

## Psychological interventions to improve glycaemic control in patients with type 1 diabetes: systematic review and meta-analysis of randomised controlled trials

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### Abstract

**Objective** To determine whether psychological interventions have any effect on glycaemic control in people with type 1 diabetes.

**Design** Systematic review and meta-analysis of psychological therapies to assess their effectiveness in improving glycaemic control in type 1 diabetes.

**Data sources** Medline, PsycINFO, Embase, and Cochrane central register of controlled trials searched to September 2004.

**Review methods** All included studies were randomised controlled trials in children (including adolescents) or adults with type 1 diabetes that evaluated the effect of a psychological therapy (counselling, cognitive behaviour therapy, family systems therapy, and psychodynamic therapy) on control of diabetes. Data were extracted on sample size, age, duration of diabetes, type of psychological therapy, its mode of delivery, and type of intervention in control group.

**Main outcome measures** Glycaemic control measured by percentage of glycated haemoglobin and psychological distress. Pooled standardised effect sizes were calculated.

**Results** 29 trials were eligible for the systematic review and 21 trials for the meta-analysis. In the 10 studies of children and adolescents included in the meta-analysis, the mean percentage of glycated haemoglobin was significantly reduced in those who had received a psychological intervention compared with those in the control group (pooled standardised mean difference  $-0.35$  (95% confidence interval  $-0.66$  to  $-0.04$ ), equivalent to a 0.48% (0.05% to 0.91%) absolute reduction in glycated haemoglobin. In the 11 studies in adults the pooled standardised mean difference was  $-0.17$  ( $-0.45$  to  $0.10$ ), equivalent to 0.22% ( $-0.13\%$  to  $0.56\%$ ) absolute reduction in glycated haemoglobin. Psychological distress was significantly lower in the intervention groups in children and adolescents (pooled standardised effect size  $-0.46$ ,  $-0.83$  to  $-0.10$ ) but not in adults ( $-0.25$ ,  $-0.51$  to  $0.01$ ).

**Conclusion** Psychological treatments can slightly improve glycaemic control in children and adolescents with diabetes but have no effect in adults.

### Introduction

Suboptimal glycaemic control<sup>1 2</sup> and complications of diabetes are associated with depression,<sup>3</sup> eating problems,<sup>4</sup> and fears specific to diabetes.<sup>5 6</sup> Evidence of effectiveness of psychological therapies in improving diabetes outcomes is poor; previous reviews have not adequately distinguished between educational and psychological interventions, between type 1 and type 2 diabetes, between randomised and non-randomised trials, or between adults and children when the latter are dependants.<sup>1 7 8</sup> Children and adolescents have different clinical needs, are assessed by paediatric specialists, and have access to different resources. Educational interventions use didactic and enhanced learning methods to improve self management, by reducing identifiable gaps in knowledge. Psychological therapies use the therapeutic alliance between patient and therapist, in which the patient's problems are understood in terms of emotions, cognitions, and behaviours.

We conducted a systematic review and meta-analysis of randomised controlled trials on the effectiveness of psychological therapies in improving glycaemic control in type 1 diabetes. The review was stratified into children and adolescents versus adults. We also assessed whether psychological therapies were effective in reducing psychological distress.

### Methods

#### Selection of studies

All studies eligible for inclusion were trials of a psychological intervention, published or unpublished, involving children, adolescents, and adults with a diagnosis of type 1 or insulin dependent diabetes and written in any language.

We categorised type of psychological treatment into four categories: supportive or counselling therapy, cognitive behaviour therapy, psychoanalytically informed therapies, and family systems therapy (see

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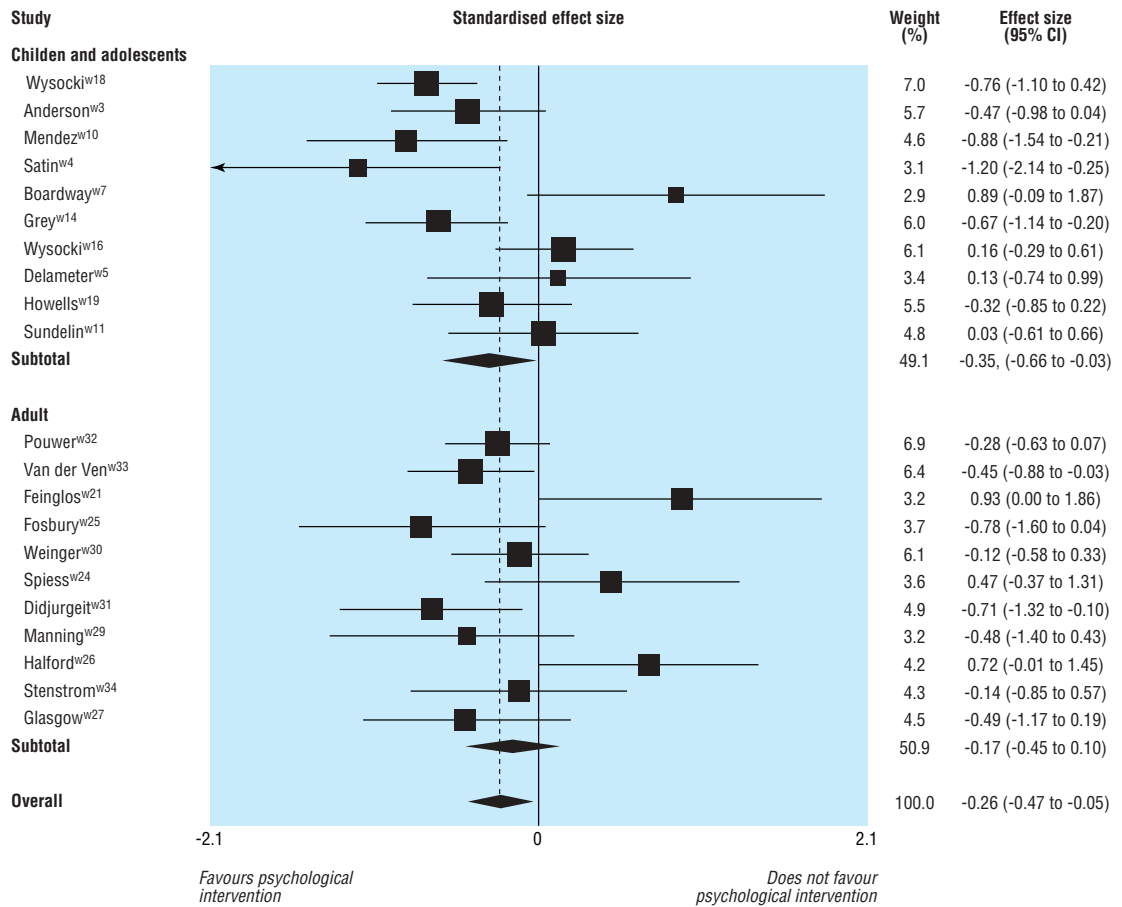
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The search strategy, QUOROM flow chart, and tables of, and references to, included studies (w1-w34) are on *bmj.com*.



**Fig 1** Standardised effects of psychological intervention on percentage of glycated haemoglobin in children and adolescents and in adults

bmj.com). Delivery of the psychological therapy was defined as individual, group, or family. We included studies where the control group was non-psychological or less intensive psychological treatment. Our main outcome measures were long term glycaemic control measured by percentage of glycated haemoglobin. Our subsidiary outcome was a continuous measure of psychological distress.

**Search strategy**

We searched the Cochrane central register of controlled trials on the *Cochrane Library*, Medline, Embase, and PsycINFO using the search terms: psychological therapies and mood disorders; diabetes mellitus and clinical trials (see bmj.com). We also hand searched conference proceedings for 1997-2004. We searched the reference lists of included studies and reviews for additional studies and contacted leading authors and experts for additional data.

**Data extraction**

Two authors (KI and KW) independently rated abstracts of controlled trials of a psychological intervention in patients with any form of diabetes. Hard copies of studies were then obtained and the reviewers independently extracted data. Differences were resolved through discussions and consensus. We restricted selection to studies that described patients with type 1 diabetes or insulin dependent diabetes. The minimum number of sessions to define a psychological

therapy was one. We coded type of therapy, number of sessions, duration of therapy, and format of delivery (defined as individual, group, or family (including multiple families)). We included trials where glycaemic control was a secondary outcome. See bmj.com for details.

**Statistical analysis**

We used Stata 8 with user contributed commands for meta-analyses for the analyses. We standardised the difference in mean change scores for glycaemic control (and for psychological functioning) from baseline to follow-up between treatment groups by dividing by the pooled standard deviation (SD) of the change scores within the group. See bmj.com. We calculated the standard error of each study's standardised effect size estimate from the estimated effect and the study's group sizes.

The standardised effect sizes were pooled with a random effects model as we expected heterogeneity because of the variety of psychological treatments and settings. The assumption of homogeneity of true effect sizes was assessed formally by applying Cochran's Q test. The standardised effect sizes were also back transformed into percentage glycated haemoglobin.

We assessed whether conclusions were sensitive to restricting studies to subgroups that might modify the effects of therapy, such as family setting in children

and adolescent studies or type of therapy in adult studies.

The presence of publication bias for the main experimental hypothesis of psychological intervention effects on glycaemic control was assessed informally by a funnel plot and formally by its direct statistical analogue (Begg's adjusted rank correlation test).

**Quality assessment**

We assessed studies for quality based on the three main quality criteria (selection bias, attrition bias, detection bias). Psychological treatments do not allow for blinding or concealment from the therapist or patient. Studies were subdivided into the three categories: A (all quality criteria met—low risk of bias), B (one or more of the quality criteria partly met—moderate risk of bias), and C (one or more criteria not met—high risk of bias).

**Results**

**Systematic review**

The search strategy identified 3488 studies from which 121 full hard copies were selected for further extraction (see QUOROM flow chart on bmj.com). There was 95.4% agreement about which abstracts to include for retrieval of full hard copies ( $\kappa$  0.70, 95% confidence interval 0.68 to 0.73). Sixteen randomised controlled trials of psychological interventions in children and adolescents and 13 in adults met the criteria for inclusion (see bmj.com).

All but two trials<sup>w18 w20</sup> in children and adolescents had sample sizes <100. The most common mode of delivery was multiple family or parent group. Adolescence was the most common specified clinical group. The mean duration of diabetes was 5.6 (SD 2.07) years and the mean duration of follow-up was 11.4 (7.0) months. One study was rated quality A<sup>w19</sup>; eight studies were published after the CONSORT consensus. Seven studies examined cognitive

behaviour therapy,<sup>w1-3 w7 w9 w10 w14</sup> six studies were of counselling,<sup>w5 w6 w8 w18-20</sup> and three studies used family systems therapy.<sup>w4 w11 w16</sup>

All but two trials<sup>w32 w33</sup> in adults had sample sizes less than 100. Eight studies used either group format or a combination of group and individual formats. The clinical subgroups were suboptimal glycaemic control,<sup>w21 w25 w30 w33</sup> new onset diabetes,<sup>w24</sup> complications,<sup>w31</sup> and obesity.<sup>w29</sup> The mean duration of diabetes was 14.1 (SD 6.85) years and the mean duration of follow-up was 7.2 (SD 4.8) months. One study was rated as quality A.<sup>w24</sup> Most trials examined cognitive behaviour therapy,<sup>w21-23 w26 w29-31w33 w34</sup> two examined psychoanalytical techniques,<sup>w24 w25</sup> and two examined counselling.<sup>w27 w32</sup>

**Meta-analysis of glycaemic control**

There were 10 studies in children and adolescents (n=543 participants) and 11 in adults (n=516 participants) with data that could be pooled. With random effects meta-analyses, there was a small to moderate pooled estimate of the mean standardised effect sizes (-0.35 (95% confidence interval -0.66 to -0.04, P=0.03) combined across all studies in children, but this association was attenuated when we combined data across all studies in adults (-0.17, -0.45 to 0.10, P=0.22) (fig 1). The standardised effects translated into absolute reductions in glycated haemoglobin of 0.48% (0.05% to 0.91%) for children and adolescents and of 0.22% (-0.13% to 0.56%) for adults. Cochran's Q test indicated heterogeneity (P=0.002 for studies in child and adolescents and P=0.02 in studies in adults).

For the sensitivity analysis, restriction to family therapies slightly increased the pooled standardised effect of therapy for children and adolescents (-0.41, -0.79 to -0.03, P=0.03). Restriction to group cognitive behaviour therapy further attenuated the pooled standardised effect size for adults (0.02, -0.41 to 0.44, P=0.95).

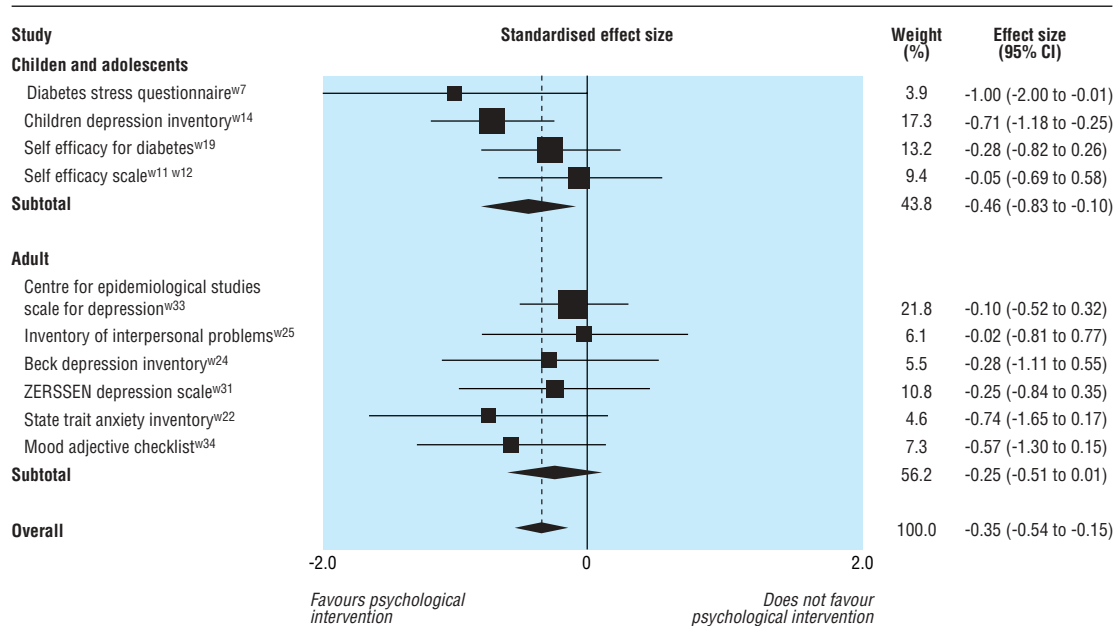


Fig 2 Standardised effects of psychological intervention on psychological distress for children and adolescents and adults

### Publication bias

A funnel plot based on all 21 studies with glycaemic control measures did not indicate any publication bias nor did the formal test ( $P=0.17$ ).

### Meta-analysis of psychological distress

Ten studies had data on psychological outcomes ( $n=417$  participants) that could be pooled in a meta-analysis. All selected studies reported an improvement in psychological distress (fig 2).

With random effects meta-analyses the pooled estimate of the mean therapy effect on psychological distress for children and adolescents was moderate (standardised effect size  $-0.46$ ,  $-0.83$  to  $-0.10$ ,  $P=0.013$ ). The effect was attenuated in adults (standardised effect size  $-0.25$ ,  $-0.51$  to  $0.01$ ,  $P=0.059$ ). Cochran's Q test did not find any evidence for heterogeneity in psychological distress effects (children and adolescents  $P=0.23$ ; adults  $P=0.74$ ).

### Discussion

In this systematic review of psychological interventions for improving diabetes control, psychological therapy was associated with a significant improvement in glycaemic control in the 10 studies in children and adolescents, with a pooled absolute reduction in glycated haemoglobin of 0.5%. In the 11 studies in adults in the meta-analysis this association was smaller and not significant.

The methodological quality of most studies was moderate to poor. The estimated 0.5% reduction in glycated haemoglobin in children and adolescents was small but sufficient to reduce the risk of development and progression of diabetic microvascular complications.<sup>9</sup> The success of psychological interventions in children may be explained by higher levels of psychological distress in children and their families; cohort studies have reported that family functioning is associated with glycaemic control.<sup>10</sup> Alternatively parents of children with diabetes may be more responsive to psychological interventions than their offspring, as has been suggested in caregivers of adolescents with eating disorders.<sup>11</sup>

Most of the psychological interventions used variants of cognitive behaviour therapy. No trial tested the effectiveness of motivational interviewing therapies, and only two studies used psychoanalytical therapies,<sup>w24 w25</sup> suggesting these are understudied.

Only one study targeted people with manifest psychological problems.<sup>w16</sup> Our review found that group interventions may have potentially underestimated effect sizes in the sensitivity analysis.

### Conclusions

We found weak evidence for the effectiveness of psychological treatments in improving glycaemic control in children and adolescents but not in adults. Future research should focus on improving methods to CONSORT standards, developing and refining theoretically based models for psychological interventions specific for diabetes, incorporating patients' preferences, and examining which types of therapies are effective for which subgroups of people with diabetes.

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### What is already known on this topic

Suboptimal glycaemic control in people with type 1 diabetes is associated with increased psychological distress, morbidity, and mortality

Individual randomised controlled trials suggest that psychological treatments may help to improve glycaemic control

### What this study adds

There is weak evidence that psychological treatments could improve glycaemic control in children and adolescents and no evidence of an effect in adults

Cognitive behaviour therapy techniques were more common than counselling or psychoanalytical techniques

Family therapies may be more effective than individual therapies for children and adolescents with diabetes

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