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Systematic Review

Disease-related knowledge, health behaviours and clinical outcomes following an educational intervention in patients with diabetes according to their health literacy level: a systematic review

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Abstract

Background: The effectiveness of education programs designed to improve disease-related knowledge and change behaviours in people with diabetes has been established. Low health literacy (HL) is considered a barrier to improving health outcomes in people with diabetes. The evidence of the effects of education programs considering HL levels in diabetes has not been previously systematically reviewed. **Aim**: This systematic review aimed to verify the impact of education on patients' knowledge, health behaviour change and clinical outcomes in patients with diabetes with low and marginal Health Literacy (HL). **Methods**: A literature search of electronic databases was conducted for published articles from database inception to April 2020. Eligible articles included assessment of HL, disease-related knowledge, health behaviours (physical activity, diet, smoking cessation, medication adherence, self-care), and clinical outcomes (diabetes management based on A1C values, self-efficacy, perceived susceptibility of complications, self-reported medical care, patient activation, and diabetes-related distress) in diabetes patients that receive any type of education intervention. **Results:** Overall, 8 articles were included, of which 4 (50%) were RCTs. Four studies were considered "fair" quality. The most used screening instrument to assess HL was the Test of Functional Health Literacy in Adults short form (S-TOFHLA; n=5, 62.5%). All studies showed improvement in disease-related knowledge and behaviour after an education program, regardless of HL level. The overall quality of the evidence of the studies was graded as low to very low according to the GRADE scale. Included studies differed substantially in their education programs characteristics, such as mode of delivery and intervention content. **Conclusion**: Educational interventions can improve knowledge, change behaviour and improve clinical outcomes of diabetic patients with low or marginal health literacy.

Keywords: Health Literacy; Health Outcomes; Diabetes Mellitus; Education; Systematic Review.

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How can the results of this study be used in clinical practice?

- Healthcare providers should measure their patients' health literacy level and create their care plan in accordance to this characteristic.
- Educational strategies are important tools in the care of diabetic patients, even the ones with low to marginal health literacy.
- Disease-related knowledge of diabetes patients should be assessed.

Introduction

Diabetes is a chronic disease that affects more than 460 million people worldwide[1]. About 5 million adults died from diabetes in 2015 and the number of deaths is set to rise sharply by 2040[1,2]. Furthermore, it is one of the most costly diseases, being associated with 12% of global health expenditure in health services, loss of productivity and disability[1]. The most prevalent type of diabetes is type 2, which is directly related to obesity and is totally preventable[1,2]. Global organizations such as the International Diabetes Federation (IDF) and the World Health Organization (WHO) have proposed preventive measures for the disease to reduce costs and promote quality of life for people with diabetes[1-3]. One of these measures is patient education. Education, self-management, and empowerment are considered key points in managing diabetes[1-4].

Patient education is defined as "[...] the process by which health professionals – including physiotherapists - and others impart information to patients that will alter their health behaviours or improve their health status" [5:25]. Research has demonstrated a positive effect of diabetes education in prevention[1,3,6], knowledge[1,3], behaviour change[1,3], and avoidance of complications related to the disease[3,6]. The true goal of diabetes education should always be to improve patients' self-management abilities. This change can help them navigate through daily challenges in their care and ultimately promote short- and long-term quality of life[7-9]. However, studies have shown that only 20% of all patients with diabetes receive information about diabetes complications and risk factors from their healthcare providers[10].

Health literacy (HL) addresses personal and organizational components. Personal health literacy is defined as the degree to which individuals can find, understand, and use information and services to inform health-related decisions and actions for themselves and others. Organizational health literacy is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others[11]. Inadequate/low and marginal HL is common in patients with chronic diseases (including patients with diabetes), and considered a potential barrier to improve disease-related knowledge[12], behaviour change, and better health outcomes[13-15]. Adequate health literacy in the context of diabetes includes many skills that are critical to patients for managing their condition and navigating the health care environment, including reading labels and pill bottles, comprehending appointment information and following verbal directions[16].

Previous systematic reviews have confirmed the clinical effectiveness of patient education models designed to patients with diabetes[16-22]; however, none of them have evaluated the effect of education programs on disease-related knowledge and behaviour change considering HL levels in diabetes. Furthermore, a recent systematic review has also identified a gap in the literature regarding the relationship between HL and self-efficacy[22]. Thus, the objective of this systematic review was to verify the impact of education on disease-related knowledge, health behaviour change and clinical outcomes in patients with diabetes with low and marginal HL.

Methods

Design

This systematic review was registered prospectively with the Open Science Framework (OSF: https://osf.io/8qmg5/). Data is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[23]. Literature published from data inception until April 2020 was searched using the MEDLINE, PsycINFO, CINAHL, EMBASE and Cochrane CENTRAL databases, in conjunction with an information specialist. The search string explored the topics of diabetes mellitus (condition), health literacy, outcomes (knowledge, behaviour change and clinical parameters) and RCTs. Search terms were specific to each database. The search strategy for all databases is shown in the online Supplementary Material (please visit https://cpcrjournal.org/).

Inclusion and exclusion criteria

The following categories defined the inclusion criteria:

1) Design: randomized controlled trials (RCT) and quasi-experimental studies with educational interventions were included. Observational and qualitative studies were not included in this review. Reviews were identified as a source of additional primary studies.
2) Participants: patients with type I or II diabetes were considered for inclusion.
3) Intervention: any educational interventions about diabetes and its management, delivered by a healthcare provider were included. In order to be included, the educational intervention had to be described in accordance with the reporting guidelines for behaviour change interventions developed by Workgroup for intervention, development and evaluation research (WIDER)[24]. Specifically, at least 3 of the 8 recommended elements for intervention description had to be detailed: characteristics of those delivering the intervention (i.e. type of healthcare professional), characteristics of the recipients, the setting (i.e. time and place of intervention), mode of delivery, the intensity (i.e. contact time), the duration (i.e. number of sessions), adherence to delivery protocols, and a detailed description of the intervention content. No specific criteria was used for the comparison group in the studies to be included in the review.
4) Outcomes: studies had to either report the impact on health behaviours (named diet, physical activity, smoking cessation, medication adherence, self-care), disease-related knowledge or clinical outcomes (named diabetes management based on A1C values, self-efficacy, perceived susceptibility of complications, self-reported medical care, patient activation, and diabetes-related

distress). In this context, self-efficacy is defined as people's beliefs in their capability to organize and execute the course of action required to deal with prospective situations[25]. Studies have shown that being highly self-efficacious is a key factor in successful chronic disease self-management[26,27].

5) Studies published in English, Spanish or Portuguese.

Data collection and analysis

Two authors independently read the titles and abstracts identified from the initial search to select studies that met our inclusion criteria. They also retrieved full-text articles and reviewed the results to determine eligibility. Any disagreements were resolved through discussion between the two investigators and, if needed, consultation with a third author.

Data extraction was undertaken by a single reviewer and checked by a second reviewer. The Downs and Black[28] scale was used to assess the quality of the studies. This tool consists of 27 items and evaluates the quality of articles in 5 areas as follows: reporting, external validity, internal validity (bias), internal validity (confounding) and power. Answers were scored 0 (no or unable to determine) or 1 (yes), except for one item in the reporting subscale, which could be scored 0, 1 or 2. Total points for each article were categorized as "good", "fair", or "poor" based on the United States Preventive Services Task Force approach[29].

Although some of the included studies were RCT, it was not possible to perform meta-analysis due to the great heterogeneity of the studies (i.e., different methods of intervention such as frequency, duration, intensity, ways of delivery). Thus, descriptive analysis was performed on the results. The quality of evidence was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE)[30]. The evaluation was based on four factors that can reduce the evidence's quality (study limitations, the inconsistency of results, indirectness of evidence, imprecision, and publication bias).

Results

Initial searching yielded 3084 records after duplicates removed. After the screen, 174 full-articles were assessed for eligibility. Overall, 8 articles were included in this systematic review[31-38]. A flow diagram depicting the search results, reasons for exclusion, and study selection is presented in Figure 1.

Characteristics of included studies

Table 1 summarizes the methodological characteristics of the 8 included studies[31-38]. Four studies were randomized controlled trials[31,33-35] and 4 were quasi-experimental[32,36-38].

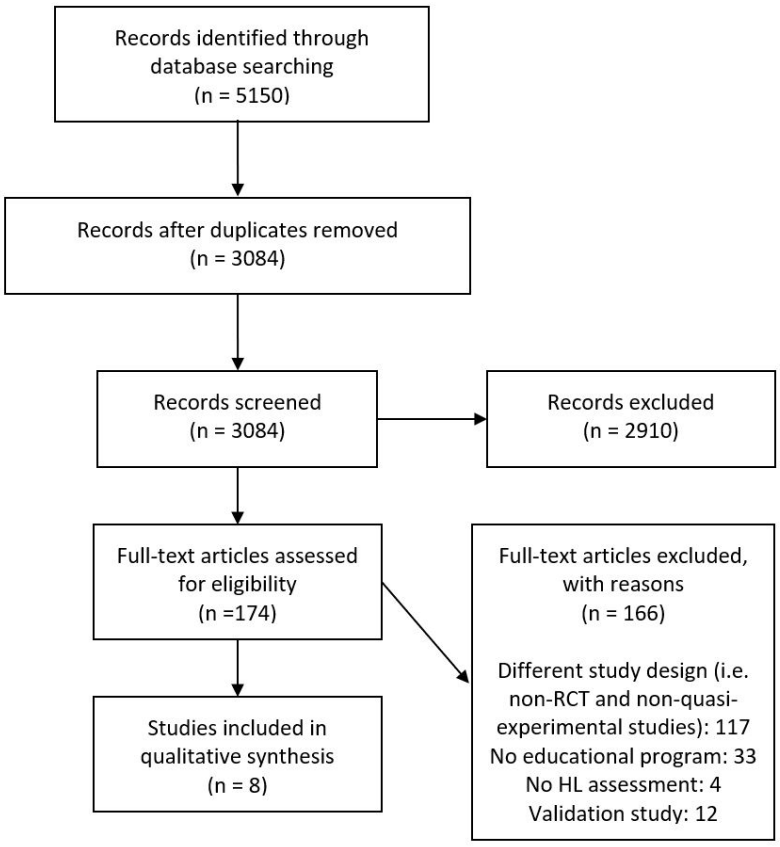

Figure 1. Flow diagram.

Table 1. Methodological characteristic of the included studies.

Study Country	Study Design Centers Sample Size **(Characteristics)**	Quality Assessment Score (Classification)	HL Screening Instrument	Prevalence of low and marginal HL	Outcome	Main results and Limitations
Gerber et al.[31] USA	RCT	19-28 (Good)	S-TOFHLA	68 (56%) - Low or marginal, intervention group	Diabetes management (hemoglobin A1c values)	Results: Among subjects with higher literacy, there was a small decrease in A1C in the control group (-0.5 vs +0.3%, p=0.043). Exploratory analysis of low literacy subjects with poor glycemic control (baseline A1C≥9.0% in 26 subjects) showed there was a greater decrease in
	5 centers			67 (55%) - Low or marginal, control group	Disease-related knowledge	A1C in the intervention group than control group (-2.1 vs -0.3%, p= 0.036). The greatest difference in perceived susceptibility was in lower– health literacy subjects (1.48 vs. 0.19, p=0.016). 0.267). Among individuals with lower health literacy, there was a trend toward greater improvement in self-efficacy for the intervention group (1.51 vs. 0.99, p=0.113).
	183 participants (54.8±11.7 years old; 66.0% women; type of diabetes NR)				Self-efficacy Self-reported medical care Perceived susceptibility of complications	Limitations: There was less computer use among elderly and lower–health literacy participants, possibly dampening the potential effect of the intervention. Inability to include the collection of behaviourally relevant data, such as adherence to clinic visits or annual eye examinations. Specific self-management improvements demonstrating behavioural change in response to specific multimedia lessons are difficult to estimate.
Kandula et al.[32] USA	Quasi-experimental	16-28 (Fair)	S-TOFHLA	16 (8%)	Disease-related knowledge	Results: Patients across all literacy levels had significant increases in knowledge scores after viewing the MDEP (p< 0.001). Patients with inadequate literacy learned significantly less after the MDEP (adjusted beta-coefficient -2.3, SE=0.70) compared to those with adequate literacy.
	2 centers 190 participants (56.0±9.3 years old; 73.0% women; 45.0% type 2 diabetes)					Limitations: Lack of a control group, a small sample size, and limited generalizability since patients were recruited from two clinics in Chicago.
Koonce et al.[33] USA	RCT	17-28 (Fair)	Three-health literacy screening questions	21 (13%)	Disease-related knowledge	Results: The intervention group members' diabetes knowledge increased significantly on average after exposure to educational materials targeted to their health literacy levels and learning style preferences. The mean number of diabetes knowledge questions answered correctly by the intervention group increased significantly after 2 weeks (Δ2.66, p<0.000), which persisted at 6 weeks (Δ2.46, p<0.00).
	1 center 128 participants (53.5±10.9 years old; 59.5% women; 100.0% type 2 diabetes)					Limitations: The majority of recruited patients tested as having adequate health literacy levels. Study follow-up period of six weeks did not allow for more long-term evaluation of intervention outcomes.
Muller et al.[34] United Kingdom	RCT	19-28 (Good)	Single item	37/478 (7.7%) – group plain text	Disease-related knowledge	Results: In both intervention groups, and across all health literacy levels, the score at follow-up was significantly higher than at baseline, indicating that participants from all groups had more positive attitudes and intentions toward physical activity after viewing the intervention materials.
	43 centers 1041 participants (62.0±11.3 years old; 36.4% women; 100.0% type 2 diabetes)			30/527 (5.7%) – group interactive	Physical activity	Limitations: This study failed in recruiting many participants with very low levels of health literacy. Not powered for examining interactions. No longer-term follow-up. No control group.

Note: HL: indicates health literacy; LHL: low health literacy; MDEP: multimedia diabetes education program; NR: not reported; RCT: randomized controlled trial; SE: standard error, S-TOFHLA the Test of Functional Health Literacy in Adults short form; TL: transformative learning; USA: United States of America.

Table 1. Continued...

Study Country	Study Design Centers Sample Size **(Characteristics)**	Quality Assessment Score (Classification)	HL Screening Instrument	Prevalence of low and marginal HL	Outcome	Main results and Limitations
Negarandeh et al.[35] Iran	RCT 1 center 127 participants (50.1±9.0 years old; 45.7% women; 100.0% type 2 diabetes)	18-28 (Good)	TOFHLA	All patients included had Low HL	Disease-related knowledge Medication adherence Diet	Results: Both educational strategies increased knowledge, as well as adherence to medications and diet among diabetes patients and low health literacy. Limitations: To use self-report instruments to measure medication and dietary adherence. To use questionnaires that were not confirmed using construct validity due to time limitation.
Ntiri and Stewart[36] USA	Quasi-experimental 2 centers 20 participants (68.1±NR years old; 65.0% women; type of diabetes NR)	9-28 (Poor)	S-TOFHLA LAD	Not reported	Disease-related knowledge	Results: The HL scores and diabetic test scores were significantly increased following the TL intervention. Limitations: Comparative educational methods as well as follow-up with other interactive classes or diabetes informational activities were not performed.
Swavely et al.[37] USA	Quasi-experimental 6 centers 106 participants (56.8±10.4 years old; 66.0% women; 100.0% type 2 diabetes)	12-28 (Fair)	S-TOFHLA	27 (25.5%)	Disease-related knowledge Self- efficacy Self-care (diet, exercise, foot care and blood glucose monitoring) Diabetes management (hemoglobin A1c values)	Results: When stratified by health literacy level, the knowledge gain was significant for both the adequate and inadequate groups ($p<0.001$). There was also a significant improvement in preprogram and post program A1C levels when compared prior to starting the LHL diabetes education program and 3 months after completion of the program ($p=0.007$). Limitations: No matched comparison group. The greater than expected time for patients to complete the program resulted in fewer available A1C values for comparison.
Wallace et al.[38] USA	Pilot quasi-experimental 3 centers 250 participants (56.0±NR years old; 64.8% women; 100.0% type 2 diabetes)	15-28 (Fair)	S-TOFHLA	72 (28.8%)	Patient activation Diabetes-related distress Self-efficacy Self-care Diabetes self-management activities Disease-related knowledge	Results: Statistically significant ($p \leq 0.001$) and clinically important (effect sizes = 0.29–0.42) improvements were observed in participants' activation, self-efficacy, diabetes-related distress, self-reported behaviours, and knowledge. Improvements were similar across literacy levels. Limitations: Lack of a control group, lack of objective clinical outcome measures, and difficulty interpreting language-based differences since language was perfectly confounded by site.

Note: HL: indicates health literacy; LHL: low health literacy; MDEP: multimedia diabetes education program; NR: not reported; RCT: randomized controlled trial; SE: standard error, S-TOFHLA the Test of Functional Health Literacy in Adults short form; TL: transformative learning; USA: United States of America.

The included studies involved 2,045 study participants from 63 centers. The majority of the studies (n=6) were undertaken in the United States, 1 in the United Kingdom, and 1 in Iran.

The quality ratings of the studies are also shown in Table 1. Overall, 3 studies were considered "good", 4 studies "fair" and 1 study was considered "poor" quality. The overall quality of the evidence of the studies was classified as low to very low according to the GRADE scale (Table 2).

This review identified four different tools used to screen HL in patients with diabetes: Test of Functional Health Literacy in Adults short form (S-TOFHLA)[39], 3 health literacy screening questions[40], a single item[41] and Literacy Assessment for Diabetes (LAD)[42]. Information regarding the different HL screening instruments used in the studies is shown in Table 1.

The prevalence of low and marginal HL is showed in Table 1. One study only included patients with low HL[35], and one study did not report the number of patients with low HL[36]. As stated before, the most used tool was S-TOFHLA and the studies that used it reported a range from 8% to 14.4% of marginal HL and 8% to 58% classified as low HL[32,37,38]. One study[31] combined marginal and low scores and reported 56% for both classifications.

Characteristics of educational interventions

Table 3 summarizes the nature of educational interventions. All included studies described at least 3 of 8 recommended elements for intervention description in details. Five studies

Table 2. GRADE.

Outcome	Effect	Number of participants (studies)	Domain assessment	Certainty in the evidence
Disease-related knowledge	All studies showed an improvement after intervention	2,045 participants (8 studies)	Study limitations: X Indirectness: √ Imprecision: √ Inconsistency: X Publication bias: √	⊕⊕⊖⊖
Behaviour change - Diet	All studies showed an improvement after intervention	483 participants (3 studies)	Study limitations: X Indirectness: √ Imprecision: X Inconsistency: X Publication bias: √	⊕⊖⊖⊖
Behaviour change - Physical activity	All studies showed an improvement after intervention	1,397 participants (3 studies)	Study limitations: X Indirectness: √ Imprecision: √ Inconsistency: X Publication bias: √	⊕⊕⊖⊖
Clinical outcome - A1c values	One study showed improvement after intervention	289 participants (2 studies)	Study limitations: X Indirectness: X Imprecision: X Inconsistency: X Publication bias: √	⊕⊖⊖⊖
Clinical outcome - Self-efficacy	All studies showed an improvement after intervention	539 participants (3 studies)	Study limitations: X Indirectness: X Imprecision: √ Inconsistency: X Publication bias: √	⊕⊖⊖⊖

High certainty ⊕⊕⊕⊕, moderate certainty ⊕⊕⊕⊖, low certainty ⊕⊕⊖⊖ and very low certainty ⊕⊖⊖⊖. √ not serious limitations; X serious limitations.

Table 3. Characteristics about the nature of educational interventions.

Study Country	Health provider delivering the intervention	Setting	Delivery format	Intensity: - Contact time - Frequency of each educational session	Mean number of educational sessions	Education content
Gerber et al.[31] USA	NR	Outpatient clinic	Computer-based	NR	NR	Introduction to diabetes Blood glucose management Oral medications and insulin Nutrition and physical activity Depression and stress Oral hygiene Prevention of complications (including eye, foot, cardiovascular, and kidney diseases)
Kandula et al.[32] USA	NR	Outpatient clinic	Computer-based	5 minutes	NR	Diabetes Blood sugar control
Koonce et al.[33] USA	NR	Outpatient clinic	Educational material (visual and read)	NR	NR	Diabetes
Muller et al.[34] UK	Team of health researchers	Outpatient clinic	Web-based materials Plain-text Web-based version	NR	NR	Physical activity
Negarandeh et al.[35] Iran	Nurse	Outpatient clinic	Teach-back Pictorial image Both individually in a private room	20 minutes Three weekly sessions	NR	Diabetes Medication Diet
Ntiri and Stewart[36] USA	Nurse	Community center	Educational class	Sixty minutes Twice a week for three weeks	6	Diabetes Diet Exercising Medications
Swavely et al.[37] USA	Diabetes educators	Primary care	Individualized Education group	13 hours of education over 12 weeks	NR	Introduction to the human body Information about the disease state
Wallace et al.[38] USA	Research assistant	Internal medicine practices	In person Telephone	Three times in one month	NR	Diet Physical activity Blood glucose monitoring Medication adherence Insulin use

Note: NR: indicates not reported; UK: United Kingdom; USA: United States of America.

reported that health professionals (e.g. nurse and diabetes educator) delivered the intervention[34-38].

All studies reported their settings and the most prevalent was outpatient clinics, considered in five studies[31-35]. The most frequent modes of delivery found were computer/web-based[31,32,34] and educational group[36,37]. Four studies[35-38] provided information about frequency of delivery, which ranged from 1 to 12 weeks. However, duration and total number of sessions were poorly reported.

Education content was focused mainly on information about diabetes (i.e.: what is diabetes, how to reduce risk and how to manage it)[31-33,35-38], nutrition[31,35,36,38], and physical activity[31,34,36,38].

This review demonstrated that on average: nurses were the most frequent educator; most educational programs were delivered in outpatient clinics; computer/web-based were the most common delivery format; the most common content approached were diabetes, physical activity and diet. Few studies provided information regarding education duration and frequency, but when reported, they varied from 5 to 20 min a day of education and 1 to 12 weeks of intervention.

Disease-related knowledge

Disease-related knowledge was assessed in eight studies[31-38] and seven tools were used, as follow: the Diabetes Knowledge Test, a 23-item questionnaire, used in two studies[33,36]; the Spoken Knowledge in Low Literacy in Diabetes (SKILLD), a 10-item tool, used in one study[37]; a 17-item diabetes knowledge questionnaire developed by the authors, designed to reflect the content[32]; a 9-item quiz created by the authors based on the intervention content[34]; a 9-item instrument developed by the authors to reflect the guide's content[38]; a 22-item questionnaire[35]; and a scale previously developed and validated using Rasch modeling[31].

Disease-related knowledge improved after intervention in all included studies. In Gerber et al.[31], even though no differences between groups were found, participants with low HL demonstrated gains compared with those having high HL. In Koonce et al.[33], the intervention group improved significantly their knowledge after exposure to educational material targeted to their health literacy levels and learning style preferences. Muller et al.[34] found significant differences between groups. The interactive group scored higher than the plain-text group ($p<0.001$). In Negarandeh et al.[35], results indicated that there were significant differences between the two intervention groups with control group ($p<0.001$), however there was no differences between the two intervention groups.

Related to the quasi-experimental studies, similar results were found. Kandula et al.[32] showed that disease-related knowledge improved significantly after intervention ($p<0.001$), however, patients with inadequate HL learned less compared to those with adequate HL. Ntiri and Stewart[36] showed a positive effect of the intervention on disease-related knowledge. Swavely et al.[37] reported that the knowledge improved after intervention in all patients, regardless HL levels. Wallace et al.[38], reported statistically significant ($p<0.001$) changes in participants' knowledge when comparing baseline and post-intervention moments.

Behaviour change

Behaviour change – diet[35,37,38], physical activity[34,37,38], and medication adherence[35] – was evaluated in four studies. Negarandeh et al.[35], showed that diet and medication adherence improved significantly between the two intervention groups with control group ($p<0.001$); however, there was no differences between the two intervention groups. Muller et al.[34] reported that participants from all groups improved the intention to perform physical activity after intervention, regardless the levels of HL ($p<0.001$). Swavely et al.[37] and Wallace et al.[38] showed statistically significant changes ($p<0.001$) in participants' diet and physical activity comparing baseline and post-intervention moments.

Clinical outcomes

The followed clinical outcomes were assessed: diabetes management (based on A1C values)[31,37], self-efficacy[31,37,38], perceived susceptibility of complications[31], self-reported medical care[31], patient activation[38], and diabetes-related distress[38]. Patient education seems to interfere mostly in self-efficacy, perceived susceptibility of complications, patient activation and diabetes-related distress.

Gerber et al.[31] showed that there was no significant differences in A1C values between groups. On the other hand, Swavely et al.[37] identified an improvement in A1C values after intervention ($p=0.007$).

Self-efficacy scores as measured on a scale of 1–10 were significantly improved at the end of the intervention ($p<0.001$) in Swavely et al.[37] study. The same result was found in Wallace et al.[38]: an improvement of self-efficacy after intervention, as well as in Gerber et al.[31].Although non-significant, there was a trend towards greater improvement in self-efficacy for the intervention group among individuals with lower health literacy.

Gerber et al.[31] showed that there was no difference between groups in self-reported medical care. However, perceived susceptibility of complications was greater for intervention group ($p=0.009$) and greatest in low HL participants ($p=0.016$). Lastly, Wallace et al.[38] reported that patient activation and diabetes-related distress changed significantly from baseline to study completion.

Discussion

This systematic review investigated the impact of patient education on disease-related knowledge, health behaviour change and clinical outcomes in patients with diabetes with low and marginal HL. Results suggest that educational interventions increase disease-related knowledge and change

behaviour after education program for patients with diabetes with low health literacy. Eight studies showed that different delivery modes (i.e. web-based, phone-based, educational material, educational classes) could improve disease-related knowledge. Furthermore, studies showed that educational interventions might promote improvements in physical activity, healthier dietary habits, medication adherence, and self-efficacy.

According to Powers et al.[43] diabetes education is a process to facilitate diabetes self-care. An efficient delivery involves clear communication and collaboration among the healthcare team, which can guarantee that proper interventions are being used[43]. Previous studies showed that with different mode of delivery (e.g. individual, group, solo and team) educational strategies could improve outcomes such as knowledge and A1C[17-19,44]. Similar results were observed in this review, where the outcomes changed after intervention as well as when compared between intervention and control groups, regardless levels of HL.

Previous studies[17,45,46] also showed that duration of intervention could vary and still promotes changes in outcomes. However, we were not able to evaluate duration in this review, because most of studies did not report details about their interventions. Furthermore, other studies[47,48] are in line with this review: appropriate educational programs to this specific population could improve results and participation.

The results presented in this review should be interpreted with caution. The extensive variety of interventions, educators, content delivered and details about duration and frequency of intervention as well as different tools used to measure the outcome mitigated the use of meta-analysis and the overall quality of the evidence of the studies was classified as low to very low according to the GRADE system. Also, generalizability is limited as only English, Spanish and Portuguese articles were included.

It is important to note that included studies differed substantially in their education programs characteristics, such as mode of delivery and interventional content. Also, most of the included studies did not report details about the education provided as recommended by WIDER[24], such as educator, duration and frequency of intervention. Without detailed information, it is difficult to draw conclusions on what is the most effective educational intervention that can positively impact patients with diabetes with limited HL. Finally, not all tools used to assess disease-related knowledge were validated.

In conclusion, this systematic review suggests that educational programs for diabetic patients with low to marginal health literacy could improve disease-related knowledge, behaviour change and clinical outcomes, even though we were not able to perform meta-analysis. It is expected that future randomized controlled trial might be conducted in a way to facilitate pooled data in meta-analysis.

Healthcare professionals involved with patients with diabetes should recognize the importance of educational programs for patients with low or marginal HL. They should implement strategies to educate diabetic patients with low or marginal HL to be able to manage their health condition. Also, assessing HL and disease-related knowledge of patients using validated instruments should be included in the standard of care of these patients.

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Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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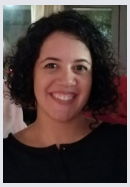

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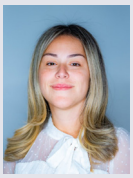

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