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REVIEW

Impact of educational interventions in reducing diabetic complications: a systematic review

Impacto de intervenções educativas na redução das complicações diabéticas: revisão sistemática

Impacto de intervenciones educativas en la reducción de las complicaciones diabéticas: revisión sistemática

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ABSTRACT

Objective: To identify in the literature evidence of the effectiveness and efficacy of educational interventions in reducing metabolic and/or vascular complications in adults with diabetes mellitus. **Method:** A systematic review performed in LILACS, IBECS, CUMED, CINAHL and Medline databases and in the online library SciELO with studies published from 2004 to 2014. **Results:** Eleven studies were included (5 randomized clinical trials and 6 quasi-experimental). We only identified studies that analyzed vascular complications. **Conclusion:** Two clinical trials demonstrated efficacy in reducing cardiovascular complications, of cataract or retinopathy and nephropathy and all the quasi-experimental studies showed effectiveness in reducing feet ulcers, peripheral neuropathy and vasculopathy, and maintenance of kidney function.

Descriptors: Health Education; Evaluation of the Efficacy-Effectiveness- of Interventions; Diabetic Complications; Diabetes *Mellitus* Type 1; Diabetes *Mellitus* Type 2.

RESUMO

Objetivo: identificar na literatura evidências da efetividade e eficácia de intervenções educativas na redução de complicações metabólicas e/ou vasculares em adultos com diabetes *mellitus*. **Método:** revisão sistemática realizada nas bases de dados LILACS, IBECS, CUMED, CINAHL e Medline e na biblioteca on-line SciELO com estudos de 2004 a 2014. **Resultados:** incluídos 11 estudos (5 ensaios clínicos randomizados e 6 quase experimentais). Apenas pesquisas que analisaram complicações vasculares foram identificadas. **Conclusão:** dois ensaios clínicos mostraram eficácia na redução de complicações cardiovasculares, da catarata ou retinopatia e nefropatia e todos os estudos quase experimentais revelaram efetividade na redução das úlceras nos pés, da vasculopatia e da neuropatia periféricas e manutenção da função renal.

Descritores: Educação em Saúde; Avaliação de Eficácia-Efetividade de Intervenções; Complicações Diabéticas; Diabetes *Mellitus* Tipo 1; Diabetes *Mellitus* Tipo 2.

RESUMEN

Objetivo: identificar en la literatura evidencias de la efectividad y eficacia de intervenciones educativas en la reducción de complicaciones metabólicas y/o vasculares en adultos con diabetes mellitus. **Método**: revisión sistemática realizada en las bases de datos LILACS, IBECS, CUMED, CINAHL y Medline, y en la biblioteca online SciELO, consultado estudios de entre 2004 y 2014. **Resultados**: fueron incluidos 11 estudios (5 ensayos clínicos randomizados y 6 cuasiexperimentales). Solamente fueron identificadas investigaciones que analizaron complicaciones vasculares. **Conclusión**: dos ensayos clínicos mostraron

eficacia en la reducción de complicaciones vasculares, de la catarata o retinopatía y de la nefropatía; y todos los estudios cuasiexperimentales revelaron efectividad en la reducción de las úlceras de pie, la vasculopatía y la neuropatía periféricas, y en el mantenimiento de la función renal.
Descriptores: Educación en Salud; Evaluación de Eficacia-Efectividad de Intervenciones; Complicaciones de la Diabetes; Diabetes Mellitus Tipo 1; Diabetes Mellitus Tipo 2.

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INTRODUCTION

Chronic non-communicable diseases (NCD), such as diabetes *mellitus* (DM), hypertension, and chronic obstructive pulmonary disease, occupy the top positions in the world mortality statistics: it is estimated that 73% of deaths in 2020 will be caused by such diseases[1]. Approximately 347 million people worldwide have DM, 90% of type 2[2]. It is estimated that this number will have increased to 353 million in 2030, making it the 7th leading cause of death[3].

From 2008 to 2010, DM and its complications accounted for 10.3% and 36.6% of the total number of hospitalizations in the Brazilian Unified Health System, with a mean cost of R$1,302 to R$1,315 per hospitalization, respectively. Among the major complications of the disease, there are acute metabolic dysfunction (ketoacidosis and hypoglycemic coma), microvascular dysfunction (nephropathy, retinopathy, and neuropathy) and macrovascular dysfunction (peripheral vascular disease, coronary artery disease, and cerebrovascular accident)[4].

As characteristic to chronic NCDs, DM treatment is complex, as it depends directly on patient education and active participation in the care plan to achieve glycemic control and prevent complications[5]. Patient education can be operationalized through different strategies, to improve their outcomes.

In the last ten years, Cochrane systematic reviews on the effectiveness and efficacy of educational interventions for individuals with diabetes in different contexts have been found in the literature: management of blood glucose, blood pressure, body mass index, and cholesterol[6-7], self-efficacy and empowerment of the patient regarding disease control[7], knowledge on DM, smoking cessation, self-management concerning diet and psychosocial outcomes[6], and foot care and prevention of fungal infections[8]. However, only one systematic review assessed the effectiveness of education in the prevention of vascular diabetic complications[8].

In this context, we question: what is the efficacy and effectiveness of educational interventions in reducing metabolic and/or vascular diabetic complications in adults with DM? The answer to this question will assist health care professionals in the choice of suitable teaching methods for better clinical outcomes for patients. Therefore, the objective of this study was to identify, in the literature, evidences of the effectiveness and efficacy of educational interventions in reducing metabolic and/or vascular diabetic complications in adults with DM.

METHOD

Ethical aspects

Due to free access to studies included in this review, as they are not documents that require ethical secrecy, no assessment by the Research Ethics Committee was necessary.

Study design

A systematic literature review, according to the flow chart of the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses" (PRISMA)[9], including experimental or quasi-experimental, primary, quantitative studies. Educational interventions of randomized clinical trials were evaluated as to efficacy, and those of quasi-experimental studies were evaluated according to effectiveness.

Inclusion criteria

Scientific articles available with full version available in English, Portuguese, or Spanish published from 2004 to 2014. This period was chosen due to the publication of the International Standards for Education on Diabetes by the International Diabetes Federation, at the end of 2013. The document contains instructions on essential information for health professionals on diabetes and its management, so the application of this knowledge and the acquisition of skills improved the care and promoted the achievement of positive outcomes for people with diabetes[10]. The search was conducted in October and November 2014, in the primary Latin American and Caribbean Literature on Health Sciences (LILACS), Spanish Bibliographic Index of Health Sciences (IBECS), CUMED, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Medline databases, and in the Scientific Electronic Library Online (SciELO).

Study protocol

Search strategy

The search strategy was defined by means of PICO[11], using the Health Science Descriptors (DECS), Medical Subject Heading (MeSH), and CINAHL Titles with the Boolean operators OR and AND, as shown in Box 1.

It is important to highlight that element C of the PICO strategy was not addressed, as the aim of this study was not to compare interventions. To ensure that the largest possible number of references was found, we decided to use filters for adults instead of descriptors or keywords, since, often, the age groups studied are not included as descriptors. The searches were conducted using the strategies on Box 2.

Box 1 - Elements of the PICO strategy

Component	Definition	Descriptors	Keywords
P: Population of interest	Adults with diabetes mellitus	Neither descriptors nor keywords were adopted. Filters for age were used in the databases.	
I: Intervention	Educational intervention	Health education Education of patients Health Education Patient Education as Topic	Education Health education Educational intervention Health Education Patient Education Diabetes Education Diabetes Educators
C: Comparison	-	-	-
O: Result/ Outcome	Reduction of metabolic and/ or vascular complications of diabetes mellitus	Complications of Diabetes Diabetic Complications Diabetes Complications Diabetic Ketoacidosis Diabetic Foot Diabetic Coma Diabetic Retinopathy Diabetic Nephropathies Diabetic Angiopathies Diabetic Cardiomyopathies	Complication diabetes Complications diabetes

Box 2 - Search Strategies used in databases, 2004-2014

Database Online Library	Search strategies
LILACS, IBECS, and CUMED - via Biblioteca Virtual de Saúde (Virtual Health Library)	(Education OR "health education" OR "educational intervention") AND (diabetes OR "complications of diabetes" OR "diabetic complications") Filters: language (English, Portuguese, and Spanish); adult; year of publication (2004 to 2014) and document type (article)
Medline - via PubMed	((((((Health Education[MeSH Terms]) OR Health Education[Title/Abstract]) OR Patient Education as Topic[MeSH Terms]) OR Patient Education[Title/Abstract]) OR Diabetes Education[Title/Abstract]) OR Diabetes Educator[Title/Abstract]) AND ((((((((((Diabetes Complications[MeSH Terms]) OR Diabetes Complications[Title/Abstract]) OR Complication diabetes[Title/Abstract]) OR Complications diabetes[Title/Abstract]) OR Diabetic Ketoacidosis[Title/Abstract]) OR Diabetic Foot[Title/Abstract]) OR Diabetic Retinopathy[Title/Abstract]) OR Diabetic Nephropathies[Title/Abstract]) OR Diabetic Angiopathies[Title/Abstract]) OR Diabetic Cardiomyopathies[Title/Abstract]) OR Diabetic Neuropathies[Title/Abstract]) Filters: language (English, Portuguese, and Spanish); year of publication (2004 to 2014) and age (Adults: 19+ years)
CINAHL - via Ebsco Host	((MH health education) OR (Health Education) OR (MH Patient Education as Topic) OR (Patient Education) OR (MH Diabetes Education) OR (diabetes education) OR (MH Diabetes Educators) OR (diabetes educator)) AND ((MH Diabetic Ketoacidosis) OR (diabetes complications) OR (MH Diabetic Foot) OR (MH diabetic coma) OR (MH Diabetic Retinopathy) OR (MH Diabetic Nephropathies) OR (MH Diabetic Angiopathies) OR (MH Diabetic Cardiomyopathies) OR (MH Diabetic Neuropathies) OR (Complication diabetes)) Filters: date of publication (20040101-20141231); age: all adults; Source type: Academic journals
SciELO - via scielo.br	Health Education OR Patient Education as Topic OR Patient Education OR Diabetes Education OR Diabetes Educator [All indexes] and Diabetes Complications OR Complication diabetes OR Complications diabetes OR Diabetic Ketoacidosis OR Diabetic Foot OR Diabetic Retinopathy OR Diabetic Nephropathies OR Diabetic Angiopathies OR Diabetic Cardiomyopathies OR Diabetic Neuropathies [All indexes] Filter: date of publication (2004 to 2014).

Selection of articles

Selection of articles was performed through analysis of title, followed by reading the abstracts for the identification of those which would be fully read, independently, by two researchers. Data were extracted from the final sample by means of an instrument containing identification data (authors, year and country of publication), study design, sample/population size, mean age of participants, mean time of evolution of DM, educational intervention performed, results, and conclusions.

Assessment of the methodological quality of studies

It was performed by two researchers, for purposes of description and not for exclusion from sample. To assess the quality of the randomized clinical trials, the Jadad Scale was used, which consists of three items directly related to research bias reduction (randomization, blinding, and destination of all participants), totaling 5 points. Studies are classified as of poor quality if the score is less than 3[12].

For quasi-experimental studies, this evaluation was performed using Downs & Black's criteria. The original questionnaire contains 27 questions, totaling score of 32 points, divided into four groups: presentation (evaluates items such as clarity in the description of the objectives, variables of confusion, probability values); external validity (related to extrapolation of the data to the population from which the sample was planned); internal validity (analysis of biases, reliability of exposure and outcome measures and use of confounding variables); and power of the study[13]. Of the 27 items originally proposed by the authors, 6 were excluded, remaining 21 questions, with maximum final score of 24. Such items were excluded because they referred to side effects of interventions (since there are no side effects arising from educational interventions) or to aspects inherent

to randomized clinical trials or case-control studies (randomization, blinding, comparison with control group). The cut-off point used to consider the study of good quality was of 12 points (>50% of the maximum score), according to criteria established in systematic review[14].

Analysis of the results

Data were presented in descriptive form and classified according to the outcomes/complications evaluated by the studies included in this review. Due to the heterogeneity of the interventions and of the characteristics of the study samples, it was not possible to perform meta-analysis.

RESULTS

Based on the search strategies and on the selection presented in the section methods, 24 studies were included for full reading, of which 11[15-25] composed the final sample. Figure 1 presents the process of selection of these studies.

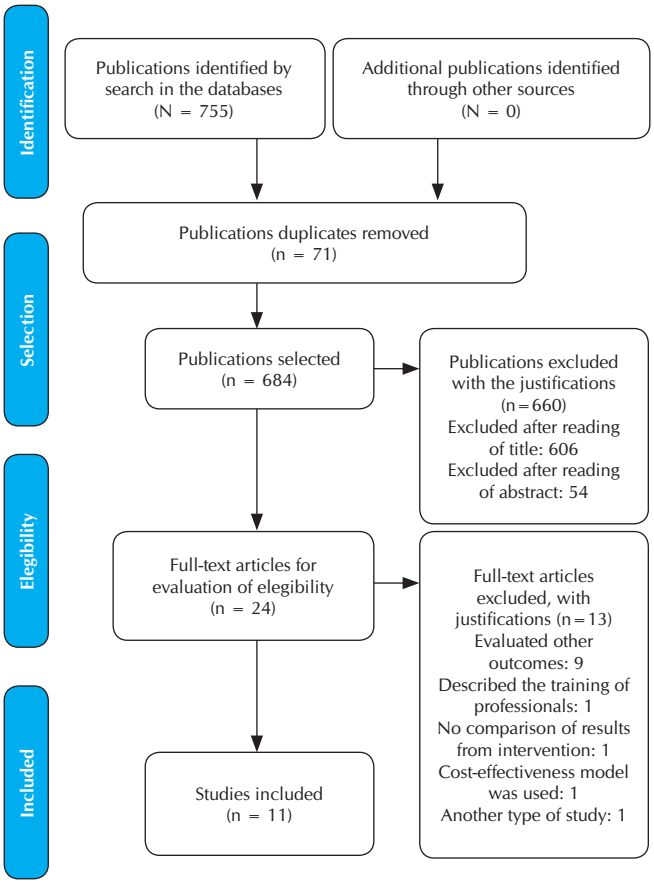

Figure 1 - Flow chart of the process of selection of studies according to PRISMA, São Paulo, Brazil, 2014

General characteristics and quality of the studies

Boxes 3 and 4 present the main characteristics, the results and the quality of the randomized clinical trials (n = 5) and of the quasi-experimental studies (n = 6), respectively.

Studies were performed on different continents: Asia (n = 6), America (n = 3) and Europe (n = 2). Most investigations (63.6%) included exclusively patients with type 2 DM[16,19-24] and three studies (27.3%) also considered those with type 1 DM[15,17,25]. One study (9.1%) included no description of the type of DM of the patients included in the sample[18].

Characteristics of samples were heterogeneous: number of patients evaluated varied from 30[23] to 4,872[24], and mean age varied from 55.8 ± 13.2[22] to 68.9 ± 9.5[16] years. Mean time of evolution of DM varied from 5.9 ± 7.1[22] to 22 ± 11.4 years[17]; however, three studies lacked this information[15,18,20]. Time of follow-up of patients after intervention varied from 3 months[22] to 7.7 years[21].

Three of the five randomized clinical trials[15,20-21] were considered to be of quality and five of the six quasi-experimental studies[16-18,22-23] were classified as of good quality.

Professionals who implemented the interventions

One study had no report on which professionals implemented the educational intervention[24]. Participation of nurses in the interventions was significant, as they were present in 80.0% of investigations[15-20, 22-23]. Some studies showed the multidisciplinary work through the participation of different professional categories in the interventions: physicians and nurses[16,19], physicians and nutritionists[19], and occupational therapists and nurses[20]. Two researches had participation solely of physicians[21] and physical therapists[25] in the educational interventions aimed at diabetic persons.

Effectiveness and efficacy of interventions in reducing diabetic complications

Of the 11 studies identified, two clinical trials showed efficacy of the intervention in reducing complications related to the cardiovascular system[21], cataract or retinopathy, and nephropathy[19,21] (Box 3). All quasi-experimental researches showed effectiveness of interventions: reduction of feet ulcers[17,22,24], of peripheral vasculopathy[16] and of peripheral neuropathy[18], in addition to the maintenance of kidney function[23] (Box 4).

Regarding interventions with positive impact on reduction of complications, most were implemented exclusively by nurses[15,17-18,22-23] or in partnership with other professionals[16,19-20]. One study had participation solely of physicians[21]. There was no similarity among mean age or time of evolution of DM in patients in the different studies. Most effective or efficient interventions consisted of individual sessions[18-23]. One study involved the community group in sessions[16] and another included the patient's family[24]. Two investigations included customized interventions with interval between educational sessions according to the risk profile of patients or presence of diabetic neuropathy, peripheral artery disease and/or deformity, history of ulcer or foot amputation[17] and use of orthoses[24]. One included telephone contact and practical training as associated measures[22] and two implemented only telephone contact as an adjuvant measure[16,23].

Box 3 - Characteristics of the randomized clinical trials on the efficacy of the educational interventions on the outcomes investigated, São Paulo, Brazil, 2004-2014

Reference, location, and Quality of the study	Design/number of patients	Interventions	Follow-up strategies	Outcomes and conclusions
Chao et al.[19], 2014 Taiwan Jadad Score: 1	A total of 500 patients with DM 2 or blood glucose levels above the normal parameters for 3 consecutive months. Age: 50 to 80 years CG: 259 (52.2% > 65 years) IG: 241 (59.2% > 65 years) Time of evolution of DM: 30.6%: DM >10 years; 27.8%: DM 5-10 years; 26.2%: DM 2-5 years; 15.4%: DM <2 years	CG: Information brochure about DM. IG: Usual care + 1 hour session per week, for 3 weeks, education on DM (general information, specific dietary suggestions, and requirements of self-care) planned by physician, nurses, and nutritionists.	Follow-up of complications at 3 and 6 months following the intervention. Variables considered for measuring of results: blood glucose level (NR:70-110 mg/dL or 90-140 mg/dL), creatinine (NR: 0.6-1.5 mg/dL), levels of glucose and protein in urine (N: both nulls), microalbumin (N: less than 30 mg), presence of cataract or retinopathy.	Outcomes presented only 6 months after the intervention: Blood glucose level after 6 months: IG 128.8±41.0 versus CG 174.4±50.1 (p<0.001) Blood glucose levels above normal after 6 months: IG 60.4% versus CG 92.4% (p<0.001) Occurrence of complications: Basal: IG 42.0% versus CG 82.1% (p=0.003) After 6 months: IG 48.4% and CG 87.0% (p=0.006). Conclusion: The intervention was efficient in improving blood glucose levels and reduced the rates of complications.
Gershater et al.[15], 2011 Sweden Jadad Score: 5	131 patients with DM, neuropathy and prior feet ulcers. Age: 35-79 years (median 64 years), 73.2% men, 67.1% with DM 2 and 32.9% with DM 1 CG: 35-79 years, median 64, 71.4% men IG: 37-78 years, median 64, 75.4% men. Time of evolution of DM: not reported.	CG: Footwear with soles adjusted for internal/external environments and recommendation of Podiatrist. Standard information based on International Consensus on Diabetic Foot and provided by a nurse specialist in DM. IG: Usual care + 1 hour group sessions with strategy of question conducted by a nurse "What are the causes of feet ulcers?" (10 sessions for men and 4 for women, 2 to 5 persons in each group who participated of sessions once).	Follow-up of new feet ulcers after 6 months of intervention, considering the classification of Wagner (level 0 represents no ulcer, level ≥ 1 represents ulcer).	Results: 58% of 98 patients who completed the follow-up developed no new feet ulcers (21 in IG and 36 in CG [NS]) Conclusion: The intervention was not efficient in reducing the incidence of new feet ulcers.
Cisneros et al.[25], 2010 Brazil Jadad Score: 1	53 diabetic patients with peripheral neuropathy. CG: 23 (22 with DM 2 and 1 with DM 1) 59.8±9.0 years of age IG: 30 (29 with DM 2 and 1 with DM 1), 64.4 ± 9.2 years of age. Mean time of evolution of DM: 14.5 ± 10.2 years.	CG: Quarterly individual consultation with a physical therapist: instructions on foot care and footwear according to spontaneous demand. IG: Usual care + 4 weekly group meetings of 90 minutes with a physical therapist. Focus group to address and discuss complications of DM, treatments, hygiene inspection and care and cleaning of feet or choice and use of footwear + games as teaching tool with questions on the subject treated at the end of each meeting. Participants received a pair of shoes at the beginning of the study and another after the fourth re-evaluation.	Follow-up of occurrence and recurrence of neuropathic lesion on feet in individual quarterly consultations in the first 18 months and 24 months after the intervention and analysis of the time until development of the lesion. Variables for measuring results: skin conditions, quality of pulses, and the presence of deformities. We applied risk classification for feet lesion: risk 1 (insensitivity), risk 2 (plantar hyperpressure and insensitivity or deformity), risk 3 (insensitivity and prior ulcer), risk 4 (insensitivity, prior ulcer, and plantar hyperpressure), and risk 5 (neuropathic fracture). Insensitivity was verified by esthesiometry and hyperpressure, by plantigraphy.	Results: Occurrence of neuropathic lesion: IG 38.1% versus CG 57.1% (p=0.317) Recurrence of neuropathic lesion: IG 16.7 versus CG 83.3 (p=0.119) Time until development of the lesion: IG versus CG (p=0.362) Conclusion: The intervention was not efficient in reducing the incidence or recurrence of neuropathic lesion in the lower limbs.

To be continued

Box 3 (concluded)

Reference, location, and Quality of the study	Design/number of patients	Interventions	Follow-up strategies	Outcomes and conclusions
Lincoln et al.[20], 2008 United Kingdom Jadad Score: 5	172 patients with DM and feet ulcers healed for at least 28 days. CG: 85, 81% with DM 2, 63±12.1 years of age IG: 87, 74% with DM 2, 64.9±10.9 years of age. Time of evolution of DM: not reported.	CG: Brochure about foot care, discharge for care with the general practitioner with or without Podiatrist and orthotics. IG: Usual care + educational home visit by nurse or occupational therapist with brief explanation about the main causes of feet ulcers, examination of feet and personal risk factors for lesions, examination of shoes and soles and use of images of feet lesions. Patients were instructed to contact the clinic when they identified problems with the feet and, after 4 weeks, the professional conducted telephone contact with the patient.	Incidence of new feet ulcers or amputations determined through the medical records and the patients' accounts (discrepancies verified by blinded observers) after 6 and 12 months of intervention.	Results: Ulcers after 6 months: No differences between the groups (IG 30% versus CG 21%) Ulcers after 12 months: No differences between the groups (41% in both) Amputations after 6 months: No differences between the groups (IG 3% versus CG 0%) Amputations after 12 months: No differences between the groups (IG 10% versus CG 11%) Conclusion: The intervention was not efficient in improving the incidence of ulcers or amputations.
Rachmani et al.[21], 2005 Israel Jadad Score: 3	141 patients with DM 2, hypertension and Dyslipidemia. CG: 70 (56.8 ± 4.0 years of age, 6.3 ± 1.9 years of time of evolution of DM). IG: 71 (57.4 ± 4.2 years of age, 6.2 ± 2.5 years of time of evolution of DM).	CG: Two standard consultations in two weeks and, thereafter, on an annual basis. IG: Usual care + individual 2-hour sessions with physicians on how to achieve precise control of modifiable risk factors. They were encouraged to call the consultants if they needed advice for to reinforce the instructions.	Evaluations twice a week in the first two weeks after the intervention and, thereafter, annually for about 7.7 years. Variables considered for measuring results: cardiovascular events (mortality by cardiovascular disease, non-fatal AMI, non-fatal stroke, CABG, TCA, amputation or vascular surgery), estimated glomerular filtration rate, retinopathy, nephropathy (identified by the albumin/creatinine ratio > 300 mg/g).	Outcomes when comparing usual care versus intervention, respectively: Results: Annual decrease in GFR: 4.6±2.1 versus 3.0±1.8 ml/min/1.73 m^2 (p=0.01); Albumin/creatinine ratio > 34 mg/mmol: 22% versus 12.5% (p=0.02); Reduction in retinopathy: 35 versus 21 patients (p=0.03) Incidence: - AMI (19 versus 15, p=0.06); CVA (17 versus CG 8, p=0.008); Nonfatal CV events (72 versus 47, p=0.001); CABG+TCA (37 versus 26, p=0.001) Conclusion: The intervention was efficient in reducing cardiovascular risk and decreased the speed of progression of microvascular disease.

Notes: TCA: transluminal coronary angioplasty; CHOL: cholesterol; CABG: coronary artery bypass graft surgery; CV: cardiovascular; DM: diabetes mellitus; DM 1: diabetes mellitus type 1; DM 2: diabetes mellitus type 2; NR: normality range; CG: control group; IG: intervention group; AMI: acute myocardial infarction; N: normal; NS: nonsignificant; GFR: glomerular filtration rate

Box 4 - Characteristics of the quasi-experimental studies on the effectiveness of educational interventions on the outcomes investigated, São Paulo, Brazil, 2004-2014

Reference, location, and Quality of the study	Design/number of patients	Interventions	Follow-up strategies	Outcomes and conclusions
Fan et al.[22], 2013 Canada Downs & Black score: 14	79 patients with DM type 2, with low risk of feet ulcers. Age: 55.8 ± 13.2 years. Time of evolution of DM: 5.9 ± 7.1 years (50% ≤ 1 year).	4 individual sessions over 3 weeks with a nurse. First 2 sessions: interactive classroom teaching and the last 2 sessions consisted of telephone contacts of 10 to 15 minutes, 1 time per week and during 2 weeks, to reinforce the information and clarify questions. 1st session: presentation and discussion of 1 hour on foot care; daily self-care of the feet. 2nd session: 1 hour practical training on feet self-care.	Basal evaluation and evaluation after 3 months: conditions of feet skin (calluses, dryness, cracks, red marks, blisters, humidity, fungal infection, lesions) and conditions of hallux nail (hygiene, length, thickness, interlocking, fungal infection), and such aspects were evaluated dichotomously (present/ absent, appropriate/ inappropriate, and normal/ abnormal).	Results: Pre vs. post intervention group, respectively: Feet skin: Calluses: 57.1% versus 44.1% (p=0.089); Dryness: 42.9% versus 58.9% (p = 0.000); Cracks: 28.6% versus 0 (p = 0.000); Red marks: 17.9% versus 0 (p = 0.001); Cracks: 17.9% versus 3.6% (p = 0.219); Blisters: 1.8% versus 0 (p = 0.500); Humidity: no events in the two evaluations; Fungal infection: 3.6% versus 0 (p = 0.248); Lesions: 0 versus 3.6% (p=0.248); Hallux nails: Proper hygiene: 80.4% versus 100% (p = 0.000); Appropriate length: 76.8% versus 94.6% (p = 0.007); Normal thickness: 80.4% versus 94.6% (p = 0.022); Interlocking: no events in the two evaluations; Fungal infection: 8.9% versus 5.8% (p=0.103); Conclusion: The intervention was effective in reducing mild problems in the feet.
Kazawa & Moriyama[23], 2013 Japan Downs & Black score: 14	30 patients with DM 2 and diabetic nephropathy. Mean age 67 ± 4.3 years, 66.7% men. Time of evolution of DM: 15.1 ± 9.2 years (2 to 30 years).	A total of 4 meetings of 60 minutes, every 15 days, in the participant's house or in outpatient clinic + 2 sessions of 30 minute by telephone or email and monthly telephone follow-up with a nurse. Use of textbooks, periodicals and study materials on DM and its complications, dietotherapy, exercise therapy, stress therapy, foot care, and drug therapy.	Assessment after 3 and 6 months: kidney function (serum creatinine, estimated glomerular filtration rate, urea nitrogen, HbA1).	Results: Pre vs. post intervention (3 and 6 months), respectively: Creatinine: 1.67 ± 0.53 versus 1.70 ± 0.52 versus 1.67 ± 0.57 (p=0.367); Glomerular filtration: 33.9 ± 13.0 versus 33.1 ± 13.3 versus 34.8 ± 15 (p=0.401) Urea nitrogen: 30.7 ± 13.1 versus 32.2 ± 14.3 versus 30.8 ± 13.2 (p=0.619) HbA1: 6.8 ± 1.5 versus 6.3 ± 0.9 versus 6.3 ± 0.9 (p=0.044) Conclusion: The intervention was effective in maintaining kidney function stable and decreasing HbA1.
Reda et al.[18], 2012 Canada Downs & Black score: 13	58 patients with DM and dialytic chronic kidney disease. Age: 62 ± 12 years. No information concerning the DM evolution time and DM type.	Inspection of feet during the hemodialysis session by a nurse trained in wound and feet care + instructions on the use of appropriate shoes, maintenance of hydration, monitoring of the development of calluses and ulcers, and on maintaining a healthy lifestyle. If ulcers were detected, referral to orthopedists, vascular surgeons, specialists in infectious diseases and in wound care. Prescription of custom soles and orthoses, as appropriate.	Basal evaluation and, after 4 to 6 months: peripheral neuropathy (evaluated by monofilament), absent pedial pulses, amputation, ulcer, Charcot foot, and adequacy of footwear.	Results: Outcomes when comparing current versus previous study, respectively: Neuropathy: 52% versus 88% (p<0.0001); Absent pedial pulses: 36% versus 17% (p<0.009); Amputation: 16% versus 27% (NS); Ulcer: 16% versus 28% (NS); Neuro-osteoarthropathy: 9% versus 15% (NS); Proper footwear: 59% versus 37% (p<0.04); Proper premanufactured footwear: 50% versus 24% (p<0.03); Proper custom footwear: 86% versus 63% (NS) Conclusion: The intervention was effective in decreasing the frequency of peripheral neuropathy, the absence of pedial pulses, and improving the adequacy of the footwear. It was not effective in reducing the frequency of amputations, ulcers, and neuro-osteoarthropathy.

To be continued

Box 4 (continuation)

Reference, location, and Quality of the study	Design/number of patients	Interventions	Follow-up strategies	Outcomes and conclusions
Chen et al.[16], 2011 Taiwan Downs & Black score: 15	323 fishermen and farmers with DM 2. Age: 68.9 ± 9.5 years. Time of evolution of DM: 8.2 ± 6.3 years.	Multidisciplinary approach with nurses and physicians. 1st phase: promoting health through education in a small community group. Control of diet, adherence to medication, foot care, mild/moderate physical activity; 2nd phase: telephone counseling 1 to 3 times per person, for 15 to 30 minutes, adapted individually according to the results of the 1st phase; Phase 3: Re-evaluation of participants at high risk, self-care of feet and peripheral vasculopathy and neuropathy.	Evaluations after 6 months: HbA1 (N: < 7%), fasting blood glucose level (N: < 130 mg/dL), peripheral neuropathy (MNSI): 5 parameters: 1. appearance of feet: deformities, dry skin, abnormal nails, calluses or infections; 2. feet ulcers; 3. test of vibration perception threshold in the back of the hallux; 4. degree of ankle reflexes; 5. feeling of pressure to the touch with monofilament. MNSI score >2 in a 10-point scale was considered neuropathy; peripheral vasculopathy (ABI: normal >0.9 and <0.89 peripheral vascular).	Results: Outcomes when comparing post-intervention versus pre-intervention. Fasting glucose level (mg/dL): 184.66 ± 36.97 versus 192.30 ± 41.16 (p = 0,002) MNSI (peripheral neuropathy): 1.93 ± 1.73 versus 2.25 ± 1.74 (p = 0.002) ABI (peripheral vasculopathy): 1.03 ± 0.14 versus 0.99 ± 0.15 (p = 0.002) Conclusion: The intervention was effective in improving most physiological variables, the peripheral vasculopathy, and the capacity for feet self-care.
Fujiwara et al.[17], 2011 Japan Downs & Black score: 14	88 patients with DM (75 with DM 2, 8 with DM 1, 5 with hyperglycemia due to use of steroids). Age: 68 ± 10.3 years. Time of evolution of DM: 22 ± 11.4 years. The classification of risk for ulcers used was based on the International Working Group on the Diabetic Foot. The patients were divided into: 52.3% with low risk of diabetic neuropathy (G0); 9.1% with diabetic neuropathy (G1); 12.5% with neuropathy and peripheral artery disease and/or deformity (G2); 26.1% with a history of ulcers or foot amputation (G3).	Program of feet care led by nurse, sessions of 30 to 60 minute per patient. G0: one session per year. Education on nail clipping and development of feet self-care skills. G1: one session every 6 months. Education on clipping the nail of the hallux, removal of keratinized layers of calluses by professional every 6 months, application of moisturizer and local antifungal medications, feet self-care skills, instructions to avoid walking barefoot, prevention of infections and burns, and referral to orthopedic center for the manufacture of custom shoes. G2: one session every 3 months. Patients with peripheral artery disease were told to avoid clipping the nail of the hallux or removing calluses alone. G3: one session every 1 to 3 months. Referral to a dermatologist for treatment and the same instructions provided to the other groups.	Incidence or recurrence of diabetic foot ulcer after 2 years. Neuropathy evaluated with monofilament (impaired sensation: one or more monofilaments not sensed in 10) and vibration perception threshold (positive if the patient answered incorrectly to at least 2 of 3 applications in the hallux). Peripheral artery disease (present when dorsal and tibial pulses were absent in the affected limb). Forefoot deformity: hallux valgus, rigid contractures of feet and bulgy metatarsal head. Feet ulcers: skin lesions distal to ankle and present for at least 2 weeks.	Results: Decreased tinea pedis severity score (p < 0.001), increased percentage of patients without tinea pedis. Improvement of calluses (p = 0.001) and degree of calluses reduced in 7 of 15 patients in groups 1 to 3. No G3 patient had recurrence of feet ulcers related to the calluses. 6 patients developed feet ulcers, but were cured with no development of gangrene Conclusion: The program was effective in reducing the occurrence of feet ulcers.

To be continued

Box 4 (concluded)

Reference, location, and Quality of the study	Design/number of patients	Interventions	Follow-up strategies	Outcomes and conclusions
Viswanathan et al.[24], 2005 India Downs & Black score: 10	4,872 patients with DM 2 with high risk of diabetic foot. Age: 60.5 ± 8.8 years Distribution of groups: 1,837 persons with DM and neuropathy (G1). 149 persons with DM, neuropathy, and deformity (G2). 1,259 persons with DM, neuropathy, deformity and feet ulcers or peripheral vascular disease (G3). Mean DM evolution time: 13.7 ± 7.6 years.	All patients received counseling in the presence of the families: education on diabetic foot and its complications, examination of the feet with a mirror, pedicure techniques, images of patients with infections, ulcers and amputations of feet, leaflets emphasizing the need of care for the feet, request of support from family for the examination of the feet. G1: education on foot care, assistance in selection of proper footwear, routine follow-up. G2 and G3: received custom orthoses to reduce pressure on feet and follow-up was carried out in more regular intervals. The implementation method and the professionals involved were not cited.	Basal evaluation and after 18 months: healing of diabetic foot ulcers, infection, new ulcer or need for surgical procedure.	Results: G1 and G2: 6 (0.3%) and 7 (4.7%) patients, respectively, developed infection or ulcer. G3: Healing of ulcers in 82% of patients who adhered to treatment versus 50% of those who did not adhere. Significantly higher proportion of new problems (26%) and need for surgical procedures (14%) among those who did not adhere versus those who adhered (5 and 3%, respectively, p<0.0001). Conclusion: The recurrence of ulcers was less frequent and the healing process faster among patients who adhered to the program.

Notes: DM: diabetes mellitus; DM 1: diabetes mellitus type 1; DM 2: diabetes mellitus type 2; CG: control group; IG: intervention group; HbA1: Glycated hemoglobin; MNSI: Michigan Neuropathy Screening Instrument; NS: nonsignificant; ABI: ankle-brachial index.

DISCUSSION

This study sought evidence as to the impact of educational interventions on reduction of vascular and metabolic complications related to DM. However, only studies that analyzed vascular complications were found, which may be associated with the importance of these complications as major causes of morbidity and mortality in patients with DM[7].

Adherence to behavioral and lifestyle modification promoted by education on DM is influenced by time of disease. A study showed that individuals with DM for less than one year showed greater adherence to proper dietary habits and to physical activity and lower levels of glycated haemoglobin after 3 years of follow-up[26]. On the other hand, patients with DM 2 diagnosed for over 20 years would have worse metabolic control due to low adherence to treatment regimen, evolution of disease with progressive dysfunction of beta cells, and no adjustment of medications when compared with those diagnosed for less than five years[27]. Thus, it is not possible to know if the evolution of DM may have influenced the negative results obtained by the studies which contained no information concerning the time of disease[15,18,20].

Investigations indicate that inadequate management of blood glucose level is a factor associated with the presence of feet ulcers[28] and with amputation among individuals with diabetic foot[29]. However, it is important to analyze the influence of educational interventions on outcomes associated with complications of DM, in addition to the specific serum levels of glucose or glycated hemoglobin. Thus, we reinforce the importance of this review, whose results will be discussed according to the microvascular and macrovascular complications of DM.

Microvascular complications: retinopathy[19,21], peripheral neuropathy[16,18,25], and nephropathy[19,21,23]

In the world, microvascular complications of DM are found in high prevalence. Approximately 93 million people have diabetic retinopathy and this is, potentially, the leading cause of visual impairment and blindness[30]. In addition, it was found, among individuals with diabetic retinopathy, coexistence of nephropathy, neuropathy, and peripheral vascular disease[31].

Diabetic peripheral neuropathy, characterized by pain, paresthesia, and sensory loss, affects approximately 50% of patients with DM both of type 1 and of type 2[32]. Diabetic nephropathy affects approximately one-third of people with DM in the world, being the leading cause of terminal renal failure associated with cardiovascular diseases and increase of mortality of patients[33].

For reduction of these complications, the majority of studies in this review[18-23] used individual sessions as strategy during the educational interventions. The individual sessions and evaluations strengthen the link with the professional, who gets to know the individual and his/her care management practices. Thus, in partnership, it is possible to develop autonomy of care[34]. On the other hand, telemonitoring, implemented by four studies included in the review[16,20,22-23], provides care, acquisition of knowledge, and reflection on self-care, being adjunct in interventions[35].

Macrovascular complications: cardiovascular diseases[21], peripheral vasculopathy[16], feet lesions[22] and ulcers[15,17-18,20,24], and amputations[18,20]

Diabetes macrovascular disease is characterized by structural and functional changes in large arteries[7]. The intervention implemented in the study with longer follow-up (7.7 years) identified in this review[21] was efficient in reducing the occurrence of cardiovascular events. The study conducted with fishermen and farmers showed, after the educational intervention, improvement of ankle-brachial index[16], considered a measure of verification of peripheral obstructive arterial disease[36].

Sensory loss secondary to peripheral diabetic neuropathy, at times, goes unnoticed by the patient and the first presentation can be feet ulcer[32]. In Brazil, the rate of amputations among individuals with diabetic foot reaches 58.2%[29,37]. In addition to inadequate control of blood glucose, other factors associated with amputation include: lack of feet examination during the most recent medical consultation, lack of instructions on the care of feet in the consultations held the previous year, and non-adherence to pharmacological treatment according to medical advice[29]. In fact, in the United States, there is a regional variation of rates of amputations of the lower limbs: in areas where there is participation of individuals with DM in classes on self-control of the disease there is fewer occurrences of amputations when compared to regions where this participation does not occur[38].

Patients with DM and ulcers on the feet have worse quality of life in the physical, social, and psychoemotional domains[39]. The DM of long evolution (on average 12.5 years) and without proper control contributes to the occurrence of ulcers. Similarly, other factors associate with the presence of feet ulcers, as the absence of plantar tactile-pressure sensitivity, thick nails, and calluses[28]. Hence, it is inferred that educational interventions that improve the care of the feet not only reduce the chance of developing ulcers in those regions, but also promote the quality of life of patients.

Verifying patient compliance to the instructions is also an important item that influences the clinical outcomes. A study carried out in the rural area of the state of Ceará with older adults of the System of Registration and Follow-up of Hypertensive and Diabetic Persons showed low adherence in self-care of the feet, as 70.3% of the patients with DM wore slippers, 55.0% used no moisturizer, and 74.0% clipped the nail improperly and did not dry the interdigital region after washing[40]. One of the studies in this review[24] found that the recurrence of feet ulcers was less frequent and the healing process faster among those who adhered to the program, despite the mean evolution of DM in these patients being long (13.7 ± 7.6 years).

The results found in this review concerning the occurrence/recurrence of feet ulcers after educational interventions were contradictory: some studies showed effectiveness[17,22,24] of the actions, while others showed they were not effective[18] nor efficient[15,20].

It is noteworthy the difficulty to compare and summarize the results of studies included in this review, since there was no similarity in the designs of educational interventions. In addition, the complications, while outcomes, were evaluated by means of different methods, not always validated, and after different follow-up periods.

In this sense, it is understood that the effectiveness of the quasi-experimental studies should be confirmed in future randomized clinical trials, with the aim of reducing the risks of biases related to selection and to measuring, thus proving the efficacy of the educational interventions. Nevertheless, the results of this review indicate possible models of educational interventions to be tested by health professionals to reduce diabetic complications.

Some limitations of this review should be considered: the restricted period covered by the data and the inclusion of articles available only in English, Portuguese, or Spanish.

CONCLUSION

This review determined that the combination of different educational interventions provided individually or in group to adult patients with DM has influence on reduction of vascular complications. Efficient interventions involved individual sessions of education on DM and instructions on self-care conducted by physicians or multidisciplinary staff (physicians, nurses, and nutritionists). These actions improved nephropathy, cataract, retinopathy, peripheral neuropathy, and cardiovascular events. Effective interventions included individual strategies, involving meetings and telephone contacts conducted by nurses who provided instructions on foot care, diet, exercise, stress control, and drug therapy. Such strategies reduced, mainly, the frequency of peripheral neuropathy, the lesions on the feet, and the worsening of kidney function in patients.

However, there is a gap in the literature concerning the effectiveness and efficacy of educational interventions, since no study makes reference to metabolic complications. Therefore, there is evident need for future randomized clinical trials that analyze the impact of these actions in the prevention of diabetic complications, particularly metabolic ones.

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