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Self-management in patients with type 2 diabetes: Group-based versus individual education. A systematic review with metaanalysis of randomized trails

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KEYWORDS

Type 2 diabetes; Educational programs; Glycemic control; Lipid profile; Body weight; Quality of life **Abstract** *Aim:* Patient education is an essential component of the treatment of type 2 diabetes mellitus (T2DM). The present meta-analysis was aimed at verifying the efficacy of group-based versus individual education for self-management in patients with T2DM.

Data synthesis: A Medline and Embase search up to January 1st, 2021, was performed, including Randomized Controlled Trials (RCT) with duration>6 months, enrolling patients with T2DM and comparing individual-based with group-based educational programs. The primary outcome was endpoint HbA1c; secondary endpoints were lipid profile, body weight, blood pressure, patients' adherence/knowledge, and quality of life. The weighed difference in means (WMD) and Mantel-Haenzel Odds Ratio (MH–OR), with 95% Confidence Interval (CI), were calculated.

We retrieved 14 RCT. No significant between-group difference in HbA1c (WMD -0.39[-0.89; 0.09] mmol/mol, p = 0.11) was observed. At metaregression analyses, longer trial duration, higher baseline mean age and duration of diabetes, and lower baseline HbA1c were correlated with greater efficacy of group-based programs in reducing HbA1c. When analyzed separately, trials excluding insulin-treated patients showed a significant reduction of HbA1c in favor of group education.

Conclusions: In patients with T2DM, group education has similar efficacy as individual education on glucose control. Group programs are associated with an improved quality of life and patients' knowledge.

Prospero and OSF registration: ID243149.

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Introduction

Patient education is an essential component of the treatment and management of type 2 diabetes mellitus [1-3]. Recommendations on educational programs are always included in treatment guidelines for type 2 diabetes, to encourage positive self-management behaviors to achieve and maintain an adequate metabolic control [1–6]. Groupbased education could have some advantages in comparison with individual education, often being less timeconsuming and funding required [4]. Several previous meta-analyses explored the effectiveness of group-based training on glucose control and patients' knowledge in people with type 2 diabetes [3,5,7,8]; yet, the comparator was often routine treatments, waiting lists, or no intervention. Only one meta-analysis attempted to compare group-with individual-based educational programs finding no differences in metabolic and psychosocial outcomes [7]. However, the number of included trials was scarce, preventing reliable conclusions. In the last few vears, several new trials were published justifying an update on the type of educational program to be recommended to patients with type 2 diabetes.

An expert panel of the Italian Association of Clinical Diabetologists (Associazione Medici Diabetologi, AMD) and the Italian Society of Diabetology (Società Italiana di Diabetologia, SID) is currently developing new guidelines for drug treatment of type 2 diabetes. This expert panel includes clinical diabetologists, a general practitioner, a dietitian, a nurse, a professional diabetes educator, as well as a health economist, and a representative of patients with diabetes.

The panel identified relevant clinical questions and patient-important outcomes critically affecting clinical decisions in diabetes clinical practice. As a consequence, a series of systematic reviews and meta-analyses of RCTs are currently underway. The current paper reports the results of a systematic review and meta-analysis of randomized trials on the differences between group-based and individual education for self-management in patients with type 2 diabetes.

Methods

This meta-analysis is reported following the criteria of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [9].

Search strategy and inclusion criteria

This meta-analysis and the protocol (see Supplementary materials) has been registered on PROSPERO with a provisional number (ID: 243149; https://www.crd.york.ac.uk/ prospero/#recordDetails) and on Open Science Framework registry (OSF | COMPARISON BETWEEN DIFFERENT EXERCISE TRAINING MODALITIES IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW AND NETWORK METANALYSIS OF RANDOMIZED CONTROLLED TRIALS.) on 2020-09-29. A Medline and Embase search up to April 30th, 2021, was performed with the following key-words: "diabetes", "education", "group", "individual". The search string is reported in Supplementary Materials (Table 1S). References of retrieved articles were manually searched for further studies. An attempt to retrieve further articles from the so-called "grey literature" was made by searching the following databases: Bielefeld Academic Search Engine (https://www.base-search.net/) and Open Grey (http:// www.opengrey.eu/).

We included Randomized Controlled Trials (RCT) with at least a follow-up of 6 months, enrolling adult patients with type 2 diabetes and comparing individual with group settings for the administration of educational programs, in which the educational curriculum was similar across treatment groups. No language or date restriction was imposed. Trials on type 1 or other forms of diabetes were also excluded. Trials with a duration shorter than 6 months were also excluded because they could hardly provide reliable information on the effects of different treatments on one of our principal outcomes, i.e. HbA1c.

Outcomes

The primary outcome of the present meta-analysis was to assess the effects of group-based in comparison with individual-based educational programs on HbA1c and fasting plasma glucose at the endpoint. Although HbA1c has a greater relevance as a treatment target in type 2 diabetes, fasting glucose was also included as co-primary endpoint, in order to avoid the exclusion of trials (if any) providing results on glycaemic control without measuring HbA1c. Secondary outcomes included Body Mass Index (BMI), waist circumference, percentage of body fat, LDLcholesterol, diastolic blood pressure (DBP), and systolic blood pressure (SBP), quality of life, and patients' adherence and knowledge at the endpoint.

Study selection

ENDNOTE X9 literature management software was used to manage the literature search records. These searches and the selection of studies were independently performed by two authors (M.M and A.B.) and conflicts resolved by a third investigator (E.M.).

Data extraction

Summary estimates of the variables of interest were extracted from the principal publication, when available; whenever needed, secondary publications and clinicaltrials.gov registry were used for retrieval of missing information, in the hierarchical order reported above. Data extraction was performed independently by two of the authors (A.B. and M.M.), and conflicts were resolved by a third investigator (E.M.).The following parameters/information were extracted: first author, publication year, National Clinical Trial (NCT) number or other registration identifiers/acronyms, sample size, duration of the trial, age, duration of diabetes, number of sessions and length, as well as baseline and endpoint HbA1c, FPG, BMI, waist circumference, body fat percentage, systolic and diastolic blood pressure, LDLcholesterol, and quality of life (QoL). Adherence to educational programs was also assessed through the number of subjects lost at follow-up.

Risk of bias assessment

The risk of bias was assessed using the Cochrane risk of bias tool for RCTs. The risk of bias was described and assessed in seven specific domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases. The results of these domains were graded as 'low' risk of bias, 'high' risk of bias, or 'uncertain' risk of bias.

The risk of bias assessment was performed independently by two reviewers (M.M. and A.B.) and conflict was resolved by a third reviewer (E. M.).

Data analysis

For each available comparison, the weighed difference in means (WMD) and Mantel-Haenzel Odds Ratio (MH–OR), with 95% Confidence Interval (CI), was calculated using random-effect models. Statistical heterogeneity was assessed by the I² test, whereas the Funnel plot for endpoint HbA1c was used to detect publication bias. Egger's regression intercept was calculated for endpoint HbA1c to confirm the visual analysis of the Funnel plot. A subgroup analysis for RCTs enrolling patients on insulin therapy or non-insulin glucose-lowering agents and metaregression analyses were performed to explore possible moderators of HbA1c reduction for group-based and individual-based education programs.

Analyses were performed using Review Manager (Rev-Man), Version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014), and Comprehensive Metanalysis V2 (Biostat Inc., NJ, USA).

Results

The trial flow summary is reported in Fig. 1S. The principal characteristics of the 14 trials fulfilling all inclusion criteria are reported in Table 1. The mean age, BMI, and HbA1c of the patients included in the present meta-analysis were 60.8 years, 30.7 kg/m², and 8.0%, respectively. The mean duration of follow-up was 14.8 months.

Out of 14 trials, 13, 4, 2, 8, 5, 10, and 9 reported information on endpoint HbA1c, FPG, waist circumference, BMI, LDL-cholesterol, blood pressure, quality of life, and patients' knowledge respectively.

The quality of studies was generally satisfactory, except for "blinding of assessors", since the majority of the studies were open-label (Fig. 2S).

Effect on glucose control

The Funnel plot for endpoint HbA1c is reported in Fig. 3S. The visual analysis of the Funnel plot did not suggest any publication bias and Egger's regression intercept confirm this result (Egger's regression intercept: 1.7[-5.1; 8.6], p = 0.59). No significant between-group difference in HbA1c at endpoint was observed (WMD -0.39[-0.89; 0.09] mmol/mol, p = 0.11), with high heterogeneity (Fig. 1). Several meta-regression analyses were performed to explain the high heterogeneity of this result. At metaregression analyses, longer trial duration, higher baseline mean age and duration of diabetes, and lower baseline mean HbA1c levels were correlated with a greater efficacy of group-based programs in reducing HbA1c (Slope -0.04 [-0.05; -0.03], p < 0.001; -0.10[-0.11; -0.09], p < 0.001; 0.26[0.06; 0.47], p = 0.012; and -0.11[-0.13; -0.10], p < 0.001) in comparison with individual settings (Fig. 5S). No effect on HbA1c was observed for the publication year (Slope: -0.01; p: 0.58) and baseline HbA1c (Slope: 0.09; p: 0.41). When analyzing separately, trials including (n = 5)and excluding (n = 6) patients treated with insulin, a significant between-group difference in HbA1c levels was observed (p for interaction: 0.008), as shown in Fig. 4S.

Few trials [10–12] reported information on FPG, showing no between-group difference (Fig. 6S).

Effect on body weight

Neither BMI nor waist circumference at endpoint showed a significant difference between group-based and individual-based education, as shown in Fig. 7S.

Effect on other endpoints

In trials reporting data on blood pressure, no significant differences between treatment arms were detected (Fig. 8S). Similar results were obtained for LDL-cholesterol, with no difference between the two interventions (Fig. 9S).

Adherence

All RCTs included reported patients lost at follow-up. There was no statistically significant difference between group and individual education as shown in Fig. 10S.

QoL and patients' knowledge

Nine [10–17] trials reported measures of patients' QoL. Different instruments were used for these assessments as reported in Tables 3S and 4S Heterogeneity of instruments and reporting prevented formal analyses, except for the diabetes quality of life (DQOL) questionnaire, which was used in three trials [10–12], showing better scores for group-based versus individual-based educational programs (Fig. 12S). The other six studies reporting information on QoL did not show any difference, except for two trials reporting better scores for several sub-scales of QoL among patients allocated to group-based education [13,14]. Nine

Table 1	Baseline	characteristics	of the	trials included	l in the	metanalysis.
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First author (ref)	Group education (#patients)	Individual education (#patients)	Trial duration (months)	# sessions	Length of session (minutes)	Professionals	HbA1 _c (%)	BMI (kg/m ²)	Duration of diabetes (years)	Insulin -treated pts (%)	Lost at follow-up (GE/IE)
Dalmau Llorca [28]	38	41	12	3	40	N, P	6.9	29.6	8.5	8	0/2
Deakin [13]	157	157	14	6	120	NR	7.7	30.7	6.7	17	11/21
Delahanty [25]	28	29	12	19	90	D	8.2	35.5	11	61	2/1
Santos [29]	93	34	12	10	120	P,D,N	7.6	NR	NR	0	0/0
Singer [18]	16	13	12	4	120	N,P	8.2	29.3	22.5	66	0/0
Sperl-Hillen [15]	243	246	6.8	4	120	N,P	NR	34.5	8.2	NR	0/0
Torres Hde [30]	54	50	6	NR	NR	NR	9.3	NR	NR	NR	31/26
Trento [12]	56	56	24	4	NR	P, Psyc.	7.4	29.5	9.6	0	13/9
Trento [10]	25	24	24	8	NR	N, D; Ped.	8.0	27.0	12.5	0	4/3
Trento [11]	421	394	48	16	NR	P, Psyc.	7.8	29.6	16.2	0	82/110
Rickheim [14]	87	83	6	4	360	N, D	8.5	34.4	1.0	0	44/34
Vadstrup [19]	70	73	6	6	90	N,P,D,P	7.8	NR	6.5	17	9/13
Van Puffelen [17]	107	102	6	4	120	N,P,PH	NR	NR	2	2.5	10/6
Withdpanywong [20]	98	98	9	4	45	N	9.1	27.6	6	0	10/6

N: Nurse; P: Physicians; PH: Pharmacist; D: Dietitian; P: Podiatrist; PH: Physical therapist; Psyc.: Psychologist; Ped.: Pedagogist.

studies [11–15,17–20] reported information on patients' knowledge. In five studies [11–13,19,20] an improvement of patients' knowledge in subjects allocated to group-based in comparison with individual-based educational programs was reported, whereas the remaining four studies [14,15,17,18] did not report any significant change.

Discussion

The efficacy on glycemic control of group-based programs on glycemic control seems to be similar to that of individual patient education. In addition, no relevant differences between the two approaches can be detected for other outcomes, such as body weight and concomitant risk factors. This result confirms previously reported findings from a meta-analysis performed on a smaller number of trials [7]. Both the present and the previous meta-analyses show a high heterogeneity, limiting their reliability. In the present meta-analysis, the availability of a higher number of studies allowed the exploration of sources of heterogeneity through meta-regression, although differences across studies in reporting prevented formal analyses on some relevant potential moderators, such as concurrent therapy with different classes of non-insulin drugs. In patients with lower HbA1c levels and treated with noninsulin glucose-lowering agents, group-based programs appeared to be more effective than individual education.

	Group			Individual			Mean Difference		Mean Difference	Risk of Bias	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	ABCDEFG	
Dalmau 2003	6.6	1.3	38	6.1	1.2	41	7.5%	0.50 [-0.05, 1.05]			
Vadstrup 2011	7.6	0.8	70	7.2	0.9	73	8.1%	0.40 [0.12, 0.68]			
Sperl-Hillen 2011	7.8	0.9	243	7.6	0.9	246	8.2%	0.20 [0.04, 0.36]	-	2200000	
Santos 2017	7.1	1	93	7	1	34	7.9%	0.10 [-0.29, 0.49]			
Rickheim 2002	6.5	0.7	87	6.5	0.9	83	8.1%	0.00 [-0.24, 0.24]	+	$\bullet \bullet \bullet \bullet \bullet \bullet \bullet$	
Singer 2018	8.2	1.2	16	8.3	1.1	13	6.6%	-0.10 [-0.94, 0.74]		$\bullet \bullet \bullet \bullet \bullet \bullet \bullet \bullet$	
Torres 2009	7.6	1.4	54	7.9	1.6	50	7.4%	-0.30 [-0.88, 0.28]			
Deakin 2006	7.4	1.3	157	7.8	1.6	157	8.0%	-0.40 [-0.72, -0.08]		$\bullet \bullet \bullet \bullet \bullet \bullet \bullet \bullet$	
Delahanty 2015	7.4	0.8	28	7.8	1.2	29	7.5%	-0.40 [-0.93, 0.13]		2200000	
Trento 2008	7.6	0.8	25	8.4	1.3	24	7.3%	-0.80 [-1.41, -0.19]		2200000	
Withidpanyawong 2019	7.8	1.8	88	8.9	1.8	92	7.5%	-1.10 [-1.63, -0.57]		2200000	
Trento 2010	7.3	0.9	421	8.8	1.2	394	8.2%	-1.50 [-1.65, -1.35]	+		
Trento 2004	7.3	1	56	9	1.6	56	7.6%	-1.70 [-2.19, -1.21]		2300000	
Total (95% CI)			1376			1292	100.0%	-0.39 [-0.87, 0.09]	•		
Heterogeneity: Tau ² = 0.73; Chi ² = 361.25, df = 12 (P < 0.00001); I ² = 97%											
Test for overall effect: Z = 1.59 (P = 0.11)									Favours [Group] Favours [Individual]		
Risk of bias legend (A) Random sequence gr (B) Allocation concealmer (C) Blinding of participant (D) Blinding of outcome a (E) Incomplete outcome of (F) Selective reporting (ref (G) Other bias	eneration nt (selec s and pe ssessm lata (attri porting b	n (sei tion t erson nent (ition t bias)	lection bias) nel (pe detectio bias)	bias) rformar on bias)	nce b)	ias)					

Figure 1 Effects on HbA1c of group-based versus individual-based education: forest plots for HbA1c.

In addition, the group approach could be more effective than the individual setting in longer-term programs. The lack of significant differences between group and individual education could be due to the fact that several available studies are relatively short. Moreover, metaregression analysis suggests that group programs could be more effective in patients with longer duration of diabetes; it is possible that individual programs are more effective and timely in addressing the complex educational needs of newly-diagnosed patients, whereas interactive group programs could be more beneficial in patients with a longer history of diabetes, who have a wider range of experiences to share with their peers. Another factor moderating the specific effects of the group setting in patient education is the type of diabetes. In a metaanalysis of studies performed in patients with type 1 diabetes, individual-based programs resulted superior to group-based programs in improving glycemic control, although the difference between treatment arms was small and clinically trivial [21]. It can be speculated that the management of insulin-treated type 2 diabetes implies the acquisition of complex technical skills, which could be obtained more easily and timely in face-to-face visits. In line with this consideration, in the present analysis group programs appeared to be more effective than individual programs in non-insulin-treated patients. It should also be recognized that three studies, overall contributing for over 25% to the final result, were performed by the same research group [10-12]. These studies provided a more favourable result on HbA1c for group education than the average of available studies. Such deviation could be due to a longer duration of trials, or to the exclusion of insulintreated patients. However, the type of professionals involved (i.e., pshychologists and/or pedagogists, together with physicians and nurses) or other specific characteristics of the setting or the interventions could have contributed to the greater success of group programs in these three studies [10-12].

Notably, group programs did not determine a greater reduction of HbA1c in comparison with individual programs, despite a greater effect on patient knowledge. This confirms that the increase of knowledge in patients with diabetes is not sufficient to improve their skills or modifying their behaviors, and therefore to ameliorate their glycemic control [22,23]. In fact, peer support has been shown to provide many benefits related to diabetes knowledge, behavioral, and psychosocial outcomes, but less evident effects on glycemic control [23,24]. In addition, type 2 diabetes is a highly heterogeneous condition, which may require differential educational contents, on the basis of differences in treatments and individual patient characteristics; an individual approach could facilitate a more accurate tailoring of educational interventions.

Long-term treatment of type 2 diabetes cannot be measured only with metabolic parameters. Quality of life, diabetes knowledge, in fact, are important goals to be pursued. In the present meta-analysis, quality of life seems to be ameliorated by group programs; in fact, the group setting is expected to improve the psychological status of participants through peer support [6]. However, this beneficial effect could be more evident in patients with higher levels of psychological distress; such characteristic was not listed among inclusion criteria in any of the trials retrieved for the present meta-analysis. Unfortunately, incomplete reporting and heterogeneity of instruments did not allow an analysis of possible moderators (such as duration of diabetes or proportion of insulin-treated patients) of the effect of group approach on quality of life and psychological well-being.

The analysis of costs was not among the aims of the present meta-analysis. Intuitively, the same educational curriculum can be administered at a lower cost collecting together a group of patients, rather than individually. Among the studies included in the meta-analysis, only two performed a formal economic analysis, reporting in one case a trivial difference in costs between group- and individual-based programs [25] and in the other, favorable cost-effectiveness for group-based intervention [12,26].

Some limitations of the present study should be acknowledged. First of all, the number of eligible studies was relatively small, and sample sizes were limited. In addition, some of the studies showed methodological limitations, which could have contributed to the heterogeneity of results. In particular, misclassification of cases, with the inclusion of patients with type 1 diabetes, could have affected the results of some of the included studies [18,25].

Moreover, the number of sessions (ranging from 3 to 19) and their length (ranging from 40 to 360 min) could have an impact on the results obtained. A formal analysis on this possible moderator was not performed due to the scarce number of trials; however, two studies with better metabolic outcomes for group-based education programs were designed with a high number of sessions [25,27]. Finally, publication year widely varies among the included studies with possible effects of different approach to diabetes on metabolic endpoints (e.g. newer and efficient glucose-lowering agents, different HbA1c targets, ecc.). However, metaregression analysis seems to exclude this possible bias on the results obtained. Unfortunately, background therapy cannot be formally analysed due to the wide heterogeneity across studies and a possible effect of changes in the clinical practice for type 2 diabetes in the last years cannot be completely ruled out.

In conclusion, in patients with type 2 diabetes group education has similar efficacy as individual education on glucose control, body weight, blood pressure, and lipid profile, although it seems to be more effective on patients' knowledge; in addition, group programs are associated with an improvement in the quality of life. Specific research on the most effective delivery of educational programs should be encouraged to strengthen the evidence base for the organization of diabetes care.

Role of the funding source

This research was performed independently of any funding, as part of the institutional activity of the investigators. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit it for publication.

Contributors

MM and **EM** were involved in each of the following points:

- 1. Design.
- 2. Data collection.
- 3. Analysis.
- 4. Writing manuscript.

AB, BDA, MG, MLM, MT and AG were involved in each of the following points:

- 1. Manuscript revision.
- 2. Data collection.

Research involving human participants and/or animals

This article does not contain any studies with human participants or animals performed by any of the authors.

Declaration of competing interest

EM has received consultancy fees from Merck and Novartis speaking fees from Astra Zeneca, Bristol Myers Squibb, Boehringer-Ingelheim, Eli-Lilly, Merck, Novo Nordisk, Sanofi, and Novartis, and research grants from Merck, Novartis, and Takeda. **MM** has received speaking fees from Astra Zeneca, Bristol Myers Squibb, Boehringer-Ingelheim, Eli-Lilly, Merck, Novo Nordisk, Sanofi, and Novartis and research grants from Bristol Myers Squibb; **AB, BDA, MG, MLM, MT and AG** have no relevant conflicts of interest to declare.

All the authors approved the final version of this manuscript. Dr. Edoardo Mannucci is the person who takes full responsibility for the work as a whole, including the study design, access to data, and the decision to submit and publish the manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.numecd.2021.10.005.

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