In Brief

This systematic review summarizes the research on interventions to improve outcomes for patients with diabetes and low literacy. We find that it is possible to improve health outcomes for patients with low literacy and to reduce disparities between patients with high and low literacy. The interventions that have been most successful combine personalized teaching with longitudinal follow-up and patient support.

Interventions to Improve Diabetes Outcomes for People With Low Literacy and Numeracy: A Systematic Literature Review

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Diabetes is complicated. Living with diabetes is more complicated. People with diabetes are tasked with learning to manipulate their own physiology in an effort to mimic normal physiology. It took evolution millions of years to sort this out, so it is not difficult to imagine why it would be hard for patients with diabetes.

That diabetes is complicated is not news. To help patients manage diabetes, we have created systems to help them understand their illness. The entire field of diabetes education has emerged, and we have shown remarkable progress and success. However, research during the past 10–15 years has shown that we are still struggling with the most vulnerable of our patients. One marker of vulnerability is low literacy.[1]

Educators know that patients with low literacy struggle more to learn many diabetes concepts, and at least one study has suggested that patients with low literacy are less likely to have good control of their blood glucose.[2] Subsequent studies have tried to untangle the relationship between low literacy and poor diabetes control. The primary hypothesis behind this research is that people with low literacy are less likely to understand self-management tasks. If one does not understand a task, he or she is unable to implement the correct self-management behavior. This theory is supported by research documenting the relationship between literacy and knowledge about health topics.[1]

One problem in this area of research is that knowledge, as we measure it in most studies, is not always related to health outcomes. This does not fit the paradigm of literacy and health research and raises questions about how best to help our patients if improving knowledge does not improve health outcomes. One possibility is that we are measuring the wrong knowledge. If we are asking about knowledge of pathophysiology or other more esoteric aspects of health, perhaps it should not surprise us that knowledge is not related to outcomes. Second, and more importantly, is that maybe our teaching does not lead to action. Are there other things that we do as clinicians and educators that help people act on knowledge gained? Finally, literacy could be just another marker of vulnerability that is related to important factors that affect outcomes via pathways other than knowledge.

Because we cannot randomly allocate literacy levels in the population, one of the best ways to understand the relationship between literacy and outcomes is to perform interventions designed to mitigate the effects of low literacy. Those interventions can be allocated randomly to find out whether they improve outcomes for people with low literacy and, even more compellingly, reduce the literacy-related disparities in outcomes. By focusing on the elements of the intervention, we can begin to hypothesize about the important characteristics of low literacy that lead to worse health outcomes.

In this review, we discuss the interventions that have been specifically designed to mitigate the effects of low literacy. Our goal is to explore the relationship between literacy and diabetes outcomes and to suggest practical clinical strategies that are most likely to be beneficial based on current research.

Conceptual Model

To make sense of the current studies, we will posit a simplified conceptual model. This model reflects the ideas of ourselves and other authors in conceiving how literacy may be related to health outcomes.[3,4] This model is not intended to cover every possible relationship, but it does help to clarify assumptions that many researchers and clinicians have about literacy and health.

In Figure 1, we demonstrate both a direct and indirect pathway linking low literacy to poorer health outcomes in diabetes. The default assumption in literacy research is that there is a direct link between literacy and health outcomes. In this pathway, literacy is related to knowledge and self-efficacy, which are both required to enact behaviors that lead to good health outcomes. Behaviors could include medication taking, self-monitoring, diet, physical activity, stress management, and information seeking, among others. In the indirect pathway, low literacy is a marker for other risk factors for poor health outcomes, including external stressors, access to care, and inadequate social networks.

Observational studies have tried to examine some of these relationships, and it has been difficult to establish a relationship between literacy and mediators that are related to health outcomes.[5] Observational studies are subject to unrecognized confounding, but intervention studies can experimentally test an intervention to mitigate a literacy-related disparity and find out whether that presumed factor is important. For example, if knowledge deficit is the main problem for people with low literacy, then providing knowledge about diabetes should narrow the disparity.

In this review, we will use the framework of this model to understand the most effective strategies for taking care of patients with diabetes and low literacy.

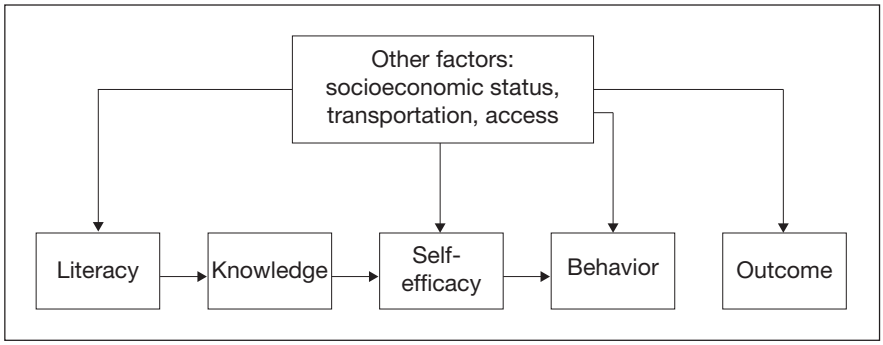

Figure 1. Potential pathways between literacy and health outcomes.

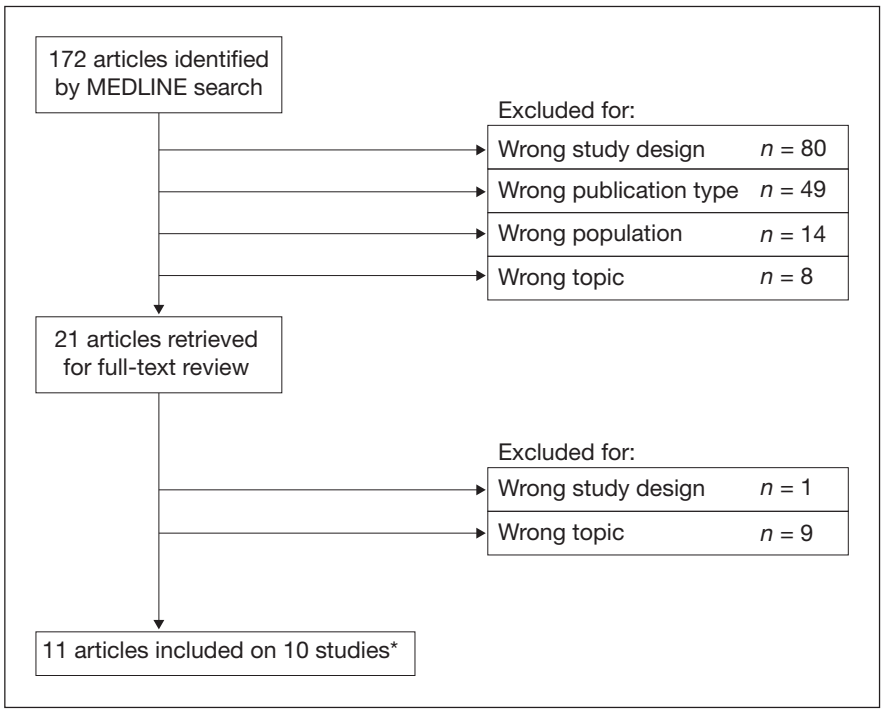

Figure 2. Flow chart of study selection.

**Two additional articles[12,15] were included as second publications on two of the studies, yielding a total of 13 articles on 10 studies.*

Methods

Key questions

Our central key question was: What interventions improve outcomes among patients with diabetes and low literacy? Based on this central question, we developed four key questions focused on elements that may be important in the link between low literacy and poorer outcomes in patients with diabetes. These were:

- What interventions improve knowledge of diabetes among patients with diabetes and low literacy?
- What interventions improve self-efficacy and self-management behaviors among patients with diabetes and low literacy?
- What interventions improve blood pressure control among patients with diabetes and low literacy?
- What interventions improve A1C among patients with diabetes and low literacy?

Inclusion and exclusion criteria

We developed inclusion and exclusion criteria based on the key questions. We included studies that tested an intervention, including randomized, controlled trials and studies with a one-group pre-post design. We excluded observational studies, review articles, case reports, and other studies that did not specifically test an intervention. We limited studies to those in which the population of focus was patients with diabetes. Because we were interested specifically in outcomes among patients with diabetes and low literacy, we excluded studies that did not specifically measure literacy among study participants. We also excluded studies that were not published in English. Although we had

specific outcomes of interest, we did not have any inclusion or exclusion criteria based on the outcomes measured or reported in the studies. We did not restrict our search by publication date.

Literature search

We searched the MEDLINE database using the key words "diabetes" and "literacy" as text words. One reviewer (EEVS) evaluated all of the abstracts from this search for inclusion or exclusion based on the criteria described above. A second reviewer (DAD) reviewed the included abstracts and agreed on inclusion. After the abstract review, both authors reviewed the full text of articles identified and reached agreement on inclusion. Included articles were abstracted into the evidence table by EEVS. The evidence table was checked for accuracy by DAD. This process is summarized in Figure 2.

Results

We included 10 studies of interventions designed to improve diabetes outcomes in patients with low literacy. Three of the studies had outcomes published in two articles each, so 13 articles were included. Table 1 summarizes these studies. Of the 10 included studies, five were randomized, controlled trials (RCTs), and five were one-group pre-post design studies. The number of participants enrolled in the studies ranged from 20 to 339; two studies included < 100 participants. The studies presented descriptive information on the age, sex, and race of the participants. Most also included the educational level of the participants. Five studies reported the insurance status of the participants, and three reported income levels. All

Table 1. Published Studies Evaluating Interventions to Improve Outcomes for Diabetic Patients With Low Literacy and/or Numeracy

Author, Year	Study Design, *n*	Intervention (I) and Control (C) Conditions	Elements of the Intervention	Outcomes/Results
Cavanaugh et al., 2009[13]	RCT, 198	I: Diabetes disease management with staff instructed in the use of the Diabetes Literacy and Numeracy Education Toolkit (DLNET) to facilitate literacy- and numeracy-sensitive diabetes education and management. Two to six visits over a 3-month period. C: Usual care in the diabetes disease management program. Staff not instructed in the use of the DLNET. One to six visits in a diabetes care program over a 3-month period.	• Disease management • Personalized teaching • Tools specifically targeted for low numeracy/literacy • Evidence-based treatment algorithms	• Self-efficacy: improvement from baseline for both groups • Self-management behaviors: no significant improvement for either group • A1C: At 3 months, both intervention and control patients had significant improvements in A1C from baseline (intervention –1.50 [95% CI –1.80 to –1.02]; control –0.80 [–1.10 to –0.30]). In adjusted analysis, there was greater improvement in A1C in the intervention group than in the control group ($P = 0.03$). At 6 months, there were no differences in A1C between intervention and control groups.
Gerber et al., 2005[11]	RCT, 244	I: Participants used an audiovisual computer kiosk to review lessons on diabetes self-care in English or Spanish. Participants were invited to use the computer as often as they would like during the following year before or after clinic visits. C: A second multimedia application with simple multiple-choice quizzes on diabetes concepts with no formal narrative instruction or testimonials.	• Multimedia education • Tools specifically targeted for low numeracy/literacy • No personal teaching	• Knowledge: no difference between intervention and control • Self-efficacy: no difference • Blood pressure: no difference • A1C: No difference except for among those with lower literacy and a baseline A1C ≥ 9%, in which there was a larger decrease in A1C in the intervention group versus the control group (–2.1 vs. –0.3%, $P = 0.036$)

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Table 1. Published Studies Evaluating Interventions to Improve Outcomes for Diabetic Patients With Low Literacy and/or Numeracy, *continued from p. 230*

Author, Year	Study Design, *n*	Intervention (I) and Control (C) Conditions	Elements of the Intervention	Outcomes/Results
Hill-Briggs et al., 2008[7]	Pre-post, 30	I: One 90-minute education class led by a diabetes educator and an education binder adapted for low literacy.	• Group education • Tools specifically targeted for low numeracy/literacy • Personalized teaching	• Knowledge: increased for below-average literacy groups (2.7 ± 1.7 to 4.7 ± 2.0, $P = 0.005$) and average (3.8 ± 1.7 to 5.7 ± 2.1, $P = 0.002$)
Kandula et al., 2009[6]	Pre-post, 190	I: Patients viewed two 5-minute multimedia diabetes education modules on a computer.	• Multimedia education • Tools specifically targeted for low numeracy/literacy • No personal teaching	• Knowledge: patients across all literacy levels had significant increases in knowledge scores after viewing the modules ($P < 0.001$). Patients with inadequate literacy learned significantly less compared to those with adequate literacy.
Ntiri et al., 2009[8]	Pre-post, 20	I: Six group educational sessions during 3 weeks by a nurse educator.	• Group education • Tools specifically targeted for low numeracy/literacy • Personalized teaching	• Knowledge: significant increase in diabetes knowledge immediately following the intervention ($P < 0.01$) and 1 month after the intervention ($P < 0.05$)
Rothman et al., 2004[18]	Pre-post, 159	I: Diabetes disease management, including educational sessions, telephone reminders, and assistance in overcoming specific barriers to care and use of specific communication techniques to improve comprehension in low-literacy populations.	• Disease management • Personalized teaching • Tools specifically targeted for low numeracy/literacy • Evidence-based treatment algorithms • Telephone counseling and reminders	• A1C: improvement in A1C of –1.9% points (95% CI –1.2 to –2.5 among patients with low literacy. Improvement in A1C of –1.8% points (95% CI –1.0 to –2.5) among patients with higher literacy. There was no significant difference in A1C improvement between the two groups.

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of the studies recruited patients from primary care practices.

All of the studies measured and reported on literacy. The short version of the Test of Functional Health Literacy in Adults (S-TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine were most often used to measure literacy. The Wide Range Achievement Test reading subtest and the Diabetes Numeracy Test were also used.

Low literacy was defined based on the scores on these tests. Different studies had different definitions of low literacy ranging from less than a fourth-grade reading level to less than a ninth-grade reading level. In general, the studies targeted populations with a high prevalence of low literacy, although the range of literacy levels varied among the studies from 20 to 90% of participants with lower/marginal literacy.

Key question 1: What interventions improve knowledge of diabetes among patients with diabetes and low literacy?

Almost all studies measured diabetes-related knowledge as an outcome of the intervention. Before any intervention, patients with low literacy generally score lower on tests of diabetes knowledge than patients with higher literacy.[6,7] As discussed above, this may be important in the pathway that links low literacy with worse diabetes outcomes.

Of the 10 intervention studies included in this review, six measured change in diabetes knowledge as an outcome.[6–12] Overall, five of the six studies showed improvement in diabetes knowledge as measured by a significant improvement in a diabetes knowledge test. Each of the studies used a different diabetes knowledge test to measure diabetes knowledge. The variation in measurement of diabetes knowledge is an important limitation of these studies.

Of the studies that looked at improvement in diabetes knowledge across literacy levels, two studies[7,9] showed similar improvement across

Table 1. Published Studies Evaluating Interventions to Improve Outcomes for Diabetic Patients With Low Literacy and/or Numeracy, ***continued from p. 231***

Author, Year	Study Design, *n*	Intervention (I) and Control (C) Conditions	Elements of the Intervention	Outcomes/Results
Rothman et al., 2005[12] and Rothman et al., 2004[17]	RCT, 217	I: Diabetes disease management, including educational sessions, telephone reminders, and assistance in overcoming specific barriers to care and use of specific communication techniques to improve comprehension in low-literacy populations. C: Usual care from a primary care physician after a 1-hour educational session.	• Disease management • Personalized teaching • Tools specifically targeted for low numeracy/literacy • Evidence-based treatment algorithms • Telephone counseling and reminders	• Knowledge: significant increase in diabetes knowledge in intervention group compared to control group. • Blood pressure: significant improvement in systolic blood pressure in intervention versus control group (adjusted difference –7.6 mmHg, $P = 0.006$). Improvements in systolic blood pressure were similar across literacy levels. • A1C: participants in the intervention group were significantly more likely to improve A1C compared to controls (adjusted difference –1.0%, P = 0.001) and more likely to obtain A1C levels < 7.0% at 12-month follow-up (adjusted odds ratio 1.9, $P = 0.05$). Intervention participants with lower literacy had more improvement in A1C than control patients (adjusted difference –1.4%, $P < 0.001$) and were significantly more likely to obtain the goal A1C of < 7.0% than the control patients (adjusted odds ratio 4.6, $P = 0.02$).

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literacy levels, and one study[6] showed less improvement among those with lower literacy. Importantly, none of these studies narrowed the disparity in knowledge by literacy level.

Multimedia diabetes education programs

Gerber et al.[11] and Kandula et al.[6] both studied multimedia diabetes education programs targeting low-literacy patients. In the study by Gerber et al., patients accessed diabetes education lessons targeting self-care objectives through a computer kiosk installed in clinic waiting rooms. Patients could access the computer lessons an unlimited number of times in the 1-year study period and then were tested at the end of the year on their diabetes knowledge. Participants with higher literacy accessed the computer lessons more often than lower-literacy participants. There was no improvement in diabetes knowledge in the intervention group compared to a control group.

Kandula et al.[6] also developed a multimedia diabetes education program. Study participants viewed two 5-minute diabetes education modules on the computer and were tested on their diabetes knowledge before and after viewing the modules. Knowledge significantly increased for participants with inadequate, marginal, and adequate literacy but increased less for those with inadequate literacy compared to those with adequate literacy.

Group educational sessions

Hill-Briggs et al.[7] and Ntiri et al.[8] studied interventions combining low-literacy educational materials with group educational sessions. In the study by Hill-Briggs et al.,[7] participants attended one 90-minute group education class and received an educational binder with printed materials. After the group session, diabetes knowledge scores increased for participants with below-average and average

Table 1. Published Studies Evaluating Interventions to Improve Outcomes for Diabetic Patients With Low Literacy and/or Numeracy, *continued from p. 232*

Author, Year	Study Design, *n*	Intervention (I) and Control (C) Conditions	Elements of the Intervention	Outcomes/Results
Schillinger et al., 2008[16] and Schillinger et al., 2009[15]	RCT, 339	I: Automated telephone disease management system with weekly calls with rotating queries that patients respond to with touch-tone commands. A care manager called patients if any responses were "out of range." C: Monthly group medical visits for 90 minutes with physician and health educator.	• Intervention A: ○ Telephone disease management ○ Tools specifically targeted for low numeracy/literacy ○ Personal response by phone if needed. ○ Creation of action plans • Intervention B: ○ Group education ○ Tools specifically targeted for low numeracy/literacy ○ Personalized teaching ○ Creation of action plans • Control: ○ Usual care	• Self-management behaviors: both interventions showed improved self-efficacy and improved diabetes-related behaviors. Both interventions engaged a majority of participants in action planning, but interestingly, weekly automated telephone disease management yielded higher engagement, especially among patients with lower literacy and limited English. Engagement was measured as a composite score of participation in the intervention, creation of action plans, and the achievement of action plans. • Blood pressure: no improvement in either intervention group • A1C: no improvement for either intervention group
Seligman et al., 2005[14]	RCT, 182	I: Physicians notified before clinic visits if their patients had low health literacy. C: No information on patient literacy was provided to the providers.	• Provider informed of literacy status of patient	• Self-efficacy: no difference between intervention and control groups in patient self-efficacy after the clinic visit • A1C: no difference in A1C at 3-month follow-up

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literacy. Ntiri et al.[8] studied a transformative learning intervention in which participants attended six 1-hour group educational sessions over 3 weeks and received diabetes educational materials adapted for patients with low literacy. After these sessions, participants' scores on the diabetes knowledge test increased. Interestingly, scores on the S-TOFHLA also increased.

Individual counseling

Wallace et al.[9] studied the impact of providing patients with a literacy-appropriate diabetes education guide accompanied by an initial brief individual counseling session (lasting ~ 15 minutes) and two follow-up telephone counseling sessions at 2 and 4 weeks. Diabetes knowledge had improved when measured 3 months after the intervention, and improvements were similar across literacy levels.

Disease management

In a randomized, controlled trial, Rothman et al.[12] examined the effectiveness of a comprehensive diabetes management program. Patients were randomized to usual care from their primary care clinician or intensive diabetes management by a diabetes care coordinator and three clinical pharmacist practitioners. Patients in the intervention group received intensive educational sessions and counseling from the clinical pharmacist practitioners. They were contacted by telephone or in person every 2–4 weeks for the 12-month duration of the study. The clinical pharmacist practitioners used an evidence-based algorithm to adjust patients' medications. A Microsoft Access database tracking outcomes was developed to proactively improve care for patients. At the 12-month follow-up, patients in the intervention group had a significant increase in diabetes knowledge compared to control subjects after 1 year of the intervention. This study did not evaluate the increase in diabetes knowledge by literacy level.

Key question 1 conclusions

Most of the interventions resulted in improvement in diabetes knowledge

Table 1. Published Studies Evaluating Interventions to Improve Outcomes for Diabetic Patients With Low Literacy and/or Numeracy, *continued from p. 233*

Author, Year	Study Design, *n*	Intervention (I) and Control (C) Conditions	Elements of the Intervention	Outcomes/Results
Wallace et al., 2009[9] and DeWalt et al., 2009[10]	Pre-post, 250	I: One ~ 15-minute counseling session centered on goal-setting and introduction to an educational guide. This was followed by two brief telephone counseling sessions at 2 and 4 weeks.	• Personalized teaching • Tools specifically targeted for low numeracy/literacy • Creation of action plans • Telephone counseling and reminders	• Knowledge: diabetes knowledge significantly improved at 3-month follow-up. Improvements were similar across literacy levels. • Self-efficacy: self-efficacy scores significantly improved. This improvement was similar across literacy levels. Spanish speakers experienced less improvement in self-efficacy levels than English speakers. • Self-management behaviors: a majority of participants reported achieving and sustaining their behavioral goals at each follow-up session. 33% reported achieving and sustaining their goals at all three follow-up sessions. Participants showed significant improvement on a scale of diabetes self-management activities. Improvements were similar across literacy levels.

among patients with low literacy, at least immediately after the intervention. Personalized education, in which patients have direct contact with a provider, may be better able to overcome the learning gap between patients with low and high literacy than multimedia interventions in which there is no personalized contact.

Key question 2: What interventions improve self-efficacy and self-management behaviors among patients with diabetes and low literacy?

Self-efficacy and self-management behaviors may also play an important role in the pathway linking low literacy to worse diabetes outcomes. Low literacy may inhibit patients' ability to learn about and participate in self-management behaviors and may limit their self-efficacy—the confidence that they can carry out the recommended behaviors. A more limited number of studies attempted to measure self-efficacy or self-management behaviors. As in the case of measurement of diabetes knowledge, there was variation among the studies in how self-efficacy and self-management behaviors were assessed. The lack of standardization in the measurement of these characteristics is an important limitation to consider in reviewing these studies.

Self-efficacy

Five studies measured the effect of an intervention on self-efficacy among patients with diabetes and low literacy.[9,11,13–15] Each of these studies used a different scale to measure self-efficacy. Three studies[9,13,15] showed improvement in self-efficacy scores, and two[11,14] showed no improvement.

More personalized, intensive interventions were more likely to improve the self-efficacy of patients with diabetes than less personalized interventions. The study by Gerber et al.[11] which evaluated a multimedia intervention for diabetes education through use of computer kiosks in clinic waiting rooms, did not find any improvement in self-efficacy scores at the 1-year follow-up. Seligman et al.[14] studied the effect of notifying physicians about their patients' limited literacy before clinic visits. Patients in the intervention (physician notified of literacy) and control (physician not notified) groups had similar self-efficacy scores measured after their clinic visits.

In contrast, more personalized interventions did improve patients' self-efficacy. In the study by Wallace et al.,[9] which assessed the impact of providing patients with a literacy-appropriate diabetes education guide accompanied by an initial brief individual counseling session and two follow-up telephone counseling sessions at 2 and 4 weeks, self-efficacy scores improved after the intervention.

This improvement was similar across literacy levels. Interestingly, however, self-efficacy levels improved for English-speaking patients but not for Spanish-speaking patients.

Cavanaugh et al.[13] evaluated the impact of providing literacy-sensitive diabetes care within an enhanced diabetes care program. Patients were randomized to an existing enhanced diabetes care program (control group) or to an enhanced diabetes care program that addressed literacy and numeracy (intervention group). Self-efficacy improved from baseline at 6 months for both control and intervention groups, but there was no significant difference between the groups.

Schillinger et al.[15] performed a three-arm, randomized, controlled trial including an automated telephone self-management program, a group medical visit program, and usual care. Both intervention arms improved diabetes self-efficacy more than usual care.

Self-management behaviors

Three studies measured the effect of an intervention on self-management behaviors among patients with diabetes and low literacy.[10,13,16] Schillinger et al.[16] and DeWalt et al.[10] focused interventions specifically on goal-setting and action plans, and the interventions resulted in an improvement in self-management behaviors. The intervention in the study by Cavanaugh et al.[13] did not specifically address goal-setting and did not result in improvement in self-management behavior.

Schillinger et al.[16] compared the effect of two different self-management support strategies. Patients were randomized to weekly automated telephone disease management with nurse call-back if needed, monthly group medical visits, or usual care. The measured outcomes were the self-reported number of action plans created and the percentage of action plans achieved. Both interventions engaged a majority of participants in action planning, but interestingly, weekly automated telephone disease management yielded higher engagement, especially among patients with lower literacy and limited English.

In another study,[9,10] patients were provided with a literacy-appropriate diabetes education guide accompanied by an initial brief individual counseling session and two follow-up telephone counseling sessions at 2 and 4 weeks that focused on goal-setting. The majority of patients in the study were able to set and achieve at least two behavioral goals. Participants in the study also showed improvement in a five-item scale of diabetes self-management activities. There were no differences in achievement of behavioral goals or improvement in the diabetes self-management activities scale by literacy level.

Cavanaugh et al.[13] studied the impact of providing literacy-sensitive diabetes care within an enhanced diabetes care program but did not specifically focus on goal-setting or action plans for behavioral change. Diabetes self-management activities were assessed by patient self-report and did not show any improvement in either the intervention or the control group between baseline and 6-month follow-up.

Key question 2 conclusions

More personalized interventions seem more effective at improving self-efficacy among patients with diabetes and low literacy. The studies that did not provide personalized diabetes education to patients did not show improvement in self-efficacy. Self-management behaviors improved with interventions focused around goal-setting and action plans. The one study that measured this outcome but did not specifically focus on goal-setting did not show any improvement in diabetes self-management activities.

Key question 3: What interventions improve blood pressure control among patients with diabetes and low literacy?

Three randomized, clinical trials[11,15,17] measured the effect of an intervention on blood pressure control in patients with diabetes and low literacy. Gerber et al.[11] did not find improvement in blood pressure control at the 1 year follow-up after a multimedia intervention using computer kiosks in clinic waiting rooms. Schillinger et al.[15] did not find improvement in blood pressure at 1 year in either of their intervention groups in comparison to usual care. Rothman et al.[17] studied the role of literacy on the effectiveness of a comprehensive diabetes management program and did find significant improvement in systolic blood pressure in patients in the diabetes management program compared to those assigned to usual care. The adjusted difference in systolic blood pressure at 1 year of follow-up was –7.6 mmHg (95% CI –13.0 to –2.2). Patient literacy status did not modify the effect of the intervention on reducing systolic blood pressure.

Key question 3 conclusions

A comprehensive diabetes management program was able to improve blood pressure at 12-month follow-up for both low- and high-literacy patients with diabetes. Neither automated telephone support nor group visits improved blood pressure, but the intervention was focused more on individual behavior change rather than on managing blood pressure medications. An impersonal multimedia education program was not able to show any improvement in blood pressure compared to controls.

Key question 4: What interventions improve A1C among patients with diabetes and low literacy?

Six studies,[11,13–15,17,18] four of which were randomized, clinical trials, examined A1C as an outcome. Three studies demonstrated improvement in A1C, and three did not show any change in A1C after the intervention. As was the case for improvement in diabetes knowledge, self-efficacy, and blood pressure control, the more personalized and intensive interventions showed improvement in A1C, and the less personalized and less intensive interventions did not show improvement.

Gerber et al.[11] showed no improvement in A1C at 12 months of follow-up after a multimedia intervention involving the use of computer kiosks for diabetes education lessons in clinic waiting rooms. Seligman et al.[14] did not find any improvement in A1C at 2–9 months of follow-up after informing physicians of patients' literacy status before clinic visits. Surprisingly, Schillinger et al.[15] did not demonstrate improved A1C in either the automated telephone management or the group visit interventions.

All three studies examining the effect of comprehensive diabetes disease management programs on A1C in patients with low literacy demonstrated improvement. In Rothman et al.'s pilot study with a one-group pre-post design,[18] all patients were enrolled in a pharmacist-led diabetes management program that included an initial

1-hour educational session and follow-up telephone calls or clinic visits every 2–4 weeks. Patients showed improvement in A1C that did not differ by literacy status. After an average of 6 months of follow-up, patients with higher literacy had a mean improvement in A1C of 1.9 percentage points, and patients with lower literacy had a mean improvement in A1C of 1.8 percentage points.

After this pilot study, Rothman et al. published the results of a randomized, controlled trial[17] examining the role of literacy on the effectiveness of a comprehensive diabetes management program. Patients were randomized to usual care from their primary care clinician or intensive diabetes management by a diabetes care coordinator and three clinical pharmacist practitioners. Patients in the intervention group received intensive educational sessions and were contacted by telephone or in person every 2–4 weeks. Low-literacy patients in the intervention group had significantly greater improvement in A1C after 12 months of follow-up than control patients (adjusted difference –1.4%; 95% CI –2.3 to –0.6%). Patients with higher literacy did benefit from the program, but the magnitude of benefit was smaller and not statistically significant.

Cavanaugh et al.[13] performed a randomized, controlled trial to test whether providing specific literacy- and numeracy-sensitive diabetes education in the context of a diabetes management program was more effective at improving outcomes than a standard diabetes management program. Patients were randomized to an existing enhanced diabetes care program or to an enhanced diabetes care program that used a specific toolkit to facilitate literacy- and numeracy-sensitive diabetes education and management. Both the intervention and the control groups had significant improvement in A1C at 3 and 6 months of follow-up. The intervention group demonstrated significantly more improvement in A1C than the control group at 3 months of follow-up (at the completion of the enhanced care program). At 6 months of follow-up (3 months after completion of the enhanced care program), there was no statistically significant difference between the intervention and control groups. This suggests that any additional benefit that patients gained from the literacy-sensitive diabetes education waned over time.

Key question 4 conclusions

In randomized, clinical trials, comprehensive diabetes disease management programs improve A1C among high- and low-literacy patients with diabetes. A specific focus on literacy-sensitive diabetes education within comprehensive disease management had some additional benefit in reduction in A1C, but this improvement was not sustained after the program ended.

Discussion

The first and most essential point of this review is that it is possible to significantly improve outcomes for diabetic patients with low literacy. We present in this review several clinical trials that successfully lowered A1C among diabetic patients with low literacy by more than 1.5%[11,13,18] and one trial that lowered systolic blood pressure by more than 7 mmHg.[17] The question of how to reproduce these findings in other clinics and settings requires first that we determine the components of the interventions that led to this success. These were complex interventions with multiple components and elements at play.

We began this review with the presentation of a conceptual model of how literacy may be related to health outcomes. In this model, there are both direct and indirect pathways that link low literacy to poorer health outcomes in diabetes. In the direct pathway, low literacy may be linked to less knowledge about diabetes, which contributes to lower self-efficacy and difficulty with self-management behaviors and adherence. The difficulty with self-management behaviors results in poorer health outcomes. In the indirect pathway, literacy may be a marker for other barriers, such as lack of transportation, lack of social support, or lack of access to health care. Low literacy is not just about diabetes; it affects all aspects of life. These other barriers make up the indirect pathways that link low literacy with poorer health outcomes.

The success of the diabetes management programs over the other educational interventions presented in this review suggests that both the direct and indirect pathways may play an important role in linking literacy with diabetes outcomes. Interventions to improve outcomes among low-literacy patients with diabetes may need to address these indirect pathways with the longitudinal relationship and support that disease management provides. Group educational interventions and multimedia interventions may improve knowledge, but there is no evidence that they improve diabetes outcomes without providing other longitudinal support for patients. It is possible that group interventions could integrate this type of support more explicitly to improve effectiveness.

The studies presented in this review also tried to support the direct pathway linking low literacy to diabetes outcomes. The successful diabetes disease management programs studied in this review did improve patients' knowledge of diabetes and self-efficacy, although it is difficult to determine whether these were important elements contributing to the success of the programs in improving A1C. Interestingly, Cavanaugh et al.[13] did not find an improvement in patient-reported self-management behaviors in patients participating in the diabetes management program but did find an improvement in A1C. This suggests that self-management behavior may not be as important as other factors in the pathway linking literacy to health outcomes. However, the improved teaching techniques may have changed unmeasured knowledge and self-management behaviors.

Based on the studies presented in this review, we can make several potential conclusions about the components of diabetes disease management programs that led to success. The first is that personalized teaching is important in helping patients with low literacy overcome barriers to good health outcomes. Interventions that did not include personal interactions with providers or educators were not as successful as programs that did.

We can also conclude that longitudinal follow-up and patient support is important to improving health outcomes. This longitudinal follow-up includes components of disease management programs that help patients overcome barriers such as lack of transportation and lack of access to medication. Rothman et al.[17] followed patients for 1 year during an ongoing diabetes management program and found improvement in A1C that did not wane over time. In contrast, participants in the study by Cavanaugh et al.[13] completed a 3-month intervention

with follow-up at 3 and 6 months. The improvement in A1C at 3-month follow-up (–1.50, 95% CI –1.80 to –1.02) had waned by the 6-month follow-up (–1.05, 95% CI –1.30 to –0.70). None of the studies in this review had follow-up beyond 1 year, which is a needed area of future research in this field.

It is difficult to make firm conclusions about the importance of literacy- and numeracy-sensitive diabetes content as part of diabetes disease management programs. The study by Cavanaugh et al.[13] addressed the question of whether specific literacy- and numeracy-sensitive content is important to diabetes management programs. The fact that there was improvement in the intervention group in this study does begin to suggest that customizing content can lead to improved outcomes compared to generic content. However, the improvement in the intervention group waned by the 6-month follow-up, and there was no longer a difference between the intervention and control groups. If the customized approaches had taught improved diabetes self-management, we would have expected those effects to persist once the intervention ended. More focus on the content of diabetes education materials within diabetes management programs is another area of needed future research.

Our systematic review confirms that there are interventions that can improve outcomes for patients with diabetes and low literacy. These interventions combine personalized teaching with longitudinal follow-up and support of patients and are able to help patients overcome not only barriers to knowledge about diabetes, but also other important barriers such as those to transportation and access to medications and medical appointments. Future studies that further explore the essential components of disease management programs that lead to success are needed as clinicians work to incorporate elements of these programs into their practices.

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