Evaluation of an educational intervention program on type 2 diabetes

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Abstract

Introduction: Process evaluation studies are recommended to improve our understanding of intervention studies.

Objective: to document the translation of a type 2 diabetes (T2DM) prevention program in the routine setting of several primary care centers.

Methods: A descriptive observational study was conducted. A passive dissemination strategy of providing training and materials to implement the intervention was used.

Results: About half of the patients examined were identified as having a high risk of developing DT2.

Conclusion: The passive diffusion strategy has produced modest process indicators related to adoption and has reduced the possibility of its standardized application in heterogeneous contexts.

Keywords: diabetes mellitus, educational intervention, program source DeCS

Resumen

Introducción: Se recomiendan estudios de evaluación de procesos para mejorar nuestra comprensión de los estudios de intervención.

Objetivo: documentar la traducción de un programa de prevención de la diabetes tipo2 (DT2) en el contexto de rutina de varios centros de atención primaria.

Métodos: Se realizó un estudio observacional descriptivo. Se utilizó una estrategia de difusión pasiva de proporcionar capacitación y materiales para llevar la intervención a la práctica.

Resultados: Se identificó que alrededor de la mitad de los pacientes examinados tenían un alto riesgo de desarrollar DT2.

Conclusión: La estrategia de difusión pasiva ha producido modestos indicadores de proceso relacionados con la adopción y ha reducido la posibilidad de su aplicación estandarizada en contextos heterogéneos.

Palabras clave: diabetes mellitus, intervención educativa, programa

fuente : DeCS

DOI Number: 10.14704/nq.2022.20.13.NQ88284 Neuro Quantology 2022; 20(13):2279-2285

Introduction

Diabetes has become a leading cause of morbidity and early mortality in most countries. Its prevalence is expected to double by 2030 and become the seventh leading worldwide cause of death. Therefore, there is growing interest in the initial results of several clinical trials in the prevention of type 2 DM through educational interventions to change lifestyles under real-world clinical practice conditions[1].

Unfortunately, this step is far from easy. The widespread adoption of a promising experimental health intervention is not accompanied by research that proves its efficacy in the specific context of the health area, characterized by work overload, with a shortage of time and training[2].

In recent years, several initiatives have evaluated the transfer of type 2 DM prevention interventions involving the promotion of healthy lifestyles to the population in the real context of primary health care (PHC)[3].

The interpretation of evidence-based interventions in routine clinical conditions is a complex challenge, and consequently, there is a gap between what is known to be effective and what is done in the course of routine care in health systems worldwide. Implementation research has emerged in the last decade as a promising way to advance knowledge on integrating proven effective interventions and treatments that are not widely and sustainably applied in routine clinical practice[4].

In this growing field of research and implementation, one of the aspects considered to determine how to improve the effectiveness, feasibility and sustainability of interventions is their implementation process. Therefore, developing, implementing and evaluating complex health interventions requires careful consideration of the outcomes obtained and the processes involved[5–7].

Process evaluations conducted within trials investigate the implementation, reception and establishment of an intervention to aid in the interpretation of final results and determine the true implications of interventions in actual practice[8].

On the other hand, a better understanding of program implementation and experienced barriers and facilitators can also help identify opportunities to optimize intervention delivery and inform future implementation and roll-out of interventions in other contexts and settings and how interventions might move from research to practice.

The present study aims to document the content of the intervention program implemented to prevent type 2 DM in collaborating centers following a classic passive implementation strategy to analyze the process of indicators of its implementation in the routine context of PHC and to discover the initial characteristics of the patient.

Method

A descriptive observational study of the 2.5-year commissioned implementation process of a prevention program for type 2 DM was conducted in 14 PHC centers. The 14 participating primary care centers were randomly assigned to intervention or control groups. This study was approved by the Universidad Regional Autónoma de Los Andes (UNIANDES).

Non-diabetic patients aged between 45 and 70 years, identified as having a high risk of developing DM2, were eligible for inclusion in the study in each of the two centers selected by convenience in the city of Ambato, Tungurahua, Ecuador.

The same identification system for high-risk patients, based on the diabetes risk scale (ERD)[7], was established in all centers. Therefore, all PHC service users aged 45-70 who attended one of the participating health centers for any reason during the program recruitment period were potential targets for administering the ERD questionnaire.

Subsequently, all detected high-risk patients

(ERD greater than 14) were invited to participate and give a patient information sheet. Exclusion criteria for being invited to enroll were regular vigorous exercise, known diabetes or any other chronic disease that made survival at six years unlikely, and any condition that could interfere with glucose metabolism or severe cognitive impairment.

In all cases, the information sheet explained that they were to be followed up for 24 months with annual medical controls consisting of blood lipid profile and glucose tolerance tests. Informed consent was obtained from each patient who agreed to participate.

After the test, patients diagnosed with DT2 were seen by their family physicians and excluded from the study. At this stage, control health centers included high-risk patients with glucose levels below 200mg/ml in the tolerance test at baseline evaluations. At the same time, intervention health centers included patients who obtained these results at baseline evaluations and agreed to participate in the new educational program.

After completing the intensive education intervention program, participants receive regular (at least once every six weeks) reinforcement educational information, mainly through telephone calls from nurses via a health communication platform.

The implementation strategy commissioned to adapt the intervention program to the environment and normal working conditions in the health centers of our health service consisted only of classic passive dissemination strategies, such as training and provision of resources (a screening tool integrated into the electronic format as a health record system and educational materials to support educational sessions).

All data relating to recruitment, demographic characteristics of the users (age, sex, socioeconomic level) and clinical variables (chronic, biological and clinical health problems and measures) were derived from the electronic medical record. These data were encrypted and managed centrally, along with other measures to safeguard anonymity and confidentiality.

The process and procedures for recruiting eligible patients from among those attending PHC centers were thoroughly evaluated and described for both intervention arms, as was the intervention delivery process within the intervention centers.

The multimorbidity level was characterized by the number of coexisting chronic health problems (from none to four or more) in the same patient. It was assessed by reviewing data from 4 years in the patients' medical records and applying a list of 52 diseases and specific criteria to consider each disease active.

Variability was also assessed in key process indicators related to program exposure at the group and center level (e.g., study participation refusal rates among those identified as high-risk) and the impact of recruitment procedures or strategies used on these indicators.

Frequencies and proportions were calculated for each of the process indicators. Means and proportions were used to describe continuous and categorical variables´ patient characteristics. The database and statistical processing of the data were performed and analyzed in the SPSS 26 statistical program (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used for the results collection, presentation and interpretation.

Results

Overall, in the seven intervention centers, only 28 out of a total of 89 (31.4%) family physicians accepted and actively collaborated in the study, while this figure was 49 out of a total of 85 (57.6%). In the control centers, 43 out of 100 family physicians and 64 out of 93 (68.8%) practicing nurses actively collaborated. High variability in the participation rate at the center level can be observed.

Table 1: characteristics of included patients

	Control (n=636) % Control (n=636)	**Cases (n=454) % Cases (n=454)**
age	59,3	59,3
% women	58	66,5
weight	82,9	80,8
Body mass index (kg/m2)	31	31
% by weight	38	35
% obese	55,4	56
Cholesterol levels mg/dl	213,7	217
Triglycerides mg/dl	124,5	122,7
Glucose levels mg/dl	104,6	104,5
Systolic blood pressure	134,7	132,5
Diastolic blood pressure	80,9	80,4
% elevated blood pressure	10,5	10,8
% of smokers	13,2	12,6
Co-morbidity		
0	16,6	15,7
1	32,7	30,3
2	24,4	25
3	14,2	13,7
4 or more	12,1	15,3

Source: statistical analysis, $p \leq 0.05$

Out of 528 eligible non-diabetic patients aged 45-70 years with high risk of developing type 2 DM started the intervention, representing a total of 48 %. Most intervention patients (n=418) selected the group format, while 28 and 8 selected the individual and mixed format, respectively. All patients (n=358), 78 % of the total, included in the intervention completed the intervention program for 330 scheduled interventions in the group format, 20 individuals and 8 mixed. At least 3 sessions were completed by 52 patients (11.3 %), while 19 patients (4.1 %) completed two sessions and 25 (5.7 %) completed a single session.

Discussion

The present study aimed to evaluate process indicators for the commissioned implementation of a primary DM intervention program under routine PHC conditions to facilitate subsequent analysis of effects and their interpretation to inform future optimization of clinical-practical implementation [10].

The main indicators that determine the potential impact of the programs are that they must be attractive to health care providers and realistic to implement in medical practice settings; the literature shows contradictions and lack of time as the main reasons for refusal to participate. In the present study, physician adoption rates within the centers were fair but improved, especially among family physicians. In five of the seven centers in each of the comparison groups, program adoption exceeded the 50% rate among nurses, and in only two was the level similarly high among family physicians[11] .

The coverage of screening procedures to identify persons at risk at age 70 was 6.2 %[8]. Although these figures could be considered low, they should be considered valuable since the program was conducted in the real context of PHC. In addition, all patients in this stratum came to the centers for any possible health complication without altering the working conditions[12].

Although these figures could be considered low, they should be considered valuable since the intervention program has been carried out in the real context of primary health care delivery without altering the usual working conditions[13]. Furthermore, all patients in that age stratum who came to the centers for any possible health complication were potential participants and were seen by professionals after solving the problem that caused their attendance[14]. Other studies aimed at translating a primary prevention program for type 2 DM to PHC have achieved indicators of greater scope ranging from 44 to 56 %, but after prior selection of patients from

electronic medical records and contacts by letter or telephone[8–10,15,16].

Not all patients detected at high risk of developing type 2 DM were finally included in the study. The operational and ethical requirements related to the research, and the real-world context of PHC, together with an evident variability in the procedures and strategies adopted between centers, have determined two important issues that could affect future analysis and interpretation of the programs: differences in refusal rates and initial comparability between the comparison groups[17]. First, collaborating physicians in the intervention group centers encountered refusals to participate in the study. This may be attributable to the fact that these patients were asked to consent to annual testing and invited to attend four educational workshop sessions. Secondly, after the exclusion of a considerable proportion of cases not diagnosed with type 2 DM (approximately 12 % in both groups), a higher proportion of women were included in the intervention group, pointing to possible partial selection[14].

These two sources of potential confounding threaten the internal validity of phase III clinical trials under controlled conditions. In the case of a phase IV implementation trial aiming to perform a broad evaluation of the translation of proven efficacy interventions into routine care, the focus should be on external validity, thus assessing effectiveness in heterogeneous, unselected, real-world clinical populations[11, 13,18]. In any case, and taking the worst-case scenario in the analysis scenario of this pooled trial as an observational study, it will be necessary to apply rigorous analytic procedures used in the analysis of the effects of this intervention to reduce and address possible confounding factors and context-specific variability in analyzing the source of the observed differences in rejection rates and in the proportion of women included[8].

First, as previously noted, with screening outreach and its efficiency in detecting high-risk patients, the refusal rate is associated with recruitment procedures and strategies. Specifically, centers that used mass screening and those that did not have patient consent to participate directly after screening by offering an additional consultation were more likely to reject[6, 12, 19,20].

Evidence has demonstrated that type 2 DM can be prevented or delayed in high-risk individuals through intensive counseling on healthy lifestyles. The intervention program's reach of 48% of all identified prediabetic patients can be considered moderate[13]. Furthermore, the quality of the intervention and the program's implementation can be considered good, as more than 80% of the patients in the intervention group finally included received all components of the education in the intervention program. This overall program attendance rate is within the range of other diabetes primary prevention measures[21,22].

Among the study's limitations are the possible non-diversity of the centers, which may not represent all PHC centers. In addition, although we have described some characteristics in terms of representativeness, in terms of size and composition of PHC, socioeconomic status of the populations served. So on, the lack of other information regarding the characteristics may limit the interpretation of the results.

Conclusions

Important information on the major factors affecting external validity must be provided to determine whether a health promotion program is feasible when translated into the real-world clinical setting. Reports from process evaluation studies on the adoption, reach, implementation and other process indicators achieved by a type 2 DM primary prevention program and the modest rates of physician adoption and potential population reach reflect the difficulties of integrating a new intervention within the established service delivery operation.

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