Development and Pilot Evaluation of Literacy-Adapted Diabetes and CVD Education in Urban, Diabetic African Americans

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BACKGROUND: Despite prevalent low literacy nationally, empirical research on the development and testing of literacy-adapted patient education remains limited.

OBJECTIVE: To describe procedures for developing and evaluating usability and acceptability of an adapted diabetes and CVD patient education.

DESIGN: Materials adaptation for literacy demand and behavioral activation criteria, and pre-/post-test intervention evaluation design.

PARTICIPANTS: Pilot sample of 30 urban African-American adults with type 2 diabetes with Below Average literacy (n=15) and Average literacy (n=15).

MEASUREMENTS: Wide Range Achievement Test (WRAT-3, Reading), assessment of diabetes and CVD knowledge, and patient rating scale.

RESULTS: Reading grade levels were: >12th, 30%; 10th–12th, 20%; 7th–9th, 10%; 4th–6th grade, 10%; and ≤3rd grade or unable to complete WRAT-3, 30%. Education materials were modified to a reading level of ≤4th grade. Knowledge improved for Below Average (2.7 to 4.7, p=0.005) and Average (3.8 to 5.7, p=0.002) literacy groups, with up to a ten-fold increase, at post-education, in the number of participants responding correctly to some content items. The print materials and class received maximum usability and acceptability ratings from patients.

CONCLUSIONS: Development of patient education meeting very low literacy criteria was feasible, effective for knowledge acquisition, and highly acceptable irrespective of literacy level.

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National assessments reveal low literacy as prevalent throughout the US, and among Black/African-American adults, fewer than 50% fall within Proficient or Intermediate literacy ranges.[1,2] Low literacy is considered a contributor to health disparities.[3,4] Yet, methods for adapting materials for low literacy are not clearly understood or widely disseminated, and there remains little empirical research testing the usability of literacy-adapted materials.[5,6] The purposes of this study were to develop a lower-literacy patient diabetes and cardiovascular disease (CVD) education and to pilot test its acceptability and usability in a sample of urban, African-American, type 2 diabetic adults with Below Average and Average literacy.

METHODS

Development of Low-Literacy Education Materials and Module

The education was developed for a larger study, Project DECIDE (Decision-Making Education for Choices In Diabetes Everyday), a randomized controlled trial of a combined diabetes and CVD education and patient problem-solving training for disease control in urban, African-American adults with type 2 diabetes and a high CVD risk profile.

Sources of patient health information were American Diabetes Association practice recommendations[7] and patient education teaching modules.[8] Three resources for development of low-literacy materials were used[9–11] for guidance in reducing literacy demand and increasing behavioral activation characteristics of original materials.[6] Additional resources were used for adapting information to meet accessibility needs due to vision impairment[12] and content needs due to physical impairment resulting from diabetes complications or older age[13] (Table 1). Reading grade level and reading ease scores for the print materials and the orally delivered intervention protocol were determined using the Flesch-Kincaid analysis, obtained via computer calculation in Microsoft Word, 2003.

The education consisted of one 90-min group education class and a participant binder containing printed materials. The education covered three content areas: facts about diabetes and heart disease; targets for control of blood sugar, blood pressure, and cholesterol; and self-management behaviors (self-monitoring, taking medications, healthy eating, physical activity).

Table 1. Examples of Adaptations Made for Low Literacy and Usability

Characteristic	Adaptations
Literacy demand*	Overall reading grade level of 4.4 (<5th grade) for information presented orally Reading grade levels of 0.5–4.0 (≤4th grade) for print patient handouts 14–16 point font size Line length ≤50 characters and spaces for print handouts Information organized into three parts with predictable sequence/flow of information Concise information limited to main points, and lists limited to ≤5 items Use of organizing headers, subheaders, and bullet points
Behavioral activation†	Content of information was behaviorally focused rather than medical information outside the context of patient behavior Specific "how to" information given to facilitate acting on recommended behaviors Handouts contained activities/worksheets both for personalization of information (e.g., discussion of target ranges for blood glucose, blood pressure, and cholesterol was accompanied by participants completing a worksheet to compare their own most recent lab results) and interaction with the content (e.g., discussion of the four self-management behaviors was accompanied by participants identifying in a handout/worksheet which behaviors were most difficult for them to do) Food shopping/food selection recommendations were made relevant with regard to available resources (e.g., neighborhood and other commonly used stores, lower cost) Physical activity recommendations were made relevant with regard to urban environments and available resources (e.g., household activities, stair climbing, planning the number of blocks to and from bus stop locations, community activities, using common items such as canned goods or detergent bottles for resistance exercises)
Functional limitations/ disability‡	Black ink on white paper for contrast Flat (non-gloss) paper Multimodal information delivery (print handouts, oral, and visual presentation using slides that matched pages in the notebooks) Physical activity recommendations for older adults and persons with disabilities Information available about products for low-vision glucose monitoring

Factors that impact approachability, readability, processing, and comprehension of print information[9–11]

†*Factors that impact meaningfulness, application, and usability of information[9–11]*

‡*Factors that impact accessibility (information acquisition) and behavioral activation for persons with functional limitations or disability[12,13]*

Procedures for Pilot Evaluation Study

Self-reported African-American adults with a diagnosis of type 2 diabetes, originally identified from an administrative database of a university-affiliated managed care organization, were mailed letters announcing the study and inviting them to hear more from a research assistant who would call the home. Persons who did not return an enclosed, refusal postcard received a telephone call from a research assistant, who described the study, invited them to participate, and screened for initial eligibility. Interested persons were scheduled for a baseline visit. At baseline, each participant was administered an informed consent procedure used in previous research with urban populations.[14] Consent documents were read aloud and provided in print. Understanding was tested using a Consent Understanding Questionnaire comprising six questions to which participants gave a yes/no response. Using this procedure, an individual who answers any question incorrectly after the material is reviewed twice is ineligible to consent to participation. All participants were able to consent.

Questionnaires were administered in interview format. A response book was provided with the response choices for visual presentation to supplement the interview. Laboratory and physical measures were taken to determine CVD risk profile for the larger study. Persons were eligible for the education class if they met high CVD risk profile criteria, defined as any of the following: hemoglobin A1c (A1C) >7.0%, systolic blood pressure >130 mmHg and diastolic blood pressure >80 mmHg, and/or LDL cholesterol >100 mg or HDL cholesterol <50 mg.[7]

This pilot study comprised the first 30 eligible participants. Each attended one 90-min education class comprising six to eight patients. Classes were led by a specialist in diabetes education and rehabilitation counseling (R.R.), using an intervention manual to standardize administration. An observer (F.H.-B.) provided quality assurance. Study personnel conducting assessments, intervention, and quality assurance were blinded to the assessed reading grade levels of study participants. The study was approved by the Johns Hopkins University Institutional Review Board.

Measures

Literacy was assessed with the Wide Range Achievement Test (WRAT-3) Reading subtest.[15] This standardized test assesses ability to recognize and name letters and pronounce words of increasing difficulty. The Manual provides psychometric data and scoring instructions for determining reading raw scores, reading grade levels, and standard scores based on age-group normative data.[15]

The Diabetes and CVD Knowledge test was developed for evaluation of the educational program. Nine items assess participants' basic knowledge about diabetes and CVD, based upon evidence-based practice recommendations[7] and ADA-recommended type 2 diabetes self-management education curricula.[8,16] Items assessed knowledge of clinical targets for fasting blood glucose, A1C, blood pressure, LDL and HDL cholesterol, and ability to identify high-fiber foods, LDL as "bad" cholesterol, and CVD risk self-management behaviors. The response format was multiple choice, with "I don't know" provided as an option in each case. A correct response yielded a score of 1 point, and an incorrect response or a response of "I don't know" yielded 0 points. Points were summed to derive a total score. Knowledge was assessed at baseline and at 1-week following the education class.

Participants rated their satisfaction with accessibility and usefulness of the education materials and class using a nine-item scale. Participants rated each item on a scale from 0

(lowest) to 5 (highest). Ratings were obtained at 1-week following the education class.

Statistical Analyses

Descriptive statistics were used to present baseline sociodemographic characteristics. WRAT-3 raw scores were converted to standard scores provided in the test manual[15] classifying participants' literacy as Above Average (standard scores ≥120), Average (standard scores 90–119), or Below Average (standard scores 48–89) relative to same-aged peers. Pre- and post-education changes in knowledge between and within literacy groups were analyzed using Wilcoxon rank test. Patient ratings of accessibility and acceptability were compared between groups using Wilcoxon rank test. Analyses were conducted using STATA, version 9.2 (College Station, TX).

RESULTS

Sample Characteristics

WRAT-3 reading levels for the 30 participants were: >12th grade, 30%; 10th–12th grade, 20%; 7th–9th grade, 10%; 4th–6th grade, 10%; and ≤3rd grade or unable to complete the test, 30%. Using standard scores, 50% had Average literacy (67% female, age 62.1 ± 11.2, education 13.7 ± 2.2 years), and 50%, Below Average literacy (53% female, age 60.9 ± 8.9, education 9.3 ± 3.3 years).

Education Effect on Knowledge Acquisition

Following the education, knowledge scores increased for Below Average (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) literacy groups. The Below Average group showed largest gains in numbers of participants responding correctly to recommended ranges for A1C (ten-fold increase) and HDL cholesterol (two-fold increase), and goals for CVD self-management (two-fold increase). In the Average group, largest gains were found in participants' correctly differentiating LDL as "bad" cholesterol (four-fold increase) and knowing the recommended range for blood pressure (two-fold increase).

Patient Ratings of Usability and Acceptability

Both groups of participants rated the education and materials as highly acceptable and usable (Table 2). Below Average participants rated amount of new information learned slightly higher than Average participants.

Table 2. Participant Ratings of Information Accessibility and Acceptability

	Below Average Literacy (n=15)	Average Literacy (n=15)	P-value
How helpful was the notebook/binder you received and the information in it?	5.00	4.9±0.3	0.32
How easy to understand was the information in your notebook/binder?	5.00	4.9±0.3	0.32
How easy to see was the information in your notebook/binder?	4.8±0.4	4.8±0.6	0.70
How helpful was the class?	5.00	4.9±0.2	0.32
How much did you feel you learned from the class?	4.9±0.4	4.4±0.7	0.04
How much of the information was new to you?	4.5±0.6	3.9±1.3	0.17
How easy to understand was the information you heard during the class?	4.9±0.3	5.00	0.32
How easy was the information to see (size, amount) during the class?	4.6±0.7	4.7±0.8	0.41
Overall, how satisfied were you with the education you received?	5.00	4.9±0.3	0.32

Each question was rated on a 0 to 5 scale, with 0 as the lowest rating (e.g., not at all, nothing, hard to understand/see) and 5 as the highest rating (e.g., extremely, everything, easy to understand/see)

DISCUSSION

Modification of diabetes and CVD patient education materials to meet a very low literacy level (≤4th grade) was feasible using available criteria and strategies for low literacy health information development.[9–11] This literacy-adapted education yielded significant knowledge gain for patients with Below Average and Average literacy. Patient ratings demonstrated that simplified, clearly presented health information was acceptable even to persons who did not fall into a low literacy range.

A well-established, standardized literacy instrument was used in this study rather than a health literacy measure. Because the goal was to modify materials to meet low literacy needs, it was important to know specifically what reading grade level needed to be achieved. Therefore, the WRAT-3 was selected, as it yields both reading grade levels and normative scores corrected for age, which otherwise confounds interpretation of literacy status. It was important to know that 30% of our sample was not only "low literate," but that they had reading skills at or below the 3rd grade level. Conventional targets that otherwise would have been applied based on a general classification of "low literate," such as <8th grade or <6th grade, would have been inadequate.

The current study employed standard education methods of printed handouts and verbal information, but adapted for lower literacy. Continued research on education materials development and methods, including examining the effectiveness of more graphic/visual presentation of information, is warranted.

Finally, it is important to note that this study examined the feasibility of modifying materials, acceptability and usability of the materials, and effectiveness for knowledge acquisition. This pilot study was not designed to examine effectiveness of the education on subsequent behaviors or clinical outcomes, which are the ultimate goal of self-management interventions. This study intentionally examined registration and understanding of information because this often overlooked step is a prerequisite for subsequent effective use of health information, particularly for patients with low literacy. Education alone is generally not sufficient for effective patient self-management of chronic disease[17] due to the challenge of applying acquired knowledge in the context of daily living and barriers to care.[18] The effectiveness of this education, combined with problem-solving training for applying knowledge, will be tested in the larger study, Project DECIDE.

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