Mini-review

An updated meta-analysis to assess the effectiveness of psychological interventions delivered by psychological specialists and generalist clinicians on glycaemic control and on psychological status

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Objective: To update a meta-analysis and determine the effectiveness of psychological interventions on glycaemic control measured by HbA1c and psychological status in type 2 diabetes and to compare effects when interventions are delivered by generalist clinicians compared to psychological specialists.

Methods: We used the original review protocol and searched the Cochrane central register of controlled trials, Medline, Embase, PsychLIT, and Google Scholar from February 2003 (end of previous review) to March 2007. We extracted data on the participants, interventions, delivery methods, comparison groups and outcome measures.

Results: 35 trials were reviewed and meta-analysis of 19 trials (n = 1431), reporting HbA1c found a reduction in HbA1c by 0.54% (–0.32; 95% CI: –0.47 to –0.16). In nine trials (n = 832) interventions were delivered by diabetes or general clinicians reducing HbA1c by 0.51% (–0.27; 95% CI: –0.50 to 0.04). In nine trials, interventions (n = 561) were delivered by psychological specialists reducing HbA1c by 0.57% (–0.36; 95% CI: –0.61 to 0.12). Meta-analysis of 13 trials reporting psychological status found psychological status to be lower in the intervention groups –0.56 (95% CI: 1.00 to –0.13), Trial quality for the majority of studies remained poor.

Conclusion: Our findings suggest that psychological and general clinicians are similarly effective in delivering psychological interventions, however, effect sizes for all clinicians have reduced since the earlier review.

Practice implications: Psychological training opportunities for generalist clinicians could lead to wider availability of effective psychological care.

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1. Introduction

1.1. Background

Diabetes is a complex metabolic condition in which the patient has a life-long responsibility for managing their condition. The first aim of diabetes management is the control of blood glucose levels, usually termed glycaemic control, which is measured by an HbA1c blood test. HbA1c measures the amount of circulating glucose in the blood over a 120-day period. The aim of treatment and patient management is to achieve HbA1c levels ≤6.5% and the UKPDS [1] established that every 1% reduction in HbA1c towards this goal carries a 14–37% reduction in serious diabetes-related complications such as heart disease, blindness and kidney disease [1]. In order to achieve optimum glycaemic control people living with diabetes have to regulate their behaviour on a daily basis. The behavioural challenges imposed by close attention to diet, medication regimens including subcutaneous insulin injections, exercise, weight management, self-monitoring of daily blood glucose levels and foot care are burdensome and have social and emotional consequences [2]. In addition to this, specific psychological problems including depressive disorders [3,4] and eating disorders [5] can manifest themselves through poor glycaemic control thus giving rise to further complications.
1.2. Previous review

Ismail et al. [2] published a systematic review and meta-analysis in 2004 which identified the potential clinical and psychological benefits of offering psychological interventions to patients with type 2 diabetes. The review [2] incorporated interventions comprising the most commonly used psychotherapeutic models used in health-care settings. They included supportive or counselling therapy (including motivational interviewing and non-directive counselling), brief psychodynamic therapy, interpersonal psychotherapy and cognitive behaviour therapy and its associated techniques including contract setting, goal setting, problem solving, activity scheduling, stress management and relaxation.

Ismail et al. [2] identified 25 trials and observed significant reductions in HbA1c of 1%, similar to that of the UKPDS [1] but notably and unlike the UKPDS, these were achieved by non-pharmacological means. Psychological distress was also reduced. The findings suggest that psychological therapies may be a useful adjunct to current routine diabetes care.

However, despite the apparent benefits of psychological care in diabetes [6–8], there remains a severe shortage of psychological specialists within mainstream health care preventing access for the majority of patients [9]. Ismail et al.’s [2] review included a number of trials in which the psychological intervention had been delivered by a physician or nurse (generalist clinicians) compared to delivery by a professional with specialist training in psychology (specialist). It is not clear whether the discipline and training of the therapist makes a difference to outcome. If psychological interventions can be effectively delivered by generalist clinicians, access to this care becomes more possible for patients.

1.3. Goals of the current study

This paper reports an update to the Ismail et al. [2] review and meta-analysis to establish whether the 1% reduction in HbA1c has been maintained and to compare the impact of the intervention on glycaemic control and psychological status if the intervention is delivered by generalist clinicians compared to psychological specialists. Additionally, the previous review was subjected to some criticism upon publication and there was concern that the small sample sizes of included trials and poor trial quality had resulted in an overestimation of treatment effect [10,11]. We will report on whether the quality of psychological intervention trials has improved subsequent to the more recent common acceptance of the CONSORT trial quality criteria [12].

2. Methods

2.1. Selection criteria

The review follows the original protocol [13] and eligible studies were randomised control trials (RCTs) utilising a psychological intervention in adults with type 2 diabetes. Studies describing psychological therapies were included as were psycho-educational studies with a detailed psychological component and where the intervention balance was more towards the psychological component. We classified the interventions based on the psychological techniques used, mode of delivery and type of control employed. Interventions not clearly describing the psychological components were omitted.

Specialist psychological therapists were defined as professionals whose speciality was in the psychological care of people and included psychologists, psychiatrists, psychotherapists and counsellors. Generalist clinicians were defined as professionals whose speciality was in the provision of general and specialist diabetes clinical care and included GPs, diabetes physicians, nurses, dieticians and occupational therapists. Outcome measures were glycaemic control measured by HbA1c and measures of psychological status (anxiety and/or depression).

2.2. Search strategy

Using the Cochrane collaboration’s optimum search strategy for randomised controlled trials the search co-ordinator from the earlier review updated the search from February 2003 to March 2007. Details of the search strategy are published elsewhere [13].

2.3. Study selection

Two authors (JS & KW) independently assessed the abstracts for inclusion in the review and inter-rater reliability was reported using Cohen’s kappa (κ) [14]. We included abstracts of papers where a controlled trial of a psychological intervention for type 2 diabetes was described. Where differences between raters, or ambiguity occurred, the full papers were retrieved and disagreements were resolved through dialogue. Three authors (JS, RA and KW) independently reviewed the full text papers for inclusion.

2.4. Data extraction

JS & RA independently extracted the data of included studies using the original extraction form. Papers written in languages other than English underwent data-extraction by a native-speaking-registered translator and RA. For studies comparing more than one intervention group we included the most intense psychologically underpinned intervention for analysis.

We recorded age of participants, numbers at baseline and follow-up, study country of origin and setting (including the format, type and duration of intervention), delivery specialist, results and we assessed the study quality. Where data was missing, we contacted the original authors for clarification in order to include in the review.

2.5. Statistical analysis

Data was entered into SPSS (version 14.0) and the meta-analysis was carried out using the meta command in STATA (intercooled version 9.0).

2.5.1. Meta-analysis and heterogeneity

When combining data in meta-analysis, no two studies are likely to be identical and heterogeneity is the variation that exists between the individual studies.

Clinical heterogeneity is described as variability amongst the participants, the interventions and study outcomes measures. Methodological heterogeneity is described as the variability in study design and risk of bias. Statistical heterogeneity is the consequence of clinical or methodological heterogeneity or both and we refer to this simply as heterogeneity. If the clinical and methodological heterogeneity was considered minimal in the studies, then a meta-analysis was deemed possible. The method for detecting heterogeneity in the studies was planned through (a) observation of the forest plot to examine how well the confidence intervals overlay; (b) performance of a Chi-squared (χ²) test with a p-value of >0.10 [15] and (c) by quantifying the effect of heterogeneity using I² [16]. A small p-value from the χ² test is used to indicate evidence of heterogeneity. However, the statistical power of this test is limited in the presence of few studies. For this reason, a p-value of less than 0.10 is often used to indicate...
heterogeneity rather than the conventional cut-off point of \( p = 0.05 \). The \( I^2 \) test is a useful adjunct to assess heterogeneity and provides a quantified measure of consistency between the trials, where values of 25%, 50% and 75% represent low, moderate and high levels of heterogeneity respectively [16].

2.5.2. Meta-analytical procedures

Meta-analysis was deemed appropriate if there were five or more trials with minimal heterogeneity for inclusion which measure the same outcome. The two outcome measures used in our meta-analysis were HbA1c and measures of psychological distress.

The mean and standard deviation at baseline and follow-up were extracted for each intervention and each outcome. The mean change from baseline (follow-up–baseline) was extracted for each outcome and this provided the within-group mean. The pooled standard deviations for the mean change scores were obtained and provided the within-group standard deviation. If this standard deviation was missing, then the square root of the baseline and follow-up variance was obtained. This approach is based on the assumption that the correlation between the baseline and follow-up outcome values is 0.5.

2.5.3. Effect size

The difference in the mean change values between the two interventions (treatment–control) divided by the pooled standard deviation for this difference provided the estimate of the effect size. This was obtained for each assessment, which was then used in the meta-analysis. The effect sizes or the standardised mean difference method expresses the size of the treatment in each trial relative to the variability observed in that trial. The method allows different measures of the same outcome to be combined because different methods for measuring the outcomes were used.

2.5.4. Random effect and fixed effect models

In order to obtain a common effect across all the studies, fixed effects and random effects meta-analysis models were computed and the results compared. With fixed effects models all of the studies that are examined as a whole are considered to have been conducted under similar conditions with similar subjects. The random effects models generally produce wider confidence intervals and allow the study outcomes to vary in a normal distribution between studies. As with the original review [2] we anticipated some heterogeneity and use of the random effects model enabled us to minimise the impact of “background noise” presented by individual studies.

2.5.5. Transformation of effect sizes

For the outcome of HbA1c, we converted the estimated pooled standardised effect size into absolute units by multiplying the estimate by the pooled S.D. of all the studies included in the meta-analysis for each outcome. In the case where different studies gave different results, reasons why effects differed across studies were assessed using meta-regression analysis (using metareg in STATA (version 9)). Both these techniques are used to see if particular characteristics of studies are related to the sizes of the treatment effect. The number of sessions and duration of therapy, which are deemed proxy measures of intensity and duration of follow-up were used as potential covariates in a regression meta-analysis.

2.6. Quality assessment

Quality assessment criteria developed by Schulz et al. [17] and Jadad et al. [18] was used to assess for selection, attrition and detection bias.

2.7. Publication bias

Publication bias is the phenomenon in which (i) positive results have a better chance of being published, (ii) are published in journals with higher impact factors (and are more likely to be retrieved in medical literature searches) and (iii) are published faster. Publication bias was estimated by using a funnel plot for the treatment effect (using the treatment difference) and its standard error [19]. In the absence of publication bias, we would expect less precise studies (small sample size, duration, follow-up) to be more affected by chance alone, thus widely scattered from the pooled estimate. As studies get larger with more events, we expect them to be closer to the pooled estimate with a resulting triangular shape (or funnel), split by a line representing the pooled estimate of the meta-analysis. Formally, the Begg’s adjusted rank correlation test was used to assess if there is a significant correlation between the standardised effect estimates and their variances [20].

2.8. Sensitivity analysis

Sensitivity analysis was performed using fixed and random effects models, by excluding borderline studies, by excluding studies using a less intensive psychological therapy as controls, by excluding studies with clinical sub-groups and by comparing poor quality studies with the higher quality studies.

2.9. Role of the funding source

The funders of the study had no involvement with any aspect of the study, including the decision to submit this report for publication.

3. Results

3.1. Description of new trials

The 2003–2007 searches identified 3218 new studies from which 48 full texts were selected for further extraction with a substantial level of agreement between the reviewers (k = 0.67) [14]. Fig. 1 shows the flow of original and newly identified studies considered for the review. Ten new trials which were published after the CONSORT statement [12] were identified for inclusion in the systematic review.

3.1.1. Study quality

One study was rated as quality B [21] and nine studies rated as C [22–30].

3.1.2. Psychological therapies used

Seven studies utilised cognitive behaviour therapy [22–28], two trials utilised counselling techniques [29,30] and one trial utilised psychotherapy [21].

3.1.3. Intervention delivery specialist

Five of these trials were delivered by generalists [23,25,26,30,31], three were delivered by psychological specialists [21,24,27] and two did not report the specialist [22,28].

3.1.4. Intervention format

The mean intervention duration was 18.3 (S.D. 11.9) weeks. The majority of studies were delivered in a 1:1 format [22,23,25,26–28,30,31] and two were delivered in a combined group and 1:1 format [21,24].
Table 1
Characteristics of studies included in the systematic review of randomised controlled trials incorporating psychological interventions for patients with type 2 diabetes.

<table>
<thead>
<tr>
<th>Year, country, reference</th>
<th>Number of participants recruited/at follow-up</th>
<th>Mean age (S.D. or range) (years)</th>
<th>Mean % glycated haemoglobin at baseline</th>
<th>Clinical subgroup (type of treatment)</th>
<th>Mean (S.D. or range) duration of diabetes (years)</th>
<th>Model and duration of therapy in intervention group</th>
<th>Model and duration of therapy in control group</th>
<th>Regimen in intervention group and speciality of therapist</th>
<th>Regimen in control group and speciality of therapist</th>
<th>Follow-up months</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>1983, Canada, Rabkin</td>
<td>40/40</td>
<td>53–9 (2–0)</td>
<td>NS</td>
<td>Sub-optimum glycaemic control (D, T) Obese (D, T)</td>
<td>5–9 (NS)</td>
<td>Group CBT for 6 weeks</td>
<td>Individual education for 6 weeks</td>
<td>Group CBT for 6 weeks</td>
<td>Individual dietary counselling sessions by nutritionist</td>
<td>3</td>
<td>C</td>
</tr>
<tr>
<td>1985, USA, Wing</td>
<td>53/50</td>
<td>55–1 (7–3)</td>
<td>9.33 (0.3)</td>
<td>Sub-optimum glycaemic control (D, T) Obese (D, T)</td>
<td>NS</td>
<td>Group CBT for 16 weeks</td>
<td>Group CBT for 16 weeks</td>
<td>Group CBT for 16 weeks</td>
<td>4 standard education sessions by psychologist and nutritionist</td>
<td>4</td>
<td>C</td>
</tr>
<tr>
<td>1986, USA, Hartwell</td>
<td>76/76</td>
<td>NS</td>
<td>8.7 (2.7)</td>
<td>Sub-optimum glycaemic control (D, T) Obese (D, T)</td>
<td>NS</td>
<td>Group CBT for 10 weeks</td>
<td>Group CBT for 10 weeks</td>
<td>Group CBT for 10 weeks</td>
<td>10 traditional education sessions by multidisciplinary diabetes team</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>1986, USA, White</td>
<td>41/32</td>
<td>61–6 (6–4)</td>
<td>12–6 (11–4)</td>
<td>Group CBT for 6 months</td>
<td>Group CBT for 6 months</td>
<td>Group education for 6 weeks</td>
<td>Group education for 6 weeks</td>
<td>16 advice/education sessions by nurse and dietician</td>
<td>6</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>1987, USA, Heitzmann</td>
<td>46/46</td>
<td>52–9 (12–1)</td>
<td>11.3 (2.3)</td>
<td>Group and individual CBT for 7 weeks</td>
<td>Group and individual CBT for 7 weeks</td>
<td>Group CBT (duration not specified)</td>
<td>Minimal relaxation training; speciality not specified</td>
<td>6*</td>
<td>B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1987, Spain, Rodriguez</td>
<td>11/11</td>
<td>60–7 (51–70)</td>
<td>NS</td>
<td>General (treatments not specified)</td>
<td>4–3 (3–7)</td>
<td>Individual CBT and education for 5 weeks</td>
<td>Individual education for 5 weeks</td>
<td>Individual education for 5 weeks</td>
<td>2 education sessions; speciality not specified</td>
<td>2</td>
<td>C</td>
</tr>
<tr>
<td>1990, Australia, Campbell</td>
<td>62/61</td>
<td>58–5 (9–0)</td>
<td>11.6 (1.9)</td>
<td>Sub-optimum glycaemic control obese (D, T, I)</td>
<td>7–5 (7–0)</td>
<td>Group counselling for 11 weeks</td>
<td>Group education for 5 weeks</td>
<td>Group education for 5 weeks</td>
<td>3 education sessions; speciality not specified</td>
<td>6</td>
<td>B</td>
</tr>
<tr>
<td>1991, USA, Wing</td>
<td>49/43</td>
<td>52–5 (7–5)</td>
<td>9.9 (2.2)</td>
<td>Obese (D, T, I)</td>
<td>NS</td>
<td>Group CBT and couple therapy for 10 weeks</td>
<td>Group CBT for 10 weeks</td>
<td>16 behavioural modification and couple therapy sessions by multidisciplinary team (project physician and trained nutritionist reported)</td>
<td>5</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>1992, USA, D’Eramo</td>
<td>54/34</td>
<td>56–0 (8–1)</td>
<td>11.1 (2.8)</td>
<td>Obese (D, T)</td>
<td>NS</td>
<td>Group education and individual counselling for 11 weeks</td>
<td>Education for 1 week</td>
<td>Regimen not described; speciality not specified</td>
<td>1 minimal education session by nurse</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>1993, USA, Boehm</td>
<td>156/135</td>
<td>58–0 (11–3)</td>
<td>NS</td>
<td>General (D, T, I)</td>
<td>NS</td>
<td>Individual CBT (duration not specified)</td>
<td>Usual care</td>
<td>Regimen not described; speciality not specified</td>
<td>NS</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>1993, USA, Lane</td>
<td>38/38</td>
<td>NS</td>
<td>10.3 (2.3)</td>
<td>Sub-optimum glycaemic control (D, T) Obese (D, T)</td>
<td>NS</td>
<td>Individual CBT for 8 weeks and intensive diabetes care for 12 months</td>
<td>Intensive diabetes care for 12 months</td>
<td>Intensive diabetes education and clinical care; speciality not specified</td>
<td>6</td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>1996, Australia, Campbell</td>
<td>118/60</td>
<td>59–5 (10–2)</td>
<td>12.6 (4.3)</td>
<td>General (D, T)</td>
<td>0–4 (0–1)</td>
<td>Individual CBT for 12 months</td>
<td>Group education for 2 weeks</td>
<td>Group education for 2 weeks</td>
<td>2 minimal education sessions by nurse and dietician</td>
<td>6</td>
<td>B</td>
</tr>
<tr>
<td>Year, country, reference</td>
<td>Number of participants recruited at follow-up</td>
<td>Mean age (S.D. or range) (years)</td>
<td>Mean (% glycated haemoglobin at baseline)</td>
<td>Clinical sub-group (type of treatment)</td>
<td>Mean (S.D. or range) duration of diabetes (years)</td>
<td>Model and duration of therapy in intervention group</td>
<td>Model and duration of therapy in control group</td>
<td>Regimen in intervention group and speciality of therapist</td>
<td>Regimen in control group and speciality of therapist</td>
<td>Follow-up months</td>
<td>Quality</td>
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<tr>
<td>1997, USA, Aikens</td>
<td>22/22</td>
<td>61–0 (10–2)</td>
<td>11.0 (1.9)</td>
<td>General (D, T, I)</td>
<td>11–0 (9–0)</td>
<td>Group CBT for 8 weeks</td>
<td>Usual care</td>
<td>6 relaxation training sessions by psychologist</td>
<td>Routine medical care; speciality not specified</td>
<td>4</td>
<td>C</td>
</tr>
<tr>
<td>1997, Australia, Henry</td>
<td>19/19</td>
<td>60–0 (47–74)</td>
<td>10.7 (1.9)</td>
<td>Sub-optimum glycaemic control, stress/ anxiety (D, T, I)</td>
<td>6–4 (1–5–23–0)</td>
<td>Group CBT for 6 weeks</td>
<td>Waiting list</td>
<td>Stress management sessions by psychologist</td>
<td>Usual practice by physician</td>
<td>2–25</td>
<td>C</td>
</tr>
<tr>
<td>1997, USA, Jablon</td>
<td>20/20</td>
<td>58–9 (7–7)</td>
<td>6.5 (1.8)</td>
<td>Sub-optimum glycaemic control (D, T) Women, obese (D, T)</td>
<td>7–9 (8–7)</td>
<td>Individual CBT for 4 weeks</td>
<td>Waiting list</td>
<td>8 relaxation therapy sessions by psychologist</td>
<td>None; speciality not specified</td>
<td>1</td>
<td>C</td>
</tr>
<tr>
<td>1997, USA, Smith</td>
<td>22/16</td>
<td>62–4 (7–0)</td>
<td>10.3 (2.2)</td>
<td>Individual CBT and individual counselling for 4 months</td>
<td>6–7 (5–4)</td>
<td>Group CBT for 4 months</td>
<td>Group CBT for 4 months</td>
<td>16 group behaviour modification by nutritionist, exercise psychologist, and psychologist</td>
<td>4</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>1998, USA, Lustman</td>
<td>51/42</td>
<td>54–8 (10–1)</td>
<td>10.3 (3.4)</td>
<td>Depression (D, T, I)</td>
<td>8–8 (9–5)</td>
<td>Group CBT and education for 10 weeks</td>
<td>Group education for 10 weeks</td>
<td>30 CBT sessions by psychologist and 20 education sessions by diabetes educator 6 behaviour modification sessions by diabetes educators</td>
<td>20 education sessions by diabetes educator</td>
<td>6*</td>
<td>A</td>
</tr>
<tr>
<td>1999, USA, Ridgeway</td>
<td>38/38</td>
<td>63–5 NS</td>
<td>12.3 (2.6)</td>
<td>General (D, T, I)</td>
<td>11–5 (NS)</td>
<td>Group CBT and education for 6 months</td>
<td>Usual care</td>
<td>Usual education for 6 months</td>
<td>Conventional diabetes care; speciality not specified</td>
<td>3</td>
<td>C</td>
</tr>
<tr>
<td>2001, China, Huang</td>
<td>59/59</td>
<td>52–3 NS</td>
<td>9.9 (2.1)</td>
<td>Depression (treatments not specified) Sedentary (D, T, I)</td>
<td>NS</td>
<td>Group counselling for 3 months</td>
<td>Usual care</td>
<td>Individual counselling for 3 months; speciality not specified</td>
<td>Internet-based education on diet &amp; medication</td>
<td>2</td>
<td>C</td>
</tr>
<tr>
<td>2001, USA, McKay</td>
<td>78/68</td>
<td>57–4 NS</td>
<td>7.8 (1.8)</td>
<td>General (treatments not specified) Sedentary (D, T, I)</td>
<td>7–4 (5–4)</td>
<td>Individual CBT for 1 month</td>
<td>Individual counselling for 3 months; speciality not specified</td>
<td>Relaxation training by psychiatrist (number of sessions not given)</td>
<td>Conventional diabetes care; speciality not specified</td>
<td>1</td>
<td>C</td>
</tr>
<tr>
<td>2002, Australia, Kenardy</td>
<td>34/32</td>
<td>55–0 (10–5)</td>
<td>7.5 (1.5)</td>
<td>Binge-eating (D, T, I)</td>
<td>3–2 (5–7)</td>
<td>Group CBT for 10 weeks</td>
<td>Usual care</td>
<td>Group counselling for 10 weeks</td>
<td>10 non-prescriptive therapy sessions by psychologist</td>
<td>2–5</td>
<td>B</td>
</tr>
<tr>
<td>2002, USA, Survit</td>
<td>108/72</td>
<td>57–4 NS</td>
<td>7.8 (1.8)</td>
<td>General (treatments not specified) Sedentary (D, T, I)</td>
<td>NS</td>
<td>Individual CBT for 2 months</td>
<td>16 Qigong relaxation training sessions by Chinese Qigong doctor (Ph.D. in medicine)</td>
<td>5 education sessions; speciality not specified</td>
<td>Conventional diabetes care; speciality not specified</td>
<td>4</td>
<td>C</td>
</tr>
<tr>
<td>2002, Japan, Tsujuuchi</td>
<td>36/26</td>
<td>62–2 NS</td>
<td>8.2 (1.7)</td>
<td>General (treatments not specified) Sedentary (D, T, I)</td>
<td>NS</td>
<td>Group CBT for 4 months</td>
<td>Group counselling for 2 weeks</td>
<td>5 education sessions; speciality not specified</td>
<td>Diet control and usual medication delivered by dietician</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>2003, China, Zeng</td>
<td>108/106</td>
<td>56.0 NS</td>
<td>10.5 (NS)</td>
<td>General (D, T, I)</td>
<td>5.5 (2–11)</td>
<td>Group and single CBT and education for 6 months</td>
<td>Individual education on diet &amp; medication</td>
<td>Combination of psychotherapist &amp; clinician</td>
<td>Diet control and usual medication delivered by dietician</td>
<td>6</td>
<td>C</td>
</tr>
<tr>
<td>Year, country, reference</td>
<td>Number of participants recruited/at follow-up</td>
<td>Mean (S.D.) or range (years)</td>
<td>Mean (S.D. or range)</td>
<td>% glycated haemoglobin at baseline</td>
<td>Clinical sub- group (type of treatment)</td>
<td>Mean (S.D. or range) duration of diabetes (years)</td>
<td>Model and duration of therapy in intervention group</td>
<td>Regimen in intervention group and speciality of therapist</td>
<td>Model and duration of therapy in control group</td>
<td>Regimen in control group and speciality of therapist</td>
<td>Follow-up months</td>
</tr>
<tr>
<td>-------------------------</td>
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<td>---------------------------------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>2005, USA, Zuo</td>
<td>300/300</td>
<td>87.3 (±1.5)</td>
<td>NS</td>
<td>51.5</td>
<td>General (D, T, I)</td>
<td>5.0 (±3.87)</td>
<td>Individual CBT for 28 days</td>
<td>24 individual relaxation sessions and 24 educational sessions with doctor, nurse and dietician</td>
<td>Usual care and medication for 6 months (single format)</td>
<td>Conventional diabetes care; speciality not specified</td>
<td>36 weeks</td>
</tr>
<tr>
<td>2005, UK, Willettmore</td>
<td>53/49</td>
<td>77.1 (±1.7)</td>
<td>NS</td>
<td>5.4 (±1.0)</td>
<td>General (D, T, I)</td>
<td>5.6 (±1.75)</td>
<td>Individual CBT for 10 weeks</td>
<td>10 sessions of biofeedback &amp; relaxation.</td>
<td>One-to-one diabetes education sessions with leaflets provided by registered nurse</td>
<td>3 (60–75 min each)</td>
<td>C</td>
</tr>
<tr>
<td>2004, UK, Kirk</td>
<td>70/59</td>
<td>57.6 (±1.6)</td>
<td>NS</td>
<td>3.0 (±1.0)</td>
<td>General (D, T, I)</td>
<td>2.7 (±0.3)</td>
<td>Individual CBT for 12 weeks</td>
<td>12 mixed sessions of health education &amp; 4 telephone consultations by psychologist</td>
<td>Usual care and standard DUK leaflets</td>
<td>Individual diet and exercise advice; speciality not specified</td>
<td>36 weeks</td>
</tr>
<tr>
<td>2004, China, Huang</td>
<td>120/105</td>
<td>8.4 (±1.6)</td>
<td>NS</td>
<td>51.5</td>
<td>General (D, T, I)</td>
<td>6.0 (±1.47)</td>
<td>Individual CBT for 6 months</td>
<td>6 nurse-coaching sessions &amp; 2 telephone support sessions over 6 months by registered nurse</td>
<td>Usual care on waiting list (single format)</td>
<td>Regular appointments with primary care provider &amp; 3–4 month interval visits to nurse, internists, family physician</td>
<td>36 weeks</td>
</tr>
<tr>
<td>2005, China, Zhao</td>
<td>80/80</td>
<td>67.3 (±1.5)</td>
<td>NS</td>
<td>28 days</td>
<td>General (D, T, I)</td>
<td>5.75 (±2.2)</td>
<td>Individual CBT for 28 days</td>
<td>8 telephone consultations over 28 days and patients to utilise relaxation techniques twice a day</td>
<td>Usual care and medication for 6 months (single format)</td>
<td>Conventional diabetes care; speciality not specified</td>
<td>28 days</td>
</tr>
<tr>
<td>2006, Germany, Siebolds</td>
<td>250/223</td>
<td>8.5 (±1.5)</td>
<td>NS</td>
<td>90</td>
<td>General (D, T)</td>
<td>5.33 (±0.67)</td>
<td>Individual CBT for 28 days</td>
<td>24 individual counselling sessions and 24 telephone consultations by psychologist</td>
<td>Usual care and medication for 6 months (single format)</td>
<td>Conventional diabetes care; speciality not specified</td>
<td>24 weeks</td>
</tr>
</tbody>
</table>
3.1.5. Participants

The mean time since diagnosis was 5.3 (S.D. 2.94) years and the mean sample size was 105.3 (S.D. 85.59).

3.1.6. Follow-up

The mean follow-up of interventions was 18.0 (S.D. 10.30) weeks.

These additional 10 trials were pooled with the previous 25 trials from the original review [2] resulting in a total of 35 trials (Table 1). Reasons for exclusion are shown in Fig. 1.

3.2. Description of included trials from original and new review

3.2.1. Sample size

The mean sample size of the 10 new trials was higher (105.3, S.D. 88.15) than the previous review (47.6, S.D. 27.5) and added 1053 (47%) more patients to the original 1190 patients (53%) to provide 2243 patients in total.

3.2.2. Study quality

Of the 35 trials one study was classified A for quality [31], 8 studies were classified as B [21,32–38] and the remaining 26 studies were classified C [22–31,39–55]. Four studies reported analysing the results by intention to treat [21,25,31,38].

3.2.3. Psychological therapies used

The majority of studies examined cognitive behaviour therapy [25,26,31,35–38,41,43,49,54] including strategies of relaxation [21–24,28,34,48,50,53–55], problem solving [26,42], contract setting [40,46], goal setting [52], self-monitoring of behaviours [32,39] and enlisting social support [44]. Seven studies used counselling techniques [27,30,32,33,45,47,51]. Four studies compared a more intensive psychological therapy with a control that was less intensive [32,37,44,51].

3.2.4. Intervention delivery specialist

Sixteen of the 35 trials were delivered by psychological specialists [21,24,27,31,33,37,38,40,42,43,47–51,53], 13 were delivered by generalists [23,25,26,30,31,35,36,39,41,44,45,52,55] and 6 did not report the specialist [22,28,32,34,46,54].

Table 1 (Continued)

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Reference</th>
<th>Number of participants recruited/at follow-up</th>
<th>Mean (S.D. or range) age (years)</th>
<th>Mean (S.D. or range) % glycated haemoglobin at base-line</th>
<th>Model and duration of diabetes (years)</th>
<th>Clinical sub-group (type of treatment)</th>
<th>Model and duration of intervention in intervention group</th>
<th>Regimen in intervention group and speciality of therapist</th>
<th>Model and duration of therapy in control group</th>
<th>Regimen in control group and speciality of therapist</th>
<th>Follow-up months</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>China</td>
<td>Ma</td>
<td>67/67</td>
<td>44.5 (NS)</td>
<td>9.15 (NS)</td>
<td>4.6 (NS)</td>
<td>Single and group psychotherapy for 6 weeks by psychologist</td>
<td>Individual treatment with gliclazide, 80 mg 3 times daily</td>
<td>Specialty not specified</td>
<td>Individual usual care by medication for 6 weeks</td>
<td>Not described and specialty not specified</td>
<td>1.5</td>
<td>B</td>
</tr>
<tr>
<td>2007</td>
<td>UK</td>
<td>Jackson</td>
<td>40/34</td>
<td>60.2 (NS)</td>
<td>NS (NS)</td>
<td>9.15 (NS)</td>
<td>Individual usual care by medication for 6 weeks by psychologist</td>
<td>Not described and specialty not specified</td>
<td>Not described and specialty not specified</td>
<td>Individual usual care for 6 weeks</td>
<td>Not described and specialty not specified</td>
<td>1.5</td>
<td>C</td>
</tr>
</tbody>
</table>

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

Fig. 1. QUORUM flow chart.
3.2.5. Intervention format

The mean duration of interventions was 13.7 (S.D. 11.06) weeks. Fourteen trials used a group format [31,33,36,37,39–42,44,48,49,51,54,55], 16 used a single format [21,22,25–28,30,31,34,35,38,43,46,50,52,53] and 5 used a combination [21,24,32,45,47]. Eleven of the 35 trials used an educational component in the intervention in addition to the psychological component [21,23,24,26,27,30,31,36,43,45,54].

3.2.6. Follow-up

The mean follow-up of interventions was 18.5 (S.D. 10.4) weeks.

3.2.7. Study location

Only 3 trials were UK-based [25,30,38] and 17 were undertaken in USA [26,28,31,32,34,36,40–42,44–48,50,52,54], 7 in China [21–24,27,51,53], 4 in Australia [33,35,39,49], 1 in Canada [39], 1 in Germany [31], 1 in Japan [55] and 1 in Spain [43]. Eight studies were translated into English (one was Spanish [43] and seven were Chinese [21–24,27,51,53]).

3.2.8. Intervention fidelity

The precise training the generalist HCPs received in delivering the psychological interventions was not described for the majority of studies. Only one of the trials delivered by the generalists described the training received [30]. None of the 35 trials reported quality assessment procedures to ensure intervention fidelity.

3.3. Meta-analysis

3.3.1. Glycaemic control

Seven new trials reported HbA1c values as their primary outcome bringing the total to 20. One study was excluded from the meta-analysis due to missing data [28]. Sixteen trials reported baseline HbA1c values for intervention and control arms at 9.53% (S.D. 1.59) and 9.66% (S.D. 1.67) respectively and three studies reported the mean difference between baseline and follow-up.

In total, 19 studies were meta-analysed, 14 of which reported improvements in HbA1c, 4 reported deterioration and 1 showed no difference (Fig. 2). With the random effects model, the pooled effect size for HbA1c was −0.32 (95% CI: −0.47 to −0.16). The treatment effect in absolute units was a decrease of 0.54% (−0.83 to −0.23) in HbA1c, indicating an improvement in glycaemic control.

The $\chi^2$ test for heterogeneity was significant ($\chi^2 = 32.29; df = 18; p = 0.020$) and $I^2$ test indicates below moderate heterogeneity (44%). There was no evidence of publication bias in the funnel plot (Fig. 3), the Egger’s test or the Begg adjusted rank correlation test ($p = 0.438$ and $p = 0.400$ respectively).

There was no statistical association between HbA1c and duration of follow-up (regression coefficient ($b$) = 0.01 (S.E. = 0.01), $p = 0.275$) or duration of therapy (regression coefficient = −0.009 (S.E. = 0.01), $p = 0.488$). However there was some evidence of an association between improvements in HbA1c and increased number of sessions (regression coefficient = −0.04 (S.E. = 0.01), $p = 0.001$).

In sensitivity analysis, the exclusion of two studies that used less intensive psychological therapy as the control intervention,

![Fig. 2. Meta-analysis illustrating the standardised effects of psychological interventions on glycaemic control.](image)

![Fig. 3. Funnel plot illustrating publication bias of psychological interventions on glycaemic control.](image)
resulted in a larger estimate of the pooled effect size (−0.54 [95% CI: −0.84 to −0.23]) equating to an absolute decrease of 0.65% (−0.94 to −0.36) in HbA1c.

3.3.2. Psychotherapist/psychologist and generalists
Psychological specialists and generalist clinicians were involved in the delivery of the interventions and meta-analyses were carried out on these two sub-groups.

The χ² test for the psychological specialists showed evidence of heterogeneity (χ² = 14.92; df = 8; p = 0.061), however the I² test illustrates below moderate heterogeneity (46%). Using the random effects model, the pooled standardised effect size estimate for HbA1c was −0.36 (−0.61 to −0.12) (Fig. 4).

The χ² test for the generalist clinicians showed evidence of heterogeneity (χ² = 16.77; df = 8; p = 0.033) and the I² test illustrated moderate risk of heterogeneity (52%). Using the random effects model, the pooled standardised effect size estimate for HbA1c was −0.36 (−0.61 to −0.12) (Fig. 5).

The treatment effect in absolute units was a decrease of 0.57% (−1.02 to −0.13) in HbA1c for the psychological specialists and a decrease of 0.51% (−1.00 to −0.01) in HbA1c for the generalist clinicians.

3.3.3. Psychological status
Five new trials reported measures of psychological status as an outcome and these were included in the meta-analysis. Of these 13
trials in total, 7 were delivered by psychological specialists, 4 were delivered by generalist clinicians which prevented a sub-group analysis by delivery specialist. Two trials did not report the specialist.

The test of heterogeneity from the random effects model indicates that the studies are statistically different ($\chi^2$ test of heterogeneity = 132.45; df = 12; $p < 0.001$). With the random effects model, the pooled effect size effect for psychological distress was $-0.56$ (95% CI: $-1.00$ to $-0.13$) (Fig. 6). The weighted mean difference was a decrease of $7.9$ units ($-12.7$ to $-3.15$) in psychological status.

There was no publication bias (plot not shown; Begg's test: $p = 0.714$). There was evidence of statistical association between improvements in psychological status and increased duration of therapy (regression coefficient = $-0.43$ (S.E. = 0.03), $p < 0.001$), increased follow-up length (regression coefficient = $0.52$ (S.E. = 0.08), $p < 0.001$) and increased number of sessions (regression coefficient = $0.15$ (S.E. = 0.14), $p < 0.001$) with the exception of one trial [22].

4. Discussion and conclusion

4.1. Discussion

The current review identified 10 additional trials to add to the original review and in total 35 RCTs were included in the review. Meta-analysis of 19 trials of psychological interventions demonstrated a $0.54\%$ reduction in HbA1c. The psychological specialists delivered a $0.57\%$ reduction in HbA1c and the generalist clinicians a $0.51\%$ reduction. The positive trend in increasing sample size was not concomitant with improvements in the reporting of potential biases and hence trial quality, which remained poor.

4.1.1. Strengths and weaknesses of the study

Permission from the original reviewers to use their Cochrane review protocol and the involvement of the original reviewers was a study strength enabling consistency between the review procedures.

The level of heterogeneity was less than ideal in particular relation to the interventions and the degree of intervention fidelity but was satisfactory in relation to the outcome of HbA1c and trial design. Pooled data from 13 trials measuring psychological distress reported a significant reduction in psychological distress in the intervention arms, however, nine different psychological measurement tools were used, three of which were Chinese. The variability in the tools and scales used to measure psychological distress between the studies are likely to introduce some methodological heterogeneity and the lack of a consistent scale between studies requires the reader to interpret these units with caution.

4.1.2. Strengths and weaknesses in relation to other studies

Our meta-analysis of trials assessing glycaemic control using measures of HbA1c found a smaller effect size compared to the $1\%$ reduction reported in the original review [2]. Consistent with the previous review [2], however, we did observe improvements in the overall effect ($0.65\%$ reduction) when two studies using a less intensive psychological therapy as controls were excluded [37,44]. Trial quality has not improved with later studies and therefore cannot account for the observed reduction in effect. It is possible that an increase in clinician consciousness regarding the impact of psychological factors on patients, may have resulted in greater levels of psychological care being experienced in the comparison groups of newer trials, thus partially accounting for the reduced effect size observed in our update. Additionally, the newer trials tended to be larger in sample size, longer in duration and follow-up and their smaller effect size had a more profound impact on the overall pooled difference.

Furthermore, we report a statistically significant association between effect size and the number of sessions in the intervention. It appears that features of intervention and trial design such as length of follow-up and duration of intervention may not be as important as the number of sessions provided. The association
between improved HbA1c and an increase in the number of sessions is possibly related to repeated exposures providing ongoing social support resulting in enhanced patient concordance and outcomes [56].

The sub-group analysis of psychological specialists and generalist clinicians indicates that generalists may be similarly effective in delivering psychological interventions in reducing HbA1c. This supports an earlier finding by Mojica et al. [57] reporting on the effectiveness of different health care providers, including generalist and psychological specialist, on smoking cessation interventions. Only one trial in our review reported the specific training received by the generalists [30], however we believe that the success achieved by the generalists may be attributed to the acquisition of additional knowledge, training and skills. The inconsistency in reporting the specific training received in most trials suggests the need for the inclusion of such data in future studies.

Nonetheless, the effectiveness observed here contributes to previous reviews suggesting that people with diabetes could benefit from receiving care from generalist clinicians and diabetes specialist professionals who have received training in delivering psychological care [58].

4.2. Conclusion

The reductions observed in HbA1c are clinically significant in reducing microvascular and macrovascular complications [1]. Furthermore, there have been previous concerns regarding the potential benefits of psychological care in patients with long-standing poor glycaemic control [59] and our findings suggest that patients with long-standing sub-optimal control may benefit from psychological interventions.

The benefits of delivering psychological interventions for people with type 2 diabetes by generalist clinicians, with additional and as yet unspecified training, have been highlighted and this has the potential to make this care more widely available.

4.3. Future recommendations

To assess the degree of effectiveness between psychological care specialists and generalist clinicians there is a need to test differences in high quality fully powered randomised control trials in UK, including more studies delivered by generalists.

Only three of the trials in this review were conducted in UK and as such the generalisability of the findings should be interpreted with caution. Additionally, in future studies there is a need to describe the training provided to intervention delivery staff and recommendations are made to quality assure interventions to both understand and assess intervention fidelity by clinician and patient.

The use of multiple measures of psychological status introduced methodological heterogeneity into the review making interpretation of findings difficult. Researchers are urged to consider these issues in their design of RCTs and also to consider further work along the lines of Herrmans et al. [60] to compare the use and outcomes of different instruments in the same populations.

4.4. Practice implications

Psychological interventions appear to be effective in improving psychological distress and glycaemic control, however there is a shortage of psychological specialists within the NHS and psychological treatments are difficult to access for most patients living with diabetes.

The findings of this study suggest that with some additional training, diabetes and generalist clinicians have the potential to effectively deliver psychological interventions and improve patient outcomes. This implies that psychological care can be made more widely available to patients across health services if they do not have to depend on a service of psychological specialists in limited supply. This study supports the recommendations of both UK and international health policy (International Diabetes Federation) for the need to provide generalist clinicians with new skills in this area [9].

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Provenance and peer review: Not commissioned; externally peer reviewed. I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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