A Randomized, Controlled Trial

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

Objective: To compare outcomes between community health worker use of a tailored, interactive, Web-based, tablet computer–delivered tool (iDecide) and use of print educational materials.

Design: Randomized, 2-group trial conducted from 2011 to 2013 (ClinicalTrials.gov: NCT01427660).

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

Participants: 188 adults with a hemoglobin A1c value greater than 7.5% (55%) or those who reported questions, concerns, or difficulty taking diabetes medications.

Intervention: Participants were randomly assigned to receive a 1- to 2-hour session with a community health worker who used iDecide or printed educational materials and 2 follow-up calls.

Measurements: Primary outcomes were changes in knowledge about antihyperglycemic medications, patient-reported medication decisional conflict, and satisfaction with antihyperglycemic medication information. Also examined were changes in diabetes distress, self-efficacy, medication adherence, and hemoglobin A1c values.

Results: Ninety-four percent of participants completed 3-month follow-up. Both groups improved across most measures. iDecide participants reported greater improvements in satisfaction with medication information (helpfulness, \( P = 0.007 \); clarity, \( P = 0.03 \)) and in diabetes distress compared with the print materials group (\( P < 0.001 \)). The other outcomes did not differ between the groups.

Limitations: The study was conducted at 1 health center during a short period. The community health workers were experienced in behavioral counseling, thereby possibly mitigating the need for additional support tools.

Conclusion: Most outcomes were similarly improved among participants receiving both types of decision-making support for diabetes medication. 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 3 months translate into better longer-term diabetes outcomes.

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terventions to meet this need among African American and Latino adults with diabetes in Detroit, Michigan. 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 to work as bridges between their ethnic, cultural, or geographic communities and health care providers (13).

Two cohorts of participants in our previous CHW-led diabetes self-management support interventions improved hemoglobin A1c (HbA1c) levels and diabetes distress compared with usual care (14, 15). An important next step in increasing the potential effect of CHWs and other lay health care 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 as part of 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).

Software programs that are being developed to automatically embed tailored content into portable e-health Web applications 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 with reliance 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 wireless 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 with CHW delivery of the same evidence-based information, without tailoring, through print consumer booklets developed by the Agency for Healthcare Research and Quality (AHRQ).

**METHODS**

**Setting**

This study was developed and implemented by using community-based participatory research 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 more than 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 HbA1c. They also provide information on administration methods, costs, medication adverse effects, risks for diabetes complications, suggested questions to discuss with health care providers, and prompts to make notes 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 community-based participatory research and user-centered design (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 into 4 main sections and includes the same content as the AHRQ consumer guides. However, its information is presented in a more graphical style suited to patients with low literacy.

Table 1 summarizes key differences between the presentation of information in iDecide and the printed materials. The first section illustrates, through animations, how diabetes affects the way glucose is processed in the body and how different medication classes, foods, and physical activity affect blood glucose. The second section includes photographs showing participants’ own risk for diabetes complications (tailored according to their baseline HbA1c) and enabling participants to explore how their risk for different complications changes with their HbA1c levels. In the third section, participants review their current diabetes medications (tailored according to their baseline HbA1c) and barriers to taking the 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 (for example, cost, adverse effects, effects on weight, and 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 (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 discover their motivation, overcome barriers to change, and develop an action plan (36).

**Recruitment and Randomization**

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 a HbA1c value greater than 7.5% in the previous 6 months or expressed concerns about current diabetes medications during the screening assessment. Exclusion criteria were age younger than 21 years, terminal health conditions, self-reported alcohol or drug abuse, and conditions (such as blindness and dementia) that would impede meaningful participation. Pregnant women and individuals who reported that they could not be contacted by telephone 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 facilitated completion of written informed consent, administered baseline surveys in English or Spanish, and measured HbA1c and blood pressure. Participants received a stipend of $20 after each assessment. Within 1 to 14 days, participants were scheduled for a visit with a CHW (at home, the clinic, or another agreed-upon place).

At the beginning of the CHW visits, participants were registered into the iDecide program and randomly assigned by the computer program, through use of a random-sequence algorithm, into 1 of 2 study groups. There were no differences between the steps to participate in either study group. 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, and the sessions using printed materials lasted approximately 1.5 hours. All 4 project CHWs were employed by CHASS and had undergone 80 hours of initial training in motivational interviewing–based communication approaches and diabetes self-management support, with 4 to 8 hours of booster training annually. The CHWs had an average of 6 years of experience leading diabetes self-management training programs with adult diabetic patients (14, 37). The CHWs reviewed the content (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-

### Table 1. Comparison of Content and Mode of Delivery Between the iDecide Study Group and the Printed Materials Group

<table>
<thead>
<tr>
<th>Variable</th>
<th>iDecide Intervention</th>
<th>AHRQ Consumer Guide Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Content (subject matter)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes information</td>
<td>Spanish and English, variety of formats (e.g., animations, interactive pictographs, issue cards)</td>
<td>Spanish and English, printed booklets (AHRQ consumer guides) with text, pictures, tables, and graphical displays</td>
</tr>
<tr>
<td>Uses patient’s own clinical and laboratory data and patient-reported information to tailor content?</td>
<td>Yes (Tailored on current HbA1c, blood pressure, current antihyperglycemic 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)</td>
<td>No</td>
</tr>
<tr>
<td>Interactive demonstration of HbA1c control on risk for complications by using tailored risk estimation?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Description of antihyperglycemic medications and their relevant harms, costs, and inconveniences</td>
<td>Presented as interactive issue cards</td>
<td>Presented in table format</td>
</tr>
<tr>
<td><strong>Delivery of content (curriculum)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motivational interviewing–based approach</td>
<td>Training of CHWs and embedded motivational interviewing prompts</td>
<td>Training of CHWs only</td>
</tr>
<tr>
<td>Tailoring/personalizing</td>
<td>Designed into the application and produced by CHW</td>
<td>Produced by CHW</td>
</tr>
<tr>
<td>Patient interaction with material</td>
<td>Reading content along with CHW, touching the tablet to select menus and follow their own path, listening and watching</td>
<td>Reading content along with CHW in printed order</td>
</tr>
<tr>
<td>Goal setting</td>
<td>Training and prompts in program</td>
<td>Training and prompts in booklets</td>
</tr>
</tbody>
</table>

AHRQ = Agency for Healthcare Research and Quality; CHW = community health worker; HbA1c = hemoglobin A1c.
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 or action steps the participant made during the session. These telephone contacts took place 3 and 6 weeks after the initial face-to-face session.

### Outcome Measures

Self-reported outcomes were measured via survey at baseline and 3 months. We designed both interventions to improve decisional conflict regarding antihyperglycemic medication (38), knowledge and beliefs about antihyperglycemic medications (39), and satisfaction with medication information (clarity and helpfulness) (22). We thus chose these as our primary outcomes. In previous interventions, improvements in diabetes care self-efficacy (40), diabetes distress (41), and medication adherence (42), as measured by the validated scales we used, were associated with subsequent improvements in HbA\(_1c\) 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 (for example, better medication adherence and less diabetes distress).

We calculated the sample size to provide 80% power to detect a small to moderate between-group effect size of 0.30 to 0.40 in our primary outcome measures, assuming a 2-tailed \(P\) value of 0.05, which would require a final sample size of 84 in each group (50). We estimated that 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 3 months from randomization, we did not consider HbA\(_1c\) a study outcome and did not power the study to detect between-group differences in HbA\(_1c\) of less than 0.5 percentage point. We needed to collect baseline HbA\(_1c\) measurements to provide tailored information in the iDecide program and for the CHW–patient discussions in both groups on risks for diabetes complications, current antihyperglycemic medications, and possible medication changes. Thus, we also decided to collect HbA\(_1c\) measurements at 3 months. These data would enable us to assess whether either group showed a trend toward lower HbA\(_1c\) values with the goal of developing longer-term interventions with reduced HbA\(_1c\) levels as a primary outcome. Baseline and 3-month HbA\(_1c\) values were measured with a Bayer DCA 2000+ point-of-care analyzer (51). The assay has a test coefficient of variation less than 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 2 study groups were compared by using \(t\)-tests for normally distributed scales and Wilcoxon rank-sum tests for non-normally distributed scales. We used Pearson chi-square statistics to assess whether each binary and 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 models for repeated measures over time, including as independent variables that were time-coded as a categorical variable, study group, time-by-group interaction, and the health literacy measures. We used the health literacy measures as covariates because education and health literacy measures were highly correlated, and the education measure had more missing responses. There were no differences in results in sensitivity analyses that substituted education for health literacy. Within the mixed-effects models, we estimated 95% CIs and \(P\) values.

Twelve of the 188 study participants, 6 from each of the 2 groups, were lost to follow-up. We conducted 3 sensitivity analyses to assess the possible effect of missing values. First, we repeated analyses by using a balanced sample of participants 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 no outcomes improved among participants missing data, using their baseline values as their 3-month follow-up values. In another sensitivity analysis, we assessed statistical significance by using a Bonferroni-adjusted \(P\) value to account for multiple testing. Analyses were conducted by using Stata software, version 13 (StataCorp).

### Role of the Funding Source

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

### RESULTS

#### Participant Flow and Baseline Data

The Consolidated Standards of Reporting Trials diagram in the Figure shows the flow of participants through the study. Of 391 contacted patients, 188 (48%) were enrolled; 93 of these were 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. Sixty percent 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. Thirty-five percent are African Americans with similar backgrounds. More participants randomly assigned to iDecide had completed high school (61%) than those assigned to the printed materials
Patients in the iDecide group were also less likely to have difficulty with written health care information (\(P/H11005\) 0.03) and were more likely to be confident when filling out medical paperwork (\(P/H11005\) 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 3 months in all our primary outcomes: decisional conflict about antihyperglycemic medications, knowledge about antihyperglycemic medications, and satisfaction with both the clarity and helpfulness of the information they received about their antihyperglycemic medications. Significant within-group improvements were also observed in both groups for most secondary outcomes: diabetes care self-efficacy, medication adherence, and HbA1c. Participants in the iDecide group achieved within-group im-
provements in diabetes distress (14.1; within-group $P < 0.001$), whereas 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 group (between-group $P = 0.028$ and $P = 0.007$, 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 group (between-group difference, 15.7; $P < 0.001$).

In sensitivity analyses, we repeated main analyses by using the three described approaches for addressing missing values, with no significant changes in results. However, when we used the Bonferroni-adjusted level of significance of 0.00625 to account for 8 tests (0.05/8), only between-group differences in changes in diabetes distress scores remained statistically significant.

**DISCUSSION**

In 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 3 months in all primary outcomes of improved medication decisional conflict, knowledge of antihyperglycemic medications, and satisfaction with information on antihyperglycemic medications. Participants in both groups also reported improvements in diabetes care self-efficacy and medication adherence and had improvements in HbA1c level. Participants in the iDecide group on average reported greater improvements in satisfaction with antihyperglymic medication information and in levels of diabetes distress than did participants in the print materials group. The only between-group difference that remained statistically significant after adjustment for multiple testing in sensitivity analyses, however, was in diabetes distress. There were no significant between-group differences in improvements between baseline and 3 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 because even already-developed applications require some staff time and re-

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**Table 2. Participant Baseline Screening Characteristics ($n = 188$)*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>iDecide ($n = 93$)</th>
<th>Print Materials ($n = 95$)</th>
<th>$P$ Value for Between-Group Difference†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>51 (8.6)</td>
<td>52 (9.4)</td>
<td>0.42</td>
</tr>
<tr>
<td>Gender, %</td>
<td>76</td>
<td>66</td>
<td>1.12</td>
</tr>
<tr>
<td>Hispanic, %</td>
<td>53</td>
<td>61</td>
<td>0.28</td>
</tr>
<tr>
<td>Black, %</td>
<td>41</td>
<td>32</td>
<td>0.19</td>
</tr>
<tr>
<td>Employment status: not working, %</td>
<td>68</td>
<td>64</td>
<td>0.50</td>
</tr>
<tr>
<td>Education: less than high school, %</td>
<td>39</td>
<td>65</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Others reads</td>
<td>3.7 (1.5)</td>
<td>3.4 (1.6)</td>
<td>0.14</td>
</tr>
<tr>
<td>Difficulty with written information</td>
<td>3.8 (1.3)</td>
<td>3.4 (1.3)</td>
<td>0.03</td>
</tr>
<tr>
<td>Confident completing forms</td>
<td>2.3 (1.3)</td>
<td>2.9 (1.5)</td>
<td>0.003</td>
</tr>
<tr>
<td>Language: Spanish, %</td>
<td>48</td>
<td>56</td>
<td>0.25</td>
</tr>
<tr>
<td>Annual income, %</td>
<td>0</td>
<td>0</td>
<td>0.91</td>
</tr>
<tr>
<td>&lt;$15 000</td>
<td>59</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td>$&gt;$15 000</td>
<td>16</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>25</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Baseline HbA1c, %</td>
<td>8.15 (1.87)</td>
<td>8.31 (2.16)</td>
<td>0.58</td>
</tr>
<tr>
<td>Duration of diabetes, y</td>
<td>8.89 (6.43)</td>
<td>9.26 (6.86)</td>
<td>0.70</td>
</tr>
<tr>
<td>Baseline insulin use, %</td>
<td>44</td>
<td>43</td>
<td>0.90</td>
</tr>
<tr>
<td>Oral antihyperglycemic medications, %</td>
<td>24</td>
<td>18</td>
<td>0.61</td>
</tr>
<tr>
<td>1 or 2</td>
<td>48</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>2 or 3</td>
<td>28</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>Self-rated health: poor to fair, %</td>
<td>54</td>
<td>53</td>
<td>0.88</td>
</tr>
<tr>
<td>Self-management: poor to fair, %</td>
<td>48</td>
<td>45</td>
<td>0.73</td>
</tr>
<tr>
<td>Eligible on basis of HbA1c &gt;7.5%, %</td>
<td>55</td>
<td>54</td>
<td>0.90</td>
</tr>
</tbody>
</table>

HbA1c = hemoglobin A1c.

* Values expressed with numbers in parentheses are the means (SDs).
† $P$ values were obtained on the basis of $t$-statistics for continuous variables and Pearson chi-square statistics for categorical variables.
‡ Values in health literacy range from 1 to 5 (1 = always; 5 = never). Two-sided tests were used to assess differences in variables between the iDecide and printed material groups.
Table 3. Summary of Within-Group and Between-Group Outcomes*

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Group</th>
<th>Outcome Measure in Time Point (Unadjusted)</th>
<th>Between-Group P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 1: Baseline</td>
<td>Time 2: Immediately After Session</td>
<td>P Value</td>
</tr>
<tr>
<td></td>
<td>Patients (n = 188), n</td>
<td>Mean (SD)</td>
<td>Between-Group P Value</td>
</tr>
<tr>
<td>Primary outcomes</td>
<td>Printed materials</td>
<td>95</td>
<td>60.7 (16.2)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>56.6 (15.7)</td>
</tr>
<tr>
<td>Knowledge about antihyperglycemic medications</td>
<td>Printed materials</td>
<td>95</td>
<td>34.8 (17.4)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>34.8 (17.6)</td>
</tr>
<tr>
<td>Satisfaction with clarity of medication information</td>
<td>Printed materials</td>
<td>95</td>
<td>69.8 (27.9)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>61.3 (33.4)</td>
</tr>
<tr>
<td>Satisfaction with helpfulness of medication information</td>
<td>Printed materials</td>
<td>95</td>
<td>77.4 (28.7)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>68.6 (33.4)</td>
</tr>
</tbody>
</table>

Secondary and exploratory outcomes

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Group</th>
<th>Outcome Measure in Time Point (Unadjusted)</th>
<th>Between-Group P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 1: Baseline</td>
<td>Time 2: Immediately After Session</td>
<td>P Value</td>
</tr>
<tr>
<td></td>
<td>Patients (n = 188), n</td>
<td>Mean (SD)</td>
<td>Between-Group P Value</td>
</tr>
<tr>
<td>Diabetes care self-efficacy</td>
<td>Printed materials</td>
<td>95</td>
<td>75.0 (19.2)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>74.6 (19.3)</td>
</tr>
<tr>
<td>Diabetes distress</td>
<td>Printed materials</td>
<td>95</td>
<td>68.0 (26.5)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>62.7 (28.3)</td>
</tr>
<tr>
<td>Medication adherence</td>
<td>Printed materials</td>
<td>95</td>
<td>83.9 (19.2)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>87.2 (13.7)</td>
</tr>
<tr>
<td>HbA1c</td>
<td>Printed materials</td>
<td>95</td>
<td>8.3 (2.2)</td>
</tr>
<tr>
<td></td>
<td>iDecide</td>
<td>93</td>
<td>8.2 (1.9)</td>
</tr>
</tbody>
</table>

HbA1c = hemoglobin A1c.

* 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 to 100, with more positive outcomes reflected by higher numbers (e.g., less medication decisional conflict, higher levels of self-reported medication adherence, and less diabetes distress are closer to 100).

Many factors in our study may have contributed to the lack of observed differences between the 2 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 that support 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 6-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 HbA1c 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 groups held at the end of the study period to explore fac-

sou resources to enter baseline data on which to tailor and maintain tablet computers 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 during a 6-month period in their HbA1c levels, diabetes distress, diabetes care self-efficacy, or medication adherence (37). This study is among 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-literacy populations (24, 25). We found no differences in most outcomes, although 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) support the value of continuing to investigate the potential of such tailored, interactive e-health tools for use by CHWs and other lay helpers with diabetic 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.
tors contributing to intervention effects, many participants in both groups highlighted the importance of the CHWs rather than the specific method (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). Because 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 diabetic patients volunteering to be peer coaches. We are now testing this hypothesis in a trial with diabetic patients trained to serve as peer coaches for other patients with poor glycemic control in a low-resource health care system.

Third, despite randomization, more 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 had 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 such e-health tools as iDecide in longer-term self-management interventions. Second, we tested the 2 models in only 1 community health center by using well-trained CHWs; thus, our results may not be generalizable 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 secondary outcomes equally well, regardless of 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 community-based participatory research methods to address health disparities and improve health care and outcomes among low-income ethnic minority adults with diabetes.

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References


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Supplement
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