Predictors Of Anxiety During The Perinatal Period In Women With Gestational Diabetes.

Volume I: Literature review, empirical paper and public domain paper.

By

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To Craig and Lily

for your endless patience, love and support.

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Overview

This thesis is submitted in partial fulfilment of the requirements for the degree of Doctor of Clinical Psychology (Clin.Psych.D) at the University of Birmingham. The thesis is divided into two volumes; research and clinical.

Volume 1: Research component.
This volume comprises three papers relating to type 1 diabetes in children and adolescents and gestational diabetes in pregnant women. The first paper is a review of the literature examining characteristics of Coping Skills Training and its impact on metabolic control and psychosocial outcomes in children and adolescents with type 1 diabetes. The second paper presents research exploring anxiety in pregnant women with gestational diabetes. It examines whether diabetes specific risk factors are associated with anxiety in this population of women over and above general risk factors known to be linked with anxiety. The third paper is a public domain paper briefly describing the key findings from the literature review and research paper and is intended for dissemination to participants and health professionals. An appendix section contains information regarding ethical approval, the measures used and the participant study information pack.

Volume 2: Clinical component.
This volume contains five Clinical Practice Reports (CPR) submitted throughout the duration of the doctoral course. CRP1 describes school related anxiety in a twelve year old boy formulated from a CBT and systemic perspective. CRP2 is the evaluation of a child and adolescent mental health cognitive behavioural therapy service. CPR3 is a case study describing a neuropsychological assessment for dementia in a seventy six year old gentleman. CPR4 presents a single case experimental design evaluating the effectiveness of cognitive behavioural therapy in the treatment of obsessional compulsive disorder in a thirty four year old woman. CPR5 contains the abstract of a presentation describing the formulation of challenging behaviours presented by a four year old boy from an attachment perspective. All names and identifying information has been changed to protect anonymity.

Volume I – Research

Volume II – Clinical Practice Reports

The impact of Coping Skills Training on metabolic control and psychosocial outcomes in children and adolescents with Type 1 Diabetes: A systematic review of the literature.

Abstract

Background: The treatment of type 1 diabetes includes daily injections of insulin and requires attention to diet, exercise, and monitoring of blood glucose levels. Coping Skills Training is an intervention based on social learning theory and aims to develop an individual's skills and ability to cope with the stressful situations related to managing diabetes on a daily basis.

Aim: This paper has reviewed the literature examining the impact of Coping Skills Training on metabolic control and psychosocial outcomes in children and adolescents and aims to: (1) Describe and compare the characteristics of CST across the available literature, (2) Provide a quality assessment of studies evaluating CST, (3) Describe the impact of CST on metabolic control and psychosocial variables in children and adolescents, in light of the quality assessment.

Method: A keyword search in Embase, Medline, PsycINFO and Pubmed Central databases yielded a total of 15 quantitative articles using a variety of designs.

Results: The small number of well-designed studies indicated that metabolic control is not improved in a limited population of children who participate in CST. However the results in adolescents are more promising.

Conclusions: The evidence on whether CST can improve psychosocial outcomes in children and adolescents is mixed and appeared dependent on the mode of delivery and whether CST is compared to routine care or diabetes related education. A summary of recommendations for future research is provided along with the clinical implications of the results described in this review.

Introduction

Type 1 Diabetes Mellitus (T1DM) is a disorder of the endocrine system, characterised by a deficiency in the production of insulin by the pancreas. The management of T1DM requires a regimen of insulin injections, attention to diet, exercise and blood glucose monitoring. Poor management is linked to serious long-term complications (Insabella, Grey, Knafl & Tamborlane, 2007). Diabetes self-management and the training of these skills is an important part of the clinical regimen and aims to enhance psychosocial outcomes and improve metabolic control to prevent complications (Norris, Engelau & Venkat Narayan, 2001).

The diagnosis of T1DM is most common in middle childhood and adolescence (Grey, Kanner & Lacey, 1999) and can present physical, mental and emotional challenges (Guthrie, Bartsocas, Jarosz-Chabot, Konstantinova, 2003). Developmental factors need to be taken into consideration when training young people in self-management skills (Guthrie et al., 2003). School age children are mostly dependent on their parents for diabetes management. However, the development of concrete operational thinking means that children of this age are able to think logically and understand the concept of concrete rules. This can facilitate the learning of self-care techniques (Grey et al., 1999). Adolescents are in the process of making sense of their own identity and are beginning the struggle for independence from family. Acceptance within a peer group is important for self-identity and being different in any way is challenging (Borus & Laffel, 2010). Compared to earlier childhood, adolescents are able to conceptualise abstract ideas and think through complex problems, which can be applied to self-management (Grey et al. 1999). However, their sense of immortality, risk taking and greater insulin resistance due to pubertal physiological changes can present difficulties in effective diabetes management (Borus & Laffel, 2010).

Previous literature indicates that children with a chronic illness are at an increased risk of psychosocial distress (Barlow & Ellard, 2006). However, good coping skills and access to good multidisciplinary resources and education can reduce this distress (Wagner, Muller-Godeffroy, Von Sengbusch, Hager & Thyen, 2005). Diabetes problem solving ability and higher self-efficacy have been found to predict greater self-care responsibility in adolescents (Holmes, Chen, Streisane,

Souter, Swift & Peterson, 2006). Previous research suggests that education on the importance of treatment adherence is relatively ineffective and the psychological and social factors underpinning treatment adherence need to be addressed in interventions (Jacobson et al., 1990). The American National standards for diabetes self-management education (Funnell et al., 2007) has identified healthy coping as essential for effective diabetes management.

Coping is defined as the "conscious and volitional effort to regulate emotion, cognition, behaviour, physiology and the environment in response to stressful events or circumstances" (Compass, 1998, p232). Coping styles have been found to be associated with social adjustment to diabetes, self-esteem and externalising behaviour problems (Meijer, Sinnema, Bijstra, Mellenbergh & Wolters, 2002). Previous research has found that adolescents with poor self-management of diabetes tend to use more avoidant and negative coping strategies, such as wishful thinking and self-blame (Grylli, Wagner, Hafferl-Gattermayer, Schober & Karwautz, 2005). In contrast more adaptive styles such as problem-focused strategies (e.g. sharing aspects of diabetes management with peers) are associated with better outcomes (Grey, Cameron & Thurber, 1991).

Coping Skills Training (CST) is an intervention based on social learning theory which proposes that individuals can develop skills to actively influence their ability to cope in stressful situations and that if these skills are practiced and rehearsed, self-efficacy will be enhanced and positive health related behaviours increased. It is hypothesised that improving coping skills in young people will improve their ability to cope with the daily stressors of managing diabetes, e.g., adhering to a healthy diet when eating out with friends (Grey, 2011; Grey & Berry, 2004).

The elements involved in CST include learning the skills involved in social problem solving, effective and assertive communication, cognitive behavioural modification, stress management and conflict resolution. Social problem solving is aimed at equipping young people with the skills necessary to handle and problem solve situations related to their diabetes and its management (Grey, 2011). Individuals are taught a problem solving structure based on that by Forman, Linney and Brondino (1990) which enables them to identify and define a problem and the desired goal; generate as many possible solutions to the problem; evaluate each

solution and its consequences; identify the preferred solution and then evaluate the outcome. CST also involves teaching communication skills with the aim of teaching individuals how to use “direct, honest and appropriate” ways of communicating with others about their diabetes which results in a positive outcome for all parties concerned (Grey & Berry, 2004, p127). Additionally, cognitive behavioural modification is used to help individuals to understand how their thoughts and feelings about their diabetes are linked and how this relates to their behaviour and diabetes management. Individuals are helped to see how generating alternatives to negative diabetes related thoughts can facilitate self-management. Group members are also taught skills in how to resolve conflict effectively so that the needs of all those involved (e.g. themselves, peers, parents or health care providers) can be taken into consideration using clear communication and problem solving skills. A variety of teaching methods are employed including role play, modelling of behaviours and skills, group discussion and didactic teaching.

The UK National Institute of Clinical Excellence (NICE; 2004) guidelines suggest research is needed to evaluate the effectiveness of behavioural and social interventions for managing psychosocial issues and non-adherence to treatment in children and young people. However, the content of such interventions are diverse (Gage, Hampson, Skinner, Hart, Storey, Foxcroft, Kimber, Cradock & McEvilly, 2004) and previous reviews of studies evaluating the efficacy of interventions tend to present outcomes from a heterogeneous range of interventions. This makes it difficult to distinguish between which interventions have greater efficacy in achieving the proposed outcomes and with what type of population, e.g. individual’s with poor levels of glycaemic control or those with high levels of mood disorders (Steed, Cooke & Newman, 2003). This is further compounded by the often poor description of what components constitute each intervention (Steed et al., 2003). To address these points in the current review it was decided to focus on Coping Skills Training and provide a synthesis of the findings of this particular intervention to date.

The focus on CST was decided upon because over the last thirty years a growing number of studies have examined CST in young people with T1DM, however, there has been no systematic review of this literature to date. Grey (2011) and

Grey & Berry (2004) have presented findings on studies of CST in young people with T1DM, but these were not systematic reviews, nor did they assess and critique the methodological quality of the studies in relation to the findings discussed. In addition, there was no description of the various components included in individual study interventions to facilitate comparisons across studies.

To address this latter point, in the current review, a structure was used to describe and compare the various components of the CST interventions presented in each paper. This structure was based on a taxonomy developed by Elasy, Ellis, Brown & Pichert (2001). The original taxonomy was designed to characterise the elements specifically within diabetes education interventions. However, recent education interventions do not focus solely on providing information on diabetes. Education programs now include a variety of techniques including technical skills training, behavioural approaches, problem solving skills and concern for the individual's diabetes related beliefs, attitudes and wellbeing (Steed, Cooke & Newman, 2003). The Elasy et al. (2001) taxonomy was designed to describe and compare these refined education programs and it was considered that the teaching process and elements of these interventions had considerable overlap with the process, content and implementation of CST. In addition, previous reviews of both diabetes education and psychosocial interventions have used structures similar to the Elasy taxonomy (e.g. Murphy, Rayman & Skinner, 2005; Gage et al., 2004), therefore it was considered that the main elements within this taxonomy provided a consistent structure relevant to the components found in CST and would facilitate the description and comparison of the interventions presented in each study.

Aims and Objectives

There are insufficient numbers of well-designed, experimental studies on CST to support a meta-analysis of the data; therefore this paper aims to present a systematic narrative review of articles irrespective of study methodology. The current review therefore aims to address the issues discussed and has three objectives; (1) describe and compare the characteristics of CST across studies using the Elasy et al., (2001) taxonomy, (2) provide a quality assessment of

studies evaluating CST, (3) describe the impact of CST on metabolic control and psychosocial variables in children and adolescents, in light of the quality assessment.

Method

A keyword search in Embase, Medline, PsycINFO and Pubmed Central databases from 1948 to November 2011 was performed. To ensure the focus of the search was on Coping Skills Training rather than on other types of diabetes related interventions, the following specific key terms were used; “coping skills” and “diabetes” or “diabetes mellitus” and “adolescen*” or “child*”. Searches were limited to the English language and age (children 7-12 years and adolescents 13-17 years). Table 1 shows the search results.

Table 1; Database search results:

Database	**Results**			
	Total hit	Limit (English language and adolescents/ children)	Articles rejected	Articles retained
Embase	72	27	20	7
Medline	56	20	15	5
PsychINFO	53	17	14	3
Pubmed	305	282	275	7

The title and abstract of each article was read and retained on the following criteria:

- The study was an evaluation of coping skills training (excluding reviews).
- Sample consisted of adolescents and/or children with type 1 diabetes.
- Outcomes included psychosocial factors and/or metabolic control.
- A quantitative (or mixed methods) design was used.

From the database search, 22 articles were identified as fulfilling the inclusion criteria. However, 6 articles were duplicated, therefore 12 articles were retained. A search of the reference section of the resulting studies was also conducted and a further 3 studies were identified as relevant, resulting in a total of 15 articles

retained for the review. Two of the fifteen papers identified in the search were oral presentations of relevant research given at an international conference. The authors of both reports were contacted and it was established that neither research project had yet been published in full but due to the limited number of studies available it was decided to include the papers within this review.

Data on the characteristics of eligible studies were extracted, including information on each intervention using the Elasy et al., (2001) taxonomy. A quality assessment was conducted using a validated framework (QualSyst; Kmet, Lee & Cook, 2004; Lee, Kmet, Lorenzetti, Godlovitch & Einsiedel, 2005) which enabled assessment of a diverse range of study designs. The assessment covers quality of reporting, internal validity (selection bias, performance bias, measurement bias, attrition bias) and external validity (generalisation of results). Previous reviews on diabetes education and psychological interventions (e.g. Norris, Engelgau and Narayan 2001; Winkley, Landau, Eisler & Ismail, 2006) suggest it is infeasible to blind participants to which group they have been assigned, therefore this has not been used as a validity criterion in this review.

Results

Study characteristics

Study characteristics of the reviewed articles are presented in table 2 and show that of the fifteen articles identified, four involved children (Ambrosino et al., 2008; Grey et al., 2009; Gross et al., 1983; Gross et al., 1982) and the remaining twelve involved adolescent samples. From the total sample, eleven discrete studies were identified (3 children and 8 adolescent). In this review, discrete studies are defined as the article that first presents the original study, follow-up articles report on analysis conducted on follow-up data of the original study and are included in this review. A variety of designs were used across studies, including case studies using multiple base line methodology (Gross et al., 1983; Gross et al., 1982; Johnson et al., 1982), non-randomised control trial (Mendez & Belendez, 1997) and experimental Randomised Controlled Trials (RCT) (Ambrosino et al., 2008; Boardway et al., 1993; Grey et al., 2009; Grey et al., 1998; Kaplan et al., 1985;

Table 2; Study Characteristics

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
Children					
1.	Ambrosino, Fennie, Whittemore, Jaser, Dowd & Grey (2008). USA	I n=49, C n=30 Group diabetes Education (GE) 8 - 12 years & parent. 4 years.	Prospective RCT	CHILD; HbA1c (at each clinic visit), diabetes related coping, diabetes related self-efficacy, diabetes QoL, diabetes family behaviours. PARENT; diabetes related coping, depressive symptoms, diabetes conflict, family adaptability. (baseline, 1 & 3 month follow-up)	Metabolic control: CST did not have a differential effect on HbA1c compared to GE group at 3 month follow-up. Psychosocial: CST did not have a differential effect on any psychosocial outcomes compared to GE group at 3 month follow-up. Both groups showed significant improvement on all psychosocial outcomes over time, except for medical self-efficacy & perceptions of family behaviour. Parents: CST group reported > change in flexibility in family roles compared to GE.
2.	Grey, Whittemore, Jaser, Ambrosino, Lindemann, Liberti, Northrup & Dziura (2009) USA	I n=53, C n=29 Group diabetes Education (GE) 8 - 12 years. 4 years.	Prospective RCT	HbA1c, (at each clinic visit),depressive symptoms, diabetes related QoL, coping, self-efficacy & family functioning. (baseline, 1, 3, 6 & 12 month).	Metabolic control: CST did not have a differential effect on HbA1c compared to GE group at 6 & 12 month follow-up. Psychosocial: CST did not have a differential impact on Qol, depressive symptoms, coping, self-efficacy or family functioning. Significant improvement over time for both groups on QoL (worry), depressive symptoms, coping & self-efficacy. Significant reduction over time in both groups on parental guidance & control.

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
3.	Gross, Heimann, Shapiro & Schultz (1983) USA	I n= 6, C n=5 Routine care. 9-12 years. Not stated.	Multiple baseline across behaviours design	HbA1c: Diabetes related social skills (Baseline, on completion of each training session, posttest, 1 & 6 week follow-up).	Metabolic control: CST did not have a differential effect on HbA1c levels compared to control group. No improvement over time in both groups. Psychosocial: sequential introduction of CST showed > eye contact & appropriateness of verbalisations from baseline. Maintained at 1 and 5 week follow-up. Speech duration and overall affect gradually > over time.
4.	Gross, Johnson, Wildman & Mullett. (1982). USA.	N=5 No control. 9-12 years. Not stated.	Multiple baseline across behaviours design.	Diabetes related social skills (Baseline, on completion of each training session, 1 & 5 week follow-up).	Metabolic control: Not measured. Psychosocial: sequential introduction of CST showed an increase in eye contact & appropriateness of verbalisations from baseline. No changes in target behaviours observed in control group.
Adolescents					
5.	Boardway, Delamater, Tomakowsky & Gutai (1993) USA.	I n=9, C n=10 Routine care. 12 - 17 years. 6 years.	Prospective RCT	HbA1c, diabetes specific distress, coping, diabetes related self-efficacy, regimen adherence, life events (at 9 month follow-up), consumer satisfaction(at 9 month follow-up). (Baseline, 3, 6, 9 month follow-up)	Metabolic control: CST had no significant differential effect on HbA1c levels compared to control group. Psychosocial: CST showed significant improvement in diabetes specific stress over time compared to control group. No significant treatment effects for maladaptive coping, diabetes related self-efficacy, regimen adherence.

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
6.	Grey, Boland, Davidson, Yu, Sullivan-Bolyai & Tamborlane (1998). USA	I n=34, C n=31 Intensive insulin treatment alone 12-20 years. 7.6 years.	Prospective RCT	HbA1c, diabetes self efficacy, depressive symptoms, coping with diabetes, Diabetes related QoL, frequency of hypoglycemic events, weight gain. (baseline, 3 months follow-up).	Metabolic control: significant improvement in HbA1c levels from baseline to 1 month follow-up in both groups (due to intensified treatment). HbA1c fell significantly faster & to a greater extent in CST group compared to control group at 1 month post initiation of intensive therapy & maintained at 3 months. Psychosocial : CST group showed a significant increase in self-efficacy, less upset about coping with diabetes, found diabetes less hard to cope with & to have less of a negative impact on QoL compared to control group.
7.	Grey, Boland, Davidson, Li & Tamborlane (2000). USA	I n=42, C n= 35 Intensive insulin treatment alone 12 -20 years. 7.6 years	Prospective RCT.	HbAc1, diabetes specific self-efficacy, depressive symptoms, coping, Diabetes QOL, frequency of severe hypoglycaemia events, Weight gain, self-report treatment regimen. (Baseline, & 1month (coping and clinical), 3, 6, and 12 months (all variables).	Metabolic control: significant improvement in HbA1c levels from baseline to 12 month follow-up in both groups (due to intensified treatment). HbA1c fell significantly faster & to a greater extent in CST group compared to control group over at 6 months and maintained at 12 months. Psychosocial: CST group reported significantly < negative impact on QoL after 12 months (greatest improvement occurred during first 3 months but maintained at 12 months), > diabetes self-efficacy & medical self-efficacy at 12 months compared to control group.

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
8	Grey, Davidson, Boland, Tamborlane (2001). USA	N=81 Intensive insulin treatment alone 12 - 20 years. 7.6 years	Prospective RCT.	HbA1c, depressive symptoms, diabetes specific family behaviours, diabetes self-efficacy, diabetes QoL. (Baseline & 12 month)	Metabolic control: > metabolic control at study entry, participation in CST, lower depressive symptoms & more parental participation in guidance & control of their child's diabetes were associated with achievement of target HbA1c levels. Psychosocial: CST, lower baseline QoL impact, less depressive symptoms were associated with less impact of diabetes on QoL.
9.	Grey, Boland, Davidson, Yu & Tamborlane (1999). USA.	I n=42, C n=35 Intensive insulin treatment alone 12 - 20 years. 7.6 years	Prospective RCT	HbAc1 (measured montly), diabetes related self-efficacy, depressive symptoms, coping with diabetes, diabetes related QoL, frequency of hypogylcemic events, weight gain. Self-report treatment regimen (baseline, 3 & 6 months).	Metabolic control: significant improvement in HbA1c levels for both groups over time due to intensified therapy at 6 months. HbA1c fell significantly faster & to a greater extent in CST group compared to control group over 6 months (greatest change between groups at 3 months). Psychosocial: CST group reported significantly less negative impact on QoL, fewer worries about diabetes in relation to Qol & greater self-efficacy to deal with general life situations compared to control group.

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
10.	Johnson, Gross & Wildman (1982). USA	N=2 No control 12 and 13 years. Not stated.	Multiple baseline-across-behaviours design	Diabetes related social skills. (4 baseline responses, after each training session, 1 week and 1 month follow-up).	Metabolic control: Not measured. Psychosocial: > eye contact & appropriate verbalisations from baseline to during training, maintained at 1 week & 1 month (for 1 child: follow-up not measured for second child.)
11	Kaplan, Chadwich & Schimmel (1985). USA	N=21 Group diabetes Education. 13 – 18 years. 6 years.	Prospective RCT	HbAc1, diabetes knowledge, attitudes and behaviour: social Support: social skills (at posttest). (Baseline, posttest, 4 months follow-up).	Metabolic control: Significant difference in HbA1c levels between the two groups at 4 month follow-up. CST group showed a small decrease while the Education group showed a slight increase. Psychosocial: better metabolic control was associated with higher self care. Poorer metabolic control was associated with greater satisfaction with social support and greater social skills. These were not compared between groups.

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
12.	Mendez & Belendez (1997) Spain.	I n=18, C n= 19 Routine care. 11-18 years. 4 years.	Prospective quasi-experimental (Non-equivalent control group) .	HbA1c, Diabetes knowledge, barriers to adherence, diabetes specific daily hassles, diabetes Family Behaviour , social skills relating to diabetes, Blood Glucose Testing skills, external factors relating to blood glucose levels. (baseline, posttest & 13 months). Daily self-monitoring of diet, physical exercise & blood glucose. Parents: diabetes knowledge, diabetes family behaviour (baseline, posttest, 13 month follow-up).	Metabolic control: CST did not have a differential effect on HbA1c compared to control group. Psychosocial: CST group showed a significant decrease in the frequency of adherence barriers, daily hassels & social skill uneasiness compared to control group at posttest, maintained at 13 month follow-up. CST group showed a significant increase in social skills response likelihood but this decreased at follow-up. CST group showed significant increase in information about diabetes compared to the control group at posttest, maintained at 13 month follow-up. CST group showed significant improvement in blood glucose testing skill (maintained at 13 month follow-up) & frequency (not maintained at follow-up). Parents: CST group showed a significant increase in diabetes knowledge & significant decrease in non- supportive parental behaviour compared to control group.

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
13.	Serlachius, Frydenberg, Northam & Cameron (2011) (Conference proceedings) Australia	N=156 Not stated. 13 - 16 years. Not stated.	Prospective RCT (conference proceedings)	Glycaemic control, coping skills, diabetes specific self-efficacy, stress levels, QoL. (baseline & 3 months).	Metabolic control: CST had no significant differential effect on glycaemic control compared to control group. Psychosocial: CST group showed significant improvement in productive coping skills, diabetes related self-efficacy, stress levels & QoL compared to control group at 3 month follow-up.
14.	Whittemore, Grey, Lindemann, Ambrosino & Jaser (2010). USA.	I n=6, C n=6 Internet Education Programme 13 - 16 years. 5.9 years.	Prospective RCT (Pilot study)	Diabetes QoL, stress, coping with diabetes, diabetes specific self-efficacy, depressive symptoms, acceptability of intervention. (baseline & 3, 6 months follow-up).	Metabolic control: Not reported. Psychosocial: Trends for better diabetes self-efficacy in both groups. CST group showed trends for better diabetes self-efficacy, coping, general diabetes treatment QoL & less perceived stress compared with education group. Education group showed trends for better diabetes communication over time. No significant differences between groups on satisfaction with intervention or how often skills were practised.

Study ID	Author (year), country of origin	Sample size, control group, Age, Mean duration of diabetes.	Design	Outcomes measured (follow-up)	Outcomes
15.	Whittemore, Jeon, Jaser, Murphy, Faulkner, Delamater, Grey (2011) USA	N= 320 Internet Education Programme. 11 - 14 years. Not stated.	Prospective RCT (conference proceedings)	HbAc1, self-management, self-efficacy, stress, coping, quality of life, family conflict. (baseline & 3 months).	Metabolic control: CST had no significant differential effect on HbA1c levels compared to Internet Education programme. Psychosocial: Internet Education Programme group showed significant improvements in self-management, perceived stress, emotional QoL compared to the CST internet group. Both groups showed significant improvements in self-efficacy, emotional QoL and a decrease in family conflict over time.

Key: I = Intervention group, C = Control group.

Whittemore et al., 2010). Two further RCTS (Serlachius et al., 2011; Whittemore et al., 2011) are the published reports of oral sessions presented at the 37th Annual meeting of the International Society for Pediatric and Adolescent Diabetes (ISPAD) (2011) and are referred to as conference proceedings in this review. Due to the limited number of studies conducted in this area, it was decided to include conference proceedings to add weight to findings. However, it is acknowledge that due to difficulties in assessing quality, the evidence is much weaker.

Quality Assessment

Table 3 shows the results of the quality assessment using the QualSyst (Kmet et al., 2004). Each quality criteria is assigned a score based on whether it has been met, ranging from 0 (no), 1 (partially) or 2 (yes). Items not applicable to a particular study design are assigned N/A and are excluded from the summary score. For each study, a (percentage) summary score was obtained by summing scores, dividing by the total possible score (excluding those marked N/A) and then multiplying by 100. The higher the (percentage) score, the better quality the study is considered to be. A previous review (Gravel et al., 2006) suggested scores below 50% on the QualSyst to be of poor quality. In the current review, scores 50% and above are considered to range from fair to good quality. With the exception of two child articles (Gross et al., 1983; Gross et al., 1982) and three adolescent articles (Johnson et al., 1982; Serlachius et al., 2011; Whittemore et al., 2011) the majority of studies included in the review scored 50% or above.

Intervention characteristics

The detail in which the characteristics were described varied and was, in general, inadequate to facilitate full comparison across studies. There was a marked lack of information on intervention characteristics stated by the two conference proceedings.

Setting & delivery

All studies, with the exception of those reporting on an internet based CST (TEENCOPE) program (Whittemore et al., 2010; Whittemore et al., 2011), used a group setting and face to face method of delivery. With the exception of articles

Table 3: Quality Assessment

Criteria	Study														
	Ambrosino et al. (2008)	**Grey et al. (2009)**	**Gross et al. (1983)**	**Gross et al. (1982)**	**Boardway et al. (1993)**	**Grey et al. (1998)**	**Grey et al. (2000)**	**Grey et al. (2001)**	**Grey et al. (1999)**	**Johnson et al. (1982)**	**Kaplan et al. (1985)**	**Mendez et al. (1997)**	**Serlachius et al. (2011)**	**Whittemore et al. (2010)**	**Whittemore et al. (2011)**
1. Question/objective sufficiently identified?	Yes	Yes	Yes	Yes	Yes	Partial	Partial	Partial	Partial	Partial	Partial	Partial	Yes	Yes	Yes
2. Study design evident and appropriate?	Yes	Yes	Yes	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Yes	Partial	Yes
3. Method of subject/comparison group selection or source of information/input variables described and appropriate?	Partial	Partial	No	No	Partial	Partial	Partial	Partial	Partial	No	Partial	Yes	No	Partial	No
4. Subject (& comparison group, if applicable) characteristics sufficiently described?	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Partial	Partial	No	Yes	Partial
5. If interventional and random allocation possible, was it described?	Partial	Partial	No	N/A	Partial	Partial	Partial	Partial	Partial	N/A	Partial	No	Partial	Partial	Partial

Criteria	Study														
	Ambrosino et al. (2008)	**Grey et al. (2009)**	**Gross et al. (1983)**	**Gross et al. (1982)**	**Boardway et al. (1993)**	**Grey et al. (1998)**	**Grey et al. (2000)**	**Grey et al. (2001)**	**Grey et al. (1999)**	**Johnson et al. (1982)**	**Kaplan et al. (1985)**	**Mendez et al. (1997)**	**Serlachius et al. (2011)**	**Whittemore et al. (2010)**	**Whittemore et al. (2011)**
6. If interventional and blinding of investigators was possible, was it reported?	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Partial	No	No	No	No	No
7. If interventional and blinding of participants was possible, was it reported?	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
8. Outcome and (if applicable) exposure measure(s) well defined and robust to measurement/ misclassification bias? Means of assessment reported?	Partial	Partial	Partial	Partial	Yes	Yes	Yes	Yes	Yes	Partial	Partial	Partial	No	Yes	Partial
9. Sample size appropriate?	Partial	Partial	No	Partial	No	Partial	Partial	Partial	Partial	Partial	Partial	Partial	Yes	Partial	Yes
10. Analytic methods described/justified for the main results?	Yes	Yes	Partial	Partial	Partial	Yes	Yes	Yes	Yes	Partial	Partial	Yes	Partial	Partial	No

Criteria	Study														
	Ambrosino et al. (2008)	**Grey et al. (2009)**	**Gross et al. (1983)**	**Gross et al. (1982)**	**Boardway et al. (1993)**	**Grey et al. (1998)**	**Grey et al. (2000)**	**Grey et al. (2001)**	**Grey et al. (1999)**	**Johnson et al. (1982)**	**Kaplan et al. (1985)**	**Mendez et al. (1997)**	**Serlachius et al. (2011)**	**Whittemore et al. (2010)**	**Whittemore et al. (2011)**
11. Some estimate of variance is reported for the main results?	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Partial	Partial	No	No	No
12. Controlled for confounding?	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Partial	Partial	Yes	Partial
13. Results reported in sufficient detail?	Yes	Yes	Partial	Partial	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial	Partial	Partial
14. Conclusions supported by the results?	Yes	Yes	Partial	Partial	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Partial	Yes	Partial
Quality summary	Good	Good	Poor	Poor	Fair	Good	Good	Good	Good	Poor	Fair	Fair	Poor	Fair	Poor

Key:
N/A = Criteria Not Applicable based on study design; Yes = Criteria fully met; Partial = Criteria partially met; No = Criteria not met.

by Grey and colleagues (Ambrosino et al., 2008: Grey et al., 1998) most studies did not state the group sizes when CST was delivered, making replication of studies difficult.

Teaching methods

A variety of teaching methods were used to deliver CST with some commonalities across studies. Role play was the most frequently used method, in nine of the 11 discrete studies (Ambrosino et al., 2008; Gross et al., 1983; Gross et al., 1982; Boardway et al., 1993; Grey et al., 1998; Johnson et al., 1982; Kaplan et al., 1985; Mendez & Belendez, 1997; Whittemore et al., 2010). and modelling of skills by the trainers was used in five (Gross et al., 1983; Gross et al., 1982; Boardway et al., 1993; Grey et al., 1998; Johnson et al., 1982). Four of the 11 discrete studies used discussion groups (Ambrosino et al., 2008; Boardway et al., 1992; Grey et al., 1998; Whittemore et al., 2010) and four used positive reinforcement to strengthen the use of appropriate skills (Gross et al., 1983; Gross et al., 1982., Johnson et al., 1982; Kaplan et al., 1985). Didactic teaching was used to deliver CST in three of the 11 discrete studies (Ambrosino, 2008; Kaplan et al., 1985; Mendez & Belendez, 1997). Didactic teaching was also used to deliver diabetes education to participants in the control groups of two studies (Ambrosino et al., 2008; Kaplan et al., 1985).

Two studies (Whittemore et al., 2010; Whittemore et al., 2011) evaluated an internet based web program (TEENCOPE) specifically developed to deliver CST. Adolescents individually accessed the CST material via the internet on a weekly basis and contributed to a discussion board monitored by a Clinical Psychologist. The pilot study (Whittemore et al., 2010) describes the content and delivery of the TEENCOPE intervention and this is followed up in a separate, large multisite trial (Whittemore et al., 2011). However, because the latter article is a conference proceeding report and insufficient intervention detail is described, it cannot be ascertained whether the program was altered following the pilot study. An internet based program was also used to deliver diabetes related education to control groups.

Content – CST package

Social problem solving related to common diabetes situations (e.g. eating out with friends) was used in all studies that described the contents of their intervention. The use of cognitive behaviour modification and cognitive restructuring was explicitly stated in four of the studies (Ambrosino et al., 2008 Boardway et al., 1993; 2008; Grey et al., 1998; Mendez & Belendez, 1997; Serlachius et al., 2011). Training in using appropriate eye contact when in social situations was explicitly stated in three studies (Gross et al., 1983; Gross et al., 1982; Johnson et al., 1982). Three studies included guided self-talk (Ambrosino et al., 2008; Mendez & Belendez, 1997; Whittemore et al., 2010), three taught stress management skills (Ambrosino et al., 2008; Boardway et al., 1993; Whittemore et al., 2010) and three studies covered diabetes specific conflict resolution (Ambrosino et al., 2008; Grey et al., 1998; Whittemore et al., 2010). Assertiveness training was explicitly stated in one study (Boardway et al., 1993) and one study (Mendez & Belendez, 1997) taught relaxation techniques and 'self-control training' but the authors failed to describe this in any detail. Specific education on insulin treatment was explicitly stated in only one CST package (Kaplan et al., 1985). None of the articles with the exception of Mendez and Belendez (1997) described their intervention protocols in sufficient detail to facilitate replication.

Parental involvement

Parents directly participated in two studies. Parents in one study (Ambrosino et al., 2008), received the same CST or education (control intervention) as their child, meeting separately but simultaneously from their children. Parents in the other study (Mendez & Belendez, 1997) participated in two sessions with their child where they received information on diabetes and its management and their role in positively reinforcing their child's adherence behaviour.

Content – control interventions

Seven of the nine discrete controlled studies described, in varying detail, the contents of their control group interventions. These fell into one of two categories, either routine clinical care or diabetes related education. Participants in the control group in three studies (Boardway et al., 1993; Grey et al., 1998; Mendez & Belendez, 1997) continued with routine care or were started on intensive insulin

therapy (Grey et al., 1998). Education was provided in the remaining four studies (Ambrosino et al., 2008; Kaplan et al., 1985; Whittemore et al., 2010; Whittemore et al., 2011) and the content appeared similar across the studies, (e.g. focusing on insulin treatment, sick days, nutrition and exercise).

Provider

Of the studies that reported information on the provider of the experimental intervention (exceptions were the conference proceedings of Serlachius et al., 2011 and Whittemore et al., 2011) a varied number of professionals were mentioned, including the researchers themselves, a diabetes nurse specialist, clinical psychologist, a psychology graduate student and diabetes specialist (e.g. endocrinologist). The majority of studies took a multidisciplinary approach, using more than one provider. Two studies appeared to use only one professional to deliver the experimental intervention; a 'mental health professional' (Ambrosino et al., 2008) and an advanced nurse practitioner (Grey et al., 1998).

Five of the nine controlled studies reported information on the provider of the control group intervention, and this appeared dependent on the content of the intervention. Of the three studies using routine care, two studies (Boardway et al. 1993; Grey et al., 1998) stated that routine care was delivered by a health care team but only Boardway et al. (1993) gave information on the professionals that made up the team (paediatric endocrinologist, registered nurse, dietician & social worker). The remaining three studies that provided diabetes related education to the control group used a variety of professionals; an advanced practice nurse (Ambrosino et al., 2008), medical specialists (e.g. endocrinologist, podiatrist; Kaplan et al., 1985) and the educational internet program (Whittemore et al., 2010) was developed by a diabetes specialist nurse, clinical psychologists and web programming team.

Intensity of intervention

Studies varied in the number of intervention sessions conducted, ranging from 5 to 15 sessions. The study by Grey and colleagues also provided monthly booster sessions over the twelve month follow-up period. Kaplan et al. (1985) provided 3 hours of training every weekday over a 3 week period in the context of a summer

school for children with diabetes. Most sessions were delivered weekly, with the exception of Gross et al. (1983) and Gross et al. (1982) who provided intervention sessions twice weekly. The duration of each session varied again across studies, ranging from 45 minutes (Gross et al., 1983; Gross et al., 1982) to 3 hours (Kaplan et al., 1985).

The number and duration of control interventions appeared dependent on what type of intervention was used. Of the three studies that used routine care (Boardway et al., 1993; Grey et al., 1998; Mendez & Belendez, 1997) only two described the frequency of contact with health care professionals and this varied. In one study, (Boardway et al., 1993) control group participants had contact with their diabetes team every 3 months and in the other study (Grey et al., 1998) this was conducted on a monthly basis. The two studies that provided information on the intensity of education control interventions (Ambrosino et al., 2008; Kaplan et al., 1985) suggests that participants in the control group received similar attention to those participants in the experimental intervention.

Metabolic control and psychosocial outcomes.

The findings of studies under review are presented separately for children and adolescents. Both discrete studies and follow-up articles are discussed in this section. Three studies (Gross et al., 1982; Johnson et al., 1982; Whittemore et al., 2010) did not use metabolic control as an outcome. Glycated haemoglobin (HbA1c) level was used as a measure of metabolic control in the remaining articles. HbA1c is assessed via a blood test and reflects the individual's average blood sugar level over the past 2-3 months.

Children

Metabolic control

Two discrete articles reported on CST and metabolic control in children (aged 8-12 years) and the results suggested that there was no significant difference in HbA1c levels in children receiving CST compared to children either receiving diabetes education (Ambrosino et al., 2008) or routine clinical care (Gross et al., 1983), 3-months following completion of the intervention. As HbA1c levels are an indication of the child's blood sugar levels over the preceding 3-months, long follow-up

periods are needed to ensure any intervention related behavioural changes have had time to impact upon metabolic control (Ellis, Speroff, Dittus, Brown, Pichert & Elasy, 2004). Grey et al. (2009) reports on the 6 and 12-month follow-up analysis of the Ambrosino et al. (2008) study and found that the null effect was maintained 6 and 12-months following the intervention, moreover there were no improvements over time from baseline to 12-month follow-up (Grey et al., 2009). The apparent lack of improvement in metabolic control in the Ambrosino et al. (2008 & follow-up study; Grey et al. 2009) study may be a result of floor effects. Participants already had good metabolic control at baseline (within the recommended limits of the American Diabetes Association), leaving little room for an effect, should one be likely to occur.

The evidential quality of Gross et al. (1983) is poor and as a consequence the findings are considered weak. The sample size is very small. There is no description of how participants were selected or assigned to groups and furthermore, there is no description of the demographic characteristics of participants. Therefore, it cannot be ascertained whether baseline characteristics were controlled between groups, resulting in little confidence that the differences in outcomes are attributed to the effects of CST. In contrast, the study by Ambrosino et al., (2008) and its follow-up article (Grey et al., 2009), was deemed to be of good quality and its findings should be considered in light of this assessment. However, the generalisation of this result is limited to a population of children using mainly pump therapy, ethnically classed as white and from high income families. To measure the extent to which these effects are found outside of these studies, further research is needed in children with poorly controlled diabetes and from a diverse population.

Children; Psychosocial outcomes

Social skills

The use of eye contact and appropriate verbalisations in difficult diabetes-related social situations was found to increase in role play scenarios in five children aged 9-12 years who underwent CST (Gross et al., 1982) and in six children of similar age who were compared to a (routine clinical care) control group (Gross et al., 1983). These social skills were measured using the Diabetes Assertiveness Test

(DAT; Gross & Johnson, 1981). Both studies used a multiple baseline design but no inferential analysis was conducted to ascertain whether the increase in eye contact and verbalisations was statistically significant. Both these studies were rated of poor quality, mainly due to the insufficient detail given on participant selection and characteristics, process of random allocation, small sample size and no mention of any possible confounding factors. The results of these studies therefore cannot confidently be attributed to the CST and should be considered with caution.

Psychosocial outcomes

Only one study examined CST in children (Ambrosino et al., 2008) and this was followed-up 12-months post intervention (Grey et al., 2009). The results indicated significant improvements in scores on diabetes-related quality of life (worry scale), depressive symptoms, coping with diabetes and diabetes-related self-efficacy. However, this effect was not significantly different from improvements also found in children receiving diabetes education, suggesting both CST and education can improve psychosocial outcomes in children with T1DM. With regards to parent outcomes, there were no significant differences in coping, depression, family functioning or the distribution of diabetes related responsibilities across child and parent between parents receiving CST and those receiving diabetes education at 3-months post intervention.

The quality of this study is good and the results therefore may be considered as robust. Strengths of this study include the low attrition rate (14%), blinding of the children's routine care providers to group allocation, good treatment fidelity and the use of Intention To Treat (ITT) analysis. The use of ITT was of particular importance as the authors found that children who completed the study were more likely to be from a white ethnic background and have mothers with higher educational level compared to those children who dropped out. However, generalisation of results is limited to a population of children with good metabolic control and relatively good psychosocial adjustment in terms of coping, self-efficacy, family function and quality of life at the start of the study.

Adolescents

Metabolic control

Findings on the effect of CST on metabolic control in adolescents are mixed. Two discrete studies (Grey et al., 1998; Kaplan et al., 1985) found significant improvement in metabolic control in adolescents aged 12-20 years who received CST compared to adolescents who received routine care (1 month post intervention; Grey et al., 1998) or diabetes education (Kaplan et al., 1985). This significant improvement was maintained over 4-months (Kaplan et al., 1985) and a 3, 6 and 12-month follow-up period (Grey et al., 1999; Grey et al., 2000). The total participant sample in Grey et al. (1998), irrespective of group allocation, received intensive insulin treatment at the start of the study. As a consequence, metabolic control was also found to be improved in the control group. However, improvement was shown to be significantly quicker and greater in adolescents who received CST compared to the control group and this was maintained over the 12-month follow-up period. The mean HbA1c level in the CST group reached target levels, while in the control group it remained above normal range. Importantly, there were no differences between groups on the type of insulin regimen used (pump versus multiple daily injections). The authors concluded that CST appears to enhance the effect of intensive insulin treatment.

The evidential quality of Grey et al. (1998) is graded as good; therefore more weight is given to these results. However, the CST group had more contact with professionals compared to the control group which has the potential to introduce performance bias and may contribute to the positive findings of CST over no intervention. In addition, the generalisation of results is limited to a population of mainly ethnically white adolescents from middle to high income families. The evidential quality of Kaplan et al. (1985) is fair; the sample is small and again consists mainly of ethnically white adolescents from middle to high income families. In addition, participants volunteered to take part in a diabetes summer camp running every day for three consecutive weeks and therefore may have been far more motivated than those who did not volunteer, limiting the generalisation of the results. There was no mention of whether data collectors were blinded to group allocation, which has the potential to introduce bias to the results. In addition, there was no discussion on whether the improvement in

HbA1c levels fell within the ‘normal range’, and so it is difficult to conclude the degree to which the CST has had a clinically relevant effect.

Two studies found no significant differential effect for CST in improving metabolic control over routine clinical care (Boardway et al., 1993; Mendez & Belendez, 1997). The quality of both these studies has been assessed as fair to moderate, therefore less weight is added to these results. Boardway et al. (1993) found that mean HbA1c levels in the CST group actually worsened compared to baseline, although the authors suggest that this may be due to two participants who were ill during the study and their higher HbA1c levels may have skewed the very small data set. The evidence of this study is considered weak due to the potential bias and limited external validity. Almost one third of the initial CST group dropped out because they were unavailable when the group was due to run, which has the potential to result in systematic differences between the two groups, biasing the findings. In addition, the overall sample consisted mainly of adolescents with a history of poor treatment adherence and metabolic control, limiting the generalisation of the results to this population.

The Mendez & Belendez (1997) study used a quasi-experimental design and found no difference in metabolic control between those who had received CST and those receiving routine care; moreover, there was no change in metabolic control over time from baseline to the 13-month follow-up period. This interestingly is in spite of participants showing a significant increase in blood glucose testing skills and frequency of testing post intervention and their parents being taught how to positively reinforce adherence behaviours. Quality assessment revealed the potential for systematic differences in the characteristics of participants between groups as not all participants were randomly assigned to groups or recruited over the same time period. Almost half of participants in the control condition were assigned to this group based on their geographical location. In addition, the sample was relatively small and consisted of adolescents who already had acceptable metabolic control, limiting results to this population.

The two conference proceedings also found no significant improvement in metabolic control in children receiving CST compared to a non-specified control

group (Serlachius et al., 2011) or internet based education (Whittemore et al., 2011). Due to the limited information presented in these reports it is difficult to assess the quality of these studies. However, both studies state they are RCTs and appear to be using satisfactory sample sizes, so the results may be considered as an indicator that metabolic control may not be improved through the use of CST. Full publication of these studies is needed to increase confidence in this finding.

Adolescents; Psychosocial outcomes

Diabetes specific stress and daily hassles

Two studies (Boardway et al., 1993; Mendez & Belendez, 1997) found adolescents who received CST reported a significant decrease over time (12-month follow-up) in the amount of perceived stress relating to daily diabetes hassles in comparison to adolescents who continued with routine clinical care. The kinds of diabetes related situations measured by the Diabetes Stress Questionnaire (as used by Boardway et al., 1993) included testing blood when with friends, not being able to eat the same foods friends are eating and parents' accusations of not staying on the diet. Mendez & Belendez, (1997) used an unpublished scale and did not provide any information on what comprises the instrument; therefore meaningful conclusions cannot be drawn from this study. The quality of both studies was rated as moderate. Both studies may be subject to selection bias, decreasing confidence that the results are attributable to the effects of CST.

General stress

The impact of group and internet based CST on the degree to which adolescents perceive situations in one's life as stressful was measured by three studies (Serlachius et al., 2011; Whittemore et al., 2010; Whittemore et al., 2011). All three studies showed a trend toward improvement in the CST group compared to baseline, an internet education program (Whittemore et al., 2010; Whittemore et al., 2011) or a non-specified control group (Serlachius, et al., 2011). However, the quality of this evidence is weak; one study reports on the preliminary findings of an internet based pilot study with a small sample and generous probability level ($p<.20$) and the other two studies are reports on conference proceedings, where

the necessary information to assess the quality of the study is not available. However, these studies do indicate that CST may have a beneficial effect on this particular psychological outcome, which future well designed studies may wish to investigate.

Diabetes specific coping.

Five studies examined the impact of CST on coping and the findings are mixed. The stronger evidence (Grey et al., 1998) suggested adolescents started on an intensive insulin regimen and receiving CST found diabetes less hard to cope with and less upsetting compared to intensively treated adolescents receiving no intervention. However, the initial apparent benefit of CST over no intervention was not found at the 12-month follow-up assessment, despite the intervention group receiving monthly booster sessions of CST. In support of Grey et al. (1998) initial, three month findings, Serlachius et al. (2011) reported a significant improvement in productive coping in adolescents who received CST compared to a non-specified control group. However, as a conference proceeding, the lack of information presented overall means it is difficult to assess the quality of the evidence and is therefore considered weaker.

The pilot study of Whittemore et al. (2010) found a trend for better coping in adolescents who received an internet based CST programme compared to adolescents using a diabetes related education internet programme. However, when this pilot study was expanded and applied to a much larger sample (Whittemore et al., 2011) the results were reversed and significantly better coping was reported in adolescents using the diabetes related education internet programme. Unfortunately, in this conference proceeding report, little information about the study is presented and no conclusions can be drawn about these inconsistence results.

Boardway et al. (1993) found there was no significant difference following CST in the frequency in which adolescents used negative coping styles (associated with poor metabolic control) in comparison to baseline or to adolescents who only received routine medical care. The evidential quality of this study is moderate with high attrition in the intervention group and no mention of Intention-to-treat analysis

being conducted. Therefore there is the potential for baseline differences between the two groups which may have contributed to the null findings.

Diabetes-related self-efficacy.

Five studies measured adolescents' perceptions of their personal competence, power and resourcefulness to successfully manage diabetes following either group CST (Boardway, et al., 1993; Grey et al., 1998; Serlachius et al., 2011) or internet based CST (Whittemore et al., 2010; Whittemore et al., 2011). The Self-efficacy for Diabetes Scale was used in all studies that reported measures. The results of these studies are mixed. There is stronger evidence (Grey et al.,1998; Serlachius et al., 2011) to suggest that diabetes-related self-efficacy is increased in adolescents' who received CST compared to intensive treatment only or non-specified control group at three months and twelve months (Grey et al., 2000) post intervention.

The findings of the two internet based studies (Whittemore et al., 2010; Whittemore et al., 2011) also indicated improvements in diabetes-related self-efficacy following CST compared to baseline scores. However, internet based diabetes education also resulted in higher self-efficacy scores in adolescents and CST was found to have no differential effect over and above education (Whittemore et al., 2011). One article reports on a pilot study and the other is a conference proceeding, therefore the evidential quality of both these studies is weak. Further well-designed studies are needed to support preliminary findings on the effect of internet based CST on self-efficacy.

Boardway et al. (1993) found no significant differences in self-efficacy between adolescents who participated in group CST and those who continued with their routine clinical care. The quality of this study is graded as moderate due to the potential for selection bias and the findings are limited to adolescents with a history of poor treatment adherence and metabolic control.

Diabetes-related Quality of Life (QoL)

Four studies assessed CST and QoL and it appears that improvement in QoL may be dependent on the mode in which CST is delivered and whether it is compared

to routine care or diabetes related education. In terms of quality of evidence, the study and follow-up articles of Grey and colleagues ranked the highest and their findings indicate that group CST is associated with improvements in diabetes-related QoL at 3, 6 and 12-months post intervention in comparison to adolescents receiving no intervention. These results are limited to a population of ethnically white adolescents from middle to high income families. Supporting this improvement in QoL following CST, a RCT using a large sample (Serlachius et al., 2011) also reported significant difference in QoL compared to a non-specified control group at 3 months post intervention. However, due to the limited information available in this conference proceeding, this evidence is considered weaker. In contrast, the two studies of more moderate quality (Whittemore et al., 2010; Whittemore et al., 2011) assessing CST delivered via the internet suggest that a diabetes-related education programme appears more effective in improving emotional QoL than CST. More research is needed in comparing internet based CST with education to increase confidence in this result.

Social Skills

Two studies (Johnson et al., 1982; Mendez & Belendez, 1997) found an increase in eye contact and appropriate verbal responses to difficult diabetes-related social situations (e.g. ordering food when out with friends) immediately following CST. However, this was not maintained at a 13-month follow-up. The quality of these studies was assessed as poor to moderate respectively. In both studies little information is given on the demographic characteristics of participants which hinder the extent to which these results can be generalised.

Consumer satisfaction

Three studies rated how satisfied participants were with the intervention they received (Boardway et al., 1993; Whittemore et al., 2010; Whittemore et al., 2011). Using scales devised by the authors these studies reported participants were generally satisfied with group, face to face CST (Boardway et al., 1993) and internet based CST (Whittemore et al., 2010; Whittemore et al., 2011).

Discussion

A total of 15 articles examining the impact of coping skills training on metabolic control and psychosocial outcomes in children and adolescents were identified in the current review. Using a taxonomy framework based on Elasy et al., (2001) the various elements of CST used across studies were reviewed and a number of common characteristics were found. However, there were also a number of inconsistencies and the lack of detail presented about what constituted both intervention and control groups will make future replication of studies difficult.

With the exception of internet based CST, face to face delivery of CST in a group setting was the most commonly used method across studies. The social support adolescents gained from meeting in small, face to face groups during the intervention may be an important factor in the success of CST and may contribute to why the internet based computer program appeared to favour diabetes education in improving psychosocial outcomes over CST. Advantages of group interventions include the feeling of being understood by others and gaining emotional support from people who share the same experiences, which increases the sense of belonging (van der Ven, 2003). This is especially important for children and adolescents (Borus & Laffel, 2010).

The teaching methods and content of the interventions had commonalities, but did vary in the amount of elements that were used. It appeared that better outcomes were found in studies whose interventions contained a variety of 'teaching methods' and broader content (e.g. Grey et al., 1998). A variety of professionals were used to provide CST, and the majority were delivered using a multi-disciplinary approach. This suggests there is flexibility in who can deliver CST indicating positive cost implications in clinical practice. The number of CST sessions also varied across studies and it appeared that a higher number were associated with better outcomes (e.g. Grey et al., 1998; Mendez & Belendez, 1997). Further well-designed studies are needed to facilitate a meta-analysis so that conclusions can be drawn about the 'optimal dose' of CST required to have a positive effect on outcomes.

The findings of this review indicated that for ethnically white children (aged 8-12 years) who are psychologically well-adjusted, from middle to high income families and with good baseline metabolic control, participation in CST did not appear to improve metabolic control or psychosocial outcomes over and above participation in a group diabetes related education program. Participation in a group with other children with diabetes did lessen diabetes-related worries and depressive symptoms and improved their perception of how they cope and manage diabetes but this was irrespective of the intervention content. As discussed previously, peer social support maybe a significant contributing factor to the success of group interventions (van der Ven, 2003) which would have been provided in both the CST group and the education group and may explain the null findings.

In addition, coping processes change over the course of development and younger children tend to use more concrete coping strategies aimed at the more concrete aspects of diabetes management (e.g. using insulin injections to lower blood glucose levels) (Brotman Band, 1990). Therefore interventions aimed at changing perceptions or feelings about diabetes may not be appropriate in younger children. The needs of this age group may be better addressed via an education format that teaches specific 'concrete' management skills.

The evidence on whether CST improves metabolic control in adolescents is inconclusive and appears dependent on the demographic characteristics of participants and whether CST is compared to routine care or diabetes education. There is strong, but a small amount of evidence (Grey et al., 1998, 1999, 2000, 2001) to suggest that CST can enhance the effects of intensive insulin treatment in improving metabolic control in white adolescents from middle to high income families. However, the increased amount of contact that these adolescents had with professionals may be a contributing factor to this outcome. The inclusion of the two conference proceedings has resulted in a greater amount of evidence to suggest CST does not improve metabolic control in adolescents. However, until the conference proceedings are published in full, this evidence is much weaker. More research using well-designed RCTs with a diverse population of adolescents is needed. Providing an equal attention control group is recommended in order to increase confidence in the results one way or the other.

The evidence from higher quality studies on whether CST improves psychosocial outcomes in adolescents is inconclusive and again, partially depends on the type of treatment adolescents are using and whether CST is compared to routine care or a diabetes education program. The inclusion of the two conference proceedings adds further weight to this conclusion. Intensive insulin treatment promotes a more flexible lifestyle (DAFNE, 2002) which may contribute to the positive effects for CST found in the studies by Grey and colleagues. However, the findings of previous research on the effect that intensive treatment has on psychosocial outcomes are mixed, with some studies suggesting improvements in quality of life (Wagner et al., 2005) while others suggest a decline (Madson, Roisman & Collins, 2002). Future studies need to control for the possible confounding effects of treatment type.

The mean number of years that participants had been diagnosed with diabetes ranged from four to six years across studies and this may have impacted on the success of CST. Previous research has found the ability of families to change and adapt diabetes-related management activities becomes less flexible over time (Northam, Anderson, Alder, Werther & Warne, 1996). CST may, therefore, have more of an impact if provided soon after diagnosis and before negative habits develop (Guthrie et al., 2003). This has implications for the timing of when CST is implemented in clinical practice.

There is strong evidence to suggest that CST has a beneficial short term impact on perceived coping when adolescents are started on intensive insulin treatment. There is also moderate evidence to suggest that CST can decrease levels of general and diabetes related stress. Previous literature suggests that coping is related to the amount of stress (demands put on the resources of the person) being experienced (e.g. Lazarus & Folkman, 1984), therefore if adolescents perceive their diabetes as being less stressful, then they may feel better able to cope. Future research should consider exploring the association between stress and coping in the context of CST.

The results of this review suggest that CST can improve adolescents' perception of their competence and confidence to manage diabetes in both the short and long

term. This is consistent with the social learning theory underpinning CST, discussed by Grey (2004, 2011) in that being able to practice the behaviours and skills required to manage everyday situations relating to diabetes can enhance self-efficacy. There is also strong but a small amount of evidence to indicate that CST is associated with improvements in quality of life both over the short and longer term. However, in this review, an internet based diabetes-related education program was also found to enhance self-efficacy and quality of life. This perhaps, is not surprising given that previous research has shown education interventions designed to teach specific treatment and management skills are associated with improved self-efficacy (e.g. Abolfotouh, Kamal, El-Bourgy & Mohamed, 2011) and quality of life (e.g. Von Sengbusch et al., 2006). This review highlights the need for more rigorous research comparing CST with diabetes education programs, distinguishing between the components that make up the respective interventions. This will facilitate a better understanding of what is effective in improving the lives of adolescents with type 1 diabetes.

Three studies indicated a high level of satisfaction and acceptability of CST as an intervention. Acceptability of an intervention by service users is of upmost importance and it is disappointing that only three studies reported on this. Previous research has found that when intervention acceptability is low, compliance is low and therefore, effectiveness will be low (Reimers, Wacker & Koeppl, 1987). A number of factors have been identified that affect the acceptability of interventions (Elliot, 1988) and should be considered both in future research and in clinical practice.

There are a number of limitations to this review which need consideration. Firstly, the strategy used to identify relevant papers was specific and used narrow key terms. This was to ensure that the focus of the search was on studies evaluating Coping Skills Training and excluded other types of diabetes interventions. However, it is acknowledged that such a narrow search strategy may not have captured all the relevant literature and the use of broader key terms may have widened the search. In an attempt to cover papers that may have been missed, an examination of the reference lists of the articles identified in the search was conducted. A further 3 articles were identified which appears to support the

suggestion that the search term may have been too narrow. Future reviews, therefore, should consider the use of broader key terms. Secondly, the possibility of publication bias cannot be ruled out. Whilst contact was made with the authors of the two unpublished conference proceedings to enquire whether any additional data on these two projects was available, no other attempt was made to ascertain the existence of grey literature relevant to this review. Therefore, data which supports the null hypothesis and remains unpublished may have been missed.

Thirdly, to facilitate the description and comparison of CST across studies a structure was used based on a taxonomy developed by Elasy et al. (2001). Although, as already mentioned in the introduction, it was felt that this taxonomy was relevant to CST, it is acknowledged that there are other taxonomies which could have been used to further enhance the description and comparison of interventions. For example, the Consolidated Standards for Reporting Trials (CONSORT; Moher, Schultz, Altman & the CONSORT Group, 2001) statement on how clinical trials should be reported in medical journals has been applied to research in behavioural medicine by Davidson, Goldstein, Kaplan, Kaufmann, Knatterund, Orleans, et al., (2003). Whilst the taxonomy developed by Elasy et al. (2004) does reflect the guidelines suggested by Davidson et al. (2003) adding further justification for its use in this review, two authors (Abraham & Michie, 2008) have suggested that reporting on the *content* of behaviour change interventions is limited by a lack of standardized vocabulary with which to describe the content of interventions. In answer to this they have developed a taxonomy of techniques used in behaviour change interventions. The aim of this taxonomy is to facilitate the identification of theory linked techniques which may be common or distinct across interventions and identify which individual or combinations of techniques are more effective. Although this review concentrated on an intervention with one underlying theoretical construct (Social Learning Theory) it was evident that the content of interventions across studies differed. The use of Abraham and Michie's (2008) categorisation system may have produced a more comprehensive picture of each intervention and facilitated comparisons across studies.

Lastly it is acknowledged that there are other validated and frequently used frameworks available to assess the methodological quality of intervention studies.

For example, Downs and Black (1998) developed an assessment criterion for both randomised and non-randomised control studies. However, as this review included a diverse range of study designs, the decision was made to use the QualSyst (Kmet et al., 2004). The QualSyst was developed to be used with quantitative, qualitative and mixed designs and the scoring criterion is adjusted to reflect these differences so that meaningful comparisons in the quality of the methodology across studies can be made.

In summary and taking these limitations into consideration, this review suggested that the effect of CST on metabolic control and psychosocial outcomes appeared contingent on age, demographic characteristics and type of insulin treatment. CST may be better suited to a face to face group format, using a range of teaching methods and clinicians may consider delivering CST shortly after diagnosis or as an adjunct to intensive insulin treatment. An increase in the number of high quality randomly controlled trials conducted in a diverse population of children and adolescents are needed to add weight to the findings to date. There needs to be satisfactory reporting of methodology in future studies perhaps using one of the frameworks suggested by Elasy et al. (2004), Davidson et al. (2003) or Abraham and Michie (2008) which include detailed descriptions of experimental and control interventions, an explanation of procedures used to select participants and how they are randomly assigned to groups. The use of equal attention control groups may reduce bias in the results.

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Predictors of Anxiety During the Perinatal Period in Women with Gestational Diabetes.

Abstract

Background: Gestational Diabetes Mellitus (GDM) is associated with adverse complications for mother and child and with an increase in maternal anxiety. Previous research on anxiety in women with GDM is limited by the use of generic anxiety measures not specific to pregnancy or diabetes and has failed to consider the impact of general risk factors known to be associated with anxiety in the general population.

Aim: This prospective longitudinal study aims to establish the prevalence and incidence of anxiety in women with GDM during the perinatal period, examine whether known risk factors for perinatal anxiety are associated with anxiety in women with GDM and to investigate whether diabetes specific risk factors predict anxiety in women with GDM over and above general risk factors.

Method: Thirty eight pregnant women (aged between 22 – 42 years) recruited from combined antenatal and diabetes clinics in the Midlands, completed a series of measures at two time points; 27-40 weeks gestation and 6-8 weeks postnatal.

Results: Diabetes related distress or level of diabetes-related social support did not predict general anxiety or pregnancy related anxiety in the perinatal period.

Conclusions: It appeared that women who reported mild levels of anxiety during the perinatal period may be individuals who were already generally anxious

Introduction

Perinatal Anxiety

Pregnancy and the transition to new motherhood is a major life event (Terry, 1991) and the mental health of childbearing women during the perinatal period and in particular postnatal depression has received a great deal of attention in the research literature (Austin & Priest, 2005). However, perinatal anxiety disorders have been studied less, despite some research suggesting that anxiety may be more common than depression (e.g. Reck, Struben, Backenstrass, Stefenelli, Reinig, Fuchs, Sohn & Mundt, 2008; Ross & McLean, 2006; Wenzel, Haugen, Jackson & Brendle, 2005).

It is commonly held that anxiety and depression co-exist and are highly correlated (Heron, O'Connor, Evans, Golding, Glover & ALSPAC, 2004; Reck et al., 2008). However recent research has found that anxiety can exist without the presence of depression. Matthey, Barnett, Howie and Kavanagh (2003) found that not all anxious mothers in their sample were depressed and a study by Miller, Pallant & Negri (2006) found that if depression had been used as the only indicator of distress in the first 6 postnatal months, 10% of their total sample of 325 women would have been overlooked. Given this type of evidence it has been suggested that postnatal depression and postnatal anxiety should be distinguished from one another in order to widen our understanding of postnatal distress and to provide appropriate, targeted treatments (Miller, Pallant & Negri, 2006).

Research examining anxiety in the perinatal period has now begun to distinguish between elevated levels of general anxiety, specific diagnosable disorders such as Panic, Obsessive Compulsive Disorder and Post Traumatic Stress Disorder (Ross & McLean, 2006) and anxiety specifically related to the current pregnancy (Dunkel Schetter & Tanner, 2012). The latter typically includes mother's fears about her health and wellbeing and that of her baby, outcome of the pregnancy, labour and birth experiences and the impending parenting role (Fairlie, Gillman & Rich-Edwards, 2009).

This wide spectrum of anxiety disorders and inconsistencies in screening methods make estimating the prevalence of anxiety during the perinatal period difficult

(Dunkel Schetter & Tanner, 2012). For general anxiety the estimated rate ranges from 6.6% to 32% (Britton, 2008; Matthey et al., 2003; Miller et al., 2006; Reck et al., 2008; Wenzel,Haugen, Jackson & Brendle, 2005;). Evidence for the stability of anxiety during this period is conflicting; some research suggests anxiety is stable across pregnancy and into the postnatal period (Heron, O;Connor, Evans, Golding, Glover & ALSPAC, 2004; Moss, Skouteris, Wertheim, Paxton & Milgrom, 2009), while other studies report differing levels of anxiety according to the stage of pregnancy (e.g. Lee, Lam, Sze Mun Lau, Shiu Yin Chong, Wai Chui, H & Yee Tak Fong, D, 2007; Skouteris, Eleanor, Werthheim, Rallis, Milgrom & Paxton, 2009) The incident rate of anxiety in the postnatal period has been found to range from 2 to 10% (Heron et al., 2004; Reck et al., 2008; Stuart, Couser, Schilder, O'Hara & Gorman, 1998). The research on pregnancy specific anxiety is far more limited, Fairlie et al., (2009) found high levels of pregnancy related anxiety in 10% of their sample of 1436 women in the first trimester of pregnancy.

A meta-analysis of the literature conducted by Littleton, Radecki Breitkopf & Berenson (2007) identified antenatal anxiety was most strongly associated with factors linked to anxiety found in the general population, including a history of psychological difficulties (depressive symptoms and low self-esteem), low levels of social support and an increased number of negative life events. In concordance with this review, a later American study by Britton (2008) found similar risk factors to be predictive of anxiety during the postnatal period; a history of depressive symptoms, socioeconomic disadvantage, low education attainment, lack of social support and low marital satisfaction were all significant predictors of high anxiety symptoms as measured by State Trait Anxiety Inventory (STAI; Spielberger, 1983) immediately before hospital discharge and one month postnatal. A history of anxiety or the presence of anxiety during pregnancy was also found to be a strong predictor of anxiety in the postnatal period (Britton 2008; Heron et al., 2004; Matthey et al., 2003;). What limits this previous research is the use of general measures of anxiety such as the STAI. Such measures have been validated for use in the general population but there is much less evidence for its validity in the postnatal period (Britton, 2008).

Research on perinatal anxiety is important due to a body of evidence suggesting anxiety can have numerous adverse effects on both mother and child. Studies indicate general anxiety in early pregnancy may be associated with a higher risk of pre-eclampsia (Kurki Hiilesmaa, Raitasalo, Mattila & Ylikorkala, 2000), premature birth (Roesch, Dunkel-Schetter, Woo & Hobel, 2004) and maternal negative attitudes toward the baby (Engle, Scrimshaw, Zambrana & Dunkel-Schetter, 1990). Pregnancy specific anxiety is consistently and independently associated with premature birth (Kramer, Lydon, Segun, Goulet, Kahn & McNamara, 2009; Roesch et al., 2004). Neurobiological research has shown that maternal anxiety during pregnancy and the activation of the mother's Hypothalamic Pituitary Adrenal Axis (HPA axis) can affect the development of the foetal HPA axis, limbic system and prefrontal cortex (Van den Bergh, Mulder, Mennes & Glover, 2005). This in turn, is linked to regulation problems, poorer social interactions, attention difficulties, language difficulties, irritability, impulsivity and emotional difficulties in the child (Van den Bergh et al., 2005). Postnatal maternal anxiety has been found to affect the mother-child interaction which can also impact on the cognitive, emotional and social-behavioural development of the child (Austin & Priest, 2005). Anxious mothers have been found to be controlling, more critical and display less warmth and positivity toward their child compared to non-anxious mothers. This is considered to be strongly associated with the development of anxiety in the child themselves (Whaley, Pinto & Sigman, 1999; Schneider, Houweling, Gommlich-Schneider, Klein, Nundel & Wolke, 2009).

Gestational Diabetes

There is an increased interest in the link between Gestational Diabetes Mellitus (GDM) and perinatal mental health. GDM is described as intolerance to carbohydrates which has its onset or is first recognised during pregnancy (Diabetes UK, Evans & O'Brian, 2005). It is detected by a routine blood glucose-screening test. This is usually performed during the second trimester of pregnancy in women who have risk factors for developing diabetes such as obesity, rapidly increasing pregnancy weight, advancing maternal age and a family history of diabetes (Berkowitz, Lapinski, Wein & Lee, 1992). The reported prevalence rate of GDM varies according to the criteria used for diagnosing GDM and inconsistent screening techniques (Berkowitz et al., 1992; Lawson & Rajaram, 1994). GDM is

estimated to be present in 5% of pregnancies (Diabetes UK, 2012), which is higher than the percentage (1.8%) of pregnancies estimated to be affected by pre-existing diabetes (Lawrence, Contreras, Wansu & Sacks, 2008).

Gestational diabetes can transform a low risk pregnancy into one that is considered high risk (Evans & O'Brian, 2005) and associated with a number of potentially serious complications for both mother and child. This includes a high risk of Caesarean section, premature delivery and pre-eclampsia in the mother, macrosomia (high birth weight), shoulder dystocia or birth injury, jaundice and the need for intensive neonatal care for the baby (Hyperglyceamia and Adverse Pregnancy Outcomes Study Group, 2008). Macrosomia is a common complication of GDM and has been associated with a higher risk of hypoglycaemia in the newborn (Mitanchez, 2010). Good glycaemic control is essential in reducing these complications (Lawson & Rajaram, 1994). A large well-designed study found the rate of serious perinatal outcomes (death, macrosomia, bone fracture and nerve palsy) was significantly lower in women who received intensive diabetes treatment compared to women who received routine antenatal care (Crowther, Hiller, Moss, McPhee, Jeffries & Robinson, 2005). The treatment regimen required to obtain good glycaemic control requires constant self-monitoring of blood glucose levels, adherence to a healthy diet and for some women, daily injections of insulin and although the relationship is unclear, research has shown that distress is correlated with increased glucose levels and hyperglycaemia (Anderson, Grigsby, Freedland, de Groot, McGill & Clouse, 2002; Lawson & Rajaram, 1994). Distress is considered to have adverse effects on compliance with vital self-care regimens (Lawson & Rajaram, 1994).

It is reasonable to assume therefore that the intensive treatment required to obtain good glycaemic control, the high risk of pregnancy and birth complications and possible adverse outcomes for the child have the potential to increase the levels of anxiety and distress in pregnant women with GDM. Indeed, high rates of diabetes specific distress have been found in the general adult diabetic population, with people reporting worries about the possible development of serious complications and feelings of guilt and anxiety regarding diabetes regimen (Grigsby, Anderson, Freedland, Clouse & Lustman, 2002; Polonsky et al., 1995). Compared to the general population, higher rates of psychological disturbance

including depression, anxiety or both have been found in people with diabetes (Peyrot & Rubin, 1997) with some studies suggesting that anxiety is more prevalent than depression (e.g. Lloyd, Dyert & Barnett, 2000; Peyrot & Rubin, 1997).

There is, however, very little research on anxiety in women with GDM and inconsistencies in methodology result in inconclusive findings, making it difficult to draw conclusions about the prevalence and nature of anxiety in this population. Rumbold and Crowther (2002) measured anxiety on the STAI (Spielberger, 1983) and found there was no difference in the rate of anxiety between women with or without GDM either before screening, at the time of diagnosis (24-28 weeks gestation) or later at 36 weeks gestation. In contrast, Daniells, Grenyer, Davis, Coleman, Burgess & Moses (2003) reported high levels of anxiety on the STAI (Spielberger, 1983) at the time of diagnosis (30 weeks gestation) but found anxiety levels had reduced when the women were measured again, 6 weeks later. The authors concluded the high levels of anxiety were an understandable reaction to the diagnosis. In line with this, Crowther et al. (2005) found levels of anxiety, as measured by the STAI-SF (Spielberger, 1983) fell within normal ranges six weeks after receiving a diagnosis of GDM and this was maintained at 3 months postnatal, irrespective of whether women were receiving intensive treatment or routine care. When looking at what factors are associated with mood in women with GDM, Langer and Langer (2000) found that 21% of the variance in mood disturbance (POMS-BI) at 37-38 weeks gestation was explained by higher maternal age, being single and blood glucose levels.

Previous research which aims to enhance our understanding of anxiety in women with GDM in the perinatal period is limited by methodology. All studies mentioned used generic measures of anxiety or mood which are not specific to pregnancy or diabetes. Pregnancy is associated with physiological change and variation in hormone levels, therefore, measures that include the assessment of physical manifestations of anxiety such as fatigue and appetite change may impact on the validity and reliability of these measures (Johnson & Slade, 2003). GDM can have serious adverse consequences on the outcomes of pregnancy, birth and the newborn child and it would be reasonable to assume this would impact on women's anxiety related to the current pregnancy. Research has shown concerns

women have over their pregnancy and the birth of their baby are weakly correlated with general feelings of anxiety (Roesch et al., 2004), therefore measures of general anxiety are unlikely to capture the context specific anxiety associated with pregnancy. None of the studies mentioned have measured anxiety related to pregnancy. In addition, given the growing amount of evidence which suggests risk factors associated with anxiety in the general population are also found during pregnancy, none of the mentioned studies (Daniells et al., 2003; Rumbold & Crowther, 2002; Spirito, Williams, Ruggiero, Bond, McGarvey & Coustan, 1989), with the exception of Langer and Langer (2000), have controlled for the impact of psychosocial risk factors on anxiety in women with GDM. This study therefore attempts to address these factors and establish the prevalence of both general anxiety and pregnancy related anxiety in the perinatal period and explore whether general risk factors for anxiety, diabetes related management difficulties and diabetes related social support are associated with anxiety in women with GDM.

Aims

In summary, this study aims to conduct a prospective, longitudinal study of anxiety in pregnant women diagnosed with Gestational Diabetes Mellitus in order to;

i) Establish the prevalence and incidence of anxiety in women with gestational diabetes during the perinatal period.
ii) Examine whether known risk factors of perinatal anxiety are associated with anxiety in women with gestational diabetes.
iii) Investigate whether diabetes specific risk factors (perceived problems with diabetes management and diabetes related social support) predict anxiety in women with gestational diabetes over and above general risk factors.

Method and Materials

Design

A prospective longitudinal survey design was used in the current study. This study is part of a larger research project exploring mood states in women with gestational diabetes and aims to collect data over three time points; Time 1 (2nd &

3rd Trimester); Time 2 (6-8 weeks postnatal) and Time 3 (12 weeks postnatal). This paper reports on analysis of data collected during the first two time points (Time 1 and Time 2). Ethical approval for the study was granted by the West Midlands Research Ethics Committee reference number 10/H1208/61 (appendix 1).

Participants and Recruitment

Participants were recruited from combined antenatal and diabetes clinics in two hospitals in the Midlands over a 12 month period from January 2011 to December 2011. Women deemed to be at high risk of developing diabetes during pregnancy were referred to hospital by their community midwife to undertake an Oral Glucose Tolerance Test (OGTT). Risk factors for GDM include; a positive urine glucose screening test, previous history of GDM, obesity, family history of Type II diabetes, previously given birth to an infant weighing 4.5kg or greater or a previous unexplained stillbirth or neonatal death). Women who obtained a positive OGTT (indicating the presence of Gestational Diabetes) were invited to attend a joint diabetes and obstetric clinic at the hospital. Women attending this clinic were approached by the researcher who gave them a letter inviting them to take part, a study information pack and a study participation consent form (appendix 2). Women were excluded from the study if they were aged under 18 years, had pre-existing diabetes, were unable to communicate in English, were receiving specialist psychiatric care or had a current mental illness (other than Postnatal Depression) or learning disability.

At Time 1 (3rd Trimester - 27-40 weeks of pregnancy) 137 women were approached for the study. Of these, 12 (8.75%) women declined to participate and 11 (8.02%) did not meet the inclusion criteria (all did not speak and/or read English). Of the remaining 114 women, 37 (32.5%) gave consent to participate but did not complete and return Time 1 questionnaires, the response rate at Time 1 therefore was n = 77 (67.5%).

At Time 2 (6-8 weeks postnatal) questionnaires were posted to 77 women who completed questionnaires at Time 1. Of these, 38 (49.4%) women completed and returned Time 2 questionnaire packs. In the current study, analysis was

performed on data provided by the 38 participants who completed both Time 1 and Time 2 questionnaire packs.

Sample Characteristics

Women were aged between 22 - 42 years (*Mean* = 32.26, *sd* = 4.70). The majority of women (36; 94.7%) were married, cohabiting or partnered. The remaining 2 (5.3%) women reported they were either single/separated or divorced. Looking at Educational attainment, 6 (15.8%) women had obtained a postgraduate qualification, 17 (44.7%) had gained a first degree and of the remaining women, 11 (28.9%) had completed a further education qualification e.g. GNVQ. The remaining 3 (7.9%) finished their education after secondary school and 1 (2.6%) woman reported she had no qualifications.

Information was also obtained on ethnicity; 25 (65.8%) women reported their ethnicity as White British, 4 (10.5%) reported White Other and 5 (13.2%) women reported they were Asian (Indian/ Bangladeshi). One (2.6%) women reported she was Black African and one (2.6%) women indicated 'Other'. Body Mass Index (BMI) was calculated using information available on women's weight and height. BMI was calculated for 24 women; 3 (7.9%) women fell within the 'normal' range (BMI range 18.5 – 24.9); 11 (28.9%) women fell within the 'overweight' range (BMI range 25 – 29.9) and 10 (26.3%) women fell within the obese category (BMI ≥ 30).

Twenty one (55.3%) women were primiparous mothers (pregnant with their first child) and the remaining 17 (44.7%) were multiparous. Information on the outcome of delivery was available on 36 women and indicated that one infant was transferred to another hospital following birth and 3 infants were admitted to Neonatal Intensive Care following birth. Twelve (31.6%) women experienced a normal vaginal delivery, 6 (15.8%) required an assisted (instrumental) delivery, 8 (21.1%) had an elective caesarean section and 10 (26.3%) women had a caesarean section whilst in labour. Of the 38 babies delivered, 36 (94.7%) were delivered at term (≥ 37weeks gestation) whilst 2 (5.3%) infants were born prematurely before 37 weeks gestation.

Measures

The questionnaire packs sent out at Time 1 and Time 2 can be found in appendix 3 and 4 respectively. Only those measures included in the current study have been described here. Results from additional measures included in the questionnaire packs are reported in a separate paper.

1). The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983).

The HADS is a 14-item self-report scale measuring depressive and anxious symptoms. A total score and two subscale scores can be derived from the measure: anxiety e.g. “I get very frightened or have panic feelings for apparently no reason at all” and depression e.g. “I have lost interest in things”. Items are rated on a four-point Likert scale with higher scores indicating greater symptom severity in the previous week. A literature review found the optimal cut off score for detecting both anxiety and depression ‘caseness’ was ≥8 (Bjelland, Dahl, Haug & Neckelmann; 2002). Reliability of the HADS anxiety scale, ranged from α = .68 to .93 (mean α .83) and for the depression scale ranged between α = .67 to .90 (mean α = of .82). Internal consistency was found to be high (clinical sample α = .91; non-clinical sample α = .89) with good to very good levels of concurrent validity (Bjelland et al., 2002). Cronbach’s alpha for the current sample was found to be reliable (α = .72).

2) Postnatal Depression Predictors Inventory (PDPI-revised version, Beck, 2002).

The PDPI-Revised is a self-report measure developed from a meta-analysis (Beck 2001) of 13 risk factors reported to be significantly related to postnatal distress. Each risk factor is assessed by a varying number of questions, scored either yes or no. The first 10 risk factors relate to the antenatal period e.g. current life stress, whether the pregnancy is wanted, marital status & social support and was completed during pregnancy. Scores range from 0 to 32. The remaining three risk factors relate to the postnatal period e.g. child temperament, childcare stress & maternity blues. A total scale score can be obtained by summing each item and in addition, each individual item can be scored separately. For the purposes of the current study individual item scores are used as potential predictor variables. Concurrent validity for both antenatal and postnatal versions (measured at two

time points; 2 months & 6 months postnatal) were good .53. .57 & .63 respectively. Predictive validity for the antenatal version ranged from .37 - .42. Reliability has been found to be good (α = .83) (Records, Rice & Beck, 2007).

3) WHO-5 Well-being Index (Bech, 2004)

This is a short self-report scale designed to assess the level of emotional well-being over the previous 14 days. The scale comprises of 5 questions focused on positive effect e.g. “I have felt cheerful and in good spirits” and “My daily life has been filled with things that interest me”. Each item is scored on a 6 point Likert Scale ranging from 0 (at no time) to 5 (all of the time), higher scores indicate better wellbeing. Studies have examined the screening properties of the WHO-5 in adults with and without diabetes and found excellent sensitivity (94-100%) and specificity (78%) (Lowe et al 2004; Awata et al 2007). Adequate reliability and validity of the Japanese version of the WHO-5 has been found in the context of detecting depression in people with diabetes (α = .89) (Awata et al., 2007). In the current sample of women, Cronbach’s alpha was reliable (α = .79).

4) Pregnancy Related Anxiety Scale (Rini, Dunkel-Schetter, Wadhwa & Sandman, 1999)

This self-report measure was specifically designed for use in pregnancy research. It contains 10 items assessing women’s feelings about her health during pregnancy (e.g. “I am concerned (worried) about developing medical problems during my pregnancy”); the health of her baby (e.g. “I am concerned (worried) about how the baby is growing and developing inside of me”) and her feelings about labour and delivery (e.g. “I am confident about having a normal childbirth”). Each item is scored on a 4 point Likert scale ranging from 1 (not at all or never) to 4 (very much or almost all of the time), higher scores indicate higher levels of anxiety. Reliability has been found to range from (α = .75 to .85). In the current sample reliability was found to be acceptable (α = .60).

5) Emotional Support (Social Adjustment Scale; Weissman & Bothwell 1976).

Perceived emotional support was measured using three items from the Social Adjustment Scale which was designed specifically for use during child rearing years. The three questions measure the opportunity to discuss one’s feelings with

friends; relatives and partner (e.g. Have you been able to talk about your feelings and problems with at least one friend during the last month?). Items are scored on a 5 point Likert scale ranging from 1 (I could always talk freely about my feelings) to 5 (I was never able to talk about my feelings). Higher scores indicated lower perceived emotional support. Concurrent validity of the scale ranged from .22 to .63 finding sensitivity to differences in adjustment among different patient groups (Weismann, Olfson, Gameroff, Feder & Fuentes (2001). In the current sample Cronbach's alpha was found to be acceptable (α = .60).

6) Problem Areas In Diabetes (PAID; Polonsky et al., 1996).

This is a 20-item self-report measure of diabetes related emotional distress. Each item represents an area of diabetes related distress ranging from anger ("feeling angry when you think about having diabetes"), interpersonal distress ("feeling friends/family are not supportive of diabetes management efforts"), anxiety ("worrying about the future and possibility of serious complications") to frustration ("feeling unsatisfied with your diabetes physician"). The items are scored on a 5 point Likert scale which ranges from 0 (no problem) to 4 (serious problem). A total scale score is calculated with higher scores indicating higher levels of distress. A score of equal to or greater than 40 is indicative of a high level of distress (Hermanns, Kulzer, Krichbaum, Kubiak & Haak, 2006). The authors assessed the scale's reliability and validity and found a high level of internal reliability (Cronbach's alpha = .95). Concurrent validity ranged from .57 to .63 and significantly moderate predictive validity was also found (scores ranging from .19 to .49). In the current sample excellent reliability was found (α = .94).

7) Multidimensional Diabetes Questionnaire (Section 1) (MDQ; Talbot, Nouwen, Gingras, Gosselin & Audet, 1997).

In the current study, the Social Support scale from section 1 of the MDQ was used to explore participants' perceptions of diabetes related social support. The scale comprises of 4 items which look at perceived social support from a significant other, family, friends and health professionals (e.g. "To what extent does your spouse or significant other support you with your diabetes?"). Responses are rated on 7 point Likert scales ranging from; 0 (not at all) to 6 (extremely) with higher scores indicating higher perceived levels of social support. Adequate

construct validity was found via confirmatory factor analysis conducted by the authors and Cronbach's alpha showed good internal consistency for this subscale (α = .77). In the current sample, Cronbach's alpha showed good reliability (α = .73).

Demographic information

Demographic information included education, ethnicity, and number of previous pregnancies. Information on obstetric outcome, mode of delivery and whether the baby was born prematurely (≤ 37 weeks gestation) was obtained at Time 2 from women's medical records held at the clinic.

Procedure

Women between 26-40 weeks of pregnancy and who had obtained a positive OGTT were approached by the study researcher whilst attending the combined diabetes and obstetric clinic. The researcher explained the purpose and nature of the research and talked through confidentiality and anonymity issues. Women agreeing to take part were asked to complete the contact details sheet (name, address and telephone number) and sign the consent form. They were then given the Time 1 questionnaire pack and a stamped addressed envelope in which to return completed questionnaires.

Information on the actual delivery date and obstetric outcome of those women who completed and returned Time 1 questionnaire pack was obtained via medical records. Six to eight weeks after the birth of their baby these women were sent a letter reminding them of the research, the Time 2 questionnaire pack and a return stamped addressed envelope. If questionnaires were not returned within two weeks women were contacted by telephone to remind them of the research and ask whether they would still like to take part.

Sample size

The number of participants required for the study was calculated using a rule of thumb recommended by Tabachnick & Fidell (2007) for multiple regression analysis (50 + 8 x the number of predictor variables being entered into the regression). In the current study the maximum number of predictor variables

entered into a regression analysis was 6, therefore a minimum of 98 participants was required.

Results

Data Checks

A number of variables were found to violate the assumption of normal distribution and consequently these variables were subjected to transformations to improve their distribution. A square root transformation was used to improve the positively skewed distributions of HADS Anxiety at Time 2. A (Reflect) square root transformation improved the negatively skewed distribution of the WHO-5. A number of variables (self-esteem, social support, marital satisfaction and life stress) as measured by the PDPI, number of children and the ESQ were also found to be skewed. Attempts to transform these variables did not improve their distribution, consequently they were not transformed. Further checks for outliers, linearity, homoscedasticity and multicollinearity were also performed using SPSS Regression as recommend by Tabachnick & Fidell (2007). These checks indicated violation of homoscedasticity. Tabachnick & Fidell (2007) suggest that heteroscedasticity may occur when some variables are skewed and others are not, but they report that although the violation of homoscedasticity can weaken, it does not invalidate the analysis. No other violations of the assumptions of data were found.

Completers and non-completers

Women who completed Time 1 questionnaires only (non-completers; *n* = 39) were compared on demographic information with women who completed questionnaires at Time 1 and Time 2 (Completers; *n* = 38) in order to determine any differences between the two groups of women. Table 1 shows the means (standard deviation), range and significance of the demographic information for both groups.

Independent sample t-tests found no significant differences in age or level of deprivation between women who completed and women who did not. Mann-Whitney U tests revealed a significant difference between the two groups on

Table 1; Comparisons between completers and non-completers

Characteristic	Non-completers *N* = 39	Completers *N* = 38
	Mean (*sd*)	**Mean (*sd*)**
Age	31.64 (6.77)	32.26 (4.70)
SES	20.27 (16.90)	20.44 (16.22)
Marital Satisfaction	41.97	35.95*
	Frequencies (%)	**Frequencies (%)**
Educational Attainment		
< Degree level	18 (46.2%)	14 (36.8%)
≥ Degree level	18 (46.2%)	24 (63.2%)
Marital Status		
Married/partnered	37 (94.9%)	36 (94.9%)
Single/separated/divorced	2 (5.1%)	2 (5.1%)
Ethnicity		
White British	20 (52.6%)	25 (67.6%)
Number of pregnancies		
Primiparous	12 (30.8%)	21 (55.3%)*
Multiparious	27 (69.2%)	17 (44.3%)*
Delivery outcome		
Special Care	2 (6.9%)	3 (8.3%)
Transferred out	0	1 (2.8%)
Mode of delivery	*N* = 29	*N* = 36
Normal Vaginal	16 (55.2%)	12 (33.3%)
Assisted Vaginal	1 (3.4%)	6 (16.7%)
Elective Caesarian	7 (24.1%)	8 (22.2%)
Caesarian in Labour	5 (17.2%)	10 (27.8%)
Premature Birth	2 (5.6%)	2 (5.3%)
Views on pregnancy		
Planned Yes	26 (66.7%)	28 (73.7%)
No	13 (33.3%)	10 (26.3%)
Wanted Yes	39 (100%)	38 (100%)
No	0	0

*$p < .05$

marital satisfaction. Non-completers had significantly higher marital satisfaction compared to women who completed questionnaires at both time points ($z = -2.03$, $p = .04$). In addition, significantly more women who participated at both time points were primiparous compared to women who dropped out ($z = -1.94$, $p = .05$). Chi-square analysis found that the two groups of women did not significantly differ on

education status, mode of delivery, outcome of delivery, the existence of previous depression, marital status, ethnicity, BMI category, whether the pregnancy was planned or wanted and whether the baby was born prematurely.

Independent samples t-tests found the two groups of women did not significantly differ in their reported levels of general anxiety during pregnancy, as measured by the HADS Anxiety scale (Time 1) (t = .014, df = 74, p = .26) or on their reported levels of pregnancy specific anxiety as measured by the PRAS (Time 1) (t = -.32, df = 74, p = .74).

Hypothesis Testing

*Prevalence and Incidence of Anxiety During and After Pregnancy***.**

Prevalence rates were calculated using percentages. During pregnancy (Time 1) a third of women (n = 12, 31.6%) scored at or above the cut off score for anxiety 'caseness' on the HADS. This group of women were compared with those women who scored below the cut off score for (HADS) general anxiety (n = 26, 68.4%) on demographic information in order to determine any differences between the two groups of women. Table 2 shows the means (standard deviations) or frequencies for both groups.

Independent sample t-tests found no significant differences in age, (t = -.94, df = 35, p = .35) or level of deprivation, (t = -.03, df = 35, p = .98) between women who scored at or above the cut off score for general anxiety 'caseness' and those who scored below. A Mann-Whitney U test revealed no significant difference between women who scored at or above the cut off score (Md = 19.54) and those who scored below (Md = 18.74) on marital satisfaction *U = 143.5,* (z = -.54, p = .59). Chi-square analysis found that the two groups of women did not significantly differ on education status (χ^2 (1, n = 37) = .95, p = .33), marital status (χ^2 (1, n = 37) = .29, p = .59), ethnicity (χ^2 (2, n = 37) = 3.25, p = .19), delivery outcome (χ^2 (2, n = 35) = 2.07, p = .36), mode of delivery (χ^2 (2, n = 35) = 4.48, p = .18), number of pregnancies (χ^2 (1, n = 37), .24, p = .63), whether the baby was born prematurely (χ^2 (1, n = 37) = . 05, p = .82) and whether the baby was planned (χ^2 (1, n = 37) = .12, p = .75).

Table 2; Comparison of demographic information between women who scored below HADS 'caseness' cut-off score (Low HADS anxiety) and those who scored at or above the cut-off point (High HADS anxiety).

Characteristic	Low HADS anxiety *N* = 26	High HADS anxiety *N* = 12
	Mean (*sd*)	Mean (*sd*)
Age	31.7 (4.32)	33.25 (5.60)
SES	20.10 (17.98)	20.28 (13.0)
Marital Satisfaction	18.74	19.74
	Frequencies (%)	Frequencies (%)
Educational Attainment		
< degree level	12 (48.0%)	3 (25.0%)
≥ degree level	13 (52.0%)	9 (75.0%)
Marital Status		
Married/partnered	24 (96.0%)	11 (91.7%)
Single/separated/divorced	1 (4.0%)	1 (4.0%)
Ethnicity		
White British	16 (64.0%)	9 (75.0%)
Number of pregnancies		
Primiparous	13 (52.0%)	8 (66.7%)
Multiparious	12 (48.0%)	4 (33.3%)
Delivery outcome		
Special Care	3 (12.5%)	0
Transferred out	1 (4.2%)	0
Mode of delivery	N=24	N=11
Normal Vaginal	8 (33.3%)	3 (27.3%)
Assisted Vaginal	2 (8.3%)	4 (36.4%)
Elective Caesarian	7 (29.2%)	1 (9.1%)
Caesarian in Labour	7 (29.2%)	3 (27.3)
Premature Birth	2 (8.0%)	0
Views on pregnancy		
Planned Yes	18 (72.0%)	10 (83.3%)
No	7 (28.0%)	2 (16.7%)
Wanted Yes	25 (100%)	12 (100%)
No	0	0

The proportion of women who scored at or above the cut off score for general anxiety 'caseness' on the HADS (n = 12, 31.6%) was significantly higher than the proportion of women (13.2%, *n* = 5) in the postnatal period. There were no new incidences of anxiety 'caseness' at Time 2 when women who reported anxiety at Time 1 were excluded. Of the sample of *n* = 12 women who did report anxiety during pregnancy, 41.6% of these reported anxiety at Time 2.

In women who reported HADS anxiety at Time 1, the mean score (*M* = 9, *sd* = 1.3) is indicative of mild anxiety and a Wilcoxon Signed Ranks Test found that this did not differ significantly from the mean score (*M* = 10, *sd* = 1.8) at Time 2 (*z* = -3.58, *p* < .001).

When examining pregnancy related anxiety, there are no published cut off scores indicating 'caseness' for the PRAS. Scores can range from 10 to 40 with higher scores indicating higher anxiety. In the current study, the mean score for the PRAS was 20.14 (*sd* 3.16) and minimum and maximum scores ranged from 13 to 26 indicating low to moderate levels of pregnancy related anxiety.

Antenatal Anxiety

Risk factors associated with general and pregnancy specific anxiety.

Pearson'r *R* or Spearman's *Rho* (where appropriate) correlational analysis were performed between Time 1 HADS Anxiety, Time 1 PRAS and Time 1 Independent Variables (risk factors). The results of these correlations are shown in Table 2.

Table 3 shows weak, non-significant, correlations between pregnancy related anxiety (PRAS) and general anxiety (HADS Anxiety) at Time 1 (*r* = .20); the PRAS and general risk factors at Time 1 and the PRAS and diabetes related risk factors at Time 1.

However, there were significant moderate correlations between general anxiety (HADS Anxiety) at Time 1 and two general risk factors; HADS Depression (*r* = .56, *p* < .01) and , (reflect square root) WHO-5 (*rho* = -.67, *p* < .01). There was a significant moderate correlation between HADS anxiety at Time 1 and diabetes related distress as measured by the PAID (*r* = .48, *p* < .01).

Table 3; Correlation coefficients for General Anxiety, Pregnancy Related Anxiety and general and diabetes related risk factors.

Risk Factors (Time 1)	Mean (*sd*)	General Anxiety (HADS; Time 1) *r*$_p$ or *rho*	Pregnancy Related Anxiety (PRAS; Time 1)
HADS Anxiety	5.14 (3.40)	-	*r*$_p$ .20
PRAS	20.14 (3.16)	*r*$_p$ .20	-
HADS Depression	5.08 (3.05)	*r*$_p$.56**	*r*$_p$ .33
WHO-5	60.74 (16.08)	*rho* -.67**	*r*$_p$ .16
ESQ	4.45 (1.90)	*rho* .28	*rho* -.09
PDPI Life Stress	.68 (1.07)	*rho* .29	*rho* .22
PDPI Social support	1.26 (2.54)	*rho* .16	*rho* .07
PDPI Self Esteem	2.00 (.23)	*rho* .08	*rho* .15
PDPI Marital Satisfaction	32.26 (4.71)	*rho* -.07	*rho* -.22
Mother's Age	.68 (1.07)	*r*$_p$ .01	*r*$_p$ -.12
PAID	1.26 (2.54)	*r*$_p$ .48**	*r*$_p$ .16
MDQ Social Support	2.00 (.23)	*r*$_p$ -.27	*r*$_p$ -.16

*$p < .05$, **$p < .01$

Hierarchical multiple regression was used to explore the association between diabetes related distress (PAID) and general anxiety (HADS Anxiety) in women with GDM during pregnancy, after controlling for the influence of the two general risk factors (HADS Depression and (reflect square root) WHO-5 that significantly correlated with HADS Anxiety. The results are displayed in Table 4. Time 1 HADS anxiety was entered as the Dependent Variable. In the first step, HADS Depression and (reflect square root) WHO-5 were entered into the equation. The overall model explained 50% of the variance in Time 1 HADS anxiety, with only the WHO-5 contributing significantly to the model. In step 2, diabetes distress (PAID) was entered into the model, adding a further 0.7% of the variance in Time 1 HADS anxiety but this did not add significantly to the model; (R^2 change = .005,

F change (1,33) = .49, *p* = .49). In the final model (reflect square root) WHO-5 was the only variable to contribute significantly to the model once the overlapping effects of all other variables were statistically removed (*β* = .48, *p* = .01), explaining 12% of the variance in Time 1 HADS Anxiety (semi partial correlation coefficient = .35).

Table 4; Results of Hierarchical Multiple Regression predicting Anxiety during pregnancy.

Model	R^2	Adjusted R^2	*F*	R^2 change	*F*	*β*	*Sr*
Block 1	.50	.47	16.93**				
WHO-5						.48*	.35
HADS Dep						.22	.18
Block 2	.51	.46	11.28**	.007	.49		
PAID						.11	.09

*$p < .01$, **$p < .001$

Postnatal Anxiety

Risk Factors associated with postnatal anxiety.

Chi square tests for independence indicated there was no significant association between HADS Anxiety at Time 2 (dichotomised into scores above and below 8) and delivery outcome, mode of delivery, premature birth, whether the pregnancy was planned and history of depression prior to the pregnancy.

Pearson's *R* or Spearman's *Rho* (where appropriate) correlational analysis were performed on Time 2 HADS Anxiety and Independent Variables at Time 1. The results are shown in Table 5. There was a significant strong correlation between general anxiety (HADS) at Time 2 and HADS anxiety at Time 1 (*r* = .77, *p* < .01) and there were significant moderate correlations between Time 2 HADS anxiety and HADS Depression Time 1 (*r* = .58, *p* <.01); (reflect square root) WHO-5 Time 1 (*rho* = -.62, *p* < .01) and Life Stress (*rho* = .48, *p* < .01). There were significant moderate correlations between HADS Anxiety at Time 2 and diabetes related distress (PAID) (*r* = .52, *p* < .01) and diabetes related social support (MDQ Social Support) (*r* = -.36, *p* < .05).

Table 5; Correlational coefficients for Time 2 HADS anxiety scores and measures at Time 1.

Time 1 Variables	Mean (*sd*)	General Anxiety (SQRT) (HADS; Time 2)
Time 2 HADS Anxiety	3.32 (3.33)	
Time 1 HADS Anxiety	5.14 (3.40)	r^p .77**
HADS Depression	5.08 (3.05)	r^p .58**
WHO-5	60.74 (16.08)	*rho* -.62**
PAID	24.21 (18.01)	r^p .52**
PRAS	20.14 (3.16)	r^p .25
ESQ	4.45 (1.90)	*rho* .29
MDQ Social Support	4.51 (1.20)	r^p -.36*
PDPI Life stress	.68 (1.07)	*rho* .48**
PDPI Social Support	1.26 (2.54)	*rho* .24
PDPI Self Esteem	2.00 (.23)	*rho* .17
PDPI Marital Satisfaction	.05 (.23)	*rho* .23
Mother's Age	32.26 (4.71)	r^p .01

*p < .05, **p < .01.

Hierarchical multiple regression was used to explore whether diabetes related risk factors as measured by the PAID and MDQ Social Support scales predict postnatal anxiety in women with GDM, after controlling for the influence of general risk factors. HADS Anxiety at Time 2 was entered as the Dependent Variable (Table 6). In the first step, Time 1 HADS Anxiety, Time 1 HADS Depression, Time 1 (reflect square root) WHO-5 and Time 1 Life Stress was entered into the equation. The overall model explained 67% of the variance in HADS Anxiety at Time 2, with only Time 1 HADS Anxiety contributing significantly to the model. In step 2, diabetes related distress (PAID) and diabetes related social support (MDQ) were entered into the model, adding a futher 0.4% of the variance in Time 2 HADS Anxiety. However, this was not significant (R^2 *c*hange = .004, *F* change (2,29) = .20, p = .82). In the final model, Time 1 HADS Anxiety was the only variable to contribute significantly to the model once the overlapping effects of all other

variables were statistically removed (β = .52, p < .01), explaining 13% of the variance (semi partial coefficient = .36).

Table 6; Hierarchical Multiple Regression predicting Postnatal Anxiety

Model	R^2	Adjusted R^2	F	R^2 change	F	β	Sr
Block 1	.67	.62	15.76**				
(TI) HADS Anxiety						.52*	.36
WHO-5						.13	.08
HADS Dep						.13	.10
Life Stress						.16	.13
Block 2	.68	.61	10.03**	.004	.20		
PAID						.07	.05
MDQ Social support						-.03	-.03

*p < .01, **p < .001

Discussion

The aim of this prospective, longitudinal study was to examine anxiety during the perinatal period in women diagnosed with Gestational Diabetes Mellitus (GDM). The main findings indicated that women in this sample, reported low to moderate levels of pregnancy specific anxiety during pregnancy. A third of the sample reported mild general anxiety during pregnancy but significantly fewer women reported general anxiety in the postnatal period. There were no new incidents of general anxiety in the postnatal period once antenatal anxiety was accounted for. A small number of mood related risk factors known to be associated with general anxiety during the perinatal period were found to be associated with general anxiety in this sample of women with GDM. Lastly, although diabetes specific risk factors were found to be associated with general anxiety in the perinatal period this was not associated with general anxiety in women with GDM over and above emotional well-being and general anxiety during pregnancy.

Prevalence of anxiety

In the current study, women reported low to moderate levels of antenatal pregnancy specific anxiety which only weakly correlated with general anxiety. This weak association is in line with the findings of Roesch et al. (2004) who found scores on the STAI (Spielberger, 1983) to be weakly correlated with scores on a four item Pregnancy Specific Anxiety scale (PSA). This suggests that the two scales may be measuring different constructs of anxiety and the concerns that women may have about their pregnancy and the birth of their child appear to be weakly related to their feelings of general anxiety. This has important implications for future research in perinatal mental health; adding support to Dunkel-Schetter and Tanner's (2012) position that anxiety specific to the current pregnancy should be considered separately from general anxiety in pregnant women.

Pregnancy specific anxiety was found to be weakly correlated with risk factors that are known to be associated with general anxiety, such as depression, social support, self-esteem and life stress. Interestingly, there was only a weak association between pregnancy specific anxiety and diabetes related distress and levels of diabetes related social support. It is encouraging to find the distress associated with GDM appears not to be associated with women's pregnancy specific anxiety levels, especially in light of the known serious complications and adverse outcomes that can result from diabetes in pregnancy. The reason for these weak associations is unclear. However, there is evidence to show that a wanted pregnancy may be a protective factor over negative affect. In the current sample, although 26% of women had not planned their pregnancy, 100% stated that they wanted the pregnancy. Gurung, Dunkel-Schetter, Collins, Rini & Hobel (2005) looked at attitudes towards pregnancy as a predictor of anxiety. The results indicated after controlling for socio-demographic variables and life stress, wanting the baby and feeling positively about the pregnancy were strongly related to lower levels of perceived anxiety throughout the duration of women's pregnancy. The authors suggested that a positive attitude diminishes the experience of stress, possibly leading to better psychological outcomes.

Most women's scores on the HADS Anxiety scale during pregnancy and following birth indicated no clinically relevant symptoms of general anxiety. However, mild

anxiety was detected in a third of women in this study, which appears higher than the prevalence of general anxiety found in the general pregnant population (e.g. Matthey et al., 2003; Miller et al., 2006; Reck et al., 2008; Wenzel et al., 2005) but lower than in the general diabetes population (Grigsby et al., 2002). An interaction effect may account for this, the complex antenatal care and high concern over the well-being of the mother and baby that accompanies a diagnosis of GDM may account for the higher prevalence rate in women with GDM compared to the general pregnant population (York, Brown, Armstrong Persily & Jacobson, 1996). The protective factor of having a wanted pregnancy (Gurung et al., 2005) and the knowledge that for many women GDM is resolved once the baby is born may explain the lower prevalence rate compared to the general diabetes population. The finding that the percentage of women reporting mild anxiety in the postnatal period was significantly lower than the percentage of women during pregnancy appears to add weight to this idea. The possibility of these factors having an interaction effect on anxiety requires further investigation and could be the focus of future research. Despite fewer women reporting anxiety in the postnatal period compared to during pregnancy, the mean scores of anxiety symptoms did not differ over the two time points. This is in contrast to previous research (Daniells et al., 2003; Spirito et al., 1989) who found a reduction in levels of anxiety in the postnatal period compared to the time of GDM diagnosis and concluded a diagnosis of GDM has a negative but short lived impact on women. The results of the current study may suggest that for some women, anxiety may not be confined to the time of diagnosis nor be as short lived as suggested by previous research.

Risk factors for perinatal anxiety.

In the current study general risk factors of depression and low emotional well-being were found to be significantly associated with general anxiety during pregnancy. In addition, diabetes related distress was also found to be moderately associated with general anxiety during pregnancy, suggesting higher levels of emotional distress related to the management of diabetes is associated with higher levels of general anxiety. However the results of the regression analysis during pregnancy indicated that diabetes related distress was found to explain only a negligible amount of the variance (0.7%) in general anxiety while

depressive symptoms and emotional well-being explained half, with the strongest significant risk factor being low emotional well-being.

In the postnatal period, general anxiety was significantly associated with depression, low emotional well-being and anxiety during pregnancy and with diabetes related distress and diabetes related social support. In line with general anxiety during pregnancy, diabetes related distress and social support again explained only a very small amount of the variance in postnatal anxiety with the general risk factors accounting for a third of the variance. The strongest predictor of postnatal general anxiety was antenatal anxiety. These results support the findings of previous research in both the general pregnant population (Heron et al., 2004) and general diabetes population and indicate that a women's general emotional state may be more of a risk factor for developing anxiety when diagnosed with GDM than the diagnosis itself. Two large prospective studies in the general diabetes population support this idea. A large prospective cohort study conducted in the UK (Paddison, French, Kinmonth, Prevost, Griffin & Sutton, 2011), using the HADS, measured general anxiety and depression immediately after their sample had screened either positive or negative for diabetes and again twelve months later. They found that anxiety and depression at diagnosis was the strongest predictor of anxiety and depression at twelve months. This was *irrespective* of whether they had screened positive or negative for diabetes and after controlling for demographic and clinical characteristics (e.g. illness-related beliefs, BMI, age and gender). The authors concluded it is not a diagnosis of diabetes that is important in determining anxiety and depression twelve months after screening but personal emotional disposition, such as trait anxiety. A large scale Norwegian study conducted over 10 years involving adults with type I and type 2 diabetes (Engum, 2007) found that having type 2 diabetes is unlikely to increase the risk of developing anxiety or depressive symptoms. However, higher levels of anxiety or depression appear to increase the risk of onset of type 2 diabetes and this is independent of the effects of previously established risk factors for diabetes, for example being physically inactive, a smoker or obese.

Conclusion

Women who have been diagnosed with GDM report mild to moderate levels of pregnancy specific anxiety but this is not linked with risk factors found to be associated with general anxiety or with diabetes related risk factors. Mild levels of general anxiety were found in a third of this sample during this pregnancy. Taking the findings of previous literature (e.g. Engum, 2007; Heron et al., 2004; Paddison et al., 2011) into consideration, the results of the current study may suggest that the women in the current sample who reported mild levels of general anxiety during pregnancy and in the postnatal period may well be individuals who are generally anxious. Reported levels of distress related to GDM and lack of diabetes related social support may not be a risk factor for general anxiety either during or after pregnancy, over and above women's general emotional well-being and levels of anxiety. It is reassuring to find that diabetes related risk factors do not appear to be associated with women's level of general anxiety. However for a percentage of women who are anxious during pregnancy the findings of the current study suggest these women are likely to continue to be anxious once the baby is born.

A strength of the current study is the use of an anxiety measure which excludes the physical symptoms of distress which could be confused with the physiological and hormonal factors related to pregnancy and/or diabetes. Most studies use the Speilberg State Trait Anxiety Inventory (STAI) but there has been little research on the reliability of this measure in women who are pregnant or have recently delivered (Johnson & Slade, 2003). The current study also used a measure which assesses pregnancy specific anxiety, strengthening the validity and reliability of this research. The weak, non-significant correlation between pregnancy related anxiety (PRAS) and the HADS Anxiety scale in the current study, suggests that the two scales did measure two different aspects of anxiety and that one is not necessarily associated with the other. There are no published cut off scores for the PRAS; higher scores indicate a higher level of pregnancy specific anxiety. It is difficult therefore to make any definite conclusions about the level of pregnancy specific anxiety found in women with GDM in this study, but this finding does support Littleton et al. (2007) proposal that anxiety specific to pregnancy (e.g. concerns about pregnancy, birth and health of the baby) are not adequately

captured by general measures and this should be considered when conducting future research.

Limitations

This study reports on the preliminary results of a much larger study examining mood in the perinatal period in women diagnosed with gestational diabetes. Consequently there are a number of limitations which need to be acknowledged. There was no control group used in this study which precludes any inferences being made about whether the levels of anxiety symptoms found in participants were directly linked to receiving a diagnosis of GDM. The aim of this study, however, was to explore anxiety in pregnant women with GDM and this design therefore makes it difficult to include a meaningful control group. However, one possibility would have been to include a comparison group of women who were deemed to be at high risk of developing GDM and had been tested but had received a negative result. In the present paper, time constraints on the completion of this project and the lack of available researchers to recruit participants would have prevented the recruitment of such a control group. Future research, therefore, should consider the inclusion of a control group, which would further strengthen the robustness of findings.

The number of participants recruited into the study was small and fell short of that recommended by the Tabachnick & Fidell (2007) calculation. A small sample can result in a lack of statistical power, which may be insufficient to capture a relationship should any exist. In addition, the multiple regression assumptions of normal distribution and homoscedasticity were found to be violated in the current data and although this does not necessarily invalidate, it can weaken the analysis (Tabachnick & Fidell, 2007). Furthermore, in response to the assumption violations, non-parametric tests were used,which produce more conservative results. The robustness of this study and the extent to which meaningful conclusions can be made is therefore limited and the results of this study should be regarded with caution. The small sample size may partially reflect the number of women who completed questionnaires at Time 1 but did not complete at Time 2. The reason for this dropout is unclear. It may be considered that for many women, GDM is resolved following the birth of the baby and may no longer be a

major concern relative to the role of caring for a newborn. New motherhood may take priority over dedicating time and energy to continuing with the research. A much larger sample size from the continued recruitment of participants into the larger study should increase the validity of future analysis.

In addition, participants were highly educated and the majority classified themselves as White British. There was self-selective attrition and the group of women who did not complete Time 2 questionnaires were more likely to have more than one child and reported a higher level of marital satisfaction than those women who participated at Time 1 and Time 2, all of which may indicate that the sample was not wholly representative of the population. However, these two groups of women did not differ on a wide range of other psychosocial variables nor did they differ on the level of reported general anxiety or pregnancy related anxiety during pregnancy.

The use of self-report scales do have some limitations; they can be subject to response bias and thus considered as an unreliable measure of clinical symptoms (Heron et al., 2004) and when looking at the prevalence of anxiety in the current study, scores on the HADS were dichotomised in order to detect 'cases' of general anxiety. There are several difficulties with categorising continuous variables, for example it may lead to the reduction of statistical power due to the loss of information and the increased risk of making a false positive result. In addition, individuals close to but on either side of the cut-off point, are characterised as being very different (Altman & Royston, 2006). In addition, there were no measures of the various subtypes of anxiety (e.g. Panic or PTSD) in women either prior to or during pregnancy in the current research. Previous research has shown that pregnancy can exacerbate already existing conditions or is associated with the onset of such disorders (Altshuler, Hendrick & Cohen, 2000), and may confound the results. The use of psychiatric interview in future research may address these limitations. However, , it should be noted that this study is not assuming participants have a diagnosable anxiety disorder. There is a distinction between the clinical implications of a diagnosed anxiety disorder and the elevated symptoms of anxiety (Britton, 2008). Austin & Priest (2005) cautions against the over-diagnosis of clinical disorders in the perinatal period which he states may actually represent "transient disturbances" associated with pregnancy. The finding

that over half of the women who reported anxiety during pregnancy did not do so six weeks following birth lends support to this idea.

Clinical Implications.

The findings of the current study suggest that there is a relatively high prevalence of mild anxiety in women diagnosed with GDM during the perinatal period. While it is reassuring that diabetes related risk factors appear not to be predictive of this anxiety, a percentage of women who are generally anxious during pregnancy remain so after giving birth. Given the serious adverse consequences that anxiety can have on both the mother and child this has important implications for routine screening of women during pregnancy. Women who have been diagnosed with GDM are frequently in contact with both obstetric and diabetes specialists, even more so than women deemed to have a low risk pregnancy. This puts these clinicians ideally placed to screen and monitor anxiety in this population of women so that early intervention strategies can be put into place to reduce the known adverse outcomes of perinatal anxiety. In addition, anxiety specific to pregnancy and general anxiety have been found to be separate constructs and clinicians should take this into consideration when screening for anxiety.

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Public Domain Paper

A review of the literature on Coping Skills Training in Children and Adolescents with Type 1 Diabetes Mellitus and research on Predictors of Anxiety in Women with Gestational Diabetes.

This paper aims to provide a brief summary of the key findings of two areas of research. The first part reports on a review of the literature examining Coping Skills Training in Children and Adolescents with Type 1 Diabetes Mellitus. The second part describes a research study exploring anxiety in women diagnosed with Gestational Diabetes.

Part one: *Literature review*.

Background

The treatment of Type 1 Diabetes (T1DM) includes daily injections of insulin and requires attention to diet, exercise and regular monitoring of blood glucose levels to achieve a good level of metabolic control. Poor metabolic control has been linked to serious long-term complications (Insabella, Grey, Knafl & Tamborlane, 2007). Training young people to self-manage their diabetes is essential in preventing these complications and reducing the distress of living and dealing with diabetes on a daily basis. Coping Skills Training (CST) is an intervention which is designed to help individuals develop skills to actively manage diabetes. Practising and rehearsing skills is considered to enhance the young person's confidence in their ability to manage diabetes and increase their engagement in positive health-related behaviours (Grey, 2011; Grey & Berry, 2004).

Aim

Over the last thirty years a growing number of studies have examined CST in young people and this paper reviewed the literature to date. The review had three aims; to describe and compare the characteristics of CST across studies, provide a quality assessment of studies evaluating CST and describe the impact of CST on metabolic control and psychosocial outcomes in children and adolescents with T1DM.

Method

A keyword search in Embase, Medline, PsycINFO and Pubmed Central databases and a hand search of the reference section of relevant articles identified 15 studies that were reviewed.

Results

Better outcomes were found in studies that used face to face delivery of CST in a group setting, a variety of teaching methods, contained broad content and provided a higher number of intervention sessions. It appeared that CST can be delivered by a variety of professionals which has positive cost implications for clinical practice. Study results indicated that for a limited population of children (aged 8-12 years), participation in CST did not improve metabolic control or psychosocial outcomes over and above participation in a group diabetes education program. Children of this age tend to use concrete coping strategies e.g. using insulin to lower blood glucose levels (Brotman Band, 1990), therefore interventions aimed at changing perceptions or feelings about diabetes may not be appropriate in younger children.

There is strong but small amount of evidence to suggest that CST can enhance the efficacy of intensive insulin treatment in improving metabolic control in ethnically white adolescents from middle to high income families. There is also evidence to suggest that CST can decrease levels of diabetes-related distress and improve quality of life and adolescents' perception of their competence, confidence and ability to cope with diabetes. However, these results appeared dependent on the demographic characteristics of participants, the type of treatment adolescents are using and whether CST was compared to adolescents receiving a diabetes-related education program or continuing with their routine medical care.

Conclusions

The effect of CST on metabolic control and psychosocial outcomes appeared dependent on the age of the young person, demographic characteristics and type of insulin treatment. An increase in the number of high quality, randomly

controlled studies conducted with a diverse population of children and young people is needed to add weight to the findings of this review.

Part two: *Research paper*.

Background

The primary aim of this research was an exploration of perinatal anxiety in women diagnosed with Gestational Diabetes Mellitus. Gestational diabetes has been associated with a number of complications for both the mother and baby and requires attention to diet, exercise, regular monitoring of blood glucose levels and for some women daily injections of insulin (HAPO, 2008). Previous research has found distress is common in the general diabetes population (Grigsby, Anderson, Freedland, Clouse & Lustman, 2002) and it would reasonable to assume that GDM has the potential to increase the levels of anxiety and distress in pregnant women with GDM. Previous research on anxiety in women with GDM is limited by the use of generic anxiety measures which are not specific to pregnancy or diabetes. In addition, previous research has failed to take into consideration the impact of general risk factors associated with anxiety in the general population.

Aim

A prospective study of anxiety in pregnant women with Gestational Diabetes Mellitus was conducted in order to: Establish the prevalence and incidence of anxiety in women with GDM during the perinatal period. Examine whether known risk factors of perinatal anxiety are associated with anxiety in women with gestational diabetes and investigate whether diabetes specific risk factors (perceived problems with diabetes management and diabetes related social support) predict anxiety in women with gestational diabetes over and above general risk factors.

Method

Design: A prospective, longitudinal survey design was used to explore the aims of this study. Women completed a questionnaire pack over two time points; at 27-40 weeks gestation and at 6-8 weeks postnatal. Ethical approval was granted by West Midlands Research Ethics Committee.

Participants: Women diagnosed with Gestational Diabetes were recruited from combined antenatal and diabetes clinics in two hospitals in the Midlands over a 12 month period. Thirty eight women, aged between 22 – 42 years consented to take part in the research and completed questionnaires at both time points.
Measures: Women completed the following measures, The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), Postnatal Depression Predictors Inventory (PDPI-revised version; Beck, 2002), WHO-5 Well-being Index (Bech, 2004), Pregnancy Related Anxiety Scale (PRAS; Rini, Dunkel-Schetter, Wadhwa & Sandman, 1999), Emotional Support (Weissman & Bothwell, 1976), Problem Areas In Diabetes (PAID; Polonsky et al., 1995), Multidimensional Diabetes Questionnaire (MDQ; Talbot, Nouwen, Gingras, Gosselin & Audet, 1997). Demographic information was also collected and included education, ethnicity, number of children, obstetric outcome, mode of delivery and whether the baby was born prematurely.

Results

In this sample of women diagnosed with Gestational Diabetes, low to moderate levels of pregnancy related anxiety were reported but this was not associated with risk factors found to be associated with general anxiety or diabetes-related distress and diabetes-related social support. Pregnancy related anxiety was not associated with general anxiety, suggesting these two anxiety constructs are separate.

A third of women reported mild general anxiety during pregnancy but significantly fewer women reported anxiety in the postnatal period. There were no new incidents of general anxiety in the postnatal period once antenatal anxiety was taken into consideration. Low emotional well-being during pregnancy was associated with higher levels of anxiety during pregnancy. Antenatal anxiety was the strongest predictor of higher levels of anxiety in the postnatal period. Diabetes related distress and social support did not appear to be associated with perinatal anxiety over and above general emotional well-being.

Conclusion

Diabetes related distress and level of diabetes-related social support did not appear to be associated with general anxiety or pregnancy related anxiety. It appears that women in this study who reported mild levels of anxiety during the perinatal period may well be individuals who are already generally anxious. Women who have been diagnosed with gestational diabetes come into frequent contact with obstetric and diabetes specialists, putting these clinicians ideally placed to monitor anxiety in this population of women so that early intervention strategies can be put in place. Clinicians may wish to consider measuring pregnancy related anxiety and general anxiety as separate constructs.

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Appendix 1

REC Approval

(Please note this has been removed for confidentiality purposes)

Appendix 2

Participant Study Pack

Appendix 3

Antenatal Questionnaires (Time 1)

Appendix 4

Postnatal Questionnaires (Time 2)