Effectiveness of disease-management programs for improving diabetes care: a meta-analysis

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CRD summary
The review found that disease management programmes were moderately effective in improving glycaemic control among adults with diabetes. The most effective components of the programmes appeared to be high frequency patient contact and the ability for disease managers to adjust treatment. Limitations in the review process and reporting mean that the authors' conclusions should be treated with some caution.

Authors' objectives
To assess the effectiveness of disease management programmes for improving glycaemic control in adults with diabetes mellitus and to study which programme components were associated with effectiveness.

Searching
MEDLINE, Scopus, Web of Science and The Cochrane Library were searched from inception to December 2009 for trials published in English. Brief search terms and the full MEDLINE search strategy were given in the review. Reference lists of included studies were searched.

Study selection
Randomised controlled trials of disease management interventions in adults with type 1 or type 2 diabetes mellitus were eligible for inclusion. Disease management was defined as ongoing proactive follow-up of patients with at least two of five components for patient education, coaching, treatment adjustment, monitoring and care co-ordination. Studies needed to report both pre- and post-intervention haemoglobin A1c (HbA1c) levels; post-intervention levels had to be assessed after at least 12 weeks of follow-up. Studies of interventions that did not involve direct contact between disease manager and patient or where this was unclear, unspecified or exclusively based on contact by Internet or mail were not eligible for inclusion.

Interventions involved telephone and/or face-to-face contact and ranged in duration ranged from 1.5 to 48 months. Most interventions involved a nurse and/or other health care worker. Most interventions had four or more components and these most commonly included patient education, coaching and disease monitoring. Control groups in most studies received usual care (not further defined). All studies except three included only patients with type 2 or a mixture of patients with type 1 and 2 diabetes. Mean age of participants was 57.6 years (standard deviation 7.3). Nearly half of the participants were men.

Two reviewers assessed the studies for relevance. It was not clear how discrepancies were resolved.

Assessment of study quality
Low quality was defined in three ways: overall drop-out rate of more than 20% or drop out rate not reported; a difference in drop-out rate of 7% or higher between study arms or drop-out rate not reported; and unclear information on allocation concealment.

It appeared that two reviewers performed the validity assessment. It was not clear how discrepancies were resolved.

Data extraction
Data were extracted to enable calculation of change in HbA1c in intervention and control groups and the standard deviation of the change. Missing data on standard deviation of HbA1c were imputed based on baseline HbA1c. Where more than one post-intervention HbA1c level was reported, the first was used. Frequency of contact with the disease manager was classified in three levels: low (less than one contact monthly per patient), moderate (one contact monthly per patient) and high (several contacts monthly per patient). Adverse events were hypoglycaemic episodes (defined differently across studies), hospital admission and death. Where data were missing, the original authors were contacted by email.

Two reviewers independently extracted data. It was not clear how discrepancies were resolved, except for the
calculation of frequency of contact where discrepancies were reviewed by a third reviewer and a consensus was reached.

**Methods of synthesis**

Pooled standardised mean difference (SMD) in HbA1c between intervention and control groups, with 95% confidence intervals (CIs) was calculated using a random-effects model. Heterogeneity was assessed with $I^2$ and $T^2$.

Meta-regression was used to determine the contribution of patient characteristics and components of the disease management programmes to the between-study variance and expressed as standardised mean change in HbA1c. The degree of heterogeneity explained was expressed as a percentage change of the between-study variance.

Three sensitivity analyses excluded studies that met criteria used to define low quality.

**Results of the review**

Forty-one trials set in North America, Europe and Asia were included in the review. The reported number of participants differed between the text and tables, but appeared to be more than 7,745. Drop-out rates ranged from zero to 39.8% and the drop-out rate difference between study arms ranged from zero to 26.1%. Allocation concealment was adequate in 15 studies.

The intervention improved glycaemic control (SMD -0.38, 95% CI -0.47 to -0.29) corresponding to an absolute mean difference in HbA1c of 0.51% between the intervention and control groups. There was evidence of statistical heterogeneity between studies ($I^2=66\%$).

Univariate meta-regression showed that the effect of the intervention was greater in studies where the mean HbA1c was 8% or more compared with less than 8% (SMD -0.45, 95% CI -0.56 to -0.34 compared to SMD -0.14, 95% CI -0.25 to -0.05).

Programmes in which the disease manager could start or modify treatment were associated with a greater improvement in HbA1c compared to those that could not (SMD -0.60, 95% CI -0.73 to -0.47 compared to SMD -0.28, 95% CI -0.37 to -0.18).

Programmes with a high frequency of contact led to a significantly greater reduction in HbA1c compared to those with low frequency (SMD -0.56, 95% CI -0.72 to -0.40 compared to SMD -0.30, 95% CI -0.54 to 0.06). There was no difference in the effect of intervention between moderate and low frequency programmes.

No multivariable meta-regression results were reported. Sensitivity analyses showed that the results were robust to exclusion of studies defined as low quality.

Six out of nine studies that reported data on hypoglycaemic events found no difference in rate between intervention and control groups; two of the remaining three found a higher rate in the control compared to intervention group. No overall difference between groups was found in 20 studies that reported mortality. Data on hospital admissions were not clearly or systematically reported.

**Authors’ conclusions**

Disease management programmes moderately reduced HbA1c levels among adults with diabetes. The most effective components of the programmes appeared to be a high frequency of patient contact and the ability for disease managers to adjust treatment.

**CRD commentary**

The authors searched several databases. Exclusion of papers not in English risked language bias. The authors stated that the included studies were published from 1990 onward; it was not clear whether there were no relevant studies before 1990 or if this was a date restriction implemented by the authors and omitted from the list of inclusion criteria. No attempt was made to identify unpublished studies or assess possible publication bias. Other risks of bias and error in the review process were minimised by the use of two reviewers for study selection, data extraction and quality assessment. The results were robust to the quality assessment performed, but key attributes of quality (such as randomisation and blinding) were not reported on.
It was unclear how many participants were included in the review as data in tables and text were not consistent. The meta-analysis used was appropriate. As the meta-regression used to investigate sources of heterogeneity was univariate, these results could have been confounded and therefore may be unreliable. The authors noted that their reported findings were probably underestimated as usual care in RCTs was often better than that provided in clinical practice.

Given the potential limitations in the review process, reporting and analysis, the authors' conclusions should be treated with some caution.

**Implications of the review for practice and research**

**Practice:** The authors stated that disease management programmes with intensive patient contact that targeted patients at high risk of diabetes complications should be given priority and disease managers should be allowed to start or modify medical treatment proactively.

**Research:** The authors stated that more research was needed on the long term impact of disease management programmes on diabetes outcomes and whether patient groups in addition to those with unstable diabetes could benefit from such programmes. High quality cost-effectiveness studies of disease management programmes were needed.

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