Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes

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Summary

Background Adherence difficulties and psychological problems are associated with poor glycaemic control in diabetes. We undertook a systematic review and meta-analysis of psychological therapies to assess their effectiveness in improving glycaemic control in type 2 diabetes.

Methods We searched MEDLINE, PsychINFO, EMBASE, and the Cochrane Central Register of Controlled Trials up to January, 2003. Eligible studies were randomised controlled trials that involved people with type 2 diabetes and evaluated a psychological therapy (counselling, cognitive behaviour therapy, or psychodynamic therapy) to improve diabetes control. We extracted the number of participants, their age, duration of diabetes, glycaemic control, type of psychological therapy, its mode of delivery, and type of intervention in the control group. The main outcome was long-term glycaemic control measured by percentage of glycated haemoglobin. Blood glucose concentration, weight, and psychological distress were also measured. Pooled standardised effect sizes were calculated.

Findings 25 trials were eligible for the review. In 12 trials, the mean percentage glycated haemoglobin was lower in people assigned a psychological intervention than in the control group (usual care, education, waiting list, or attention control); the pooled mean difference was −0·32 (95% CI −0·57 to −0·07) equivalent to an absolute difference of −0·76%. There were non-significant differences in blood glucose concentration (eight trials; −0·11 [−0·65 to 0·42]) and weight gain (nine trials; 0·37 [−0·18 to 0·93]). Psychological distress was significantly lower in the intervention groups (five trials; −0·58 [−0·95 to −0·20]).

Interpretation In type 2 diabetes, there are improvements in long-term glycaemic control and psychological distress but not in weight control or blood glucose concentration in people who receive psychological therapies.

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Introduction

People with type 2 diabetes have to adhere to many self-care responsibilities to achieve optimum glycaemic control. The tasks include: modification of lifestyle, such as diet, exercise, and weight; self-monitoring of blood glucose concentrations; foot care; and administration of oral medication and, increasingly, insulin injections. Difficulties in adhering to these tasks can be associated with suboptimum glycaemic control even in the most intensively managed groups.[1] Psychological problems such as depressive disorders[2–4] and eating disorders[5,6] are common and are associated with suboptimum glycaemic control[7] and diabetes complications.[8]

Previous systematic reviews of non-pharmacological interventions did not adequately distinguish between educational and psychological interventions, between type 1 and type 2 diabetes, or between randomised and non-randomised trials.[9–13] The distinction between education and psychological therapy is clinically important because they differ (but are not mutually exclusive) in their theoretical basis, training, clinical skills, and implications for resources. Educational interventions are based on didactic and enhanced learning methods which aim to improve diabetes self-management by increasing knowledge. Psychological therapies use the therapeutic alliance between the patient and the therapist to bring about change in emotional, cognitive, and behavioural functioning, including adherence.[14]

In view of the rising prevalence of type 2 diabetes,[15] a potential limit to pharmacological interventions,[1] and effectiveness of psychological therapies for depression[16] and eating disorders,[17] more sophisticated non-pharmacological approaches are needed. Our aims were to carry out a systematic review and meta-analysis of randomised controlled trials assessing the effectiveness of psychological therapies in improving glycaemic control in adults with type 2 diabetes and in reducing psychological distress and bodyweight.

Methods
Criteria for selecting studies
The protocol was peer reviewed and published in the Cochrane Database of Systematic Reviews.[18] We followed the QUORUM guidelines.[19]

Studies eligible for inclusion were randomised controlled trials of a psychological intervention, published or unpublished, involving adult (18 years and older) patients with a diagnosis of type 2 or non-insulin-dependent diabetes. We classified the type of psychological intervention into psychotherapeutic models most commonly used in health-care settings. These were: supportive or counselling therapy;[20] cognitive behaviour therapy;[21,22] brief psychodynamic psychotherapy;[23] and interpersonal psychotherapy.[24] Studies that did not explicitly label their intervention were included if they used one or more psychological techniques that could be

coded into one of these categories. Techniques such as relaxation, activity scheduling, problem solving, goal setting, contract setting, cognitive restructuring, and stress management were classified as cognitive behaviour therapy.[25,26] Techniques such as motivational interviewing[27] and non-directive counselling[20] were classified under the counselling model. Techniques not clearly described were excluded. We defined the mode of delivery as individual, group, or family (including couple) therapy. We defined the control group as usual care, education, waiting list, or attention controls.

Our main outcome measures were long-term glycaemic control based on the percentage of glycated haemoglobin, which included HbA_{1c}, HbA_1, and other measurements of glycated haemoglobin made by different methods, and the blood glucose concentration, which included whole-blood, plasma, and serum glucose concentrations. Our subsidiary outcome measures were bodyweight (body-mass index and weight change in pounds or kilograms) and psychological distress if a continuous measure of anxiety or depression was used.

Search strategy

The following electronic libraries were searched according to the Cochrane Collaboration's optimum search strategy for randomised controlled trials for each database: the Cochrane Central Register of Controlled Trials on the Cochrane Library (issue 4, 2002); MEDLINE (1966 to

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2427 abstracts screened
1094 identified by electronic search
  23 references in reviews
839 conference proceedings

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93 full texts of potentially relevant studies retrieved

→ Reasons for exclusion from review:
  29 type 1 diabetes
   9 type 1/2 diabetes combined
  13 type 2 diabetes but not RCT
   2 duplicate publication
  12 educational intervention
   3 mixed chronic disease

↓

25 trials included in systematic review

→ Trials excluded from meta-analysis of each outcome owing to missing data:
  13 glycated haemoglobin
  17 blood glucose concentration
  16 bodyweight
  20 psychological status

↓

Trials with sufficient data to include in meta-analysis by outcome:
  12 glycated haemoglobin
   8 blood glucose concentration
   9 bodyweight
   5 psychological status

Figure 1: Stages of systematic review of randomised controlled trials of the effectiveness of psychological interventions for improving glycaemic control in type 2 diabetes mellitus
RCT=randomised controlled trial.

January, 2003); EMBASE (1980 to January, 2003); and PsychINFO, including PsychLIT (1974 to January, 2003). The following search terms were used for MEDLINE and adapted for each other database: "psychological therapies" and "mood disorders" according to the Cochrane Collaboration Depression, Anxiety, and Neurosis Group search strategy; "diabetes mellitus" and "clinical trials" according to the Cochrane Collaboration Metabolic and Endocrine Disorder Group general diabetes search strategy (for further details, please contact the corresponding author). The proceedings of conferences during 1997 to 2002 on diabetes (American Diabetes Association, Diabetes UK [formerly British Diabetic Association], European Association for the Study of Diabetes, International Diabetes Federation) were searched under psychological, educational, or behavioural headings for reports of any trials using psychological therapies. The reference lists of included studies and reviews were searched for additional studies. Leading authors of each included trial and experts on this subject were contacted for additional data on published or unpublished trials.

Data extraction

The abstracts of studies identified by the electronic searches were independently inspected by two of us (KI and KW) and inter-rater reliability for selection into the review was reported by use of Cohen's κ.[28] We included abstracts that described a controlled trial of a psychological intervention in patients with diabetes. At this stage, no distinction was made between type of diabetes. In the case of ambiguity or differences between raters the full original article was retrieved for the next stage.

KI and KW independently extracted data from each full copy of those reports selected for further review. Differences over inclusion of studies were resolved through discussions and consensus. Studies written in a language other than English were translated by native-speaking psychiatrists. Quasi-randomised controlled trials and N-of-1 trials were excluded. We included only the first treatment group of cross-over trials. For studies with several intervention groups, we reported the study only once in any one analysis. If there was more than one intervention group, we took the most psychologically intensive intervention as the experimental one. Intensity was defined by type of therapy (most intense was psychodynamic/interpersonal followed by cognitive behaviour therapy, then counselling), number of sessions, and duration of therapy. We coded in a standard way the following characteristics of the study sample: country of origin; number of participants at baseline and at follow-up; age; baseline glycaemic control; clinical subgroups; type of diabetes treatment; and duration of diabetes. We coded the characteristics of the therapy in the intervention and control groups: type and duration of therapy; mode of delivery; specialist; number of sessions; and length of follow-up.

Statistical analysis

Data were entered into SPSS (version 11.0). A descriptive summary of the information extracted from included trials was made. We set a minimum requirement of five studies with adequate data before conducting a meta-analysis for each outcome.

We used the within-group SD of the differences (change scores) from baseline to follow-up for each outcome to calculate the SE of the effect size for each study. If the SD of the change score was missing, we used
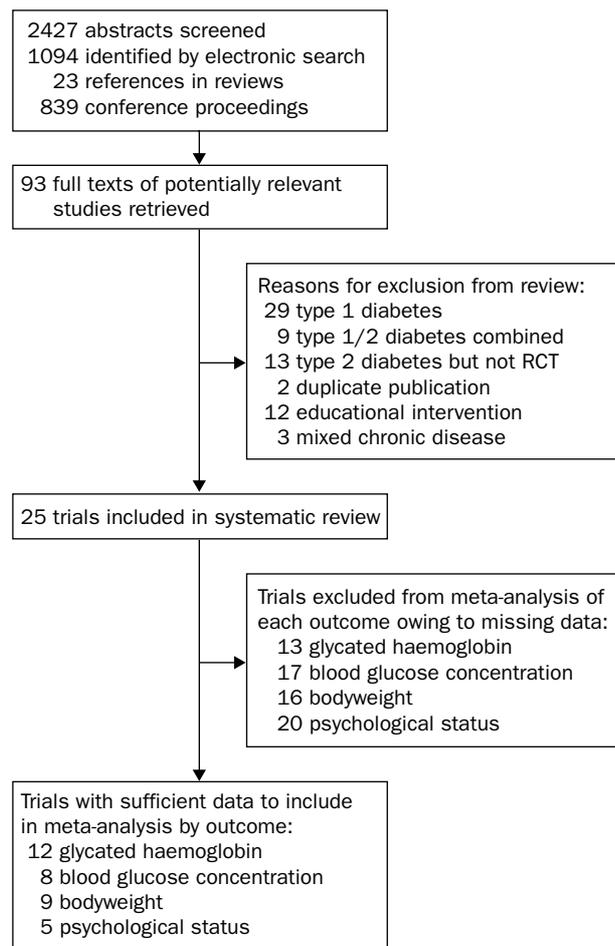
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the square root of the average of the baseline and follow-up variance in each group. This approach is based on the assumption that the correlation between the baseline and the follow-up outcome values was 0·5. We then standardised the effect sizes by dividing them and their SE by the SD. This standardisation allows different measures of the same outcome to be combined because different methods for measuring glycated haemoglobin, blood glucose, and weight were used. We calculated individual effect sizes for the percentage of glycated haemoglobin, blood glucose concentration, weight, and psychological distress.

The effect sizes were pooled by use of a random-effects model because we expected heterogeneity between studies. Unlike fixed-effects meta-analysis, a random-effects approach explicitly allows for such heterogeneity between studies by permitting the true effects estimated by the studies to differ between studies. These true effects are assumed to have a normal distribution in the population of studies, and the aim of the meta-analysis is to estimate the mean of this distribution. Random-effects models generally produce wider CI and are therefore more conservative than fixed-effects models. We assessed heterogeneity between the trials by the χ^2 test for heterogeneity. The meta-analysis was carried out using the metan command[29] in STATA (version 8).

For glycated haemoglobin and blood glucose, we converted the estimated pooled standardised effect size into absolute units by multiplying the estimate by the pooled SD of all studies included in the meta-analysis for each outcome. We assessed potential publication bias by a funnel plot[30] and Begg's adjusted rank correlation test[31] for glycated haemoglobin.

We used a random-effects regression to assess other potential factors that could be independently associated with glycated haemoglobin. Regression models were estimated for number of sessions and duration of therapy, which are deemed proxy measures of intensity of treatment and for duration of follow-up. We tested the robustness of the meta-analysis for long-term glycaemic control in sensitivity analyses by comparing random-effects and fixed-effects pooled standardised effect sizes. We compared the pooled effect size of psychological interventions against all control groups and against those control groups excluding studies constituting another psychological therapy.

Quality assessment

The quality of randomised studies was assessed on the presence or absence of descriptions of three main criteria specified by Schulz and Jadad and their colleagues:[32,33] selection bias (randomisation procedure and allocation concealment); attrition bias (withdrawals, dropouts, and intention-to-treat analysis); and detection bias (masking of outcome assessors but not patients and therapists, because psychotherapy cannot be concealed). Three categories were defined: all quality criteria were met with
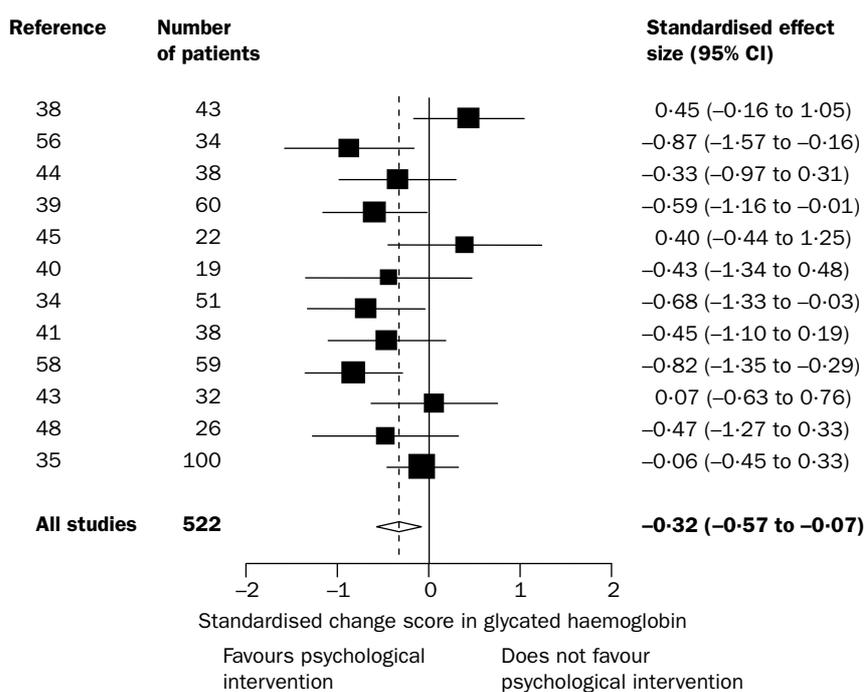

Reference	Number of patients		Standardised effect size (95% CI)
38	43		0·45 (–0·16 to 1·05)
56	34		–0·87 (–1·57 to –0·16)
44	38		–0·33 (–0·97 to 0·31)
39	60		–0·59 (–1·16 to –0·01)
45	22		0·40 (–0·44 to 1·25)
40	19		–0·43 (–1·34 to 0·48)
34	51		–0·68 (–1·33 to –0·03)
41	38		–0·45 (–1·10 to 0·19)
58	59		–0·82 (–1·35 to –0·29)
43	32		0·07 (–0·63 to 0·76)
48	26		–0·47 (–1·27 to 0·33)
35	100		–0·06 (–0·45 to 0·33)
All studies	**522**		**–0·32 (–0·57 to –0·07)**

Standardised change score in glycated haemoglobin

Favours psychological intervention — Does not favour psychological intervention

Figure 2: Meta-analysis of standardised change scores in glycated haemoglobin in psychological-intervention group compared with control group
*Unpublished data used for calculation of effect size.

low risk of bias (A); at least one of the quality criteria was only partly met with moderate risk of bias (B); and at least one criterion was not met with high risk of bias (C).

Results

The search strategy identified 2427 studies from which 93 full texts were selected for further extraction (figure 1). There was 89·6% agreement as to which abstracts from the electronic databases to select for retrieval of full texts ($\kappa=0\cdot64$). Data extraction from the full texts identified 25 randomised controlled trials that met the criteria for the systematic review. Reasons for exclusion from the review and meta-analysis are shown in figure 1.

The studies included in the systematic review are listed in the table. One study was classified as A for quality[34] and seven studies as B for quality. Two studies explicitly stated that analyses were by intention to treat.[34,35] Most studies used either the cognitive behaviour model[34–43] or its strategies such as relaxation techniques,[44–48] problem-solving,[49] contract setting,[50,51] goal setting,[52] self-monitoring of behaviours,[53,54] and enlisting social support.[38] Four trials assessed counselling techniques.[55–58] There were no trials that used a psychodynamic or interpersonal model of therapy, and four trials compared a more intensive psychological therapy with a control less intensive therapy.[38,43,54,58] Three studies had to be translated into English.[37,47,58]

For glycated haemoglobin there were 12 studies in the review with data that could be pooled. Most reported an improvement in the glycated haemoglobin (figure 2). With a random-effects model, the pooled standardised difference in the decrease in glycated haemoglobin between patients assigned a psychological intervention and those in the control group was –0·32 (95% CI –0·57

Year, country, and reference	Number of participants recruited/ at follow-up	Mean age (SD or range), years	Mean (SD) % glycated haemoglobin at baseline	Clinical subgroup (type of treatment)	Mean (SD or range) duration of diabetes, years	Model and duration of therapy in intervention group	Regimen in intervention group and specialty of therapist	Model and duration of therapy in control group	Regimen in control group and specialty of therapist	Follow-up, months	Quality
1983, Canada[53]	40/40	53·9 (2·0)	NS	Sub-optimum glycaemic control (D,T)	NS	Group CBT for 6 weeks	6 behaviour modification sessions by nutritionist	Individual education for 6 weeks	2 individual dietary counselling sessions by nutritionist	3	C
1985, USA[50]	53/50	55·1 (7·3)	9·3 (0·3)	Obese (D,T)	5·9 (NS)	Group CBT for 16 weeks	16 behaviour modification sessions by psychologist and nutritionist	Group education for 16 weeks	4 standard education sessions by psychologist and nutritionist	4	C
1986, USA[36]	76/76	NS	8·7 (2·7)	Suboptimum glycaemic control (D,T,I)	NS	Group CBT for 10 weeks	14 CBT sessions by dietician and exercise leader	Group education for 10 weeks	10 traditional education sessions by multidisciplinary diabetes team	6	C
1986, USA[49]	41/32	61·6 (6·4)	11·3 (3·1)	Men, obese, suboptimum glycaemic control (D,T,I)	12·6 (11·4)	Group CBT for 6 months	16 group management sessions by psychologist	Group education for 6 months	16 advice/education sessions by nurse and dietician	6	C
1987, USA[54]	46/46	52·9 (12·1)	11·3 (2·3)	General (D,T,I)	NS	Group and individual CBT for 7 weeks	7 group and 9 individual CBT sessions; specialty not specified	Group CBT (duration not specified)	Minimal relaxation training; specialty not specified	6*	B
1987, Spain[37]	11/11	60·7 (51–70)	NS	General (treatments not specified)	4·3 (3·7)	Individual CBT and education for 5 weeks	3 CBT sessions and 2 education sessions by psychologist	Individual education for 5 weeks	2 education sessions; specialty not specified	2	C
1990, Australia[55]	62/61	58·5 (9·0)	11·6 (1·9)	Suboptimum glycaemic control, obese (D,T,I)	7·5 (7·0)	Group counselling for 11 weeks	Cognitive motivational therapy (number of sessions NS) by physician, dietician, and psychologist	Group education (duration not specified)	3 education sessions; specialty not specified	6	B
1991, USA[38]	49/43	52·5 (7·5)	9·9 (2·2)	Obese (D,T,I)	NS	Group CBT and couple therapy for 10 weeks	16 behavioural modification and couple therapy sessions by multidisci-plinary team	Group CBT for 10 weeks	16 behavioural modification sessions by multidisciplinary team	5	C
1992, USA[56]	54/34	56·0 (8·1)	11·1 (2·8)	Obese (D,T)	NS	Group education and individual counselling for 11 weeks	11 intensive group education and 2 individual counselling sessions by nurse	Education for 1 week	1 minimal education session by nurse	6	C
1993, USA[51]	156/135	58·0 (11·3)	NS	General (D,T,I)	NS	Individual CBT (duration not specified)	Behaviour modification (number of sessions NS) by nurse	Usual care	Regimen not described; specialty not specified	NS	C
1993, USA[44]	38/38	NS	10·3 (2·3)	Suboptimum glycaemic control (D,T)	NS	Individual CBT for 8 weeks and intensive diabetes care for 12 months	8 relaxation training sessions and intensive diabetes care; specialty not specified	Intensive diabetes care for 12 months	Intensive diabetes education and clinical care; specialty not specified	6	B
1996, Australia[39]	118/60	59·5 (10·2)	12·6 (4·3)	General (D,T)	0·4 (0·1)	Individual CBT for 12 months	6 CBT sessions by nurse educator	Group education for 2 weeks	2 minimal education sessions by nurse educator and dietician	6	B
1997, USA[45]	22/22	61·0 (10·2)	11·0 (1·9)	General (D,T,I)	11·0 (9·0)	Group CBT for 8 weeks	6 relaxation training sessions by psychologist	Usual care	Routine medical care; specialty not specified	4	C
1997, Australia[40]	19/19	60·0 (47–74)	10·7 (1·9)	Suboptimum glycaemic control, stress/anxiety (D,T,I)	6·4 (1·5–23·0)	Group CBT for 6 weeks	6 stress management sessions by psychologist	Waiting list	Usual practice by physician	2·25	C
1997, USA[46]	20/20	58·9 (7·7)	6·5 (1·8)	Suboptimum glycaemic control (D,T)	7·9 (8·7)	Individual CBT for 4 weeks	8 relaxation therapy sessions by psycho-physiologist	Waiting list	None; specialty not specified	1	C

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Year, country, and reference	Number of participants recruited/ at follow-up	Mean age (SD or range), years	Mean (SD) % glycated haemoglobin at baseline	Clinical subgroup (type of treatment)	Mean (SD or range) duration of diabetes, years	Model and duration of therapy in intervention group	Regimen in intervention group and specialty of therapist	Model and duration of therapy in control group	Regimen in control group and specialty of therapist	Follow-up, months	Quality
1997, USA[57]	22/16	62·4 (7·0)	10·3 (2·2)	Women, obese (D,T)	6·7 (5·4)	Group CBT and individual counselling for 4 months	16 group behaviour modification sessions by nutritionist, exercise physiologist, and psychologist and 3 individual motivational interviewing sessions by psychologist	Group CBT for 4 months	16 group behaviour modification sessions by nutritionist, exercise physiologist, and psychologist	4	C
1998, USA[34]	51/42	54·8 (10·1)	10·3 (3·4)	Depression (D,T,I)	8·8 (9·5)	Group CBT and education for 10 weeks	30 CBT sessions by psychologist and 20 education sessions by diabetes educator	Group education for 10 weeks	20 education sessions by diabetes educator	6*	A
1999, USA[41]	38/38	63·5 (NS)	12·3 (2·6)	General (D,T,I)	11·5 (NS)	Group CBT and education for 6 months	6 behaviour modification sessions and education by diabetes educators	Usual care	Usual office visits by family physicians	6	B
2001, China[58]	59/59	NS	9·9 (2·1)	Depression (treatments not specified)	NS	Group counselling for 3 months	24 supportive psychotherapy sessions by psychiatrist	Usual care	Conventional diabetes care; specialty not specified	3	C
2001, USA[52]	78/68	52·3 (NS)	NS	Sedentary (D,T,I)	NS	Individual CBT for 8 weeks	Internet-based physical activity intervention by occupational therapist	Individual education (duration not specified)	Internet-based education; specialty not specified	2	C
2001, China[47]	59/56	57·4 (9·4)	NS	General (treatments not specified)	7·4 (5·4)	Individual CBT for 1 month	Relaxation training (number of sessions not given) by psychiatrist	Usual care (duration not specified)	Conventional diabetes care; specialty not specified	1	C
2002, Australia[43]	34/32	55·0 (10·5)	7·5 (1·5)	Binge-eating (D,T,I)	3·2 (5·7)	Group CBT for 10 weeks	10 CBT sessions by psychologist	Group counselling for 10 weeks	10 non-prescriptive therapy sessions by psychologist	2·5	B
2002, USA[42]	108/72	57·4 (10·9)	7·8 (1·8)	General (D,T)	NS	Group CBT and education for 2 months	5 education and stress management training sessions; specialty not specified	Group education for 2 months	5 education sessions; specialty not specified	12	C
2002, Japan[48]	36/26	62·2 (8·2)	8·2 (1·7)	General (treatments not specified)	NS	Group CBT for 4 months	16 Qi-gong relaxation training sessions by Chinese Qi-gong doctor	Waiting list	Conventional diabetes care; specialty not specified	4	C
In press, UK[35]	100/94	59·5 (NS)	8·4 (1·6)	Suboptimum glycaemic control (D,T,I)	8 (NS)	Individual CBT for 7 weeks	4 motivational interviewing sessions and goal setting by psychologist	Usual care	Usual diabetes care; specialty not specified	3	B

NS=not stated, data missing; D=diet; T=tablets; I=insulin; CBT=cognitive behavioural therapy. *Change in HbA1c was recorded from end of treatment to end of follow-up.

Psychological interventions in type 2 diabetes: characteristics of randomised controlled trials of psychological interventions in people with type 2 diabetes included in the systematic review
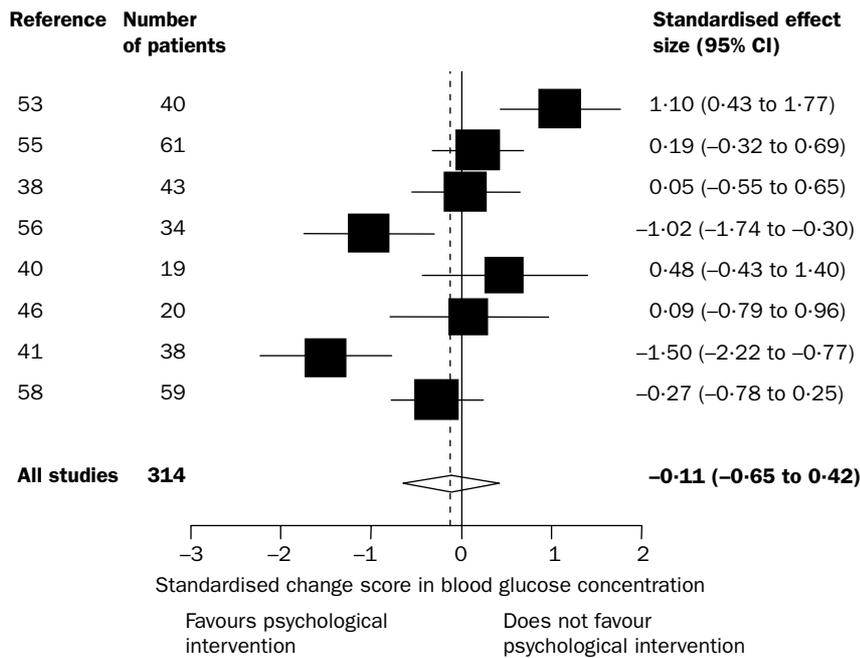
Figure 3: **Meta-analysis of standardised change scores in glucose concentration in psychological-intervention group compared with control group**

to −0·07). The treatment effect in absolute units was a decrease of 0·76% (−1·34 to −0·18) in glycated haemoglobin. The χ^2 test for heterogeneity was significant (p=0·04). The pooled estimate with a fixed-effects model was similar (−0·32 [−0·49 to −0·14]).

We repeated the meta-analysis excluding the two studies[38,43] in which the control was a less intensive psychological therapy. We found a larger estimate of the pooled effect size (−0·44 [−0·67 to −0·22]) with a random-effects model, which approximated to a decrease of 1·06% (−1·61 to −0·51) in glycated haemoglobin. The test for heterogeneity was not significant (p=0·21). There was no evidence for publication bias in the funnel plot (not shown), in the Begg adjusted rank correlation test (p=0·54), or the Egger test (p=0·94). In the random-effects regression analyses, number of sessions (regression coefficient −0·02, p=0·34), duration of the psychological intervention (regression coefficient −0·01, p=0·25), and duration of follow–up (regression coefficient −0·01, p=0·49) were not associated with glycated haemoglobin percentage.

Eight studies in the review had outcome data on blood glucose. There was no evidence that psychological therapies improved current blood glucose concentrations (figure 3). With a random-effects model, the pooled standardised difference in the decrease in blood glucose concentration between patients assigned a psychological therapy and
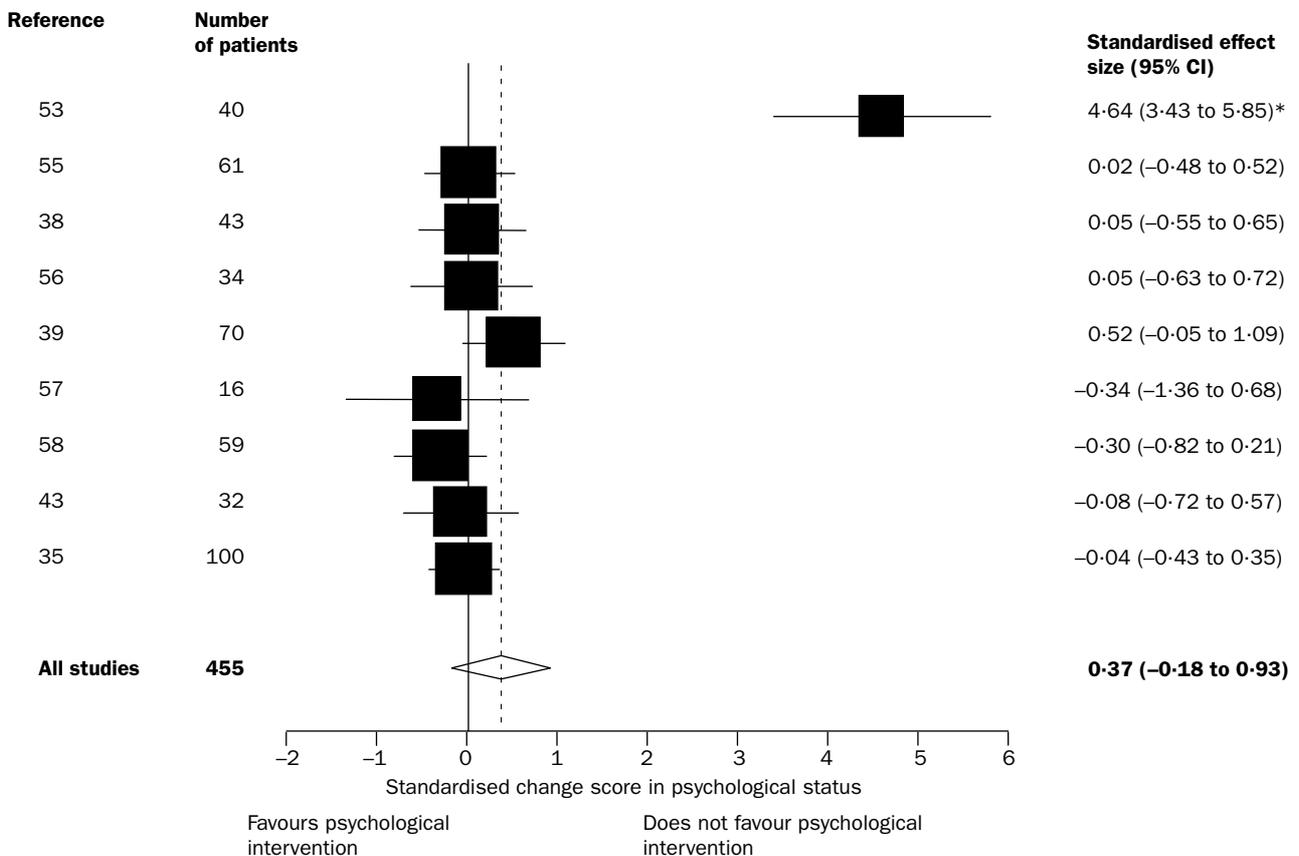

Figure 4: **Meta-analysis of standardised change scores in weight in psychological-intervention group compared with control group**
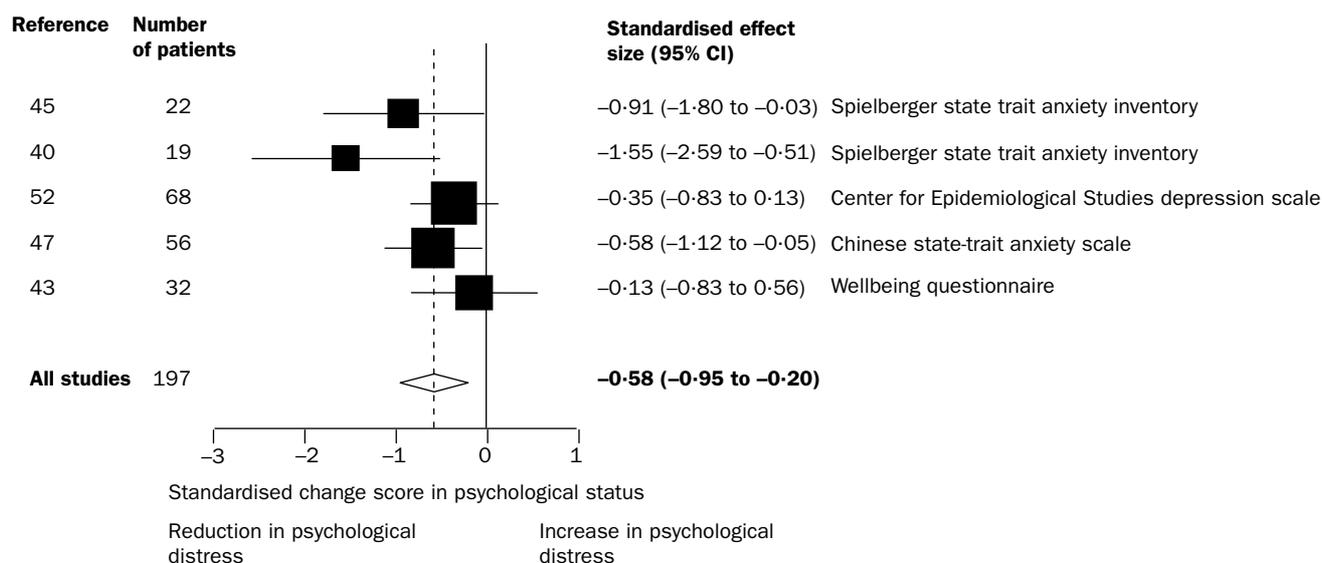*Possible outlier.

Figure 5: **Meta-analysis of standardised change scores in psychological status in psychological-intervention group compared with control group**

those in the control group was −0·11 (−0·65 to 0·42), which approximated to a difference of 0·20 mmol/L (−1·34 to 0·91) in absolute units. The χ^2 test for heterogeneity was significant (p<0·005), but the fixed-effects pooled standardised change score in the blood glucose concentration did not differ much from the random-effects estimate (−0·12 [−0·34 to 0·10]).

Nine studies in the review had outcome data on weight change. With a random-effects model, psychological therapies were associated with a non-significant increase in weight; the pooled standardised effect size was 0·37 (−0·18 to 0·93; figure 4). One early study[53] appeared to be an outlier; when it was omitted, the overall effect of psychological therapies on weight was neglible (0 [−0·20 to 0·20]).

Four studies in the review addressed specific psychological problems such as depression, binge eating, and stress.[34,40,43,58] Figure 5 lists the five studies that had data on psychological status; psychological therapies were effective in reducing psychological distress. With a random-effects model, the pooled standardised difference in the effect on psychological distress was −0·58 (−0·95 to −0·20) between patients assigned a psychological therapy and those in the control group. There was no evidence of heterogeneity (p=0·11).

Discussion

We identified 25 randomised controlled trials comparing psychological interventions for improving control of diabetes with a control group of usual care, education, waiting list, or attention control. In a meta-analysis of 12 of these trials, psychological therapies resulted in significantly better glycaemic control approximating to an absolute difference of 0·76% in glycated haemoglobin. When studies that used a less intensive psychological therapy as a comparison were excluded, the pooled effect size was larger, representing a difference of 1·00% in glycated haemoglobin. These effects are large enough to reduce the risk of development and progression of diabetic microvascular complications.[1] We also found that psychological therapy was associated with a reduction in psychological distress but did not appear to affect weight control or blood glucose concentration.

Most of the studies were of moderate to poor quality in the reporting of potential biases. Most had small sample

sizes. These factors could explain the borderline heterogeneity observed in the pooled estimate of improvement in glycated haemoglobin. Could we have over-interpreted interventions as psychological inter-ventions when reports were not explicit about the type of therapy? We believe not, for at least three reasons. First, cognitive behaviour therapy is an umbrella for a wide range of psychological techniques designed to bring about change in thinking patterns and behaviours.[26] Second, psychological therapies and education are not mutually exclusive and could coexist as separate interventions as they did in one study we identified.[56] Third, our focused search strategy was based on psychotherapy, not education, and studies with ambiguous descriptions of the intervention were excluded. Although this approach overcame some heterogeneity caused by combination of psychotherapy with education in previous reviews,[12–14] there is a small possibility we may have missed studies with interventions that were labelled as education but were psychotherapy.

Most of the psychological interventions used variants of cognitive behaviour therapy. Earlier studies used behavioural modification techniques such as contract setting and reward systems, which are used widely in weight reduction programmes.[59] More recent studies applied a wider range of cognitive behaviour techniques.[34,35,43] Motivational interviewing was the second most common therapy tested but there were not enough studies to compare with other psychological therapies. It was originally developed as a counselling style for people with unhealthy lifestyles[27] and its potential in type 2 diabetes seems a natural extension.

The lack of an association between duration or number of sessions and improvement in glycaemic control conflicts with evidence that more intensive psychological treatments are more effective in depression.[16] One explanation is that the interventions were perhaps too similar for a difference to be detectable. Most were brief or time-limited therapy conventionally defined as a duration of around 6 months. The short duration of follow-up in most studies may explain the lack of association with glycaemic control.

The lack of effectiveness of psychological therapies on blood glucose concentrations could be due to the small number of studies, but another possibility is that the mean

blood glucose masked wider fluctuations in the concentration as patients' overall control began to improve. The lack of reduction in weight was surprising. Perhaps weight loss would be slow because psychological therapies encourage long-term lifestyle changes.

Only a few studies targeted specific subgroups with manifest psychological problems such as depression,[34,58] binge-eating disorders,[43] or stress.[40] The finding that psychological therapies reduced distress is potentially clinically important given that the prevalence of depression in diabetes is around 10–15%.[2] These measures were self-reported; since masking of the intervention from patients in psychotherapy studies is impossible, there is a risk of reporting bias overestimating psychological functioning.

Most of the studies originated in the USA, where health insurance influences resources. This factor partly explains the excess of group therapies. Although peer support and social learning are valuable tools in group therapy, a group setting may not be appropriate for discussion of personal psychological problems such as binge-eating and sexual dysfunction.

The first study we included was published in 1983. Despite 20 years of changes in practice in diabetes and mental health, there were surprisingly few innovations. One study used the internet to develop a programme based on cognitive behaviour therapy.[52] No studies used psychodynamic or interpersonal therapy techniques. These are more specialised techniques but the high degree of psychological distress in diabetes clinics suggests that patients may be more willing than physicians assume to discuss their diabetes in the context of their life experiences.

This review shows that adjuvant psychological treatments can be effective in improving certain features of diabetes control but the type of therapy that is most effective and the subgroups of patients most likely to benefit are not clear.

References

1 UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. *Lancet* 1998; **352:** 837–53.

2 Gavard J, Lustman P, Clouse R. Prevalence of depression in adults with diabetes: an epidemiological evaluation. *Diabetes Care* 1993; **16:** 1167–78.

3 Lustman P, Griffith L, Freedland K, Clouse R. The course of major depression in diabetes. *Gen Hosp Psychiatry* 1997; **19:** 138–43.

4 de Groot M, Jacobson A, Samson J, Welch G. Glycemic control and major depression in patients with type 1 and type 2 diabetes mellitus. *J Psychosom Res* 1999; **46:** 425–35.

5 Herpetz S, Albus C, Lichtblau K, Kohle K, Mann K, Senf W. Relationship of weight and eating disorders in type 2 diabetic patients: a multicenter study. *Int J Eat Disord* 2000; **28:** 68–77.

6 Kenardy J, Mensch M, Bowen K, Pearson S-A. A comparison of eating behaviours in newly diagnosed NIDDM patients and case-matched control subjects. *Diabetes Care* 1994; **17:** 1197–99.

7 Lustman P, Anderson R, Freedland K, de Groot M, Carney R, Clouse R. Depression and poor glycaemic control: a meta-analytic review of the literature. *Diabetes Care* 2000; **23:** 934–42.

8 de Groot M, Anderson R, Freedland K, Clouse R, Lustman P. Association of depression and diabetes complications: a meta-analysis. *Psychosom Med* 2001; **63:** 619–30.

9 Brown S. Meta-analysis of diabetes patient education research: variations in intervention effects across studies. *Res Nurs Health* 1992; **15:** 409–19.

10 Griffin S, Kinmonth AL, Skinner C, Kelly J. Educational and psychosocial interventions for adults with diabetes: report to the British Diabetic Association. London: British Diabetic Association, 1998.

11 Meca J, Rodriguez J, Alcazar A. Meta-analysis de las intervenciones conductuales en el tratamiento de la diabetes en Espana. *Rev Psicol Gral Aplic* 1998; **51:** 501–16.

12 Norris S, Engelgau M, Venkat Naryan K. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care* 2001; **24:** 561–87.

13 Snoek F, Skinner T. Psychological counselling in problematic diabetes: does it help? *Diabet Med* 2002; **19:** 265–73.

14 Hodes M, Moorey S. Psychological treatment in disease and illness. London: Gaskell, 1993.

15 Amos A, McCarty D, Zimmet P. The rising global burden of diabetes and its complications: estimates and projections to the year 2010. *Diabet Med* 1997; **14:** S7–85.

16 Churchill R, Hunot V, Corney R, et al. A systematic review of controlled trials of the effectiveness and cost-effectiveness of brief psychological treatments for depression. *Health Technol Assess* 2001; **5:** 1–173.

17 Fairburn C, Jones R, Peveler R, et al. Three psychological treatments for bulimia nervosa: a comparative trial. *Arch Gen Psychiatry* 1991; **48:** 462–69.

18 Ismail K, McGuire H, Winkley K. Psychological interventions for improving glycaemic control in patients with diabetes mellitus (Cochrane Review). In: *The Cochrane Library*, Issue 2, 2001. Oxford: Update Software.

19 Moher D, Cook D, Eastwood S, Olkin I, Rennie D, Stroup DF, for the QUORUM Group. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUORUM statement. *Lancet* 1999; **354:** 1896–900.

20 Rogers C. Client centred psychotherapy. London: Constable, 1976.

21 Beck A. Cognitive therapy and the emotional disorders. New York: Meridian, 1976.

22 Meichenbaum D. Cognitive-behavior modification: an integrative approach. New York: Plenum, 1977.

23 Malan D. A study of brief psychotherapy. London: Plenum Press, 1963.

24 Klerman G, Weissman M, Rounsaville B, Chevron E. Interpersonal psychotherapy of depressions. New York: Basic Books, 1984.

25 Moorey S, Williams R. Behavioural and cognitive therapies. In: Murray R, Hill P, McGuffin P, eds. The essentials of postgraduate psychiatry. Cambridge: Cambridge University Press, 1997: 636–49.

26 Hawton K, Salkovskis P, Kirk J, Clark D. Cognitive behaviour therapy for psychiatric problems: a practical guide. Oxford: Oxford Medical Publications, 1989.

27 Miller W, Rollnick S. Motivational interviewing: preparing people to change addictive behaviour. New York: Guildford Press, 1991.

28 Fleiss J. Statistical methods for rates and proportions, 2nd edn. New York: Wiley, 1981.

29 Bradburn MJ, Deeks JJ, Altman DG. sbe24 Metan: an alternative meta-analysis command. *Stata Technical Bulletin* 1998; **44:** 4–15.

30 Egger M, Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple graphical test. *BMJ* 1997; **315:** 629–34.

31 Begg C, Mazumdar M. Operating characteristics of a rank correlation test for publication bias. *Biometrics* 1994; **50:** 1088–101.

32 Schulz K, Chalmers I, Hayes R, Altman D. Empirical evidence for bias: dimensions of methodological quality associated with estimates of treatment effects in controlled trials. *JAMA* 1995; **273:** 403–12.

33 Jadad A, Moore R, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996; **17:** 1–12.

34 Lustman P, Griffith L, Freedland K, Kissel S, Clouse R. Cognitive behavior therapy for depression in type 2 diabetes mellitus: a randomized, controlled trial. *Ann Intern Med* 1998; **129:** 613–21.

35 Clark M, Hampson S, Avery L, Simpson R. Effects of a tailored lifestyle self-management intervention in patients with type 2 diabetes. *Br J Health Psychol* (in press).

36 Hartwell S, Kaplan R, Wallace J. Comparison of behavioral interventions for control of type II diabetes mellitus. *Behav Ther* 1986; **17:** 447–61.

37 Rodriguez F, Alvarez M. Modificacion de conducta y mejora en el cumplimiento del tratamiento en diabeticos tipo II. *Rev Esp Ter Comportamiento* 1987; **5:** 233–47.

38 Wing R, Marcus M, Epstein L, Jawad A. A 'family-based' approach to the treatment of obese type II diabetic patients. *J Consult Clin Psychol* 1991; **59:** 156–62.

39 Campbell E, Redman S, Moffitt P, Sanson-Fisher R. The relative effectiveness of educational and behavioral instruction programs for patients with NIDDM: a randomized trial. *Diabetes Educ* 1996; **22:** 379–86.

40 Henry J, Wilson P, Bruce D, Chisholm D, Rawling P. Cognitive-behavioural stress management for patients with non-insulin dependent diabetes mellitus. *Psychology Health Med* 1997; **2:** 109–18.

41 Ridgeway N, Harvill D, Harvill L, Falin T, Forester GM, Gose O. Improved control of Type 2 diabetes mellitus: a practical education/behavior modification program in a primary care clinic. *South Med J* 1999; **92:** 667–72.

42 Surwit R, Van Tilburg M, Zucker N, et al. Stress management improves long-term glycaemic control in type 2 diabetes. *Diabetes Care* 2002; **25:** 30–34.

43 Kenardy J, Mensch M, Bowen K, Green B, Walton J. Group therapy for binge eating in type 2 diabetes: a randomized trial. *Diabetes Med* 2002; **19:** 234–39.

44 Lane J, McCaskill C, Ross, SL, Feinglos M, Surwit R. Relaxation training for NIDDM. *Diabetes Care* 1993; **16:** 1087–94.

45 Aikens J, Kiolbasa T, Sobel R. Psychological predictors of glycemic change with relaxation training in non-insulin-dependent diabetes mellitus. *Psychother Psychosom* 1997; **66:** 302–06.

46 Jablon S, Naliboff B, Gilmore S, Rosenthal M. Effects of relaxation training on glucose tolerance and diabetic control in type II diabetes. *Appl Psychophysiol Biofeedback* 1997; **22:** 155–69.

47 Zhu X, Gong Y, Yao S. The effect of biofeedback assisted relaxation training on cytokines in patients with type II diabetes. *Chin J Clin Psychol* 2001; **9:** 170–72.

48 Tsujiuchi T, Kumano H, Yoshiuchi K, et al. The effect of Qi-Gong relaxation exercise on the control of type 2 diabetes mellitus. *Diabetes Care* 2002; **25:** 241–42.

49 White N, Carnahan J, Nugent C, Iwaoka T, Dodson M. Management of obese patients with diabetes mellitus: comparison of advice education with group management. *Diabetes Care* 1986; **9:** 490–96.

50 Wing R, Epstein L, Nowalk M, Koeske R, Hagg S. Behavior change, weight loss, and physiological improvements in type II diabetic patients. *J Consult Clin Psychol* 1985; **53:** 111–22.

51 Boehm S, Schlenk E, Raleigh E, Ronis D. Behavioral analysis and behavioral strategies to improve self-management of type II diabetes. *Clin Nurs Res* 1993; **2:** 327–44.

52 McKay H, King D, Eakin E, Seeley J, Glasgow R. The Diabetes Network internet-based physical activity intervention. *Diabetes Care* 2001; **24:** 1328–34.

53 Rabkin S, Boyko E, Wilson A, Streja D. A randomized clinical trial comparing behavior modification and individual counseling in the nutritional therapy of non-insulin-dependent diabetes mellitus: comparison of the effect of blood sugar, body weight, and serum lipids. *Diabetes Care* 1983; **6:** 50–56.

54 Heitzmann C, Kaplan R, Wilson D, Sandler J. Sex differences in weight loss among adults with type II diabetes mellitus. *J Behav Med* 1987; **10:** 197–211.

55 Campbell L, Barth R, Gosper J, Jupp J, Simons L, Chisholm D. Impact of intensive educational approach to dietary change in NIDDM. *Diabetes Care* 1990; **13:** 841–47.

56 D'Eramo-Melkus G, Wylie-Rosett J, Hagan J. Metabolic impact of education in NIDDM. *Diabetes Care* 1992; **15:** 864–69.

57 Smith D, Heckemeyer C, Kratt P, Mason D. Motivational interviewing to improve adherence to a behavioural weight-control program for older obese women with NIDDM. *Diabetes Care* 1997; **20:** 52–54.

58 Huang X, Song L, Li T. The effect of social support on type II diabetes with depression. *Chin J Clin Psychol* 2001; **9:** 187–89.

59 Jeffery R, Drewnowski A, Epstein L, et al. Long-term maintenance of weight loss: current status. *Health Psychol* 2000; **19** (1 suppl)**:** 5–16.