Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes
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CRD summary
This review assessed the effects of educational and behavioural interventions on body weight and glycaemic control in patients with type 2 diabetes. The authors concluded that these interventions can improve glycaemic control, but the evidence is not yet overwhelming. The studies used a variety of different interventions and produced different results, suggesting that the effect of the interventions may not be consistent.

Authors’ objectives
To assess the effects of educational and behavioural interventions on body weight and glycaemic control in patients with type 2 diabetes.

Searching
MEDLINE was searched from 1966 to 1999 for studies published in the English language; the keywords and MeSH terms were stated. The Cochrane Library was also searched and manual searches of Diabetes Care (1990 to 1999), references supplied by experts and the authors’ colleagues, and reference lists in previous meta-analyses and reviews, were conducted. Published abstracts from the American Diabetes Association 57th, 58th and 59th National Scientific Sessions (1997 to 1999) were searched online.

Study selection

Study designs of evaluations included in the review
Randomised controlled trials (RCTs) that enrolled at least 10 patients were eligible for inclusion. Randomisation had to be of individual patients. Studies that randomised clinicians were only included if they presented outcomes for the patients. In the included studies, the duration of follow-up ranged from 1 to 26 months.

Specific interventions included in the review
Studies of educational and behavioural component interventions were eligible for inclusion. The studies had to have a clear behavioural or counselling element aimed at improving long-term diabetes self-care. Studies of drug interventions were excluded.

The included studies used a variety of interventions. The majority of the studies (70%) used an intervention that focused on diet; 57% of studies emphasised exercise. Other intervention elements included medications or measurement of blood glucose, foot care, pathophysiology of diabetes and its complications, education about diabetes, and urine testing. Most studies (56%) had usual medical care as the control intervention; other studies used minimal intervention as the control. The professionals carrying out the interventions were nurses, dieticians, physicians, psychologists, exercise physiologists and health educators. The interventions were mainly conducted in an out-patient clinic (96%) and most used group (52%) and/or individual (65%) counselling of the patients. Other intervention elements included telephone outreach, clinician prompting, clinician education, computer programs, instruction packs and audiovisual materials. In the included studies, the duration of the interventions ranged from 1 to 19 months (median 5 months) and the median number of intervention visits was 8.5 (range: 2 to 52).

Participants included in the review
Studies of patients with type 2 diabetes were eligible for inclusion. Studies that only included patients with type 1 diabetes were excluded. In the included studies, the mean percentage of patients with type 2 diabetes was 99% (range: 93 to 100), the mean age (17 studies) was 57 years, the mean duration of diabetes was 9 years, the mean percentage of female patients was 58%, the mean percentage on insulin was 53%, and the mean percentage on oral drugs was 41%. Few studies reported the inclusion of African-American or Hispanic people. Most of the studies (83%) recruited patients from out-patient clinics.
Outcomes assessed in the review
Only studies that assessed glycaemic control or weight, and presented data on effect sizes and standard deviations, were included in the meta-analysis. The review assessed measures of glycohaemoglobin (total Ghb, HbA1 and HbA1C), fasting blood glucose and body weight.

How were decisions on the relevance of primary studies made?
Two reviewers used some of the inclusion criteria to select studies, but no other information on how the studies were selected was given.

Assessment of study quality
Validity was assessed and scored using the criteria described by Detsky et al.: method of randomisation, criteria for measuring the outcomes, inclusion and exclusion criteria, description of the interventions, and statistical analysis. Each criterion was scored equally and the maximum possible score was 1. The quality scores were classified as low (less than 0.65), moderate (0.65 to 0.79) and high (greater than 0.79). Two reviewers independently assessed validity and resolved any disagreements through discussion or with the senior author. Agreement between the reviewers on validity scores was low (kappa 0.13).

Data extraction
Two reviewers independently extracted the data and resolved any disagreements through discussion with the senior author. The data extracted included study characteristics and design.

For studies reporting adequate data, the standardised mean difference from baseline to follow-up between treatment groups was calculated for measures of glycohaemoglobin, fasting blood glucose and body weight. Data from all intervention arms were incorporated into the summary statistics.

Methods of synthesis
How were the studies combined?
The characteristics of the included studies were summarised in the text of the review. Studies that presented sufficient data were combined using meta-analysis. Pooled standardised mean differences (effect sizes) for glycohaemoglobin measures, fasting blood glucose and body weight were calculated using a random-effects model. Analyses of the difference in fasting blood glucose between intervention groups were conducted, with no weighting and with weighting by study precision and by sample size. Meta-analyses were conducted for each of the measures of glycohaemoglobin (total Ghb, HbA1 and HbA1C). Data from abstracts of the American Diabetes Association were not included in the meta-analysis of published data. The possibility of publication bias was explored using a funnel plot.

How were differences between studies investigated?
Subgroup analyses were used to explore the influence of the following factors on glycohaemoglobin: country (USA versus international); quality (high quality versus lower quality); sample size (100 or more versus less than 100); person carrying out the intervention (physician, nurse, dietician); group or individual instruction; and topic of instruction (diet, exercise, medication and monitoring).

Results of the review
Sixty-three RCTs were eligible for inclusion. Eighteen RCTs (2,720 patients) were included in the meta-analysis.

The median quality score of the 18 RCTs included in the meta-analysis was 0.71 (range: 0.53 to 0.98). The mean percentage of eligible patients that were randomised was 79%. The mean percentage of patients who were followed up was 82% (range: 36 to 100).

The funnel plot suggested the possibility of publication bias, with positive results more likely to have been published.

Main analyses (18 RCTs).
Glycaemic control.

The meta-analysis showed that interventions significantly reduced glycohaemoglobin compared with control. The effect size was 0.43 (P=0.003).

RCTs conducted in the USA showed smaller effect sizes than international RCTs (-0.26, P=0.001 versus 0.89, P non significant).

Interventions in high-quality RCTs significantly reduced glycohaemoglobin compared with control (effect size 0.51, P=0.001), but there was no significant difference between interventions for lower quality RCTs (effect size 0.38, P non significant).

RCTs with larger sample sizes showed greater reductions in glycohaemoglobin, compared with control, than smaller RCTs (-0.65, P=0.16 versus 0.31, P=0.048).

The effect size for RCTs using physicians to carry out the intervention was 0.18 (P=0.229); when using nurses and dieticians, the effect sizes were -0.71 (P=0.022) and 0.88 (P=0.043), respectively.

RCTs using interventions with groups had similar effects to interventions using individuals (-0.62, P=0.005 and 0.70, P=0.015).

RCTs of interventions that focused on medication had larger effect sizes (-0.72, P=0.032) than interventions that focused on exercise (-0.69, P=0.007), diet (-0.51, P=0.008) and blood glucose self-monitoring (-0.20, P<0.001).

Other analyses (63 RCTs).

Fasting blood glucose.

The studies showed that interventions had a non significant, moderate effect size on the mean fasting blood glucose. The difference was 12.22 mg/dL (weighted by precision), but the studies were statistically heterogeneous (P<0.05). The difference was -24.0 when weighted by sample size and 12.4 when unweighted.

Measures of glycohaemoglobin.

Only the meta-analysis of HbA1C reached statistical significance (effect size 0.52%, P=0.02). The effect sizes for glycohaemoglobin and HbA1 were not statistically significant (the results were reported).

Weight.

The studies showed a small reduction in weight with the intervention, but the reduction was not statistically significant (the results were reported).

**Authors' conclusions**

Educational and behavioural interventions may improve glycaemic control in patients with type 2 diabetes, but the evidence is not yet overwhelming.

**CRD commentary**

The review question was clear in terms of the study design, participants, intervention and outcomes. Several relevant sources were searched and the search terms were stated. The search was conducted up to 1999, yet the paper was published in 2003. Reasons for not updating the search to reflect more recent research were not given. The authors acknowledged that their limited attempts to locate unpublished studies raises the possibility of publication bias and the funnel plot did suggest the presence of publication bias. In addition, by limiting the literature search to studies published in English, some relevant studies might have been omitted. The methods used to select the studies were not described, so it is not known whether efforts were made to reduce errors and bias. Two reviewers independently
assessed validity and extracted the data, thus reducing the potential for bias and errors. Only RCTs were included and
validity was assessed using specified established criteria.

The characteristics of the studies included in the main analyses were clearly summarised in the text of the review.
Heterogeneity was formally assessed, but was not consistently reported. The forest plot showed evidence for
heterogeneity in the analysis of glycaemic control, and this suggests it might not have been appropriate to pool the
studies. The influence on the results of various factors was explored. The evidence presented appears to support the
authors' conclusions, although the apparent heterogeneity among studies for the main outcome (glycaemic control)
should be noted.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that future studies should be well designed and conducted RCTs that determine the most
effective elements of interventions and assess a wide range of risk factors such as blood-pressure and lipids.

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