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Cognitive behavioral interventions for diabetes in Mexico

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Review article

ABSTRACT

Background
Diabetes mellitus (DM) is highly prevalent in Mexico. It is estimated that only a quarter of such cases are metabolically controlled. Control of DM requires effective interventions, such as cognitive behavioral therapy.

Objective
To conduct a subject review of cognitive behavioral interventions used in Mexico to improve the control of DM.

Method
Cognitive behavioral interventions for the review were obtained from databases (Redalyc, Dialnet, SciELO), the TESIUNAM Catalog, specialist libraries, books, references of the analyzed studies, and consultations with experts. Studies carried out between 1990 and 2014 were included. Certain variables related to the intervention were analyzed; to evaluate the methodological characteristics, the criteria set by the CONSORT (Consolidated Standards of Reporting Trials) were used.

Results
Nineteen studies that met the inclusion criteria were included. Eleven interventions were looking for improved adherence to treatment and/or self-care, 11 were looking for improved mood, and 10 were looking for better quality of life and/or psychological well-being. Of the 19 studies, 18 reported favorable results for control of DM. Only 2 studies met with more than 50% of the criteria suggested by the CONSORT.

Discussion and conclusion
The scope of the interventions is short, because study samples averaged just 26.21 participants and follow-up periods averaged 2.15 months. Most of the studies do not, (or only partially) meet with CONSORT criteria, putting into question the effects achieved in the interventions.

Key words: Interventions studies, cognitive behavioral therapy, diabetes mellitus.

RESUMEN

Antecedentes
La *diabetes mellitus* (DM) tiene una alta prevalencia en México. Se estima que sólo una cuarta parte de los casos está metabólicamente controlada. Se requiere de intervenciones eficaces que coadyuven a controlarla, como las cognitivo conductuales.

Objetivo
Realizar una revisión por temas de las intervenciones cognitivo conductuales utilizadas en México para mejorar el control de la DM.

Método
Las intervenciones cognitivo conductuales para la revisión se obtuvieron de bases de datos (Redalyc, Dialnet, SciELO), el Catálogo TESIUNAM, centros de documentación especializados, libros, referencias de los estudios analizados y consulta a expertos. Se incluyeron trabajos realizados entre 1990 y 2014. Se analizaron variables relacionadas con la intervención y para evaluar las características metodológicas se utilizaron los criterios del CONSORT (Consolidated Standards of Reporting Trials / Estándares Consolidados de Reporte de Ensayos).

Resultados
Fueron incluidos diecinueve estudios que cumplían con los criterios necesarios. 11 intervenciones buscaban mejorar la adherencia al tratamiento y/o al autocuidado; 11 mejorar el estado de ánimo y 10 buscaban aumentar la calidad de vida y/o bienestar psicológico. De los 19 estudios, 18 reportaron resultados favorables para el control de la DM. Sólo dos estudios cumplieron con más del 50% de los criterios sugeridos por el CONSORT.

Discusión y conclusión
Los alcances de las intervenciones son cortos, ya que las muestras de los estudios apenas promedian 26.21 participantes y los periodos de seguimiento promedian 2.15 meses. La mayoría de los estudios no cumple (o solo parcialmente) con los criterios del CONSORT, lo cual pone en discusión los efectos alcanzados en las intervenciones.

Palabras clave: Estudios de intervenciones, terapia cognitivo conductual, diabetes mellitus.

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BACKGROUND

Diabetes Mellitus (DM) is a chronic non-communicable disease (CNCD) highly prevalent in Mexico; according to the International Diabetes Federation (IDF),[1] while it is 8.1% in Central and South America, it is 11.92% in Mexico. Thus, 70281 deaths of persons between 20-79 years of age, were caused by this disease in this country during 2013.[1]

DM provokes complications which affect the life quality of people and which causes problems to their families. Besides, it is a cause of great expense for the sanitary authorities. For instance, it is esteemed that in Mexico,[2] during 2010, approximately ten billion pesos were invested for the attention in direct cost (medical appointments/diagnosis, medication, hospitalization, complications) as well as indirect (premature mortality, permanent disability, temporary disability).

Notwithstanding, the greatest problem is not spending this large amount of money, but the inefficiency of the health system, since the number of patients who reach the right parameters of metabolic control is almost inexistent.[3]

According to the analysis[4] of the data from the National Health and Nutrition Survey (ENSANUT) 2012 regarding DM, it is esteemed that 21.7% of the patients surveyed reported to have a severe metabolic control vigilance by means of blood glucose measurement, and 7.7% by means of glycosylated haemoglobin (HbA1C) The same study identified that only 25% of the persons suffering the disease were metabolically controlled at the time, 24.7% were high risk (HbA1c 7% to 9%) and 49.8% very high risk (HbA1c>9%).

DM treatment implies modifying behaviors related to eating and exercising; this is a difficult task and patients therefore constantly abandon treatment. Moreover, in many cases there is comorbidity with depression and stress,[5] which are also obstacles in continuing the treatment.

Thence, different strategies have been implemented to improve DM control. Scientific reports have identified the preference for educational interventions;[6-9] however, in spite of favorable results regarding the acquisition of knowledge about the disease,[10] changes do not last after some period of time and there is no overall approach to the abilities required to reach metabolic control. In order to achieve it, it would be important for people to train in abilities of self-care, adherence to treatment and identification of barriers, as well as of the facing of stressful situations.[11]

In the psychological realm, cognitive behavioral approach has proven useful for people with DM to develop the skills (regarding self-care, adherence to treatment, identification of barriers, and facing of stressful situations) needed to achieve metabolic control.[12] Besides, this approach has proven effective in dealing with comorbid disorders such as depression, even in the elderly, an age group of highly prevalent DM.[13] Cognitive behavioral interventions are characterized by combining techniques based on behavioral models such as classical and operational conditioning, and cognitive techniques as well as social learning techniques.

Notwithstanding, interventions under this approach have not always had the same objectives. Some are focused on granting the skills to face stress and improve life quality;[14-19] while the purpose of others stresses primarily the development of skills to attain adherence to treatment.[20-23] While it may be difficult, it is necessary for interventions to focus on strategies for metabolic control without leaving aside the improvement of life quality of those with DM.

Thus, the objective of the present study was to make a subject review of cognitive behavioral interventions made to improve control of DM in Mexico. On the one hand, subject reviews attempt to synthesize results and conclusions of publications related to a certain topic and, on the other, to analyze their methodological characteristics. For that, they will be used the criteria for non-pharmacological treatment proposed by Consolidated Standards of Reporting Trials (CONSORT),[24] with the intention of identifying opportunity areas and making the proper recommendations.

METHOD

Search and selection of studies

In the search of studies, the following sources were considered: a) computer data bases (Redalyc, Dialnet, SciELO); b) TESIUNAM catalog; c) Google Scholar; d) specialized journals (Psicología y Salud, SALUD MENTAL, Revista Mexicana de Psicología); d) books on DM published between 1990 and 2014; e) references of the analyzed studies; f) consultation with researchers and experts. Consultation was made through e-mail and they were asked for data of yet unpublished works which complied with the inclusion criteria. In data bases, search was done by using the following descriptors: "diabet****" and "cognitive-behavioral**" in the title, key words and contents.

Once the documents were available, those works which fulfilled the following inclusion criteria were selected: 1. Referring to adherence to treatment and/or self-care, metabolic control, mood, quality of life and/or psychological wellbeing in DM; 2. Made in Mexico with Mexican populations; 3. Made between 1990 and 2014; 4. Carried out based on cognitive behavioral techniques; 5. Pre-test/post-test designs; 6. Group designs (N = 1 designs were discarded). Such search process yielded 19 studies which complied with all of these criteria.

Study codification

Selected studies have differential characteristics related to interventions, the disease, and the characteristics of persons suffering DM who partake of them. For the present

study, the different variables were grouped into: 1. Characteristics of the intervention, 2. Characteristics of the participant, 3. Contextual characteristics, 4. Methodological characteristics, and 5. Extrinsic characteristics.[25]

The codified characteristics of the intervention were: a) the purpose of the intervention (adherence to treatment, glycemic control, mood and quality of life); b) intervention techniques according to its theoretical foundations[26] (classical conditioning, operational conditioning, social learning theory, cognitive and self-control); c) kind of intervention (individual and group); d) mode of the intervention (in-person or by phone); e) training of relatives (yes or no, total number of sessions, and total of training hours); f) comorbidity (yes or no); g) offered by health professionals (psychologists, nutritionists, physicians, or nurses); h) duration of the intervention (in weeks, in hours by subject and average hours per week).

Characteristics of the participant: a) type of diabetes (DM1, DM2 or both); b) age (average years); c) gender (% of men participating in the sample); d) duration of illness (in years).

Contextual characteristics: site of treatment (health center, clinic, hospital, diabetics center, or universities).

Methodological characteristics: a) sample size; b) experimental mortality (number and percentage of subjects who abandon the intervention; c) follow up (in months). Besides, for the revision of methodological rigor, the criteria proposed by the CONSORT were applied. Originally published in 1996, it is a set of criteria used in the assessment of the presentation of research reports of randomized controlled trials, proposed by a group of health professionals, statisticians and editors.[27] Based on the guidelines set by CONSORT, a specific proposal was designed for the assessment of randomized trials of non-pharmacological treatment such as psychotherapy and behavioral interventions. It consists of 22 items grouped into five sections. 1. Title and abstract; 2. Introduction (background); 3. Method (participants, interventions, objectives, results, sample size, randomization-generation sequence, assignation concealment, implementation, blinding, and statistical methods); 4. Results (flow of participants, implementation of the intervention, recruitment, baseline data, analyzed numbers, data and estimation, complementary analysis, and adverse events); 5. Discussion (interpretation, generalization, general evidences).[24]

Extrinsic characteristics: a) date of the study; b) published (yes or no).

RESULTS

1. Characteristics of the intervention

Regarding the goal of the intervention, most of the works analyzed (13 out of 19) had more than one goal. Eleven were looking for improved adherence to treatment and/or self-care, 11 were also looking for improved mood, mainly focusing on depression, anxiety and stress and 10 were looking for better quality of life and/or psychological well-being.

As for the techniques used in the different interventions, 17 used two or more groups of techniques; only two works reported the exclusive use of techniques based on the social learning theory. The technique that were more widely used were cognitive and self-control (17), 15 interventions used those based in social learning theory and 14 those of classical conditioning. Only one intervention included techniques based on operational conditioning.

Group intervention was used in 13 interventions (68.42%); while five were individual (26.31%) and only one reported individual and group sessions (5.26%).

In-person mode was predominantly used (94.73%); only one took place on the phone (5.26%).

Regarding the training of relatives, only three out of 19 interventions included it. The average time devoted to relatives was 24 hours.

About comorbidity, nine interventions (47.36%) included participants with comorbid chronic diseases, mainly hypertension; five (26.31%) specified in their exclusion criteria not admitting patients with chronic comorbid diseases. The remaining five (26.31%) did not specify whether the participants suffered from DM along another CNCD.

Regarding the health professionals participating in interventions sessions, 11 out of the 19 works explicitly mentions the participation of the psychologist. Only two studies mention the participation of a nutritionist; two of them mention a physician and none of them mention the participation of a nurse or another health professional explicitly.

Table 1 shows the other results of the variables related with characteristics of the intervention.

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Table 1. Characteristics of the intervention

Variables	Number of studies	Minimum	Maximum	Mean	Standard deviation
Duration (in weeks)	19	4	30	12.00	5.99
Duration (total of hours per participant)	17	6	60	22.54	11.98
Average hours per week	17	1	4	1.89	0.72
Total of family sessions	3	8	16	12.00	4.00
Total hours of family sessions	3	24	24	24.00	0.00

Table 2. Characteristics of the participant

Variables	*N*	Minimum	Maximum	Mean	S. D.
Average age (in years)	14	13.25	72.50	56.54	14.41
Gender (% male)	18	5.88	75.00	30.36	21.15
Duration of illness	4	7.00	17.50	11.90	5.68

Table 3. Methodological characteristics

Variables	*N*	Minimum	Maximum	Mean	S. D.
Sample	19	8	120	26.21	29.12
Experimental mortality (% of subjects)	17	0	80	8.52	19.43
Follow up (in months)	19	0	6	2.15	2.52

Regarding the results of the interventions, 17 studies reported favorable changes in accordance with their goals. Considering that glycosylated haemoglobin (HbA1c) is the most reliable control indicator of DM, eight out of the nine studies that made use of it reported statistically significant improvements.

2. Characteristics of the participant

Concerning this point, 16 interventions (84.21%) were specifically concerned with DM2, only one with DM1 (5.26%) and two of them (10.52%) did not specify what kind of DM did the participants suffer from (table 2).

3. Contextual characteristics

This group only included the site of treatment. It was identified that 13 interventions (68.42%) took place in sanitary institutions (health center, clinic or hospital), five of them (26.31%) in diabetics centers or universities, and one of the trials (5.26%) does not specify the site of the intervention.

4. Methodological characteristics

Concerning methodological characteristics, it can be underscored that samples held an average of 26.21 participants (SD = 29.12) and that the follow-up to assess the results of the interventions goes barely beyond two months, with an average of 2.15 months (SD = 2.52) (table 3).

Methodological rigor criteria based on CONSORT

Table 4 shows the percentages resulting from the analysis based on the 23 indicators proposed by CONSORT for non-pharmacological treatment. Regarding the category Title and Abstract, 11 studies do not specify the way of assigning the participants for the interventions, do not describe the characteristics of the treatment, do not point out who is offering it or the blinding data, while eight studies provide the aforementioned data, at least partially.

Regarding the participant selection criteria, 18 out of the 19 works mention them partially. Usually some criterion for the choice of scenarios where the participants shall be recruited is omitted, since they do not mention the reasons why a hospital, health center, diabetics club, or university is chosen. Besides, in this aspect, according to CONSORT, the selection criteria (academic degree, experience in years, etc.) for those health professionals who shall administer the interventions should be mentioned; this information is generally omitted.

Regarding the criteria for the assessment of the professionals administering the intervention, only one out of 19 studies mention the way the manner of evaluation for the adherence to the intervention protocol. Only one study mentions having assigned the participants randomly, and, in the corresponding case, those who administered the intervention to the different groups. None of the studies mentions who performed the randomization sequence or whether there was any blinding. Striving to show experimental mortality and to better analyze the results, only one study includes a flow chart of the participants or mentioned how they were assigned at random, who received the intervention, how many completed it, among other data.

5. Extrinsic characteristics

In this aspect, 10 works (52.63%) were published in research journals and nine (47.36%) are undergraduate and graduate dissertations.

DISCUSSION AND CONCLUSION

The present work offers an analysis of cognitive behavioral interventions performed in Mexico for the control of DM. All studies report favorable results, regardless of their goals. However, the analysis of the fulfillment of methodological criteria shows that 17 out of 19 studies do not comply with even 30% of the criteria suggested by CONSORT, causing the effects to be debatable.

Based on the results, a tendency can be perceived toward shorter interventions; however, it would be relevant to compare the effect of shorter and longer interventions.

Even while, at first it would be advisable to include the patient's family in the interventions, since that could improve the effects, it is important to develop projects that compare interventions with and without the participation of relatives, since there are studies which suggest that such participation does not have an influence or does not help the person suffering from DM in terms of the metabolic control of the ailment.[28,29]

Another factor to be considered in future interventions is the majority participation of women, since only an ave-

Table 4. CONSORT criteria

Section and topic	Item	% Present	% Partial	% Absent
Title and abstract	1	0.00	42.11	57.89
Introduction / Background	2	89.48	5.26	5.26
Methods				
Participants	3	5.26	94.74	0.00
Interventions	4	47.36	21.05	31.57
	4a	52.63	15.78	31.57
	4b	15.78	15.78	68.42
	4c	5.26	0.00	94.73
Objectives	5	36.84	57.89	5.26
Data	6	57.89	42.10	0.00
Sample size	7	15.78	57.89	26.31
Randomization-generation sequence	8	5.26	0.00	94.73
Assignation concealment	9	5.26	10.52	84.21
Implementation	10	0.00	0.00	100.00
Blinding (masking)	11a	0.00	10.52	89.47
	11b	0.00	0.00	100.00
Statistical methods	12	31.57	26.31	42.10
Results flow of participants	13	5.26	0.00	94.73
Implementation of the intervention	14	10.52	26.31	63.15
Recruitment	15	0.00	0.00	100.00
Baseline data	16	15.78	26.31	57.89
Numbers analyzed	17	57.89	26.31	15.78
Data and estimation	18	57.89	26.31	15.78
Complementary analysis	19	31.57	5.26	63.15
Adverse events	20	0.00	5.26	94.73
Discussion Interpretation	21	5.26	42.10	52.63
Generalization	22	10.52	57.89	31.57
General evidences	23	47.36	47.36	5.26

rage of 30.36% of the participants were male. This would supply slanted data regarding the effectiveness of interventions, since in an ailment such as DM, an attitude favorable to treatment may account for a greater adherence; thence, it would not be the intervention that accounts for the results, but the willingness of people, which, though necessary, is not enough. Thence, it is advisable to consider gender equality in the different samples from other studies to identify differences that may prove significant, and that later interventions be accord to the peculiar problems that women and men face regarding the treatment of DM.

It would be important to consider the efficiency of interventions regarding the place where they are held. This is relevant since, even when sanitary scenarios are the most widely used for health revisions and the administering of interventions, it could be assessed whether there are any differences in the results, depending on whether they take place within a hospital, in a health center or in a diabetics club.

On the other hand, the size of the samples is a criterion related to statistical accuracy and, thence, with the reliability of the data, so its increase is advisable for future studies.

CONSORT emphatically recommends that the "Title and Abstract" criterion be fully complied with, which implies that the information about the assignation of participants to intervention groups be stated in the title; that the abstract describe experimental treatment, comparison between experimental groups, characteristics of health professionals implied in the administration of interventions, information about the centers where they are applied, and the kind of blinding of the study (if that were the case); this is so because such criterion is very useful in research activities such as search and bibliographic cataloguing.

Studies analyzed are usually composed of non-probabilistic samples chosen out of convenience; thence it is advised that later studies choose the sample at random to control such bias.

Most interventions have clearly defined populations, which is relevant for obtaining better clinical results. This can be appreciated in the fact that 16 out of the 19 works focus particularly on DM2. This ailment has great comorbidity with artery hypertension and other illnesses, thence, interventions must consider such factors for their design.

This work takes down, at least partially, the "grey literature" phenomenon, which refers to those documents that are published but are only distributed by means of not very conventional channels (thesis catalogs). So, thanks to catalogs of university dissertations and to consultation with experts, nine works were included.

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From the analysis of these 19 works, the need is clear to produce psychological interventions to approach DM with greater methodological control. If interventions were more efficient and had greater reach in the control of the ailment, people could have greater quality of life and the health system could benefit from reducing costs assigned to the attention of DM complications.

It is important to assess the effect of interventions, with their therapeutic components but with greater methodology control, in longer follow-up periods, and with larger samples, apart from assessing their effects on other clinical indicators such as cholesterol, triglycerides, not only HbA1c. This is essential, since in the last years there is growing comorbidity between cardiovascular problems and DM, which ends up causing many premature deaths.

A way must be found in which interventions which prove efficient are spread, included, or adapted in the health system with the intention that a larger part of the population can benefit from them. Works such as Hattori[30] and Robles[31] have shown methodological soundness.

One limitation of the present study is that, in spite of literature showing that cognitive behavioral approach is the most widely used and the most efficient when dealing with DM, there may be works based on different theoretical perspectives which may have had similar or greater efficiency, which is why it would be advisable to perform meta-analysis of works with methodological soundness to clearly identify their efficiency.

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Conflict of interest

Authors hereby declare to have no conflict of interest whatsoever.

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