with no significant changes in results. However, when using the Bonferroni adjusted level of significance of 0.00625 to account for eight tests (.05/8), only between-group differences in changes in diabetes distress scores remained statistically significant.

COMMENT

Among this population of low-income urban Latino and African American adults with diabetes and relatively low levels of formal education and health literacy, participants in both CHW-led interventions reported improvements over three months in all primary outcomes of improved medication decisional conflict, knowledge of anti-hyperglycemic medications, and satisfaction with anti-hyperglycemic medication information. Participants in both arms also reported improvements in diabetes care self-efficacy and medication adherence and had improvements in A1c level. Participants in the iDecide group on average reported greater improvements in satisfaction with anti-hyperglycemic medication information and in levels of diabetes distress than participants in the print materials group. The only between-group difference that remained statistically significant after adjusting for multiple testing in sensitivity analyses, however, was in diabetes distress. There were no significant between-group differences in improvements between baseline and three months in any other primary or secondary outcome.

Our study suggests that both models of CHW-led medication decision support were effective in improving most of our outcomes of interest, a finding consistent with the large and growing body of evidence on the benefits of CHW interventions (12, 13). These findings are encouraging for health care centers that lack resources to adapt and maintain e-health applications, as even already-developed applications require some staff time and resources to enter baseline data on which to tailor and maintain ipads with internet access. Although no study participants received usual care, in our recent prior trial among the same targeted population at CHASS, participants who received usual care had no improvements over a six-month period in their A1c levels, diabetes distress, diabetes care self-efficacy, or medication adherence (37).

This study represents one of the first efforts to respond to the call to evaluate e-Health consumer health applications for use by nontraditional caregivers such as CHWs with ethnic minority and low-literate populations (24, 25). We found no differences in most outcomes, though our findings on the incremental benefit of iDecide over high-quality print materials in participants' reported satisfaction in the helpfulness and clarity of the medication information (a primary outcome) and in reducing diabetes distress (a secondary outcome)

supports the value of continuing to investigate the potential of such tailored, interactive e-Health tools for use by CHWs and other lay helpers with diabetes patients. Satisfaction with received information on treatment options correlates with subsequent treatment satisfaction and adherence and is thus a critically important outcome (1). The iDecide software allowed personally tailored information to be delivered to participants, thus possibly increasing its personal relevance, and enabled participants to engage actively with the information. These features are impossible to achieve in a feasible way in static, print materials.

A number of factors in our study may have contributed to the lack of observed differences between the two groups in the improvements made in most measured outcomes. First, CHWs only reviewed the print materials or iDecide during a single initial face-to-face session between the CHWs and participants. Longitudinal self-management support is often essential in maintaining gains achieved through short-term programs (55). Future intervention studies need to examine which features of the iDecide program should be included in follow-up sessions with CHWs or available for patients to review on their own after the initial session (for example, making the program available to participants online or via smartphone applications and adding features supporting goal and action plan follow-up, medication change updates, and updated lists of questions and concerns for health care providers).

Second, the CHWs who led both intervention groups in this study were well-trained and experienced in delivering diabetes self-management support and counseling. CHWs in both groups also provide a six-month diabetes self-management support program for patients at CHASS (*Journey to Health/Camino a la Salud*) that is more effective than usual care in improving A1c levels and other diabetes outcomes (37). Their level of expertise may have contributed to the improvements from baseline in both groups and may have reduced our chance of identifying an improvement signal with the e-Health tools. In fact, in a focus group among a sample of participants from both arms held at the end of the study period to explore factors contributing to intervention effects, many participants in both groups highlighted the importance of the CHWs rather than the specific modality (iDecide or printed materials). This is similar to what patients with diabetes reported in a qualitative study of the use of similar decision aids with primary care providers (56). Since many health care systems in low-resource settings do not have highly trained CHWs or other outreach workers and often have already-burdened health care staff, it will be important to investigate whether e-Health programs such as iDecide may be even more helpful in assisting less experienced CHWs, other lay health workers, or diabetes patients volunteering to be peer coaches. We are now testing this hypothesis in a trial with diabetes patients trained to serve as peer coaches for other patients with poor glycemic control in a low-resource health care system. A third factor is that, in spite of randomization, a higher percentage of participants who had completed high school and had higher health literacy ended up in the iDecide group. We had hypothesized that the vivid graphical displays and animations in iDecide might be especially more effective than text-heavy print materials among patients with low health literacy. We are now exploring this hypothesis in moderator analyses of intervention effects.

Our study has limitations. As already noted, participants were exposed to the printed or electronic materials in only one session. It will be important to evaluate the effectiveness of e-Health tools like iDecide in longer-term self-management interventions. Second, we tested the two models in only one community health center using well-trained CHWs and thus our results may not generalize to other populations and settings. It will be important to examine the effectiveness of such e-Health tools when used by lay health workers or peers with minimal behavioral counseling training and experience.

In conclusion, medication decision support delivered by highly trained CHWs improved most primary and second outcomes equally well whether the CHWs were using high-quality print materials or interactive, tailored e-Health tools. The e-Health tools, however, led to incremental improvements in satisfaction with the received information on medications and in diabetes distress levels. This study illustrates the potential of combining advances in health information technology with CBPR methods to address health disparities and improve health care and outcomes among low-income ethnic minority adults with diabetes.

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Figure 1.
IDEcide CONSORT Flow Diagram

Comparison between Content and Mode of Delivery between iDecide Study Group and the Printed Materials Group

Table 1

Content (subject matter)	iDecide Intervention	AHRQ Consumer Guide Intervention
Diabetes Information	Spanish and English. Variety of formats (animations, interactive pictographs, issue cards, etc.)	Spanish and English. Print booklets (AHRQ* Consumer guides) with text, pictures, tables, and graphical displays
Uses patient own clinical and laboratory data and patient-reported information to tailor content	Yes (Tailored on current A1c, blood pressure, current anti-hyperglycemic medications, duration of diabetes, reported personal values, level and source of social support, self-efficacy, medication adherence, and reported specific barriers to taking medications and other diabetes self-care)	No
Interactive demonstration of HbA1c control on risk of complications, using tailored risk estimation	Yes	No
Description of anti-hyperglycemic medications and their relevant harms, costs, and inconveniences	Presented as interactive issue cards	Presented in table format
Delivery of Content (Curriculum)	CHW** using iDecide	CHW using Consumer Guides
Motivational Interviewing –based approach	Training of CHWs + embedded Motivational Interviewing prompts	Training of CHWs only
Tailoring/personalizing	Designed into the application and produced by CHW.	Produced by the CHW
Patient Interaction with material	Reading content along with CHW, touching the tablet to select menus and follow their own path, listening and watching.	Reading content along with CHW in printed order.
Goal Setting	Training and prompts in program.	Training and prompts in booklets

* AHRQ is abbreviation for Agency for Healthcare Quality and Research

** CHW is abbreviation for Community Health Worker

Table 2

Participant Baseline Screening Characteristics (N=188)

Characteristic	iDecide (N=93)		Print Materials (N=95)		P-value
	% or mean (SD)	N. of missing	% or mean (SD)	N. of missing	
Age in years	51 (8.6)	0	52 (9.4)	0	0.42
Female gender	76%	0	66%	1	0.12
Hispanic	53%	0	61%	1	0.28
Black	53%	0	32%	0	0.19
Employment Status: Not Working	68%	1	64%	1	0.50
Education: Less than High School	39%	2	65%	2	<0.001
Health Literacy [†] :					
Someone else reads	3.7 (1.5)	0	3.4 (1.6)	0	0.14
Difficulty with written information	3.8 (1.3)	0	3.4 (1.3)	0	0.03
Confident filling forms	2.3 (1.3)	0	2.9 (1.5)	0	0.003
Language: Spanish	48%	0	56%	0	0.25
Annual Income		0		0	0.91
\$15,000	59%		61%		
>\$15,000	16%		17%		
Prefer not to say	25%		22%		
Baseline A1c	8.15 (1.87)	0	8.31 (2.16)	0	0.58
Duration of Diabetes in years	8.89 (6.43)	0	9.26 (6.86)	0	0.70
Baseline Insulin use	44%	0	43%	0	0.90
Number of oral anti-hyperglycemic medications		0		0	0.61
0	24%		18%		
1	48%		50%		
2 or 3	28%		32%		
Self-Rated Health: Poor to Fair	54%	0	53%	0	0.88
Self-management: Poor to Fair	48%	1	45%	0	0.73
Eligible on basis of A1c >7.5%	55%	0	54%	0	0.90

Note:

[†] Values in health literacy range from 1 to 5 (1=Always and 5=Never).

Two-sided tests were used to assess differences in variables between iDecide and the printed material group. P-values were obtained based on t-statistics for continuous variables and based on Person's chi-square statistics for categorical variables.

Table 3

Summary of Within-Group and Between-Group Outcomes

Outcome Variable	Group	Outcome Measure in Time Point =					Change over Time (adjusted)		
		(unadjusted)					Time 3 - Time 1		
		Immediately after session					From Baseline to 3 Months		
		N= 188	Mean (SD)	Between group P-value	N= 187	Mean (SD)	Between group P-value	Mean (95% CI)	Within group P-value
I. Primary Outcomes									
Medication Decisional Conflict	Printed Materials	95	60.7 (16.2)	0.07	95	74.4 (14.7)	0.74	11.5 (8.2 to 14.8)	<0.001
	iDecide	93	56.6 (15.7)		91	74.5 (13.7)		14.1 (10.7 to 17.4)	<0.001
Knowledge about Anti-Hyperglycemic Medications	Printed Materials	95	34.8 (17.4)	0.93	95	52.5 (20.3)	0.81	10.8 (6.4 to 15.1)	<0.001
	iDecide	93	34.8 (17.6)		92	51.3 (20.2)		12.8 (8.4 to 17.2)	<0.001
Satisfaction with Clarity of Medication Information	Printed Materials	95	69.8 (27.9)	0.12	95	88.4 (16.0)	0.56	13.0 (7.1 to 18.7)	<0.001
	iDecide	93	61.3 (33.4)		92	89 (17.5)		22.2 (16.3 to 28.0)	<0.001
Satisfaction with Helpfulness of Medication Information	Printed Materials	95	77.4 (28.7)	0.10	95	91.1 (15.1)	0.4	10.2 (4.5 to 15.9)	<0.001
	iDecide	93	68.6 (33.4)		92	92 (15.9)		21.5 (15.7 to 27.3)	<0.001
II. Secondary and Exploratory Outcomes									
Diabetes Care Self-Efficacy	Printed Materials	95	75.0 (19.2)	0.98	94	82.9 (15.9)	0.14	4.8 (1.8 to 7.7)	0.002
	iDecide	93	74.6 (19.3)		92	86.8 (12.5)		8.1 (5.0 to 11.1)	<0.001
Diabetes Distress	Printed Materials	95	68.0 (26.5)	0.21				-1.6 (-6.9 to 3.7)	0.555
	iDecide	93	62.7 (28.3)		87	76.9 (22.3)	0.05	14.1 (8.7 to 19.5)	<0.001
Medication Adherence	Printed Materials	95	83.9 (19.2)	0.45	89	89.7 (11.9)	0.86	5.7 (2.5 to 8.8)	<0.001
	iDecide	93	87.2 (13.7)		87	90.5 (10.8)		3.4 (0.2 to 6.6)	0.036
A1c	Printed Materials	95	8.3 (2.2)	0.88	89	7.9 (1.9)	0.46	-0.3 (-0.5 to -0.05)	0.016
	iDecide	93	8.2 (1.9)		86	7.8 (1.7)		-0.4 (-0.6 to -0.2)	0.001

Note: Means of each outcome measure at each time point are unadjusted. Means in changes in each outcome measure are estimated from linear mixed-effect models, adjusted for baseline health literacy. All self-reported scales have a range of 0-100 with more positive outcomes reflected by higher numbers (e.g., less medication decisional conflict, higher levels of self-reported medication adherence, and lower diabetes distress are closer to 100.)

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