Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes


CRD summary
This individual patient data meta-analysis evaluated the effectiveness of self monitoring interventions for blood glucose levels in patients with non-insulin treated type 2 diabetes. The authors concluded that no clinically meaningful effect in glycated haemoglobin level was evident. The conclusion seems reliable, despite a small caveat of some unreported details.

Authors' objectives
To evaluate the effectiveness of self monitoring interventions for blood glucose levels in patients with non-insulin treated type 2 diabetes.

Searching
MEDLINE and EMBASE were searched from April 2009 to June 2010. Search terms were reported. Systematic reviews, Current Controlled Trials and conference proceedings and abstracts were scanned for further studies.

Study selection
Eligible for inclusion were randomised controlled trials (RCTs) that compared a self-monitoring intervention (specifically to improve disease outcomes) with clinical management (without self-monitoring or any attempt to modify risk factor or behaviour) in patients with non-insulin treated type 2 diabetes. The primary outcome of interest was glycated haemoglobin level (HbA₁c) at six months. Secondary outcomes of interest were blood pressure and serum cholesterol level.

The included trials were published between 2002 and 2008. Trials were conducted in USA and Europe (two were in UK) and lasted between six and 12 months. Most of the included patients had established type 2 diabetes and (where reported) were new to testing. There were slightly more men than women. Mean age was 60.1 years. Mean body mass index was 30.9. Median duration of diabetes was 36 months. Baseline HbA₁c was 67.0 mmol/mol (8.3%). Various interventions and intensities were described. Most interventions were based on lifestyle management or drug adjustment and (where specified) delivered in specialist, community and general practice settings.

The authors did not report how many reviewers were involved in the selection of trials.

Assessment of study quality
Trial quality was assessed on randomisation, allocation concealment, blinded outcome assessment, loss to follow-up, funding source, follow-up rates, sample size more than 80 patients and trial duration lasting more than six months.

Individual patient data (IPD) were verified with the trialists.

The authors did not report how many reviewers were involved in the quality assessment of trials.

Data extraction
IPD were obtained from the principal investigators. Intention-to-treat data were collected to enable calculation of effect estimates (adjusted for age, sex and duration of diabetes) and 95% confidence intervals. Missing data were imputed by the missing indicator method or in a regression analysis. The authors did not state whether whole IPD datasets were unavailable for any of the eligible studies.

It was unclear how many reviewers extracted or checked the data.

Methods of synthesis
HbA₁c was presented at three, six and 12 months after the intervention. A two-level regression model was applied: level one (patients) and level two (trials) with trial-specific differences as random-effects and assuming a common treatment
effect across trials. Sensitivity analyses were carried out to examine the effect of trials with higher rates of loss to follow-up and trials that contained co-interventions. Subgroup analyses were conducted to isolate the potential impacts of patient age, sex, baseline HbA1c, duration of diabetes and whether participants were new to testing.

Results of the review
Six RCTs (2,552 patients, range 89 to 689) were included in the review. Three trials described the randomisation method and all conducted allocation concealment and blinded outcome assessment. Loss to follow-up ranged from 2% to 31%. Four trials were industry sponsored.

HbA1c was significantly reduced as a result of self-monitoring interventions at six months (adjusted estimate -2.7 mmol/mol, 95% CI -3.9 to -1.6; six trials), which represented a 0.25% decrease.

Significant reductions were also reported at three months (-2.0 mmol/mol, 95% CI -3.2 to -0.9; five trials) and 12 months (-2.5 mmol/mol -4.1 to -0.9; three trials), which represented decreases of 18% (three months) and 23% (12 months).

There were no statistically significant differences for blood pressure (three trials) and serum cholesterol (three trials) outcomes.

Subgroup analysis did not generally show any significant differences, but trials that analysed the impact of patients new to testing were too small to ascertain this with confidence. Sensitivity analysis did not materially alter the main analysis. The authors stated that there was no evidence of heterogeneity in outcomes.

Authors’ conclusions
No evidence of a clinically-meaningful effect (based on 0.50% decrease) for reducing HbA1c by self-monitoring interventions for patients with non-insulin treated type 2 diabetes was evident in this review.

CRD commentary
The review question was clear. Inclusion criteria were sufficiently replicable. The search strategy included relevant sources and attempts were made to identify unpublished studies. Relevant quality assessment criteria were applied to the include trials and overall quality appeared to be reasonable. Steps were taken to verify individual patient data. The review process was not reported for study selection and assessment of trial quality, so potential for error and bias could not be ruled out.

Study details were presented and clinical variation was evident. Statistical heterogeneity could not be verified, but the two-stage plan for synthesis represented good practice. However, the model was not fully specified in the paper. Appropriate variables were explored in subgroup and sensitivity analyses. There were discrepancies between the abstract and text in terms of percentage reductions in HbA1c at three and 12 months, but this did not appear to affect the clinical relevance of the findings.

The authors’ conclusion reflects the evidence presented. The conclusion seems reliable, despite a small caveat of some unreported details.

Implications of the review for practice and research
Practice: The authors stated that there was no convincing evidence to support routine use of self-monitoring to improve glycaemic control in patients with non-insulin treated type 2 diabetes.

Research: The authors stated that further large scale trials were needed. These should include exploration of co-interventions designed to enhance the effectiveness of self monitoring and look at the impact of intermittent use of self monitoring in addition to regular use.

Funding
National Institute for Health Research (NIHR) School of Primary Care, UK; NIHR Oxford Biomedical Research Centre, UK.

Bibliographic details

PubMedID
22371867

DOI
10.1136/bmj.e486

Original Paper URL
http://www.bmj.com/content/344/bmj.e486

Additional Data URL
http://www.bmj.com/content/344/bmj.e486?tab=related#webextra

Indexing Status
Subject indexing assigned by NLM

MeSH
Blood Glucose /analysis /metabolism; Blood Glucose Self-Monitoring; Diabetes Mellitus, Type 2 /blood /drug therapy; Hemoglobin A, Glycosylated /analysis /metabolism; Humans; Hypoglycemic Agents /therapeutic use; Randomized Controlled Trials as Topic

AccessionNumber
12012012653

Date bibliographic record published
14/03/2012

Date abstract record published
23/03/2012

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.