



Mediating the effect of self-care management intervention in type 2 diabetes: a meta-analysis of 47 randomised controlled trials

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CRD summary

The review found that self-care management was associated with a greater reduction in HbA1c levels than no self-care management in patients with type 2 diabetes. Strong evidence of heterogeneity in the results, a lack of quality assessments in interpretation of the findings and a large number of unadjusted comparisons mean the author's conclusions should be treated with caution.

Authors' objectives

To assess the effects of self-care management interventions in improving glycaemic control in type 2 diabetes and to determine the impact of different study characteristics on the magnitude of the effect.

Searching

MEDLINE, EMBASE, CINAHL, PsycINFO, The Cochrane Library, SveMed, Bibliotek.dk and Web of Science were searched from inception to November 2007 without language restrictions; search terms were reported. Reference lists of retrieved studies and meta-analyses were searched for additional studies.

Study selection

Eligible studies were randomised controlled trials (RCTs) that assessed the effect of self-care interventions that used behavioural or educational strategies compared to control with no intervention in adult patients (>18 years) diagnosed with type 2 diabetes. The primary outcome was change in HbA1c. Studies were excluded if they were abstracts, did not clearly describe the intervention techniques or were not published in English or Nordic languages.

Eighteen of the included studies used a behavioural psychosocial technique and 29 used an educational technique as the intervention method. Interventions were delivered either by group or individual sessions over various lengths of time by a variety of therapists and practitioners. Mean participant age in each intervention category was 61 and 59 years (where stated). Duration of diabetes ranged from 4.3 to 13.4 years. Mean HbA1c levels for intervention groups ranged from 5.6% to 11.8% and ranged from 6.1% to 11.8% for control groups.

Two reviewers selected studies for inclusion. Differences were resolved through consensus.

Assessment of study quality

Study quality was assessed according to Cochrane criteria; these included description of randomisation procedure and allocation concealment, whether intention-to-treat analysis was used and assessment of potential bias from unequal and high rates of withdrawals and dropouts.

The authors did not state how many reviewers performed the quality assessment.

Data extraction

Self-care management was categorised in two subgroups: educational interventions and behavioural psychosocial interventions. Mean differences (MD) between groups for individual differences between baseline and follow-up HbA1c values were calculated, together with standard errors and 95% confidence intervals. Where data were not reported, the authors calculated values by imputation. Study characteristics were extracted to determine any factors that could influence effect sizes.

Two reviewers independently extracted data.





Methods of synthesis

Studies were pooled in a meta-analysis using a random-effects model. Heterogeneity was assessed using the X2 test. Potential publication bias was assessed by inspection of a funnel plot, Begg's adjusted rank correlation test and Egger's test.

A univariate meta-regression was used to identify potential factors associated with the treatment effect. These factors were categorised into subgroups: type of intervention (behavioural or educational), sample size (99), year of publication (2004), mean duration of diabetes (8.5 years), baseline glycated haemoglobin (HbA1c 8.5%), duration of intervention (month nine), follow-up period (month 12) and age (60.5 years). Where studies included multiple intervention groups, each intervention group was compared to the control group and considered as an individual study.

Results of the review

Forty-seven RCTs (n=8,870) were included in the review. Data on the quality of individual studies were reported in tables. Most studies did not report on all the quality criteria. Follow-up ranged from two months to eight years.

Self-care management was associated with a significantly greater decrease in HbA1c levels when compared with control (MD -0.36%, 95% CI -0.21 to -0.51). There was evidence of significant statistical heterogeneity. Results were similar for the analysis using a random effects model. There was no evidence of significant publication bias.

Univariate meta-regression analysis indicated that there was a significantly larger reduction in HbA1c levels in studies with sample size 99 or less compared to larger studies (MD -0.42%, p=0.007) and in studies with follow-up periods of 12 months or less compared with studies with longer follow-up (MD 0.49%, p=0.017). There was a non-significant larger reduction in HbA1c in studies that used educational techniques compared to studies that used behavioural techniques (p=0.107) and in studies with an intervention duration of nine months or less compared to studies with longer duration (p=0.077). There was no evidence of a difference in levels between subgroups defined by year of publication, mean duration of diabetes, mean HbA1c at baseline and age.

Authors' conclusions

In type 2 diabetes, there were improvements in glycaemic control in people who received self-care management treatment, especially where programmes were compact with sessions closely grouped together; effects may have decreased over time. Educational techniques appeared to be more advantageous than behavioural techniques.

CRD commentary

The review addressed a clear research question. Inclusion criteria appeared appropriate. Several relevant sources were searched. No explicit attempt was made to locate unpublished studies, but formal assessment found no evidence of publication bias. The restriction to studies published in English and Nordic languages meant that language bias could not be excluded. Appropriate methods were used to select studies and extract data. The tool used for quality assessment was appropriate, but the method used for assessment was not reported and so reviewer bias and error could not be excluded. Quality assessments were reported for the individual studies in tables, but were not summarised and not taken into account in the analyses. Synthesis of study results and assessment of heterogeneity was appropriate. Evidence of statistical heterogeneity was found for the main analysis. The dichotomisation of many of the subgroups by ascertainment of the cut points according to the medians of their distributions appeared arbitrary as it was unrelated to any evidence of their effects on the outcome. Use of meta-regression to determine potential factors that might influence overall results was appropriate, but no adjustments were made for multiple comparisons.

Due to the strong evidence of heterogeneity in the results, the lack of quality assessments in interpretation of the findings and the large number of unadjusted comparisons, the author's conclusions should be treated with caution.

Implications of the review for practice and research

<u>Practice</u>: The authors stated that the form of self-care management may have an impact on effectiveness and practicability in clinical practice.





Research: The authors stated that further research with long follow-up periods was required to establish the most effective regimen in terms of intervention frequency, intensity and duration, subgroups of patients might benefit and who should provide the intervention. Research was required to determine whether changes can be maintained after completed treatment or whether permanent treatment was necessary in maintaining lifestyle changes in diabetes self care.

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