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Title: The detection and management of Diabetes Distress in people with Type 1 Diabetes

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Key words:

Diabetes distress; type 1; review; interventions; correlation

Abbreviations used: DD Diabetes distress, RCT Randomised Controlled Trial, HbA1c Glycated Haemoglobin, DAFNE Dose Adjustment For Normal Eating, DSME Diabetes Self-Management Education, PAID Problem Areas In Diabetes Scale, DDS Diabetes Distress Scale, SD Standard Deviation, CGM Continuous Glucose Monitoring, CBT Cognitive Behaviour Therapy.
Abstract
Diabetes distress (DD) represents a significant clinical burden in which levels of DD are related to both HbA1c and some self-management behaviours. DD is related to, but different from, depression. Differences in DD experienced in people with type 1 and type 2 have been observed. Commonly measured by the Problem Areas in Diabetes Scale and the Diabetes Distress Scale, rates of elevated DD in research study participants range 20-30%. Risk factors for elevated DD in type 1 are a longer duration of diabetes, severe hypoglycaemia, younger age and being female. A systematic review of intervention studies assessing DD identified eight RCTs and nine pre-post design studies. Only three studies targeted DD with the intervention. Intervention types were diabetes self-management education (DSME); psychologically informed self-management and; devices. DSME pre-post studies, namely the DAFNE programme (Dose Adjustment For Normal Eating), produced more consistent improvements in DD and HbA1c at follow up. Psychologically informed self-management were more heterogeneous but several RCTs were effective in reducing DD. Group interventions offered the greatest benefits across intervention designs.

Introduction
Diabetes Distress (DD) has been increasingly recognised in research practice for two decades but has only recently achieved a sharper focus in clinical practice. Much of the research attention has been in type 2 diabetes. This paper is the first to review the evidence for DD in type 1 diabetes. We present a definition of DD and consider it's associations with the important diabetes end points of glycaemic control, self-management behaviours and depression. Rates of elevated DD in research populations and the relative merits of screening for DD are considered. We present a systematic review of interventions for managing DD in clinical environments. The paper concludes with a number of research priorities to further our understanding of DD in people with type 1 diabetes.
Definition of Diabetes Distress

Diabetes distress (DD) reflects a range of different emotional response to patient’s perceptions of health threats balanced against an appraisal of available coping resources, and it is content-related necessitating a focus on distinguishing among the different sources of distress in diabetes so that specific interventions can be initiated (1). Esbitt et al (2) explain that DD is “predicated on a variety of medical, contextual and individual factors, not on the presence of a psychiatric condition” (p35).

Manifestation of Diabetes Distress in type 1 and type 2 diabetes

Some studies suggest that DD does not discriminate by diabetes type (3, 4), but it cannot be presumed that emotional problems are similarly experienced, and have the same consequences in Type 1 and 2 diabetes. Indeed, the most commonly reported emotional problems in Type 1 diabetes relate to hypoglycaemia and complications; worry about the future and complications, feeling burnt out/overwhelmed, and worrying about low blood sugar reactions (5-7), whereas in Type 2 diabetes emotional distress relates more to goal setting and food restrictions (7). Qualitative work confirms stressors unique to Type 1 diabetes; realisation of the possible consequences of previously poor self-management as adolescents, apprehension about pregnancy, anxiety about being perceived to have Type 2 diabetes, frustration competing for resources with Type 2 diabetes and a great many concerns specific to insulin use (8, 9). Our own case note documentary analysis observed differences in the manifestation of DD in the two populations (10). Type 1 case notes revealed core issues resulting in elevated DD being lack of diabetes control and fear of associated complications with common behavioural manifestations resulting in the maintenance of high blood glucose levels; low levels of blood glucose monitoring and medication non-concordance. In contrast, type 2 case notes indicated; isolation, work related issues, family demands, obesity and lack of knowledge. We found some diabetes distress themes reported in both type 1 and 2; neuropathic pain, fear of complications, fear of hypoglycaemia, poor sleep, loss of medication or diet control, dietary control (calorie restriction in type 2 and carbohydrate counting in type 1), loss of independence and lack of support. It is clear from this early understanding of differences in DD that different management foci may be required.

Diabetes Distress related to depression

Previous psychological research in diabetes has focussed on depression, but it is now apparent that there has been a lack of clarity and precision in the measurement of depression in diabetes (1, 11). Depression and DD are strongly associated in Type 2 (12) but also in Type 1 diabetes (9, 13). Prospective research in mixed diabetes samples suggests a bidirectional association (7, 14, 15), with
emerging evidence in Type 1 diabetes that DD exacerbates the risk of incident depressive symptoms two fold (16). Depression assessment constitutes a symptom count irrespective of cause or context, whereas DD reflects an emotional response to the adversity associated with living with and managing diabetes (11), and Fisher et al (1) explain that “exclusively symptom based depression scores most likely capture the affect component of DD” (p769). Qualitative studies suggest that where a person with type 1 diabetes has depression it is often related to their experience of diabetes (9, 17). Fisher et al (1) explain that emotional distress in diabetes should be considered “a single continuous dimension that has two primary characteristics: content and severity; that the primary content of emotional distress among these individuals include diabetes, it’s management, other life stresses and other contributors (e.g. personal characteristics, life history and genetics)” (p764). There is therefore a need to move beyond conceptualising ‘distress’ in diabetes as diagnosable depression and recognise the impact of disease-related factors on emotional well-being (18).

Measurement of Diabetes Distress
The concept of DD emerged alongside the development of the Problem Areas in Diabetes (PAID) scale (19), with later revisions resulting in the Diabetes Distress Scale (DDS) (20). We recently completed work to distinguish between measures of DD (unpublished data). The PAID was developed with a sample predominantly comprised of people with Type 1 diabetes (19), and the psychometric properties of the DDS for adults with Type 1 diabetes has recently been established (21). These measures have been extensively psychometrically evaluated in type 1 and type 2 diabetes (22), parents (23), adolescents (24) and languages and cultures (21, 25, 26). Qualitative work, however, suggests additional aspects of DD important in Type 1 diabetes are omitted from these measures; fear of hypoglycaemia, problems maintaining a normal work-life balance, fatigue (21), and guilt about social burden, for example the possibility of an emergency (9). As a result of these concerns, the Type 1 Diabetes Distress Scale (DDS-T1) was recently developed (27). The DDS and DDS-T1 are comprised of empirically established sub-scales such as the DDS emotional burden and regimen distress sub-scales (20, 27) and have been employed in research studies (28). Short forms and screeners such as the DDS2 and PAID-5 are also available (3, 29-31).

Relationship to endpoints in Type 1 diabetes

HbA1c
Cross-sectional evidence has consistently shown that any one point in time someone with elevated DD is likely also to have high HbA1c in type 1 diabetes (5, 32). However, DD is not prospectively
related to HbA1c when baseline HbA1c is controlled for; someone experiencing higher DD is not apparently at risk of increasing their HbA1c, or indeed developing high HbA1c, as a result of this initial distress, at follow up. (33) (34) However, some evidence in type 1 diabetes suggests that intervention related changes in DD are associated with changes in HbA1c with a marginally significant trend suggesting these concurrent changes are related although causality cannot be inferred (35). This mirrors findings in Type 2 diabetes (36). Furthermore, Weinger et al (2001) found that high baseline DD hampers improvement in HbA1 suggesting that interventions must address existing DD to evidence improvement in clinical outcomes(35). Some unpublished studies have failed to support an association between DD and HbA1c in Type 1 diabetes though (37, 38), suggesting a complex relationship between these variables that requires further exploration. DD has been shown to explain the relationship between depressive symptoms and HbA1c (3, 39). This mirrors evidence in mixed and Type 2 diabetes samples (7, 40-42).

**Self-management behaviours**
Cross-sectional evidence suggests that DD impacts self-management behaviors in Type 1 diabetes, namely less physical activity, poorer diet (21) and eating styles that are associated with overeating and high HbA1c (6) and insulin restriction (43, 44) . Other studies suggest DD is not associated with self-monitoring of blood glucose, smoking and alcohol consumption, and that its association with physical activity may be explained by more general emotional distress (13). This evidence base is very much underdeveloped at present, though. Martyn-Nemeth (2014) identified that there may be a level at which DD becomes immobilising resulting in fewer behaviours to avoid hypoglycaemia at very high levels of DD (6). Sturt et al (2015b) found that in type 1 and 2, people with elevated diabetes distress alongside psychological morbidity, including low mood, were unable to convert strongly desired self-care intentions into actions (10). Conversely, individuals with diabetes distress only were more successful at initiating self-care behaviours’ and developing self-efficacy indicating that DD alone is easier to target (10). Other mixed type and type 2 only studies have found that it is the co-morbidity of DD and depression that is associated with the highest levels of HbA1c (45-47). This suggests that when you have both DD and depression it impacts the most on self-management behaviours that aim to control glycaemia and becomes most difficult to resolve.

**Regimen distress and diabetes endpoints**
Research in Type 1 diabetes has explicitly demonstrated that the element of DD that appears to drive the aforementioned associations with HbA1c, and self-management behaviour, is regimen distress (6, 21, 33, 35, 39, 48). The smallest change in regimen distress which can be subjectively
realised by individuals, 0.5 SD change, is associated with a difference of 7 mmol/mol (0.6%) in HbA1c (39).

**Thresholds for, and rates of, clinically relevant DD**

No epidemiological studies have assessed for DD therefore all data on degrees of DD amongst people with diabetes and proportions of people with diabetes experiencing elevated DD are derived from interventional or cross sectional research studies which in itself results in a likely population bias. Investigators have used a range of thresholds across type 1 and 2 populations to define elevated DD from PAID scores in the low 30s (49, 50) to 45-50 (51, 52). Studies in Type 1 diabetes have endeavoured to establish the curvilinear relationship which has been observed in type 2 between DD and HbA1c, diet and physical activity (53). In Type 2 diabetes the shape of these relationships indicated thresholds for low (a DDS mean score of 1-2), moderate (a DDS mean score of 2-3) and high (a DDS mean score over 3) clinically relevant DD; each successive increase in DD is associated with a 0.5 SD increase in HbAc1 or decrease in self-management behaviour. However, the studies in Type 1 diabetes found no evidence of these relationships (21, 39), suggesting that emotional problems have different implications in Type 1 and 2 diabetes and that in Type 1 diabetes interventions can be applied, and will be effective, at any non-zero level of DD (21).

The majority of empirical studies to date have used thresholds of PAID ≥40 and a DDS >3 to indicate elevated DD (28). In scoping the literature we identified 11 studies which have reported proportions of type 1 populations with elevated DD (2, 21, 38, 47, 54-60). These proportions range from 8% (57) to 65% (2). Nearly half of these studies (combined population of 875 participants) reported proportions of participants with elevated DD of between 17-31% (38, 47, 58, 60, 61). The mean ages of participants in these studies was between 37-52 yrs with the largest study reporting on 466 participants, mean age 37yrs, finding 28% to have elevated DD (47). A large international study with 8,500 participants (DAWN 2 study), of which 16% were type 1, found 44.6 % of the study population to have elevated DD on the PAID 5 (62). The evidence suggest that 20-30% of people with type 1 diabetes will be experiencing elevated diabetes distress that will be affecting their self-management behaviours and their glycaemic control. Given that the majority of the evidence we have observed did not have psychological morbidity inclusion criteria and that those with psychological morbidity would be regarded as hard to reach and unlikely to volunteer for research participation, it is likely that this is an underestimation of the true picture.
Specifically in Type 1 diabetes, risk factors for DD include a longer duration of diabetes (21, 63) and episodes of severe hypoglycaemia (5). Age is also negatively correlated with DD (5, 21) with adolescents and younger adults endorsing feeling scared when thinking about living with diabetes, guilty about getting off track with diabetes management, unsatisfied with their diabetes physician, discouraged with their diabetes routine, and experiencing uncomfortable interactions about diabetes with family/friends as more serious concerns than do older adults with Type 1 diabetes (5). DD is greater for women than men (21, 49, 63, 64) with women also exhibiting higher prevalence of subcutaneous insulin infusion, greater self-monitoring of blood glucose and a higher level of motivation yet no difference in HbA1c level perhaps suggesting that greater effort in maintaining HbA1c is at the cost of higher DD (49). Interestingly women, but not men, with Type 1 diabetes have been shown to experience greater DD when they live without a partner, an effect that is partly explained by social support albeit the precise mechanisms of this association have yet to be established (65).

The pros and cons of screening

Routine psychosocial screening for DD and depression has been recommended at key time points in the care pathway, including; diagnosis, annual reviews, in-patient episodes, new complications, and when issues of glycaemic control, self-management and quality of life arise (66). The incorporation of psychosocial assessment and treatment into routine care, through a collaborative team approach, is recommended (11, 66, 67), however, no screening studies involving only the assessment for DD have been conducted solely in type 1 populations. These recommendations assume firstly that the screening process is effective in detecting vulnerable people, secondly that psychosocial care pathways are routinely available and thirdly that these services are acceptable to patients. Fleer (2013) found in a mixed type 1/type 2 sample that only 36 of the 104 participants found to have elevated DD accepted further referral to psychological services (57). With limited resources, Byrne et al (2012) argue that individuals likely to benefit the most should be targeted for intervention, including those with higher diabetes distress at baseline (50). Ironically, the hard to reach group that don’t respond to screening, have the most to benefit from it (57). Conflicting evidence exists concerning diabetes healthcare professionals capacity to clinically detect diabetes distress. Pouwer et al (2006) report under detection of DD by diabetes nurse specialists in 75% of patients with established distress (68). Conversely, Sturt et al (2015a) found that clinicians were able to detect elevated DD during their routine consultations (10). Clinicians may not seek to uncover DD if local psychological care services and care pathways don’t exist for the management of elevated DD. Fleer et al (2013) suggested that where integrated systems are not available we shouldn’t be screening (57). Undertaking service audit
to identify local prevalence of elevated DD may have greater merit enabling business cases to be developed for the provision of psychological care pathways in diabetes.

The treatment and management of Diabetes Distress: a systematic review

Methods

Given the relative novelty of clinical detection and management of DD in clinical practice outside of research studies, we sought to undertake a systematic approach to the identification and appraisal of effective treatment and management strategies. We updated a previous review of effective interventions for reducing DD in type 1 and type 2 populations (28). We searched Medline, Psychinfo and Embase from March 2013 to March 2015, for additional research studies reporting diabetes distress outcomes using the full PAID or DDS. From our previous review (28) 14 type 1 studies, were included. Figure 1 illustrates our combined flow diagram of included studies. The updated search identified 293 citations and two people assessed each. Mixed diabetes population studies were included where the type 1 population data could be reported separately. One further unique experimental study was included. Two papers, published post March 2015, were identified through personal contacts. Due to heterogeneity in both intervention and research design we undertook a narrative synthesis.

Figure 1. Flow diagram of included studies

Managing diabetes distress

Seventeen studies reporting DD related intervention outcomes specifically for adults with T1DM were identified; of these 8 were RCTs, and 9 were pre-post studies. The PAID was used in 15 studies and the DDS in 2 studies. These studies are described in Table 1. Reduction of DD was the sole or co-primary outcome in two studies (56, 69) and a secondary outcome in the remainder. This indicates that the majority of studies are not targeting DD but rather determining whether an intervention targeting another outcome, worsens or improves DD. Reduction of DD was reported in all studies, however not always significantly. Our synthesis has categorised interventions into three groups: Diabetes self-management education (DSME); Self-management with a psychological component and; Devices.
Table 1. Characteristics of intervention studies

Six studies investigated DSME interventions which aimed to reduce HbA1c by providing knowledge about diabetes and the technical skills needed to manage the condition and may include goal-setting and problem-solving. All DSME intervention studies but one (50) (who did not report significance levels) reported significant reductions in DD (35, 70-73) and in HbA1c when reported (35, 71, 72). The DSME Intervention studies were pre-post design and five of the six evaluated the DAFNE programme (Dose Adjustment For Normal Eating) and thus are generally more homogeneous which may account for the consistent positive impact on DD across these DSME interventions. The RCT studies of DAFNE (74) did not report DD as an outcome and so it is not possible to be definitively convinced that DSME, and DAFNE in particular, improved DD compared to controls. A study to evaluate the impact of the DAFNE program on people with elevated DD would be an important next step in the evaluation of both DAFNE and elevated DD.

Nine studies comprised our second category, self-management interventions with a psychological component. In addition to some degree of self-management education these studies have a psychological component focusing on the multidimensional aspects and perceptions of living with diabetes. These interventions aim to develop strategies to cope with the emotional stress of managing the disease and modify unhelpful cognitions. In addition, knowledge provided by the self-management components is utilised by focusing on experiential learning that influence behaviours, psychological adaptation and glycaemic control (56, 69, 75-81). The results of these were less clear regarding significant changes in DD. Four studies showed significant reductions of DD in addition to significant reductions in HbA1c (76, 77, 80, 81). Zoffmann et al (2015) showed significant reductions of both DD and HbA1c in women but not in men (78). In two pilot studies Snoek et al (2001) showed significant reductions in Hba1c and marginally significant reduction in DD (p=0.06) and Esbit et al (2014) reported an effect size of 0.34 relating to DD but no effect on Hba1c (69, 79). Likewise, Due-Christensen (2012) reported an effect size of 0.55 relating to reduction in DD (p ≤ 0.001) but no change in HbA1c was seen (56). Interventions were primarily delivered by diabetes educators. Psychologists or psychiatrists were part of the intervention in 6 studies (56, 69, 75, 76, 79, 81). The psychological intervention components were empowerment and supportive counselling, use of self-determination approaches, and Cognitive Behaviour Therapy (CBT).

Two studies tested the efficacy of devices, Continuous Glucose Monitoring (61) and Sensor Augmented Pump therapy (82). Pump-initiation with 3 individual sessions focusing on blood glucose control reduced DD as compared to Multiple Daily Injection (MDI) treatment (82). DD was not
affected negatively by use of CGM with either real time or retrospective bio-feedback (61).

The most common feature of effective interventions across the 17 studies was the group format which likely taps into natural social support, social learning theory and social comparison theory enabling people to establish a sense of normalcy and acquire positive vicarious learning experiences which successfully aid in breaking isolation and feelings of loneliness in living with type 1 diabetes (83). Groups aimed to share how participants addressed emotional or cognitive problems in relation to performing diabetes specific behaviours and challenges in coping with the demands of diabetes. Problem-solving, goal-setting, focus on motivational barriers and facilitators were also utilised. Homework sheets were used to develop person specific knowledge of illness perception and to enhance reflection on beliefs and attitudes towards diabetes that might need to be changed or reinforced. Studies using a group format and goal setting, problem-solving, reflection, written homework, motivational focus, supportive listening, cognitive restructuring, and addressing emotional challenges seem to offer greater reductions in DD and HbA1c.

The populations under study were predominantly mid-forties with diabetes duration of more than 13 years displaying levels of DD ranging from 20 to 44.4 on PAID with the majority scoring > 30. The review has identified a lack of interventions targeting elevated DD, aiming at emerging adults and also older adults. As it seems DD is present throughout the lifespan it would be important to address this during the early years of adulthood and also in the early stages of diabetes to prevent longstanding DD. In addition, interventions targeting older adults with DD relating to a more severe disease because of complications might be beneficial.

To summarise, the management of DD in type 1 is in its infancy in relation to both research evidence and clinical practice. DSME appears to reduce DD in type 1. Psychologically enhanced self-management interventions reviewed were more heterogeneous than the DSME, predominantly DAFNE, studies that we have reviewed. Nonetheless, these theory based interventions may have the potential to address elevated DD. Group based interventions appear to have merit.

Conclusions

Summary of evidence

This comprehensive review of the topic has identified that elevated Diabetes Distress is experienced by 20-30% of people with type 1 diabetes, that there are well validated scales for assessing DD and whilst many intervention studies have assessed for it, few have targeted elevated DD. There is a
rising imperative to clinically consider the role of elevated DD when providing routine care for type 1 populations. There is growing, albeit currently underdeveloped, evidence of a relationship between DD, self-management behaviours and glycaemic control. There is enough evidence though to warrant the further exploration of the role of elevated DD in influencing HbA1c and self-management behaviours crucial to good diabetes health such as blood glucose monitoring and insulin administration or restriction.

Controversial issues

Cross-sectional evidence developed in type 2 diabetes is contradictory and ambiguous; investigators have found DD to be independently associated with some self-management behaviours and to explain some, albeit not all, of the associations of depressive symptoms with these outcomes (42, 84), others have shown that it is depressive symptoms, not DD, that exhibits an independent association with self-management behaviours (40, 85). Whilst prospective research has found self-management behaviours specifically related to diabetes, and which directly influence HbA1c (i.e. medication adherence), are influenced by DD, whereas only depressive symptoms impacts other more lifestyle oriented behaviours including those that are recommended in diabetes (40). This evidence is not available in type 1.

Recommendations for further research

As the focus of DD research has shifted to Type 1 diabetes only very recently, many important questions remain. Much of the extant research is in younger adults, for example those aged 18-35 years. Most of the research in Type 1 has been done in Scandinavian countries, namely Norway and Denmark potentially limiting the generalisability of the findings. It remains unclear whether diabetes specialist clinicians are able to detect DD clinically within their routine consultations and, more so, what is the impact on detection rates when a clear care pathway for elevated DD exists? Diabetes population screening, using the available validated tools, is not appropriate in the absence of effectiveness and cost effectiveness evidence related to caseness. Research in these areas has not yet commenced.

People with DD and without co-morbid depression may be more responsive to intervention which presents a case for research to detect and manage DD. The prevalence and natural history of DD and DD with co-morbid depression is unknown at the diabetes population level. DSME appears to reduce DD in type 1 and many national diabetes policies recommend the routine provision of DSME. People experiencing elevated DD are likely to need greater support to achieve DSME participation but the
benefits to them may well out way the additional resource required to engage them in DSME. Research to evaluate the impact of DSME in patients with elevated DD is warranted. Evidence of one to one or ehealth/mhealth interventions, and research in older age participants, is lacking.

Work delineating the prospective, time-varying, associations between DD and HbA1c and self-management behaviours, whilst accounting for depressive symptoms, is required in Type 1 diabetes. Should these relationships be confirmed, it is critical to then establish the causal linkages between these variables, the pace of the associations, the complex interactive biological, behavioural and affective mechanisms/third variables involved, and the contextual and individual difference variable that determine these associations and their causal pathways (e.g. stage of disease, age, gender, burden of disease, presence of co-morbidities) (86). Once this evidence base has been established, there is a need to then develop and test interventions targeting DD, the mechanisms that underpin the association of DD and HbA1c, and specific sub-groups at risk of high DD and for whom the DD/HbA1c association is particularly strong, in order to maximise outcomes in Type 1 diabetes. Such studies should also elicit the mechanisms, mediators and moderators of any improvement in DD and other endpoints.

A few of these questions have been explored in type 2 diabetes and there is a need to continue to understand the similarities and differences in the causes and consequences of, and treatment options for, DD as they relate to type 1 and type 2 populations.

Compliance with Ethics Guidelines

Conflict of Interest
Jackie Sturt, Kathryn Dennick, and Kate McCarthy declare that they have no conflict of interest.
Mette Due-Christensen reports salary and research funding from Foundation of European Nurses in Diabetes ((FEND)) and salary from Steno Diabetes Centre. Dr. Due-Christensen is presently employed at Steno Diabetes Centre A/S. Steno Diabetes Centre is a research hospital and an integrated part of the public Danish National Health Service that is owned by Novo Nordisk A/S. Steno Diabetes Centre receives part of its core funding from unrestricted grants from the Novo Nordisk Foundation and Novo Nordisk A/S. Dr. Due-Christensen owns shares in Novo Nordisk. No potential conflicts of interest relevant to this article exist.

Human and Animal Rights and Informed Consent
This article does not contain any studies with human or animal subjects performed by any of the authors.
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79. Esbitt SA, Batchelder AW, Tanenbaum ML, Shreck E, Gonzalez JS. “Knowing That You’re Not the Only One”: Perspectives on Group-Based Cognitive-Behavioral Therapy for Adherence and Depression (CBT-AD) in Adults With Type 1 Diabetes. Cognitive and Behavioral Practice. 2014 (0).
Fig 1: Flow diagram of included studies

Citations from 2013-15 search
N=293 (with duplicates removed)

Abstracts assessed for eligibility
(n=293)

Type 1 (n=68) and Mixed (n=58) full text papers reviewed

Excluded n=125
76 Conference papers
12 Duplicates
16 Non-extractable T1 data
5 Paediatric
2 German
1 Literature review
1 No DD measure
1 Unable to obtain
10 Cross Section
1 Longitudinal

Included (n=1)

Identified through key contacts (n=2)

Included from previous review
Sturt et al 2015 (n=14)

Included
(n=17)

RCT = 8
Pre/Post = 9
<table>
<thead>
<tr>
<th>Reference, Year, Country, Methodology</th>
<th>Recruited, Randomised Control Trials</th>
<th>Mean Age, Intention-to-treat Y/N</th>
<th>Diabetes Distress Measure</th>
<th>Baseline Male%</th>
<th>Duration</th>
<th>Baseline HbA1c (I/C)</th>
<th>Intervention description</th>
<th>Specialty of therapist</th>
<th>Control Group</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zoffman, 2006, Denmark, RCT (78)</td>
<td>61, I: 61 / C: 25, 12m, N, NR, PAID</td>
<td>36yrs</td>
<td>1:32 (3.4)</td>
<td>I: 46 C: 50</td>
<td>1:1:100%</td>
<td>C: 40.9 (0.2)</td>
<td>Empowerment: theory based, self-determination theory (SDT), self-directed written materials encouraging reflection, goal and problem solving oriented; supportive listening, motivational focus. Group face-to-face, by diabetes educator, 7x 2hour sessions over 8 weeks.</td>
<td>Supportive listening, motivational focus</td>
<td>No specific instructions given; 2x maintenance group sessions, 2x individual sessions and 5 phone calls Log book for self-care activities and emotions, homework to enhance reflection upon self-care, supportive counselling delivered by a diabetes specialist nurse and psychologist.</td>
<td>PAID I: 25.6 (2.7); C: 36.7 (4.5), (p=0.05)</td>
</tr>
<tr>
<td>Hermanns, 2009, Germany, RCT crossover (62)</td>
<td>50, 50 crossover, 12wks, 14.75 (11.9), PAID</td>
<td>42yrs</td>
<td>30.7</td>
<td>I: 17.8 C: 18.8 (10.9)</td>
<td>1:100%; T1: 100%</td>
<td>I: 8.8 (1.3); C: 9.1 (1.1)</td>
<td>Theory based CBT, addressing psychological barriers to diabetes self-management, reframing of negative beliefs, written homework assignments. 6x group sessions delivered weekly by a psychologist.</td>
<td>Supportive listening, motivational focus</td>
<td>No specific instructions given; 2x maintenance group sessions, 2x individual sessions and 5 phone calls Log book for self-care activities and emotions, homework to enhance reflection upon self-care, supportive counselling delivered by a diabetes specialist nurse and psychologist.</td>
<td>PAID I: 34.3 reduced to 38.3; C: 49.0 reduced to 45.4 (Intervention x time, 6 months p=0.09; 12 months p=0.68)</td>
</tr>
<tr>
<td>Amsberg, 2009, Sweden, RCT (77)</td>
<td>74, 48wks, 1:36 / C: 38, 49, (20.4)</td>
<td>41yrs</td>
<td>131.1 ≥7.5</td>
<td>I: 21.6 (10.8)</td>
<td>1:100%; T1:100%</td>
<td>C: 33.4 (17.3)</td>
<td>Order of condition randomized.</td>
<td>Supportive listening, motivational focus</td>
<td>No specific instructions given; 2x maintenance group sessions, 2x individual sessions and 5 phone calls Log book for self-care activities and emotions, homework to enhance reflection upon self-care, supportive counselling delivered by a diabetes specialist nurse and psychologist.</td>
<td>PAID I: 22.92; C: 29.8 (p=0.004)</td>
</tr>
<tr>
<td>Hermanides, 2011, European, RCT (83)</td>
<td>83, I: 22 / C: 21, 26wks, 16.9 (19.7), PAID</td>
<td>39yrs</td>
<td>1:32.4</td>
<td>I: 37yrs C: 37yrs (18.0)</td>
<td>1:100%; T1:100%</td>
<td>I: 8.45 (0.95)</td>
<td>Sensor augmented insulin pump treatment, 26 weeks. 1st 13 weeks no specific instructions given; 2nd 13 weeks advised to carbohydrate count.</td>
<td>Supportive listening, motivational focus</td>
<td>No specific instructions given; 2x maintenance group sessions, 2x individual sessions and 5 phone calls Log book for self-care activities and emotions, homework to enhance reflection upon self-care, supportive counselling delivered by a diabetes specialist nurse and psychologist.</td>
<td>PAID I: 21.0 (19.3) (p=0.03) in favour of Sensor-Augmented Insulin Pump Group. Sensor augmented insulin pump therapy was associated with an improvement in diabetes related distress.</td>
</tr>
</tbody>
</table>
Insulin dose adjustment according to food intake aiming at knowledge and self-management, behavioural strategies, with diabetes, Theory based CBT, group session, to improve coping individual provided).

8 weeks educational programme either BGAT or diabetes nurse to optimise glycaemic control diabetes clinic MDT, weekly phone contact from nurse specialists.

Diabetes motivation strengthening Empowerment to- treated Y/N, -treated C:19.6 (12.8) to C:46yrs, C:35.2 (11.2) to C:35yrs, (16.0)

Family members or other close relations were invited to attend one session on social support. Delivered by diabetes educators.

Control: usual DSME programme: written materials, health professional delivered, 12x 90min group sessions. Empowerment/self-management theory based, CBT, Diabetes motivation strengthening (DIAMOS) for patients with subclinical depression, 5x 90min group sessions plus telephone support. Coping with diabetes related challenges, goal setting and problem-solving, motivational strategies, self-directed written materials. Delivered by diabetes psychologist.

Control group 5x 90min group education intervention delivered by a healthcare professional.

PAID: Difference between I & C (p<0.001); I: (Men -2.6; Women -15.3) (p=0.0024)

The flexible self-directed determination intervention benefitted younger adult women by significantly improving glycaemic control and decreasing diabetes related distress. No effect was seen among men. HbA1c: I-0.4%; C: 0.1% (p=0.073)

<table>
<thead>
<tr>
<th>Reference, Year, Country, Methodology</th>
<th>Recruited, I/C group size, Duration of follow-up, Primary outcome, Diabetes Distress Measure</th>
<th>Mean Age, Male%, T1%, Diabetes duration</th>
<th>Baseline Diabetes Distress (I/C)</th>
<th>Baseline HbA1c % (I/C)</th>
<th>Intervention regime and model</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hermanns, 2013, German, RCT (81)</td>
<td>160, 6m, Y, HbA1c, DDS</td>
<td>4.7yrs, 64yrs, T1: 62%, T1:100%, C:19.3 (13.4)</td>
<td>1.2</td>
<td>8.3 (1.1);</td>
<td>Empowerment/self-management theory based, (PRIMAS), written materials, homework, problem solving, goal setting according to addressing emotional problems, 12x 90min group sessions twice weekly over 6 weeks, Family members or other close relations were invited to attend one session on social support. Delivered by diabetes educators. Control: usual DSME programme: written materials, health professional delivered, 12x 90min group sessions.</td>
<td>DDS: I -0.3 (0.7); C -0.1 (0.4) (p=0.032) The intervention was superior in reducing diabetes distress, HbA1c and increasing empowerment, self-efficacy and satisfaction with insulin therapy. Both groups improved awareness of hypoglycaemia, diabetes knowledge, self-care behaviour and reduced severe hypoglycaemia incidents with no significant between group differences. HbA1c in I compared to C (-0.4 ± 1.5% vs. 0.0 ± 0.6%) (p &lt; 0.012)</td>
</tr>
<tr>
<td>Hermanns, 2015, German, RCT (82)</td>
<td>214, 12m, Y, Depressive symptoms, PAID</td>
<td>43yrs, 59%, T1:100%, C:14.2 (10.5)</td>
<td>40.3 (3.4)</td>
<td>8.9 (1.8)</td>
<td>Empowerment/self-management theory based, CBT, Diabetes motivation strengthening (DIAMOS) for patients with subclinical depression, 5x 90min group sessions plus telephone support. Coping with diabetes related challenges, goal setting and problem-solving, motivational strategies, self-directed written materials. Delivered by diabetes psychologist. Control group 5x 90min group education intervention delivered by a healthcare professional.</td>
<td>PAID: I -13.0 (18.9) (p&lt;0.001); I: 0.2 (16.9) (p=0.022) Type 1 specific: more T1 in control group; analysis stratified by diabetes type no significant interaction effects observed except diabetes acceptance (less impact on diabetes acceptance in T1 than T2), DIAMOS efficacious in treating sub-threshold depression and elevated Diabetes Distress more effectively than education alone. Additionally it prevents deterioration from sub to major depression. HbA1c: I-0.5 (2.0) p=0.018; C: 0.7 (17) p=0.001</td>
</tr>
<tr>
<td>Zoffman, 2015, Denmark, RCT (79)</td>
<td>200, 15m, Y, HbA1c, PAID</td>
<td>26yrs, 100%, T1:100%, C:17.3 (6.8)</td>
<td>36.4 (20.0)</td>
<td>9.5 (1.3);</td>
<td>Empowerment theory based SDT, self-directed written materials encouraging reflection, goal and problem solving oriented, supportive listening, motivational focus. 7x either 1hr individual sessions or 2.5hr group sessions, over max 12 months. Delivered by diabetes nurse specialists. Control group received usual care (3-4 monthly appointment with diabetes specialist).</td>
<td>PAID: Difference between I &amp; C (p&lt;0.001); I: (Men -2.6; Women -15.3) (p=0.0024)</td>
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Pre/Post Intervention Studies

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<tr>
<th>Recruited, I/C group size, Duration of follow-up, Primary outcome, Diabetes Distress Measure</th>
<th>Mean Age, Male%, T1%, Diabetes duration</th>
<th>Baseline Diabetes Distress (I/C)</th>
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<tbody>
<tr>
<td>Weiniger, 2001, American, Pre/Post (36)</td>
<td>55, 6m, Y, Emotion/Attitude barriers, PAID</td>
<td>44yrs, T1:100%, C:40.0 (3.4)</td>
<td></td>
<td>Medical/education programme, 8 weeks with monthly diabetes clinic MDT, weekly phone contact from diabetes nurse to optimise glycaemic control in addition 8 weeks educational programme either BGAT or cholesterol education (no information on group or individual provided).</td>
<td>PAID reduced from 40 to 31 (p&lt;0.01) Newly learned self-management needs assistance to be incorporated into lifestyle. Intervention needs to help identify potential barriers and the necessary steps to achieve self-management goals. PAID particularly useful as a screening tool for patients attempting to improve glycaemic control. HbA1c 9.0% to 7.8% (p&lt;0.0001) PAID reduced 39.9 (16.0) to 31.2 (17.4) (p&lt;0.06) CBGT is feasible in a poorly controlled group; Perceived barriers were decreased significantly; general wellbeing was maintained. HbA1c reduced 9.3% (12) to 8.5% (9.9) (p=0.04);</td>
</tr>
<tr>
<td>Snoek, 2001, Dutch, Pre/Post (70)</td>
<td>24, 6m, N, HbA1c, PAID</td>
<td>35yrs, T1:100%, C:39.9 (38)</td>
<td></td>
<td>Theory based CBT, group session, to improve coping with diabetes, cognitive restructuring, stress management, supportive strategies, and homework. 4x1.5hrs weekly sessions delivered by a diabetes nurse specialist and diabetes psychologist.</td>
<td>PAID 25 (15-45) reduced to 16.25 (10-30) (p&lt;0.0001) Improved glycaemic control; reduced severe hypoglycaemia incidents, improved QOL. HbA1c reduced 8.2% to 7.8%</td>
</tr>
<tr>
<td>McIntyre, 2010, Australia, Pre/Post (74)</td>
<td>145, 12m, N, HbA1c</td>
<td>43yrs, T1:100%, C:25.0 (15-45)</td>
<td></td>
<td>DAFNE programme, theory based, 5 consecutive whole days delivered in groups, to increase diabetes knowledge and self-management skills relating to insulin dose adjustment according to food intake aiming to</td>
<td>PAID 25 (15-45) reduced to 16.25 (10-30) (p&lt;0.0001) Improved glycaemic control; reduced severe hypoglycaemia incidents, improved QOL. HbA1c reduced 8.2% to 7.8%</td>
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<td>Reference, Country, Methodology</td>
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<td>Engle, 2011, Australia, Pre/Post (71)</td>
<td>144, NA, 12m, Wellbeing &amp; coping, PAID</td>
<td>45yrs, 35, T1:100%, 17.7 (12.42)</td>
<td>1:31.94 (18.27)</td>
<td>NR</td>
<td>DAFNE programme (See McIntyre 2010)</td>
</tr>
<tr>
<td>Keen, 2013, UK, Pre/Post (73)</td>
<td>124, NA, 12m, N, HbA1c, PAID</td>
<td>43yrs, 56, T1:100%, 17.8 (11.0)</td>
<td>20 (12.5-33.8)</td>
<td>8.6%</td>
<td>DAFNE programme (See McIntyre 2010)</td>
</tr>
<tr>
<td>Byrne, 2012, UK, Pre/Post (51)</td>
<td>437, NA, 18m, N, Predictors of QOL outcomes, PAID</td>
<td>41yrs, 46, T1:100%, 15.9 (10.8)</td>
<td>PAID ≥ 33: 166/423, PAID &lt; 32: 257/423</td>
<td>8.3 (1.4)</td>
<td>DAFNE programme (See McIntyre 2010)</td>
</tr>
<tr>
<td>Due-Christensen, 2012, Denmark, Pre/Post (57)</td>
<td>54, NA, 12m, N, Diabetes related distress, PAID</td>
<td>44yrs, 20, T1:100%, 21 (11.7)</td>
<td>37.36 (16.16) ≥40: 29</td>
<td>8.2 (1.3)</td>
<td>Empowerment theory based, 8 x 2hr 15min group sessions over 3-4 months, peer directed themes e.g. fear of complications, role of the social network, acceptance of diabetes. Motivational strategies, homework sheets to enhance reflection, goal setting, and problem-solving. Delivered by MDT.</td>
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<tr>
<td>Hopkins, 2012, UK, Pre/Post (72)</td>
<td>639, NA, 12m, N, Impact in routine practice, PAID</td>
<td>42yrs, 25.2, T1:100%, 18.0 (12.1)</td>
<td>8.51 (1.41)</td>
<td>DAFNE programme (See McIntyre 2010)</td>
<td>PAID: 25.2 (17.4) reduced to 16.7 (14.1). (p&lt;0.001) DAFNE reduces diabetes related distress, improves well-being, reduces glycaemic rates and restores hypoglycaemia awareness. HbA1c fell by 0.27% (p&lt;0.001)</td>
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<tr>
<td>Edge, 2014, American, Pre/Post (80)</td>
<td>11, NA, 3m, N, Feasibility of group CBT, DDS</td>
<td>40yrs, 3.19, T1:100%, 22.30yrs (11.69)</td>
<td>8.56 (1.04)</td>
<td>Theory based CBT, group-based intervention for depression and adherence, 10x 60-90min sessions over 10 weeks: self-management, depression and diabetes related distress in an integrative manner including; problem solving, goal setting, motivational consultation,</td>
<td>DDS Pre 3.19 (0.97), Post 2.82 (0.98) (Cohen’s d=0.34) Participation in a group CBT was acceptable, associated with reductions in diabetes distress and depressive symptoms. HbA1c mean pre score 8.56% post score 8.73% (Cohen’s d = -0.08)</td>
</tr>
</tbody>
</table>

at patient autonomy, delivered by diabetes specialists MDT.
Table 1. Characteristics of intervention studies