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Mediators and Moderators of Improvements in Medication Adherence: Secondary Analysis of a Community Health Worker–Led Diabetes Medication Self-Management Support Program

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Abstract

Objective. In a randomized controlled trial we compared two models of community health worker–led diabetes medication decision support for low-income Latino and African American adults with diabetes. Most outcomes were improved when community health workers used either an interactive e-Health tool or print materials. This article investigates mediators and moderators of improved medication adherence in these two models. *Method*. Because both programs significantly improved satisfaction with medication information, medication knowledge, and decisional conflict, we examined whether improvements in each of these outcomes in turn were associated with improvements in self-reported medication adherence, and if so, whether these improvements were mediated by improvements in diabetes self-efficacy or diabetes distress. Potential moderators of improvement included gender, race/ethnicity, age, education, insulin use, health literacy, and baseline self-efficacy, diabetes distress, and A1c. *Results*. A total of 176 participants (94%) completed all assessments. After adjusting for potential confounders, only increased satisfaction with medication information was correlated with improved medication adherence (p = .024). Improved self-efficacy, but not diabetes distress, was associated with improvements in both satisfaction with medication information and medication adherence. However, the Sobel–Goodman Mediation test did not support improvements in self-efficacy as a mechanism by which improved satisfaction led to better adherence. None of the examined variables achieved statistical significance as moderators. *Conclusions*. Improvements in satisfaction with medication information but not in medication knowledge or decision conflict were associated with improvements in medication adherence. Interventions that target low-income ethnic and racial minorities may need to focus on increasing participants' satisfaction with information provided on diabetes medications and not just improving their knowledge about medications. Future research should explore in more depth other possible mediators and moderators of improvements in medication adherence in low-income minority populations.

Keywords

chronic disease management, community health worker, computer-mediated health promotion, diabetes, health behavior, lay health workers, patient education, randomized controlled trial, self-management, tailored e-health, tailored or targeted interventions

More than 25 million people in the United States have type 2 diabetes (Centers for Disease Control and Prevention, 2011). The demands of managing diabetes are costly, complex, and time consuming (American Diabetes Association, 2013). Patients must initiate and sustain multiple self-management behaviors between health care visits (Montori, Gafni, & Charles, 2006). Yet patient adherence to prescribed medications and other recommended self-management behaviors is often low (Cramer, 2004), which can lead to

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Table 1. Participant Baseline Screening Characteristics (N = 188).

	iDecide (n = 93)		Print materials (n = 95)		Between-group difference
Characteristic	% or M (SD)	No. of missing	% or M (SD)	No. of missing	p value
Age in years	51 (8.6)	0	52 (9.4)	0	.42
Female gender	76%	0	66%	1	.12
Hispanic	53%	0	61%	1	.28
African American	41%	0	32%	0	.19
Health literacy[a]					
Confident filling forms	2.3 (1.3)	0	2.9 (1.5)	0	.003

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

increased rates of hospitalizations, emergency room visits (Jha, Aubert, Yao, Teagarden, & Epstein, 2012), complications, and mortality (Ho et al., 2006). Diabetic patients from ethnic minorities and of lower socioeconomic status tend to have lower medication adherence (Rolnick, Pawloski, Hedblom, Asche, & Bruzek, 2013; Trinacty et al., 2009), higher risk of morbidity and mortality, and lower quality of care than White and higher SES patients (Lanting, Joung, Mackenbach, Lamberts, & Bootsma, 2005).

There is thus a pressing need to develop interventions to support and improve self-management among low-income, ethnic and racial minority diabetic patients. A growing body of evidence supports the effectiveness of interventions that are culturally tailored (Peek, Cargill, & Huang, 2007), involve one-on-one interpersonal interactions with trusted supporters such as community health workers (CHWs; Betancourt, Duong, & Bondaryk, 2012), and are community based (M. Shah, Kaselitz, & Heisler, 2013). CHWs both educate and provide support to patients, thereby increasing patients' confidence and motivation to care for their diabetes (Heisler et al., 2009). Interventions using CHWs have found improvements in HbA1c and diabetes knowledge (Duggan et al., 2014) and could therefore be a powerful tool for reducing diabetes health disparities. Tailored e-Health tools also show promise for patient education and decision support, but have not been widely tested in CHW and other lay health worker interventions among populations with low health literacy.

Many factors influence whether patients take their diabetes medications as prescribed (Anderson & Funnell, 2000). Both patients' knowledge of medications (MK; Ahmad, Ramli, Islahudin, & Paraidathathu, 2013; Al-Qazaz et al., 2011; Munoz, Dorado, Guerrero, & Martinez, 2014; Weymiller et al., 2007) and satisfaction with information provided on their prescribed medications (Alhewiti, 2014; Horne, Hankins, & Jenkins, 2001) have been associated with medication adherence. Medication knowledge has long been acknowledged as important in understanding of and adherence to medication regimens. However, individuals differ in their preferences for the amount of information received and means of information delivery (Horne et al., 2001). Satisfaction with medication information is thus also an important measure to assess quality of an education intervention.

In a recent randomized controlled trial (Heisler et al., 2014), we examined whether two CHW-led approaches would improve satisfaction with diabetes medication information, diabetes medication knowledge, and decrease medication decisional conflict among low-income Latino and African American adults with type 2 diabetes receiving care at a federally qualified health center in southwest Detroit. Participants were randomized to one of two groups receiving a brief CHW-led intervention consisting of an initial home visit and two follow-up calls. One group received the services of the CHW using the iPad decision aid (iDecide) tool, an interactive tailored e-health tool, while the other received the CHW services providing the same information through printed diabetes materials. The print materials included both information on diabetes and diabetes medications (oral and insulin) including effectiveness, cost, and side effects. The iDecide tool was designed to be more accessible to patients with low health literacy. It consisted of animations describing diabetes disease processes, graphical depictions related to the patient's personal diabetes risk profile, and interactive options for patients to explore how their risk profile could change at different A1c levels and how they could choose a specific medication based on their preferences related to cost, effectiveness, and side effects.

Both groups achieved significant improvements in the main outcomes of satisfaction with medication information, medication knowledge, and decisional conflict 3 months after the intervention. Improvements in satisfaction with medication information and diabetes distress in the iDecide group were significantly greater than in the printed materials group. Tables 1 and 2 contain participant baseline screening characteristics and each measure's means and standard deviations at baseline and 3-month follow-up, respectively.

To guide the development of future interventions building on this work, it is important to understand whether the improvements observed in our primary outcomes of satisfaction with medication information, medication knowledge, and decisional conflict were in turn associated with improvements in medication adherence. In designing our decision support intervention, we hypothesized that these three

Table 2. Summary of Main Outcome Variables and Potential Mediators.

		Outcome measure in time point (unadjusted)						Change over time (adjusted)		
		Time 1: Baseline (*N* = 188)			Time 3: Three months later (*N* = 176)			Time 3 − 1: From baseline to 3 months		
Variable	Group	*n*	*M* (*SD*)	Between group *p* value	*n*	*M* (*SD*)	Between group *p* value	*M* (95% CI)	Within group *p* value	Between group *p* value
Medication adherence (MA)	Print	95	83.9 (19.2)	.45	89	89.7 (11.9)	.86	5.7 (2.5 to 8.8)	**<.001**	.33
	iDecide	93	87.2 (13.7)		87	90.5 (10.8)		3.4 (0.2 to 6.6)	**.036**	
Main outcome variables										
Satisfaction with medication information (SMI)	Print	95	77.4 (28.7)	.10	89	87.6 (17.9)	.29	10.2 (4.5 to 15.9)	**<.001**	**.007**
	iDecide	93	68.6 (33.4)		87	90.4 (17.2)		21.5 (15.7 to 27.3)	**<.001**	
Medication knowledge (MK)	Print	95	34.8 (17.4)	.93	89	45.7 (21.8)	.84	10.8 (6.4 to 15.1)	**<.001**	.51
	iDecide	93	34.8 (17.6)		87	47.4 (18.5)		12.8 (8.4 to 17.2)	**<.001**	
Decisional conflict (DC)	Print	95	60.7 (16.2)	.07	89	72.3 (13.2)	.53	11.5 (8.2 to 14.8)	**<.001**	.3
	iDecide	93	56.6 (15.7)		86	70.9 (13.7)		14.1 (10.7 to 17.4)	**<.001**	
Potential mediators										
Self-efficacy (SE)	Print	95	75.0 (19.2)	.98	89	80.0 (16.6)	.05	4.8 (1.8 to 7.7)	**.002**	.13
	iDecide	93	74.6 (19.3)		87	83.3 (19.5)		8.1 (5.0 to 11.1)	**<.001**	
Diabetes distress (DD)	Print	95	68.0 (26.5)	.21	89	66.5 (30.7)	.05	-1.6 (-6.9 to 3.7)	.555	**<.001**
	iDecide	93	62.7 (28.3)		87	76.9 (22.3)		14.1 (8.7 to 19.5)	**<.001**	

Note. *p* values are bolded if less than 0.05. 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 lower diabetes distress are closer to 100).

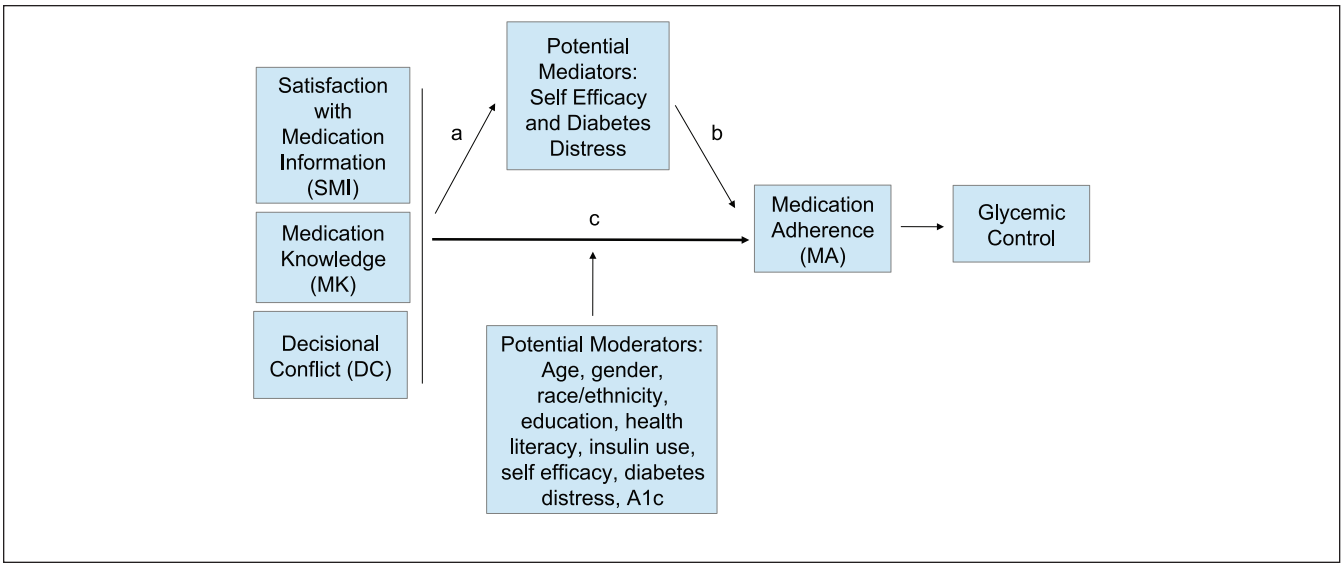

Figure 1. Conceptual model.

outcomes would be associated with improved medication adherence. If one or more of these primary outcomes were associated with improved medication adherence, it is also important to understand the mechanisms ("mediators") for these observed effects. Multiple studies have found strong associations between increased self-efficacy (K. R. Lorig et al., 2001; Mishali, Omer, & Heymann, 2011; Nakahara et al., 2006; K. M. Nelson, McFarland, & Reiber, 2007) and decreased diabetes distress (Aikens, 2012; Fisher et al., 2013; Fisher, Glasgow, & Strycker, 2010) with improved medication adherence and other diabetes clinical outcomes. We hypothesized that by improving participants' satisfaction with information received on their diabetes medications, knowledge of these medications, and decisional conflict about taking these medications, our intervention might in turn increase their self-efficacy and reduce the distress associated with their diabetes, both of which could contribute to improvements in medication adherence (see Figure 1). The current study was not powered to detect differences in A1c of less than 0.5%. Medication adherence was thus our main outcome variable, but we included glycemic control in our conceptual model as a reminder that medication adherence is an important contributor to glycemic control.

Equally important as identifying mediators of effects is understanding characteristics of participants who gained the most benefit from these CHW-led interventions in order to guide targeting of future similar interventions. Such baseline characteristics that show an interactive effect with intervention outcomes are called "moderators" (Kraemer, Wilson, Fairburn, & Agras, 2002). In this article, we examined potential mediators and moderators of the intervention's effect according to the original conceptual model that informed the design of the intervention (Figure 1). Along with baseline patient characteristics such as age, gender, race/ethnicity, education level, health literacy, insulin use, and A1c, we also examined baseline self-efficacy and diabetes distress levels as potential moderators as we hypothesized participants with low self-efficacy and high diabetes distress at baseline might benefit disproportionately from the intervention, even if intervention effects were not mediated by improvements in these.

Our specific questions were the following:

1. Are improvements achieved in both intervention groups in satisfaction with diabetes medication information, medication knowledge, and decisional conflict in turn associated with improvements in medication adherence?
2. Are diabetes self-efficacy or diabetes distress significant mediators in the relationship between improvements in our primary outcomes and changes in medication adherence?
3. Do baseline characteristics of age, gender, race/ethnicity, education level, health literacy, insulin use, self-efficacy, diabetes distress or A1c moderate the relationship between change in our primary outcomes and change in medication adherence?

Method

Setting, Recruitment, Intervention, and Measures

Details on recruitment, interventions, outcomes, and results of the randomized controlled trial are described briefly and in detail elsewhere (Heisler et al., 2014). Self-reported outcome measures were collected using validated surveys at baseline and 3 months. All measures were scaled from 0 to 100, with higher numbers indicating more positive outcomes

(e.g., better medication adherence, lower diabetes distress). Outcome measures included the following (see the appendix for complete measures):

1. *Medication adherence:* A validated eight-item scale of self-reported medication adherence (Morisky, Green, & Levine, 1986). Participants were asked to consider their diabetes medications in answering the questions.
2. *Satisfaction with medication information:* This three-item scale has been used in prior diabetes medication decision tool randomized controlled trials (Mullan et al., 2009; Weymiller et al., 2007). Participants are asked to describe their satisfaction with the amount, clarity, and helpfulness of the information they had received from their health care team (including CHWs) about their "blood sugar medications."
3. *Medication knowledge:* This consists of 11 true/false questions about the effects of diabetes medications (Weymiller et al., 2007).
4. *Decisional conflict:* This scale consists of 16 questions focusing on the confidence the participant felt about key aspects of decision making about their anti–hyperglycemic medications (O'Connor, 1995).

Scales used to assess potential mediators and moderators were the following:

5. *Diabetes self-efficacy*: This five-item scale focuses on how confident the participant feels in five key areas related to managing diabetes (A. Lorig, 1986).
6. *Diabetes distress*: This is a two-item scale assessing the extent to which the participant has been troubled over the prior month by "feeling overwhelmed by the demands of living with my diabetes" and/or "feeling that I am often failing with my health routine" (Polonsky et al., 2005).
7. *Health literacy*: This was measured with a single validated item: "How often do you have problems understanding written materials?" with five response options ranging from *Always* to *Never* (Chew, Bradley, & Boyko, 2004).

Both groups improved significantly for most outcomes over the 3 months (see Table 2; Heisler et al., 2014). Thus, in the analysis of the current article we examined whether the observed improvements in the outcomes in both groups were associated with medication adherence and what baseline characteristics in both groups may have moderated improvements in outcomes.

Statistical Analyses

To examine whether changes in satisfaction with medication information, medication knowledge, or decisional conflict were associated with changes in medication adherence over the course of the 3-month intervention, we performed bivariate and multivariate linear regressions with each of these as the principal independent variables and change in adherence as the outcome variable. Covariates include gender, race/ethnicity, and health literacy.

We next conducted tests of whether self-efficacy or diabetes distress were mediators in the bivariate relationships between each of our three primary outcomes and medication adherence. We sequentially assessed the following relationships because for a variable to be a mediator there must be a significant relationship between each of the following (see Figure 1 for mediation model):

1. Between the explanatory variable and the outcome (c)
2. Between the explanatory variable and the potential mediator (a);
3. Between the potential mediator and the outcome variable (b)

Multivariate linear regressions were used to determine the significance of each relationship. If all three relationships were significant, then Sobel–Goodman Mediation Tests were conducted to assess whether Relationship (c) decreased significantly on the addition of the mediator to the model (Aroian, 1944; Bruin, 2006; MacKinnon & Dwyer, 1993; MacKinnon, Warsi, & Dwyer, 1995; Preacher & Hayes, 2004).

Finally, we assessed whether sociodemographic factors (sex, race/ethnicity, age) or baseline clinical and psychosocial attributes (education level, health literacy, insulin use, HbA1c, self-efficacy, diabetes distress) moderated the relationship between change in satisfaction with medication information, medication knowledge, or decisional conflict and change in adherence. For this analysis, we added an interaction term of each of the three explanatory variables and the potential moderator to the multivariate linear regression with change in adherence as the outcome variable. We then examined the significance of the interaction term to determine whether the relationship was significantly different for different subgroups. Finally, we examined relationships between change in each of our primary outcomes and change in medication adherence within each subgroup.

Results

Description of the Sample

A total of 176 participants (94%) completed all assessments. Relevant patient baseline characteristics are reported in Table 1. The average age was 51.5 years, 71% were women, 57% were Latino, 50% were African American, 31% were unemployed, and mean HbA1c was 8.22%.

Results of Main Relationships

Results from linear regressions showed a significant association between change in satisfaction with medication

Table 3. Main Relationships.

	Outcome: Correlation with change in medication adherence			
	Bivariate		Multivariate[a]	
Outcome variables	Coefficient	*p* value	Coefficient	*p* value
1. Change in satisfaction with medication information	.084	**.024**	.092	**.019**
2. Change in medication knowledge	.085	.140	.085	.155
3. Change in decisional conflict	.031	.674	.035	.646

Note. *p* values are bolded if less than 0.05.
[a]Covariates include sex, race/ethnicity, and baseline health literacy level.

Table 4. Results of Mediation Tests.

	Correlation with predictor and outcome[a]					
	Change in SMI (relationship a)		Change in MA (relationship b)		Sobel–Goodman mediation test	
Potential mediator	Coefficient	*p* value	Coefficient	*p* value	Indirect effect	*p* value
1. Self-efficacy	.087	**.022**	.165	**.039**	.012	.169
2. Diabetes distress	.104	.137	—	—	—	—

Note. *p* values are bolded if less than 0.05. SMI = satisfaction with information provided on their prescribed medications; MA = medication adherence.
[a]See Figure 1 for mediation model.

information and change in medication adherence (p = .024). This relationship remained significant after controlling for gender, race/ethnicity, and health literacy (p = .019). However, changes in medication knowledge and in decisional conflict were not significantly related with change in adherence (p = .67 and p = .14, respectively; Table 3).

Results of Mediator Analysis

Change in satisfaction with medication information was the only study outcome variable that was significantly associated with change in medication adherence. Therefore, we focused on the relationship between change in satisfaction and change in adherence to assess whether diabetes self-efficacy and diabetes distress were potential mediators in the relationship. As shown in Table 4, self-efficacy was significantly related with change in satisfaction with medication information (coefficient .087, p = .022) and with change in adherence (coefficient .165, p = .039) while diabetes distress was not. To determine the indirect effect—the amount of variation in change in adherence as explained by change in satisfaction with medication information through the mechanism of change in self-efficacy—we then performed the Sobel–Goodman Mediation tests. The test results did not support self-efficacy as a significant mediator, as the effect of change in satisfaction with medication information on change in adherence was not significantly reduced by the addition of self-efficacy to the model (indirect effect = .012, p = .169).

Results of Moderator Analyses

Table 5 shows the results of the moderator analyses. The group difference in the association between change in satisfaction with medication information and change in medication adherence was not statistically significant for any of the potential moderators, although there was a trend toward significance for baseline A1C level (≤7 vs. >7; p = .060). Our subgroup analyses show that the relationship was significant for those with high baseline A1c (coefficient .173, p = .003) but not for those with lower baseline A1c (coefficient .031, p = .543). Similarly, change in satisfaction with medication information was significantly associated with change in adherence for women (coefficient .098, p = .033) and participants not using insulin at baseline (coefficient .133, p = .014), with high self-efficacy (coefficient .138, p = .014), with less than a high school education (coefficient .134, p = .016), with identifying as African American (coefficient .046, p = .046), and with lower health literacy levels (coefficient .136, p = .005). We did not find any significant relationship between change in satisfaction with medication information and change in adherence among men, or among participants using insulin, with low self-efficacy, with more than a high school education, identifying as Latin, or with higher health literacy levels.

Discussion

In this sample of low-income Latino and African American adults with diabetes, improvements in satisfaction with

Table 5. Moderator Results.

Potential moderator	Coefficient	*p* value	Difference in coefficient	*p* value
Gender				
Female	.098	**.033**	.022	.804
Male	.076	.317		
Race/ethnicity				
Hispanic	.075	.221	H&AA: .036	.658
African American	.112	**.046**		
Other	.092	.497	H&O: .017	.911
Age				
<50	.100	.134	.022	.789
>50	.079	.097		
Education level				
<High school	.134	**.016**	.077	.314
>High school	.056	.313		
Health literacy				
Low	.136	**.005**	.112	.119
High	.017	.786		
Insulin use				
Not using	.133	**.014**	.079	.297
Using	.055	.318		
Baseline self-efficacy				
Low	.023	.672	.116	.125
High	.138	**.013**		
Baseline diabetes distress				
Low	.073	.113	.043	.603
High	.116	.101		
Baseline HbA1c				
<7%	.031	.543	.142	.060
>7%	.173	**.003**		

Note. *p* values are bolded if less than 0.05. H&O = Hispanic and others; H&AA = Hispanic and African American.

medication information were associated with better medication adherence, but improvements in medication knowledge and decisional conflict were not. Among examined possible mechanisms by which improved satisfaction with medication information led to improved medication adherence, improved diabetes self-efficacy was associated with improvements in both satisfaction with medication information and medication adherence, but these improvements did not meet rigorous analytical standards to be considered a mediator of the improvements. Similarly, none of our examined participant characteristics met criteria to be considered moderators of the relationship between improved satisfaction with medication information and medication adherence. Thus, our principal positive finding was that satisfaction with medication information was the only study outcome independently associated with concomitant improvements in participants' medication adherence.

This finding builds on prior research showing that, especially among historically underserved racial and ethnic groups, feeling trust in one's health care providers and satisfaction in their communication and information provided are central to improving important health behaviors such as adherence (Salvalaggio et al., 2013; van Servellen & Lombardi, 2005). In an earlier study among diabetes patients in this same clinic population, we found that objective knowledge of one's last A1c was associated with better diabetes care understanding but not with better diabetes care self-efficacy or reported self-management behaviors (Heisler, Piette, Spencer, Kieffer, & Vijan, 2005). Studies among ethnic and racial minority adults with diabetes or hypertension similarly have found that higher levels of trust in health care providers are associated with increased medication adherence (Elder et al., 2012), satisfaction (White et al., 2015), reduced emotional disease burden (Slean, Jacobs, Lahiff, Fisher, & Fernandez, 2012), and improved disease self-care (Bonds et al., 2004). More broadly, trust has also been correlated with self-reported health outcomes (Safran et al., 1998), patient satisfaction, continuity with the same provider, and medication adherence (Thom, Ribisl, Stewart, & Luke, 1999). Furthermore, positive evaluations of providers' communication and shared decision making are associated with increased engagement in communication with providers (Lyles et al., 2013) while negative evaluations are associated with medication nonadherence (Bauer et al., 2014; Ratanawongsa et al., 2013).

Especially among populations who have experienced disproportionate levels of discrimination and poor treatment in formal institutions such as health care systems, it is not surprising that feelings of trust in and satisfaction with the information provided on their medications are such strong predictors of improved medication adherence. Since CHWs share cultural and linguistic similarities with the population of patients they serve, they are especially well-positioned to increase trust in and satisfaction with the information they provide. This is also likely another important factor explaining the effectiveness of CHW interventions in these populations (M. Shah et al., 2013; M. K. Shah, Heisler, & Davis, 2014; Spencer et al., 2011).

Although both of our interventions effectively decreased participants' conflict about making decisions about their anti–hyperglycemic medications, this decrease was not an independent contributor to improved medication adherence. Many decision aid developers have argued that reducing decisional conflict should be an important objective of decision aids. Yet our findings are similar to the findings of a 2014 Cochrane Review on 115 studies of effectiveness of decision aids for people facing health treatment or screening decisions. That review concluded that although there was high-quality evidence that decision aids compared with usual care reduced decisional conflict related to feeling uninformed and unclear about their personal values, this reduction did not translate into improved adherence with the chosen option (Stacey et al., 2014). Moreover, while the measure we used for decisional conflict has been used repeatedly in studies on the effectiveness of decision aids, most of these have evaluated aids for decisions about onetime treatment options (e.g., breast cancer surgical options) and not for long-term treatment options. Although almost half of our study participants were eligible for our study because they voiced concerns or difficulty taking their diabetes medications, it is not clear that high decisional conflict about their medication choices was a significant factor in their difficulties. Moreover, a growing number of experts argue that decisional conflict is not necessarily a bad thing, especially in the face of the ongoing decisions that of necessity must be made about taking long-term medications in which ambivalence, revision, and changing one's mind may be beneficial (W. L. Nelson, Han, Fagerlin, Stefanek, & Ubel, 2007). For example, W. L. Nelson et al. (2007) suggest that understanding the uncertainty of outcomes can result in a high decisional conflict score, regardless of a patient's satisfaction with her decision in the face of that uncertainty. Thus, although the interventions led on average to decreased decisional conflict, it is thus perhaps not surprising that these decreases did not in turn translate into improved medication adherence.

None of our hypothesized moderators of improvements were significant. Several prior studies of models in which lay workers or peers provide more intensive support and educational outreach to adults with diabetes have found that these interventions are especially effective in participants with low health literacy and high baseline levels of diabetes distress, poor medication adherence, and self-management (Moskowitz, Thom, Hessler, Ghorob, & Bodenheimer, 2013; Piette, Resnicow, Choi, & Heisler, 2013; Rothman et al., 2004). In our sample, while there was a trend toward significantly greater effectiveness among participants with lower levels of formal education and health literacy, this did not achieve statistical significance. Of note, however, most of our study participants had relatively low health literacy, and 52% of all participants had less than a high school education. We thus had less variation in these participant characteristics than some prior studies.

Limitations

This study has several limitations. First, this study was conducted at a single federally qualified health center and thus our results may not generalize to other settings or populations. Second, low variation in several of the variables may have contributed to the limited ability to detect moderator effects. Last, there are also likely other potential moderators and mediators of intervention effectiveness that may be important and were not measured in this study. For example, our findings on the importance of participants' improvements in their satisfaction with the information received on diabetes medications suggests that trust in providers might be both an important mediator and moderator of intervention effects. Another important mediator that we did not examine is participants' level of motivation to take medications and improve medication adherence. Further research is needed to identify and understand unmeasured aspects of these interventions that contributed to their effectiveness. However, in light of the paucity of prior research on effective medication decisional support for low-income populations with low health literacy and formal education, this study points to a number of promising directions for research. In particular, future assessments should include well-validated measures of levels of trust and satisfaction with key aspects of information and service delivery, as well as on the potentially crucial role of trust in the individuals delivering interventions.

Implications for Research and Practice

Our key finding was that improvements in satisfaction with medication information were associated with increases in medication adherence. An important implication of this finding for research is the need to identify what aspects of interventions enhance satisfaction with information received. In both arms of this intervention, the intervention was delivered by trusted CHWs in home visits in which the worker took time to review information on diabetes medications and address participants' questions. This face-to-face relationship in a home setting appeared to increase satisfaction with the information on medications provided regardless of whether the information was through an interactive, tailored e-health tool or through print materials.

Our findings suggest the importance of including measures of satisfaction with information provided in assessments of educational programs. They further suggest that decisional conflict may not be an important outcome measure in the evaluations of efforts to inform long-term and reversible decisions in the same way that it has been used for time-sensitive and irreversible decisions, such as with breast cancer treatment. Finally, we underscore the importance of further investigation into the mediators and moderators of medication adherence among low-income and minority patients. This knowledge will be invaluable to better designing and targeting future interventions to improve the health of underserved patients.

Conclusion

In conclusion, in the two models of CHW-led medication decision support we evaluated, observed improvements in satisfaction with the information received on diabetes medications, but not medication knowledge or decisional conflict, were associated with improvements in diabetes medication adherence in this study population of low-income Latino and African American adults. Interventions that target low-income ethnic and racial minorities need to focus on increasing participants' satisfaction with the information provided on diabetes medications and not just improving their knowledge about medications.

Appendix

Outcome Scales

A. Medication Adherence (MA): Morisky Medication Adherence Scale

Responses: Never Rarely Sometimes Often Always

1. Thinking back to the past 4 weeks, do you ever forget to take your medications?
2. Are you careless at times about taking your medication?
3. When you feel better, do you sometimes stop taking your medication?
4. Sometimes, if you feel wore when you take the medicine, do you stop taking it?

B. Medication Knowledge (MK)

Responses: True False Don't Know

1. Some diabetes medications can cause me to gain weight.
2. Some diabetes medications can cause me to lose weight.
3. Some diabetes medications can lower sugar levels in my blood to the point where I feel sick (hypoglycemia).
4. Because of its adverse effects, doctors should give insulin only after all other medications have failed to control diabetes.
5. Diabetes medications should not be combined with each other.
6. On average, all diabetes medications, except insulin, have similar ability to lower hemoglobin A1c (measure of sugar control in the past 3 months).
7. Insulin use can cause the need for leg amputations.
8. The least effective medication to lower hemoglobinA1c (measure of sugar control in the last 3 months) is insulin.
9. All diabetes medications should be used at least twice a day.
10. All diabetes medications either make you gain weight or lower sugar levels in your blood until you are sick (hypoglycemia).
11. The main adverse effects of insulin are weight gain and getting sick with low blood sugars (hypoglycemia).

C. Satisfaction With Medication Information

Scale: 1 = Too little information to 4 = Just the right amount of information to 7 = Too much information

1. How would you describe the amount of information that you have received about your blood sugar medications from your health care team?

Scale: 1 = Not at all clear to 4 = Somewhat clear to 7 = Extremely clear

2. How would you describe the clarity of information about your blood sugar medications that you receive from your health care team?

Scale: 1 = Not at all helpful to 4 = Somewhat helpful to 7 = Extremely helpful

3. How helpful is the information about your blood sugar medications from your health care team?*

**Note*. Only #3 (satisfaction with helpfulness of medication information) was used in the present study, as these were considered to be measuring different questions.

D. Decisional Conflict (DC): From O'Connor

Responses: Strongly disagree Disagree Neither agree nor disagree Agree Strongly agree

1. I know all the medication options that are available to me

2. I know the benefits of each option
3. I know the risks and side effects of each option
4. I am clear about which benefits matter most to me
5. I am clear about which risks and side effects matter most
6. I am clear about which is most important to me (the benefits or the risks and side effects)
7. I have enough support from others to make a choice
8. I am choosing without pressure from others
9. I have enough advice to make a choice
10. I am clear about the best choice for me
11. I feel sure about what to choose
12. This decision is easy for me to make
13. I feel I have made an informed choice about my medications
14. My decision shows what is important to me
15. I expect to stick with my decision
16. I am satisfied with my decision

E. Self-Efficacy (SE): Lorig Self-Efficacy Scale

Scale: 1 = Not at all confident to 10 = Totally confident

1. How confident are you that you can do all the things necessary to manage your diabetes on a regular basis?
2. How confident are you that you can judge when the changes in your diabetes mean you should visit a doctor?
3. How confident are you that you can do the different tasks and activities needed to manage your diabetes?
4. How confident are you that you can do things other than just taking medication to reduce how much your diabetes affects your everyday life?
5. How confident are you that you can take all your recommended doses of prescribed medications?

F. Diabetes Distress Scale (DD)

Responses: Not a problem | A slight problem | A moderate problem | A somewhat serious problem | A serious problem | A very serious problem

1. Feeling overwhelmed by the demands of living with my diabetes
2. Feeling that I am often failing with my health routine

G. Health Literacy Scale: Chew Health Literacy Screening

Responses: Extremely | Quite a Bit | Somewhat | A Little | Not at All

1. How confident are you filling out forms by yourself?

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