

A Thesis Submitted in Partial Fulfilment of the Regulations for the Degree of  
Doctor of Clinical Psychology (Clin.Psy.D.) in the University of Birmingham

## **Volume I**

# **Diabetes and Depression**

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# THESIS OVERVIEW

This thesis is submitted in partial fulfilment of the requirement for the Degree of Doctor of Clinical Psychology at the School of Psychology, University of Birmingham. It comprises two research papers, a public dissemination document, and five clinical practice reports.

Volume 1 of the thesis contains the research component. Paper one is a systematic review of longitudinal studies looking at the association between depression and diabetes complications. Paper two describes a prospective longitudinal study, examining risk factors for postnatal depression in women with gestational diabetes. Paper three is a public dissemination document, providing a lay summary of the study described in detail in paper two.

Volume 2 of the thesis contains clinical practice reports (CPRs). The reports reflect work conducted during clinical placements, as follows: 1) psychological models CPR (A cognitive-behavioural and psychodynamic formulation of Samuel, a 28-year old man with phobia of falling following an acquired brain injury); 2) service-related CPR (Adherence to initial goal planning meeting clinical standard in an outpatient brain injury rehabilitation service. Factors acting as barriers and facilitators); 3) single-case experimental design CPR (Cognitive behavioural intervention in the case of Alice, a 15-year old White British female with obsessive-compulsive symptoms); 4) case study CPR (The case of Monique, a 55-year old White British female with mild learning disabilities presenting with challenging behaviour. A behavioural approach to formulation and intervention); 5) case-study CPR – abstract (The case of Martin, a 67-year old White British male presenting with hypochondriasis. A cognitive behavioural approach to formulation and intervention). Names and other identifying materials in all the reports were changed in order to protect confidentiality.

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**THE ASSOCIATION BETWEEN DEPRESSION AND DIABETES  
COMPLICATIONS: A SYSTEMATIC REVIEW**

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## ABSTRACT

**Aims** *A meta-analysis conducted by de Groot et al in 2001 examined the magnitude and consistency of the relationship between depression and diabetes complications. However, all studies included were cross-sectional, and therefore no causality could be established. The current study aims to update and further examine the relationship between depression and diabetes complications by focusing on longitudinal studies.*

**Methods** *Medline, PsycINFO and Embase databases were searched for articles published in English language journals between 2000 and 2011. All studies that investigated the relationship between depression and diabetes micro- and macrovascular complications were included. Quality assessment of included studies was also conducted.*

**Results** *Ten prospective longitudinal studies met the inclusion criteria and were incorporated in the current review. Eight studies examined the relationship between baseline depression and incident micro- and macrovascular diabetes complications. Two studies examined the association between baseline diabetes complications and higher risk of depression at follow-up. Only one study had good methodological quality.*

**Conclusions** *The relationship between depression and diabetes complications appears to be bidirectional. The underlying mechanisms remain unclear and warrant further research.*

**Keywords:** *diabetes complications, depression, systematic review*

# INTRODUCTION

## 1.1 Diabetes mellitus

Diabetes mellitus is a metabolic disease characterised by high blood glucose levels, due to the body's inability to produce sufficient insulin or to use insulin efficiently. Common risk factors include a first degree family member with diabetes, being overweight, high blood pressure, and ethnicity (i.e. people from a Black or Asian background).

### *Diabetes prevalence*

In the UK, 2.6 million people have a diagnosis of diabetes, with a further 500,000 estimated to be unaware of their condition (Diabetes UK, 2010). The prevalence is predicted to increase to four million by 2025 (Diabetes UK, 2010). The cost of diabetes care in the UK is estimated at £1.3 billion, accounting for 9% of all hospital costs (Wanless, 2002).

In the United States (US), diabetes affects 18.8 million people, with a further 7 million people estimated to live with undiagnosed diabetes (Centers for Disease Control and Prevention, 2011). The risk of death for people with diabetes is twice that of people of similar age without diabetes; diabetes is the seventh leading cause of death in the US (Centers for Disease Control and Prevention, 2011). Diabetes costs were estimated at \$174 billion in 2007, with an additional \$58 billion in indirect costs, due to disability, work loss and premature mortality (Centers for Disease Control and Prevention, 2011).

### *Diabetes complications*

Chronic complications of diabetes include microvascular (i.e. damage to small blood vessels) and macrovascular disease (i.e. damage to arteries).

Microvascular complications of diabetes include: a) *diabetic retinopathy*, where the blood vessels in the retina are affected; it can lead to vision impairment and blindness; b) *diabetic neuropathy*, consisting of decreased sensation in the extremities (usually starting with the feet) and vascular damage, which can lead to increase rates of foot ulcers and infection, and possibly necrosis and gangrene; it is the most common cause of amputation of toes and feet. Diabetic neuropathies are believed to result from diabetic microvascular injuries to small blood vessels supplying the nerves. Vascular and neural diseases are closely linked, as blood vessels rely on normal nerve function, and nerves depend on adequate blood flow; c) *diabetic nephropathy*, consisting of damage to the kidney which can lead to chronic renal failure and often requiring dialysis.

Macrovascular complications of diabetes include: a) *coronary artery disease*, leading to angina or myocardial infarction; b) *diabetic myonecrosis* or muscle ‘wasting’; c) *peripheral vascular disease*; d) *stroke*.

## **1.2. Depression**

Depression is defined in the Diagnostic and Statistics Manual (American Psychiatric Association, 2000) by the presence of several symptoms in the last two weeks (five symptoms for *major depression* and three symptoms for *minor depression*), leading to significant distress and functional impairment (see Table 1 below). Dysthymic disorder, or *dysthymia*, is another type of depression, where depressive symptoms last a long time (over 2 years), but are less severe than those of major depression (APA, 2000).

It is estimated that depression is the fourth leading cause of disability and disease in the world, likely to become the highest cause of disease burden in developed countries by 2020. Most depression prevalence data is based on self-report instruments, such as the Centre for

Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977) or the Patient Health Questionnaire – 9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001) for detecting depressive symptomatology. In the UK, depression is the most common psychiatric disorder, with a prevalence of 2.6% among 16 to 74 year old adults in the year 2000 (Singleton, Bumpstead, O'Brien, Lee, & Meltzer, 2001).

It is estimated that 6% of adults experience depressive symptoms each year, with depression constituting the third most common reason for attending a general practice consultation. One in four women and one in ten men will require treatment for depression at some point in their lives (National Institute for Clinical Excellence guideline, 2009).

**Table 1.** Symptoms listed in the DSM-IV criteria for major depressive disorder (APA, 2000) and symptoms of depression measured using self-report instruments (i.e. Centre for Epidemiologic Studies – Depression Scale, Patient Health Questionnaire)

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**DSM-IV criteria (at least 5 symptoms present nearly everyday for 2 weeks and causing significant distress and functional impairment)**

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Depressed mood

Markedly diminished interest or pleasure in all or almost all activities

Significant weight loss/gain or decreased/increased appetite

Insomnia or hypersomnia

Psychomotor agitation or retardation

Fatigue or loss of energy

Feeling of worthlessness/guilt

Diminished ability to concentrate/make decisions

Recurrent thoughts of death or suicide

---

**Symptoms of depression measured using self-report instruments**

---

Feeling sad/depressed mood

Inability to sleep

Early waking

Lack of interest/enjoyment

Tiredness/lack of energy

Loss of appetite

Feelings of guilt/worthlessness

Recurrent thoughts about death/suicide

---

### **1.3. Depression and diabetes**

The prevalence of depression is significantly higher among people living with diabetes than the general population (Ali, Stone, Peters, Davies, & Khunti, 2006; Das-Munshi, Stewart, Ismail, Bebbington, Jenkins, & Prince, 2007). People with diabetes are 60% more likely to suffer from depression than those in the general population (prevalence data, Ali et al., 2006). It is estimated that 18% of people with diabetes also suffer from co-morbid major depression (Ali et al., 2006). After an episode of depression, patients with diabetes relapse more often than people in the general population (Lustman, Griffith, Freedland, & Clouse, 1997).

People living with diabetes are required to self-manage their diabetes, including dietary requirements, exercise, and medication adherence in order to achieve optimum blood glucose levels and thus reducing the risk of developing complications. A diagnosis of diabetes and depression is associated with poorer communication with health care professionals (Katon, 2003), greater disability in daily activities (Bruce, Davis, Starkstein, & Davis, 2005), decreased quality of life (Katon, 2008), nonadherence to treatment (Lin, Katon, Rutter, Simon, Ludman, von Korff et al., 2006), higher rates of diabetes complications (Piette, Richardson, & Valenstein 2004), higher health care costs (Egede & Ellis, 2010) and higher mortality rates (Egede & Ellis, 2010). Studies also report an increased risk of dementia in the presence of co-morbid diabetes and depression (Katon, Lin, Williams, Ciechanowski, Heckbert, Ludman et al., 2010). A qualitative meta-synthesis of patients experience of living with diabetes and depression (Gask, MacDonald, & Bower, 2011) showed that a diagnosis of diabetes is associated with a range of psychological emotions, including shock, despair, anxiety and fear, guilt, irritability, anger, 'existential insecurity', isolation, shame and feelings of dependence (Gask et al., 2011:242). However, when diabetes is suspected and is associated

with a range of unexplained symptoms, the diagnosis can be perceived as a ‘relief’. Changes in blood sugar levels can also influence mood, with poor metabolic control leading to an increase in depressive symptoms and a reduction in the effectiveness of antidepressant medication (Lustman & Clouse, 2005). Further, the impact of diabetes management on family life can be significant; the family’s reaction can function either as a buffer against depression or be a cause of distress (Gask et al., 2011). Distress and depression in people with diabetes were associated with a range of negative coping strategies, such as defensiveness, denial of vulnerability to depression and/or diabetes, intellectualisation and lying (Gask et al., 2011:242). The synthesis identified a moderator between diabetes and distress and depression, namely the sense of self. A person who sees themselves as a ‘person with diabetes’ is able to keep separate their identity from their illness; a ‘diabetic’ incorporates the diabetes into their sense of self. This impacts on their perceived control over their illness, which in turn influences diabetes self-management (Gask et al., 2011:247).

A systematic review and meta-analysis on the effectiveness of interventions for major depressive disorder in people with diabetes showed psychological and pharmacological interventions results in an improvement of depressive symptoms and additionally sometimes in diabetes self-management and blood glucose levels (van der Feltz-Cornelis, Nuyen, Stoop, Chan, Jacobson, Katon et al., 2010).

The relationship between depression and diabetes is bidirectional (Golden, Lazo, Carnethon, Bertoni, Schreiner, Diez Roux et al., 2008; Mezuk, Eaton, Albrecht, & Golden, 2008; Renn, Feliciano, & Segal, 2011). Recent systematic reviews and meta-analyses demonstrated that diabetes increases the risk of developing depression by 24% (Nouwen, Winkley, Twisk, Lloyd, Peyrot, Ismail et al., 2010). The mechanisms behind the higher prevalence rates of depression in people living with diabetes are not yet fully explained. Some argue that

biochemical changes due to living with diabetes lead to depression, while others argue that depression occurs due to the burden of living with a chronic disease and related disabilities (Campayo, Gomez-Biel, & Lobo, 2011; Renn et al., 2011; Talbot & Nouwen, 2000).

At the same time, people with depression have a 60% risk of developing type 2 diabetes (Mezuk et al., 2008). This relationship may be explained by lifestyles, i.e. a decline in health self care behaviours among people living with depression (Golden et al., 2008; Knol, Heerdink, Egberts, Geerlings, Gorter, Numans et al., 2007) or by biochemical changes linked with depression (Knol, Twisk, Beekman, Heine, Snoek, & Power, 2006).

### ***Depression and hyperglycaemia***

A meta-analysis conducted by Lustman and colleagues in 2000 underlined the association between depression and hyperglycaemia in patients with type 1 or type 2 diabetes (Lustman, Anderson, Freedland, de Groot, Carney, & Clouse, 2000). The effect size was 0.17 (small to moderate, 95%CI, 0.13-0.21). Richardson and colleagues (Richardson, Egede, Mueller, Echols, & Gebregziabher, 2008) also assessed the relationship between depression and glycaemic control in a 4-year longitudinal study and found that they were significantly associated.

However, a meta-analysis conducted by Nouwen and colleagues (Nouwen, Nefs, Caramlau, Connock, Winkley, Lloyd et al., 2011) found no significant association between elevated blood glucose levels in people with impaired glucose metabolism (IGM) or undiagnosed diabetes (UDD) and depressive symptoms. The risk of depression was similar between IGM, UDD and normal glucose metabolism (NGM) subjects. However, it should be noted that all of the included studies used a cross-sectional design. At the same time, people with known type 2 diabetes had a significantly higher risk of depression than people with IGM or UDD. The

results could be regarded as supporting the ‘diabetes as psychological burden’ hypothesis. Depression is also higher in people with chronic conditions other than diabetes such as asthma, chronic pain, and heart disease, where blood glucose levels are not elevated (Moussavi, Chatterji, Verdes, Tandon, Patel, & Ustun, 2007). Another explanation might be that people with undiagnosed diabetes have significantly lower levels of diabetes complications (Dankner, Geulayov, Olmer, & Kaplan, 2009). For example, a study conducted by Pouwer and colleagues (Pouwer, Beekman, Nijpels, Dekker, Snoek, Kostense et al., 2003) showed that diabetes alone was not associated with depressive symptoms, but living with diabetes plus diabetes complications was linked with depressive symptoms.

There is a well established link between the presence of hyperglycaemia and the risk of developing diabetes complications. Prospective studies showed an association between hyperglycaemia and the presence of microvascular complications (Genuth, 1995; Klein, 1995), myocardial infarction (Klein, 1995; UKPDS Group, 1998), stroke (Lehto, Ronnema, Pyorala, & Laakso, 1996), and macrovascular mortality (Standl, Balletshofer, Dahl, Weichenbain, Stiegler, & Hormann, 1996). Lowering blood glucose levels was found to reduce the risk of developing retinopathy, neuropathy, and nephropathy in patients living with type 1 (Reichard, Nilsson, & Rosenqvist, 1993) or type 2 diabetes (UKPDS Group, 1998).

### ***Depression and diabetes complications***

The presence of diabetes complications is associated with a higher prevalence of depression (Lustman & Clouse, 2005; van Steenbergen-Weijenburg, van Puffelen, Horn, Nuyen, van Dam, van Benthem et al., 2011). A meta-analysis conducted by de Groot and colleagues (de Groot, Anderson, Freedland, Clouse, & Lustman, 2001) examined the magnitude and consistency of the relationship between depression and diabetes complications. The authors

focused on microvascular complications (diabetic retinopathy, neuropathy, nephropathy or end stage renal disease), macrovascular complications (such as coronary artery disease), and sexual dysfunction. The authors reviewed 27 studies and found a significant and consistent relationship between depression and the diabetes complications under study. The association was positive, indicating that an increase in depressive symptoms was significantly associated with an increase in the severity and number of diabetes complications. Effect sizes ranged between 0.17 and 0.32, with an overall effect size of 0.25 (small to moderate) and were similar across type 1 and type 2 diabetes study samples. However, all included studies had a cross-sectional design, allowing the reporting of correlational findings, rather than the identification of specific directions and pathways.

### **Aim of the review**

The current systematic review follows on from the de Groot et al. (2001) meta-analysis and aims to examine further the relationship between depression and diabetes complications in longitudinal studies. A quality appraisal of included studies was also conducted.

## METHODS

### *Search strategy*

Literature searches were conducted using Medline, PsycInfo and Embase databases.

The authors of de Groot et al (2001) meta-analysis did not specify their search strategy. In order to ensure consistency, the Medline indexing of the meta-analysis was used as the starting point for the search strategy of the current systematic review.

The search strategy for Medline is presented as an example:

1 exp Diabetes Mellitus, Type 1/co, di, px [Complications, Diagnosis, Psychology]

2 exp Diabetes Mellitus, Type 2/co, di, px [Complications, Diagnosis, Psychology]

3 "diabet\*".ti,ab.

4 1 or 2 or 3

5 exp Depressive Disorder/co, di, px [Complications, Diagnosis, Psychology]

6 exp Depressive Disorder, Major/co, di, px [Complications, Diagnosis, Psychology]

7 "depress\*".ti,ab.

8 5 or 6 or 7

9 Diabetic Neuropathies/co, di, px [Complications, Diagnosis, Psychology]

10 Diabetic Nephropathies/co, di, px [Complications, Diagnosis, Psychology]

11 Diabetic Retinopathy/co, di, px [Complications, Diagnosis, Psychology]

12 Diabetic Angiopathies/co, di, px [Complications, Diagnosis, Psychology]

13 9 or 10 or 11 or 12

14 ("diabetic neuropath\*" or "diabetic nephropath\*" or "diabetic retinopath\*" or "diabetic angiopath\*").ti,ab.

15 13 or 14

16 exp Coronary Artery Disease/co, di, px [Complications, Diagnosis, Psychology]

17 "coronary artery diseas\*".ti,ab.

18 16 or 17

19 Peripheral Vascular Diseases/co, di, px [Complications, Diagnosis, Psychology]

20 "peripheral vascular diseas\*".ti,ab.

21 19 or 20

22 Stroke/co, di, px [Complications, Diagnosis, Psychology]

23 "strok\*".ti,ab.

24 22 or 23

25 Sexual Dysfunction, Physiological/co, di, px [Complications, Diagnosis, Psychology]

26 "sexual dysfunction".ti,ab.

27 25 or 26

28 15 or 18 or 21 or 24 or 27

29 4 and 8 and 28

30 exp Cohort Studies/

31 29 and 30

32 limit 31 to (english language and humans and yr="2000 - 2011" and "all adult (19 plus years)")

The search terms were adapted to meet the requirements of each database. All articles identified through the database searches were screened for potentially relevant references. Titles and/or abstracts were screened by two reviewers (IC and AN). Full texts papers were scrutinised to see if they fulfilled the inclusion criteria. Disagreement between the reviewers were solved by discussion between the two reviewers.

### ***Inclusion/exclusion criteria***

Articles meeting the following criteria were included: a) studies involving human subjects; b) studies published in English language journals between 2000 and 2011 (the 2000 cut-off was chosen because studies up to the end of 1999 were included in a meta-analysis by de Groot et al., 2001 ); c) studies involving adult participants (over 18 years old); d) longitudinal studies; e) studies examining the relationship between depression and at least one complication of type 1 or type 2 diabetes.

Studies examining the relationship between diabetes complications and both lifetime and current depression were included. Studies were excluded if they focused on gestational diabetes, impaired glucose tolerance, or pre-diabetes.

### ***Data extraction***

One reviewer conducted the data extraction process. Data of interest included: 1) name of first author; 2) publication year; 3) country; 4) study design; 5) number of participants; 6) age; 7) gender; 8) diabetes type; 9) duration of diabetes; 9) length of follow up; 10) method of depression assessment; 11) method of diabetes assessment; 12) method of diabetes complications assessment; 13) study results.

Method of depression assessment could be either a diagnosis of depression assessed by a diagnostic psychiatric interview or a self-report assessment of depressive symptoms using a questionnaire. Type of diabetes could be assessed either via self-report, testing of blood glucose levels, or extracted from medical records. Diabetes complications could be assessed either via self-report, or with the use of diagnostic tests, or extracted from medical records.

### ***Quality assessment***

Quality assessment of included studies was conducted by one reviewer using criteria for cohort studies proposed by the Centre for Reviews and Dissemination, University of York (Centre for Reviews and Dissemination, 2009). Criteria include a) choice of outcome measures; b) adequate description of study population; c) control for confounding variables (age, gender, education, socioeconomic status – shown to be independent risk factors associated with major depressive disorder in people with diabetes, Egede & Zheng, 2003), d) description of follow-up numbers; e) description of dropout rates; f) comparison of drop-out rates on key variables; g) sufficient follow-up period; h) blinding of baseline assessment (diabetes diagnosis only).

## RESULTS

### *Search results*

The Medline search yielded 187 potential articles. PsycINFO identified 34 potential articles. Embase found 112 potential articles. The search of reference lists yielded another 2 potential papers. The search protocol is presented in Appendix 1. Twenty-four full text articles were retrieved for closer examination.

Fourteen articles were excluded due to: a) no investigation of the relationship between depression and diabetes-related mortality (Lin, Heckbert, Rutter, Katon, Ciechanowski, Ludman et al., 2009; Pan, Lucas, Sun, van Damm, Franco, Willett et al., 2011; Young, von Korff, Heckbert, Ludman, Rutter, Lin et al., 2010; Winkley, Stahl, Chalder, Edmonds, & Ismail, 2007); b) absence of longitudinal data analysis on the relationship between depression and at least one diabetes complication (Boulanger, Zhao, Bao, & Russell, 2009; Bruce, Casey, Davis, Starkstein, Clarnette, Foster et al., 2006); c) no data on depression (Wexler, Grant, Wittenberg, Bosch, Cagliero, Delahanty et al., 2006); d) cross-sectional study design (Bhojani et al., 2008; Engum, Mykletun, Midthjell, Holen, & Dahl, 2005; Koroschetz, Rehm, Gockel, Brosz, Freynhagen, Tolle et al., 2011; Icks, Kruse, Dragano, Broecker-Preuss, Slominany, Mann et al., 2008); e) the relationship between depression and at least one diabetes complication was not examined (Whyte, Mulsant, Vanderbilt, Dodge, & Ganguli, 2004); f) diabetes complications were controlled for (Brown, Majumdar, Newman, & Johnson, 2006); and g) absence of discreet data on diabetes (Davis, Fujimoto, Juarez, Hodges, & Assam, 2008).

Ten articles fulfilled the inclusion criteria for the current systematic review. The selected characteristics of included studies are presented in Appendix 2. On closer examination, there

were six articles (three pairs of two articles) that were based on the same study populations. In the current review, they are presented as separate studies: 1) Roy, Peng, & Roy, 2007 and Roy, Roy, & Affouf, 2007; 2) Lin, Rutter, Katon, Heckbert, Ciechanowski, Oliver et al., 2010 and Sieu, Katon, Lin, Russo, Ludman, & Ciechanowski, 2011; and 3) Vileikyte, Peyrot, Gonzales, Rubin, Garrow, Stickings et al., 2009 and Gonzales, Vileikyte, Ulbrecht, Rubin, Garrow, Delgado et al., 2010.

### ***Sample sizes***

Studies' sample sizes ranged from 333 to 4,623 participants. The ten studies provided a total of 20,469 participants.

### ***Setting***

Nine studies were conducted in the USA (Orchard, Olson, Erbey, Williams, Forrest, Kinder et al., 2003; Black, Markides, & Ray, 2003; Roy, Peng, & Roy, 2007; Roy, Roy & Affouf, 2007; Katon, Russo, Lin, Heckbert, Ciechanowski, Ludman et al., 2009; Vileikyte et al., 2009; Gonzales et al., 2010; Lin et al., 2010; Sieu et al., 2011), and one was conducted in Australia (Bruce et al., 2005).

### ***Participants***

Three studies included participants living with type 1 diabetes (Orchard et al., 2003; Roy, Peng, & Roy, 2007; Roy, Roy, & Affouf, 2007). Four studies included participants living with type 2 diabetes (Black, Markides, & Ray, 2003; Bruce et al., 2005; Lin et al., 2010; Sieu et al., 2011). Three studies recruited participants with either type 1 or type 2 diabetes (Katon et al., 2009; Gonzales et al., 2010; Vileikyte et al., 2009).

### *Quality of studies*

The results of the quality assessment of included studies are reported in Appendix 3. All ten studies used self-report measures to determine the presence of depressive symptoms, with one study using diagnostic criteria to measure lifetime depression (Black et al., 2003). One study used a subscale of a quality of life instrument (the General Health Status Questionnaire; Gudex & Kind, 1989) to determine depression status (Bruce et al., 2005). However, they validated the depression subscale on an independent sample of 51 people with type 2 diabetes.

Diabetes status was self-reported in one study (Black et al., 2003), it was determined by using medical records in six studies (Orchard et al., 2003; Roy, Peng, & Roy, 2007; Roy, Roy, & Affouf, 2007; Katon et al., 2009; Lin et al., 2010; Sieu et al., 2011), and it was based on fasting blood glucose levels in one study (Bruce et al., 2005). The information was not provided in two studies (Vileikyte et al., 2009; Gonzales et al., 2010).

Diabetes complications were assessed using self report in one study (Black et al., 2003), medical records in three studies (Katon et al., 2009; Lin et al., 2010; Sieu et al., 2011), a combination of medical records, self-report and screening tests in one study (Roy, Peng, & Roy, 2007), and screening instruments in five studies (Orchard et al., 2003; Bruce et al., 2005; Roy, Roy, & Affouf, 2007; Vileikyte et al., 2009; Gonzales et al., 2010).

All studies gave an adequate description of the study population, including information such as age, gender, duration of diabetes, type of diabetes, education, and current diabetes complications. All studies but one (Roy, Peng, & Roy, 2007) controlled for confounding variables such as age, gender, education, socioeconomic status.

Blinding of baseline assessment for diagnosis of diabetes was not applicable for nine out of ten studies, as none of them had a group of participants without a diagnosis of diabetes. For one study (Black et al., 2003) blinding was not reported.

Nine out of ten studies (except Gonzales et al., 2010) provided a description of follow-up numbers. Only six studies provided an adequate description of drop out rates (Roy, Peng, & Roy, 2007; Roy, Roy, & Affouf, 2007; Katon et al., 2009; Vileikyte et al., 2009; Lin et al., 2010, Sieu et al., 2011) and only two studies conducted a comparison of drop-out rates between groups on key variables (Katon et al., 2009; Vileikyte et al., 2009).

Follow-up period ranged between one and ten years. Follow-up period was considered sufficient if participants were followed up for 5 years and more (Stratton, Kohner, Aldington, Turner, & Holman, 2001). All but two studies had a sufficient follow-up period (Vileikyte et al., 2009; Gonzales et al., 2010).

## **Key findings**

The key findings are summarised by direction of association between depression and diabetes complications and types of outcomes.

### ***1. Depression as a predictor of diabetes complications***

Eight studies investigated whether depression predicted the occurrence of diabetes complications.

a) Depression and various microvascular and macrovascular diabetes complications

Two studies investigated the relationship between depression and diabetes complications, without presenting specific data for different types of advanced micro- or macrovascular complications.

Black et al. (2003) examined the association between depression and incident diabetes micro- and macro-vascular complications in a 7-year longitudinal study involving Mexican Americans. Depression status was assessed using a self-report measure at baseline (Center for Epidemiologic Studies Depression Scale) and clinical diagnostic criteria (Composite International Diagnostic Interview Depression Module) at 2-year follow-up. Microvascular complications included nephropathy, neuropathy, retinopathy and amputations.

Macrovascular complications included cardiovascular disease, stroke and kidney disease. The study results showed that both current depressive symptoms and lifetime depression predicted greater incidence of micro- and macrovascular complications. At the seven year follow-up, 44% of participants with both current depressive symptoms and diabetes had developed macrovascular complications, compared with 30% who had neither condition. Forty-three percent of participants with both current depressive symptoms and diabetes had developed microvascular complications, compared with 36% with diabetes only, and 3% with neither condition. Similar results were found for lifetime depression. Sixty-four percent of participants with both diabetes and lifetime depression had macro-vascular complications at follow-up, compared with 38% with neither condition. Fifty-two percent of participants with both conditions developed microvascular complications, compared with 42% with diabetes only, and 7% with neither condition. The comorbidity of both diabetes and depression predicted not only increased risk of developing diabetes micro- and macro-vascular complications, but also earlier occurrence for microvascular complications.

Lin et al. (2010) prospectively examined the association between depression and risk of advanced micro- and macrovascular complications in people with type 2 diabetes. The study took place over a 5-year period. Depression status was assessed using the Patient Health Questionnaire (PHQ-9). Advanced microvascular complications included blindness, end-stage renal disease, amputations and renal failure deaths. Advanced macrovascular complications included myocardial infarction, stroke, cardiovascular procedures and deaths. The study findings showed that people who had major depression and diabetes at baseline, had a 36% higher risk of developing advanced microvascular complications and a 25% higher risk of developing advanced macrovascular complications five years later, than participants with diabetes and without depression.

#### b) Depression and diabetic retinopathy

Roy, Roy, & Affouf (2007) examined the longitudinal relationship between depressive symptoms, assessed using the Beck Depression Inventory (BDI, Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) and diabetic retinopathy in African-Americans living with type 1 diabetes. The results showed that being depressed at both baseline and 6 year follow-up was significantly associated with progression of diabetic retinopathy ( $OR=2.44$ , 95%CI: 1.01-5.88,  $p=0.049$ ) and progression to proliferative diabetic retinopathy ( $OR=3.19$ , 95%CI: 1.30-7.87,  $p=0.01$ ).

Sieu et al. (2011) investigated whether depressive symptoms assessed using the Patient Health Questionnaire (PHQ-9, Spitzer, 1999) were associated with a higher incidence of diabetic retinopathy in people living with type 2 diabetes. Over a five-year follow-up period, baseline severity of depressive symptoms was associated with an increased risk of incident retinopathy (15% higher for each 5-point clinically significant increase in depression severity based on the

PHQ-9 total score), when controlling for socio-demographic characteristics (i.e. age, gender, ethnicity, education, and marital status), health risk behaviours (smoking, physical activity, BMI, HbA1c) and clinical characteristics (i.e. duration of diabetes, diabetes treatment, hypertension, diabetes complications).

c) Depression and foot ulcers

Gonzales et al. (2010) examined the association between depressive symptoms and the time-to-onset of foot ulcers over an 18 months follow-up period. Participants had a diagnosis of type 1 or type 2 diabetes and moderate to severe diabetic peripheral neuropathy (DPN), but not peripheral vascular disease (PVD). Depressive symptoms were assessed using the Hospital Anxiety and Depression Scale (HADS, Zigmond & Snaith, 1983). Study results showed that depression is an independent predictor for the development of first foot ulcers. Each one standard deviation increase in HADS depression score was associated with a 48% higher risk of foot ulceration. There was no association between depression and an increased risk of developing subsequent foot ulcerations.

d) Depression and incidence of coronary vascular disease (CVD)

Orchard et al. (2003) examined independent risk factors for coronary artery disease (CAD) in people with type 1 diabetes. Depressive symptomatology was assessed using the Beck Depression Inventory and participants were followed-up over a ten-year period. Results showed that baseline depression scores were significantly associated with a 40% higher risk of incident angina ( $HR=1.40$ , 95%CI: 1.06-1.84,  $p=0.016$ ) but not hard CAD events (i.e. myocardial infarction, catheter-proven stenoses, or CAD deaths) or total CAD events.

Roy, Peng, & Roy (2007) examined the risk factors for CVD (either coronary artery disease (CAD) or stroke) in African-Americans with type 1 diabetes. Depressive status was assessed

using the Beck Depression Inventory and participants were followed-up over a 6 year period. Findings showed that baseline depression was an independent risk factor for incident CVD ( $OR=1.03$ , 95%CI: 1.001-1.06,  $p=0.04$ ).

#### e) Depression and cardiac mortality

Bruce et al. (2005) investigated the impact of depression on all-cause and cardiac mortality in people living with type 2 diabetes. The study utilised a subscale of a quality of life instrument to establish depression status. However, the authors validated the subscale using an independent sample of people with type 2 diabetes. After adjustment for demographics, diabetes-related and cardiovascular risk factors, depression status was associated with a significant 56% increase in cardiac mortality ( $HR=1.56$ , 95%CI: 1.11-2.18,  $p=0.010$ ). However, when baseline diabetes complications were added into the model, depression status was associated with a non-significant 15% increase in cardiac mortality ( $HR=1.15$ , 95%CI: 0.80-1.68,  $p=0.45$ ). Baseline micro- and macrovascular complications were a strong predictor of cardiac mortality.

## ***2. Diabetes complications as predictors of depression***

Two studies investigated whether diabetes complications predicted depression (Katon et al., 2009; Vileikyte et al., 2009).

#### i) Diabetic peripheral neuropathy and depression

Vileikyte and colleagues (2009) examined the temporal relationships between diabetic neuropathy (DPN) severity measured by the neuropathy disability score (NDS) and the vibration perception threshold (VPT), DPN somatic experiences (symptoms and foot ulceration), DPN psychological consequences (restrictions in activities of daily living [ADL]

and social self-perception) and depressive symptoms measured by Hospital Anxiety and Depression Scale – depression items (HADS-D). They found that baseline NDS was significantly associated with increased depressive symptoms at 18 months follow-up ( $\beta=0.10$ ,  $p=0.01$ ). However, the association became non significant when baseline DPN symptoms were introduced in the model and baseline unsteadiness levels were significantly associated with increased depressive symptoms ( $\beta=0.16$ ,  $p=0.001$ ). In the final model, baseline unsteadiness ( $\beta=0.10$ ,  $p<0.05$ ), baseline ADL restrictions ( $\beta=0.18$ ,  $p<0.01$ ) and changes in social self-perception from 0 to 9 months ( $\beta=0.13$ ,  $p<0.01$ ) significantly predicted increased depressive symptoms.

#### ii) Microvascular and macrovascular diabetes complications and depression

Katon and colleagues (2009) examined the longitudinal relationship between microvascular and macrovascular events and procedures during follow-up and major depression at 5 year assessment.

Microvascular events included retinopathy, and nephropathy. Macrovascular events included myocardial infarction, stroke, and peripheral vascular disease. Macrovascular procedures included coronary procedures (coronary artery bypass surgery, angioplasty, or stent replacement), cerebrovascular procedures (carotid endarterectomy) and peripheral vascular procedures (angioplasty or major vascular surgery of the aorta or peripheral vasculature). Results showed that coronary procedures during follow-up were significantly associated with 92% higher risk of prevalent major depression at 5 year assessment ( $p<0.05$ ). Microvascular or macrovascular events or other macrovascular procedures were not significantly associated with higher risk of major depression.

## DISCUSSION

Ten studies were included in the current systematic review, involving 20469 participants.

Overall, the relationship between depression and diabetes complications appears to be bidirectional.

Eight studies investigated the relationship between baseline depression status and the incident micro- and macrovascular diabetes complications at follow-up. Baseline depression status was significantly associated with an increased risk of developing micro- and macrovascular diabetes complications, particularly retinopathy, development of first foot ulcers, angina, and CVD.

Two studies investigated the relationship between baseline diabetes complications and depression status at follow-up. Diabetic neuropathy symptoms and psychological consequences (but not severity of neuropathy) were significantly associated with increased depressive symptoms at follow-up. Coronary procedures (but not micro- or macrovascular events, cerebrovascular procedures or peripheral vascular procedures) were significantly associated with incident major depression at follow-up.

Overall, the quality of the studies was adequate. Only one study (Katon et al., 2009) had good methodological quality (i.e. provided all the information set out in the Quality assessment section).

### *Potential explanatory pathways*

a) Depression leading to incident diabetes complications

A possible explanation relates to the physiological changes associated with depression. Depression has been linked to a dysregulation of the hypothalamic-pituitary-adrenal axis, activation of the sympathetic nervous system and an increase in pro-inflammatory factors (Katon, 2003; Musselman, 2003; Golden, 2007; Lustman, Penckofer, & Clouse, 2007). The resulting changes i.e. increase in circulating levels of cortisol, catecholamines, cytokines and platelet and endothelial cell adhesion factors (Katon, 2003; Miller, Stetler, Carney, Freedland, & Banks, 2002; Raison, Capuron, & Miller, 2006) may lead to increase insulin resistance and glycaemic fluctuation (Musselman, 2003). Retinal vessels are reported to be particularly sensitive to glycaemia variability (Nalysnyk, Hernandez-Medina, & Kirshnarajah, 2010; Weber & Schnell, 2009), resulting in microvascular lesions and neuroretinal damages leading to diabetic retinopathy (Cheung, Mitchell, & Wong, 2010).

Another potential explanation relates to health behaviours. Makine, Karsidag, & Kadiougly (2009) found that depressed patients with diabetes tended to delay starting the insulin treatment, which in turn may contribute to a higher risk of developing diabetes complications. Also, people with diabetes who were depressed were less likely to engage in physical exercise (Bruce et al., 2005), less likely to adhere to diet programmes and to medication (Lin, Katon, & von Korff, 2004; Peyrot & Rubin, 1999).

*Self-efficacy* may partially explain the relationship between depression and incident diabetes complications. Self-efficacy is a key concept in Bandura's Social Cognitive Theory (Bandura, 1997) and is defined as an individual's belief in their own ability to perform a specific task (Krichbaum, Aarestad, & Buehler, 2003). Self-efficacy appears to mediate the relationship between depressive symptoms and glycaemic control (Cherrington, Wallston, & Rothman, 2010). Low mood could lead to a poor sense of self-efficacy, which in turn leads to reduced adherence to self-care behaviours. Poor diabetes self-management leads to poor glycaemic

control, which in turn is known to increase the risk of developing diabetes complications. (Genuth, 1995; Klein, 1995; Lehto, Ronnema, Pyorala, & Laakso, 1996; Standl, Balletshofer, Dahl, Weichenbain, Stiegler, & Hormann, 1996; UKPDS Group, 1998).

#### b) Diabetes complications leading to incident depression

A possible explanation is that depression results from the psychological burden of living with diabetes and its related complications and disabilities (Campayo, Gomez-Biel, & Lobo, 2011; Pouwer et al., 2003; Renn, Feliciano, & Segal, 2011; Talbot & Nouwen, 2000).

The diathesis-stress model of depression (Burke & Elliott, 1999) could be used as a framework to explain the link between diabetes complications and incident depression. The model emphasises interactions between social, cognitive, and biological vulnerability factors leading to an increase in one's susceptibility to depression. Biological vulnerabilities may include a genetic predisposition to depression, temperament, and gender. Cognitive/affective vulnerabilities may include low self-esteem, a negative attribution style, external locus of control, and unsuccessful coping strategies. The social/behavioural component may include poor social relationships. In the diathesis-stress model for depression, particular features of diabetes as a chronic illness (such as illness severity represented by the presence of diabetes complications) could be viewed as stressors that interact with existing social, cognitive, and biological vulnerability factors to increase one's vulnerability to other stressors and/or precipitate the onset of depression (Burke & Elliott, 1999).

### *Limitations of this systematic review*

The results of this study should be interpreted with caution, due to reasons outlined below.

The current systematic review included only articles published in the English language, potentially missing relevant publications. The grey literature (unpublished papers, conference abstracts etc) was not scanned.

Only one study used a comparable group of participants without diabetes complications (Black et al., 2003). Three studies used participants of a particular ethnicity (Black et al., 2003; Roy, Roy, & Affouf, 2007; Roy, Peng, & Roy, 2007) limiting the generalisability of findings.

The assessment of depression status varied greatly between studies and was based on self-report questionnaires. Fisher, Skaff, & Mullan (2007) found that self-reported depressive symptoms in people living with diabetes tend to be suggestive of general emotion and diabetes-specific distress, rather than indicative of a depressive disorder. This might have resulted in an overestimation of clinically significant depression rates.

Most studies did not differentiate between current depressive symptoms and history of depression. Katon, von Korff, & Lin (2004) found that 70% of participants with diabetes described their depressive symptoms as present for 2 years or more. Also, no data were collected regarding various depressive states over time, as depression can occur over a long period of time or it can manifest itself through repeated shorter episodes. Lustman et al. (1997) showed that 70% of participants with diabetes and major depression relapsed, with an average of four episodes over a 5-year interval. In addition, there are no data on depression medication and its impact.

For the purpose of this review, it was very difficult to ascertain what constitutes a sufficient follow-up period. However, most studies indicate that the condition develops very insidiously and that it takes at least a few years if not decades before diabetes complications can be diagnosed.

A meta-analysis was not conducted, as it was deemed to be beyond the purpose of the current project.

### ***Further research and clinical implications***

Longitudinal studies provide evidence of a temporal association between depression and diabetes complications, but no clear causation. The associations between depression and diabetes complications observed in this systematic review warrant further investigation, in order to identify potential causal pathways.

Due to the negative consequences of depression in people with diabetes, such as an increased risk of developing complications, early detection and treatment for depression is important. Further research is needed in order to investigate whether interventions for depression in people with diabetes result in a delay in the occurrence of diabetes complications. At the same time, further intervention studies are needed to explore whether appropriate management and support with diabetes complications may avert the occurrence of incident depression.

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**INCIDENCE, PREVALENCE, AND RISK FACTORS FOR  
POSTNATAL DEPRESSION IN WOMEN  
WITH GESTATIONAL DIABETES**

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## ABSTRACT

**Aims** Postnatal depression is a common affective disorder following childbirth, affecting around 13% of women. Postnatal depression has been shown to affect both the mother and her baby, leading to mother-infant relationship difficulties and long-term child behavioural and cognitive problems, particularly for boys from disadvantaged backgrounds. Previous research showed that women with diabetes (pre-gestational or gestational diabetes) were almost twice as likely to experience depression in the perinatal period than women without diabetes. The current study aims to: i) establish the incidence and prevalence of postnatal depression in women with gestational diabetes in a general hospital UK population; ii) to investigate whether known risk factors of postnatal depression predict depression in women with gestational diabetes; iii) to investigate whether diabetes specific risk factors (e.g. problems with diabetes control, management, etc.) predict depression in women with gestational diabetes over and above general risk factors. **Methods:** Prospective longitudinal study. **Results** The incidence of postnatal depression in the current study was 11.5%. The prevalence of postnatal depression in the current study was 15.8%, indicating that the majority of women who are depressed postnatally are also depressed antenatally. Antenatal depression was a significant predictor of postnatal depression in women with gestational diabetes. Diabetes-specific factors were not significant predictors of postnatal depression, over and above known risk factors. However, the study had a small sample size. **Conclusions** Further research is needed to examine the role of diabetes-specific factors in predicting postnatal depression.

**Keywords:** gestational diabetes, risk factors, postnatal depression

# INTRODUCTION

## 1.1. Postnatal depression

Perinatal mental health problems following childbirth include a wide range such as ‘baby blues’, postnatal depression, anxiety, and puerperal psychosis, a serious condition requiring hospitalisation (Evins & Theofrastous, 1997). Postnatal depression is classified in DSM-IV as ‘a depressive condition that often exhibits the disabling symptoms of dysphoria, emotional lability, insomnia, confusion, anxiety, guilt and suicidal ideation’ (APA, 1994). A meta-analysis of 59 longitudinal and epidemiologic studies provided estimates of the prevalence of PND in the region of 13%, ranging from 3 to 25% of women in the year following childbirth (O’Hara & Swain, 1996). A more recent systematic review of 28 cross-sectional, cohort and case-control studies estimated the incidence rates for postnatal depression between 7.8% and 14.5%, and point prevalence rates for postnatal depression between 9.6% and 29.1% in the first six months following childbirth (Gavin, Bradley, Gaynes, Lohr, Meltzer-Brody, Gartlehner et al., 2005).

Risk factors for postnatal depression include antenatal depression, antenatal anxiety, life stress, low levels of social support, previous history of depression, socioeconomic status, marital satisfaction, childcare stress, and infant temperament (Beck, 2001; Robertson, Grace, Wallington, & Stewart, 2004).

Postnatal depression has been shown to affect both the mother and her baby, leading to mother-infant relationship difficulties (Loh & Vostanis, 2004) and long-term child behavioural (Alpern & Lyons-Ruth, 1993; Beck, 1999; Murray, Sinclair, Cooper, Ducournau,

& Turner, 1999; Sinclair and Murray, 1998) and cognitive problems (Kurtjens & Wolke, 2001), particularly for boys from disadvantaged backgrounds (Sinclair & Murray, 1998). Treatment of postnatal depression leads to improved functioning of the mother, which in turn has a positive effect on the baby and the family as a whole (Wickberg & Hwang, 1996).

The treatment of postnatal depression is as such a public health priority, and recent NICE guidance recommended that all women be screened for postnatal depression (usually at 6-8 weeks and again at 3-4 months postnatally) using two questions to identify women experiencing difficulties (NICE, 2007). The questions (known as the Whooley questions) ask the following: 'During the past month, have you often been bothered by feeling down, depressed, or hopeless?' and 'During the past month, have you often been bothered by little interest or pleasure in doing things?'. A third question is asked if the woman answers 'yes' to either of the initial questions: 'Is this something you feel you need or want help with?'. Women experiencing such problems should be offered support from professionals, and voluntary organisations.

## **1.2. Diabetes in pregnancy**

One-point-eight percent of all pregnancies are affected by pre-existing diabetes, while between 2 and 9% of all pregnancies are affected by gestational diabetes mellitus (Lawrence, Contreras, Wansu, & Sacks, 2008). Diabetes in pregnancy is associated with maternal and infant risks and complications (Evers, de Valk, & Visser, 2004; Feig & Palda, 2002). Women with gestational diabetes are at increased risk of developing type 2 diabetes (Bellamy, Casas, Hingorani, & Williams, 2009); their offspring are at increased risk of developing diabetes and cardiovascular diseases, as well as obesity later in life (Lindsay, 2000). Infants are more likely to be born prematurely and to suffer from congenital malformations (McIntyre, Thomae,

Wang, Idris, & Callaway, 2009). Women with gestational diabetes have similar rates of stillbirth as in the general population. However, women diagnosed with ‘gestational’ diabetes who have unrecognised type 2 diabetes have a 2.5 fold higher risk of stillbirth than non-diabetic pregnant women (Cundy, Gamble, Townend, Henley, MacPherson, & Roberts, 2000; Lapolla, Dalfra, Bonomo, Parretti, Mannino, Mello, et.al., 2009; Silver, Varner, Reddy, Goldenberg, Pinar, Conway, et.al., 2007).

Hjelm et al. (Hjelm, Bard, Nyberg, & Apelqvist, 2005) interviewed women diagnosed with gestational diabetes in order to explore their beliefs about their condition. Participants expressed worries about the baby’s health, as well as fear about the future development of type 2 diabetes. Midwives providing care to pregnant women with gestational diabetes described their illness as a ‘snake in paradise’ (Persson, Hornsten, Winkvist, & Mogren, 2011:80).

### **1.3. Diabetes in pregnancy and mood states**

There is an emerging interest in the link between diabetes during pregnancy and perinatal mental health (Metzger, Buchanan, & Coustan, 2007). Previous literature has established a link between diabetes and depression in the general adult population (Anderson, Freedland, Clouse, & Lustman, 2001). While the relationship between diabetes and depression is reciprocal with depression leading to increased incidence of (type 2) diabetes (Mezuk, Eaton, Albrecht, & Golden, 2008) and diabetes increasing the risk of depression (Nouwen, Nefs, Caramlau, Connock, Winkley, Lloyd et al., 2011), several factors such as diabetes distress, glycaemic control, and diabetes complications were identified as mediators between depression and diabetes (Bailey, 1996). Moreover, behavioural factors such as reduced physical activity (Koopman, Pouwer, de Bie, van Rooji, Leusink, & Pop, 2009) and increased

food intake may also play a role (Sacco, Wells, Friedman, Matthew, Perez, & Vaughan, 2007).

Several studies looked at the relationship between diabetes in pregnancy and mood states. They reported inconsistent findings with regard to the association between depression, anxiety, and diabetes in the perinatal period. In some studies, high levels of anxiety and depression were associated with a diagnosis of gestational diabetes (Danniels, Grenyer, Davis, Coleman, Burgess, & Moses, 2003; York, Brown, Armstrong, & Jacobsen, 1996). Other studies reported that the mood profile did not differ significantly between women with gestational diabetes and women without diabetes in pregnancy (Kim, Brawarsky, Jackson, Fuentes-Afflick, & Hass, 2005; Mautner, Greimer, Trutnovsky, Daghofer, Egger, & Lang, 2009). Insulin therapy did not account for higher scores of depression or anxiety (Langer & Langer, 1994; Danniels et al., 2003). Women with pre-gestational diabetes experienced higher levels of depression than women with gestational diabetes (Langer & Langer, 2000). Glycaemic control affected emotional states for women with gestational diabetes (but not for women with pre-gestational diabetes), with poor glycaemic control accounting for more emotional distress (Langer & Langer, 1998; 2000).

However, most studies did not use outcome measures specific to postnatal depression such as the Edinburgh Postnatal Depression Scale (Cox, Holder, & Sagovsky, 1987). They had either short or no postnatal follow up. In addition, the majority of studies were inadequately powered and did not account for known postnatal depression risk factors such as previous history of depression and anxiety, marital status, social support, self esteem, and infant temperament. Few studies presented information on whether participants in the control group were screened for diabetes. No studies were conducted in the UK.

In contrast, a large retrospective cohort study (N=11024 participants) conducted by Backes Kozhimanhil and colleagues (Backes Kozhimanhil, Pereira, & Harlow, 2009) was adequately powered and showed that women with diabetes (pre-gestational or gestational diabetes) were almost twice as likely to experience depression in the perinatal period (defined as depression in the six months prior to delivery and twelve months postpartum) than women without diabetes ( $OR = 1.85$ ; 95% CI= 1.45-2.36). However, this study was conducted in the US with a low income population. Coming from a disadvantaged socio-economic background may have a bigger impact in people with diabetes because of the cost of medication, dietary habits, etc., which may increase stress levels, thus contributing to the higher levels of depression. The prevalence data in this study is consistent with systematic reviews and meta-analyses examining the prevalence of depression in people with diabetes in the general population (Anderson et al., 2001; Ali, Stone, Peters, Davies, & Khunti, 2006).

Understanding whether gestational diabetes is associated with postnatal depression is important. The current study aims to add to the existing literature by examining further the incidence and prevalence of postnatal depression in women with gestational diabetes in a general hospital UK population. It also aims to explore known and diabetes-specific risk factors for postnatal depression in this particular group, namely women with gestational diabetes.

## **1.4. Study aims\***

The study aims to: i) establish the incidence and prevalence of postnatal depression in women with gestational diabetes in a general hospital UK population; ii) investigate whether known risk factors of postnatal depression predict depression in women with gestational diabetes; iii) investigate whether diabetes specific risk factors (e.g. diabetes distress, diabetes-specific social support) predict depression in women with gestational diabetes over and above general risk factors.

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\* The current study is part of a larger study also investigating the link between perinatal anxiety and gestational diabetes.

# METHODS

## 2.1. Study design

The current project is a prospective longitudinal study, involving women with a diagnosis of gestational diabetes (GDM). Participants were recruited from two hospitals in the West Midlands. One hospital's catchment's area included mainly a British White middle-class population, with pockets of socially deprived areas. The other hospital's catchment's area included a more diverse, mainly socially disadvantaged population, with pockets of wealth. The study received ethical approval from the West Midlands Research Ethics Committee, reference number 10/H1208/61 (Appendix 1).

## 2.2. Recruitment procedure

Women at high risk of developing diabetes during pregnancy were referred to the hospital by the community midwife and invited to undergo an OGTT test (oral glucose tolerance test). If the OGTT test was positive, the diabetes specialist nurse/midwife invited them to attend a joint diabetes/obstetrics clinic at 30/31 weeks gestation. When attending the clinic, women were approached and invited to participate in the current study (Appendices 2-4). Participants were followed-up at six weeks postnatal using postal questionnaires. Telephone reminders were used two weeks after the postal questionnaires were sent out.

Participants' inclusion criteria: all pregnant women identified at risk of developing gestational diabetes. Known risk factors for gestational diabetes include: previous diagnosis of gestational diabetes, first degree relative with type 2 diabetes, increasing age, ethnicity (i.e. South-Asian), pre-pregnancy obesity, and previous pregnancy which resulted in a child with

high birth weight (>90th centile, or >4,000g), (Di Cianni, Volpe, Lencioni, Miccoli, Cuccuru, Ghio et al., 2003).

Participants' exclusion criteria: living with pre-existing diabetes, < 18 years old, unable to communicate in English, receiving specialist psychiatric care or suffering from any mental illnesses (other than PND) or learning difficulties.

### **2.3. Outcome measures**

Postnatal depression: The outcome of interest was depressive symptoms at six weeks postnatal, as measured by the Edinburgh Postnatal Depression Scale (EPDS; Cox et al. (1987). The EPDS was validated on a sample of new mothers and consists of ten items using a 4-point Likert scale ranging from 0 (yes, most of the time) to 3 (no, not at all). Examples of scale items include 'I have looked forward with enjoyment to things' and 'I have blamed myself unnecessarily when things went wrong'. The scale has been used extensively in perinatal research, as well as in clinical practice as a screening instrument for women with postnatal depressive symptoms. The sensitivity of the EPDS is 86%, and specificity is 78% (Cox et al, 1987). Cronbach's alpha in the current study was .89.

Antenatal depression: antenatal depressive symptoms were measured using the depression subscale of the Hospital Anxiety and Depression Scale (HADS-D; Zigmond & Snaith, 1983). The scale measures the absence of positive affect and pleasure of every day tasks; it was designed to discriminate between somatic symptoms of physical illnesses and the assessment of anxious and depressive symptoms in medically ill people (Zigmond & Snaith, 1983). The subscale comprises 7 items using a 4-point Likert scale ranging from 3 (yes, definitely) to 0 (no, not at all). Examples of scale items include 'I still enjoy the things I used to enjoy' and 'I

feel miserable and sad'. The HADS was administered at two points in time, i.e. 2<sup>nd</sup>/3<sup>rd</sup> trimester, and six weeks postnatal. Cronbach's alpha for the current sample was .80.

Antenatal anxiety: antenatal anxiety symptoms were measured using the anxiety subscale of the HADS (HADS-A, Zigmond & Snaith, 1983). The subscale comprises 7 items using a 4-point Likert scale ranging from 3 (yes, definitely) to 0 (no, not at all). Examples of scale items include 'I feel anxious when I go out of the house on my own' and 'I am restless and can't keep still'.

Social support: the social support subscale of the Postpartum Depression Predictors Inventory (PPDI-R; Beck, 2002) was used to assess practical and emotional support. The social support subscale consists of 12 items using 'yes' or 'no' answers. Examples of scale items include 'Do you feel you receive adequate practical support from your partner?' and 'Do you feel you can confide in your partner?'. The PPDI-R was designed based on the results of a meta-analysis on risk factors for postnatal depression (Beck, 2001). The PPDI-R has concurrent validity and internal consistency (Cronbach's  $\alpha=0.83$ ), (Records, Rice, & Beck, 2007).

Diabetes-related emotional distress: Problem Areas in Diabetes survey (PAID; Polonsky, Anderson, Lohrer, Welch, Jacobson, & Schwartz, 1995) was used to measure diabetes-related emotional distress. The scale comprises 20 items using a 5-point Likert scale ranging from 0 (not a problem) to 4 (serious problem). Examples of scale items include 'Feelings constantly concerned about food and eating' and 'Worrying about low blood sugar reactions'. The scale has been used extensively in diabetes research and has high internal reliability (Cronbach's  $\alpha=0.95$ ) and concurrent validity.

Perceived diabetes interference, severity and diabetes-specific social support: the Multidimensional Diabetes Questionnaire (MDQ, Talbot, Nouwen, Gingras, Gosselin, &

Audet, 1997) is a 16-item scale using a 7-point Likert scale ranging from 0 (not at all) to 6 (extremely). The scale includes measures of perceived interference, severity, and diabetes-specific social support (mediating link stress to depression, Talbot, Nouwen, Gingras, Belanger, & Audet, 1999). The Cronbach's alpha for the current sample was .86.

We also collected data on demographic characteristics (age, education, socioeconomic status, marital status, number of children), history of depression, and obstetric outcome (mode of delivery, outcome of delivery, preterm/term delivery). (Appendices 6&7)

## **2.4. Sample size**

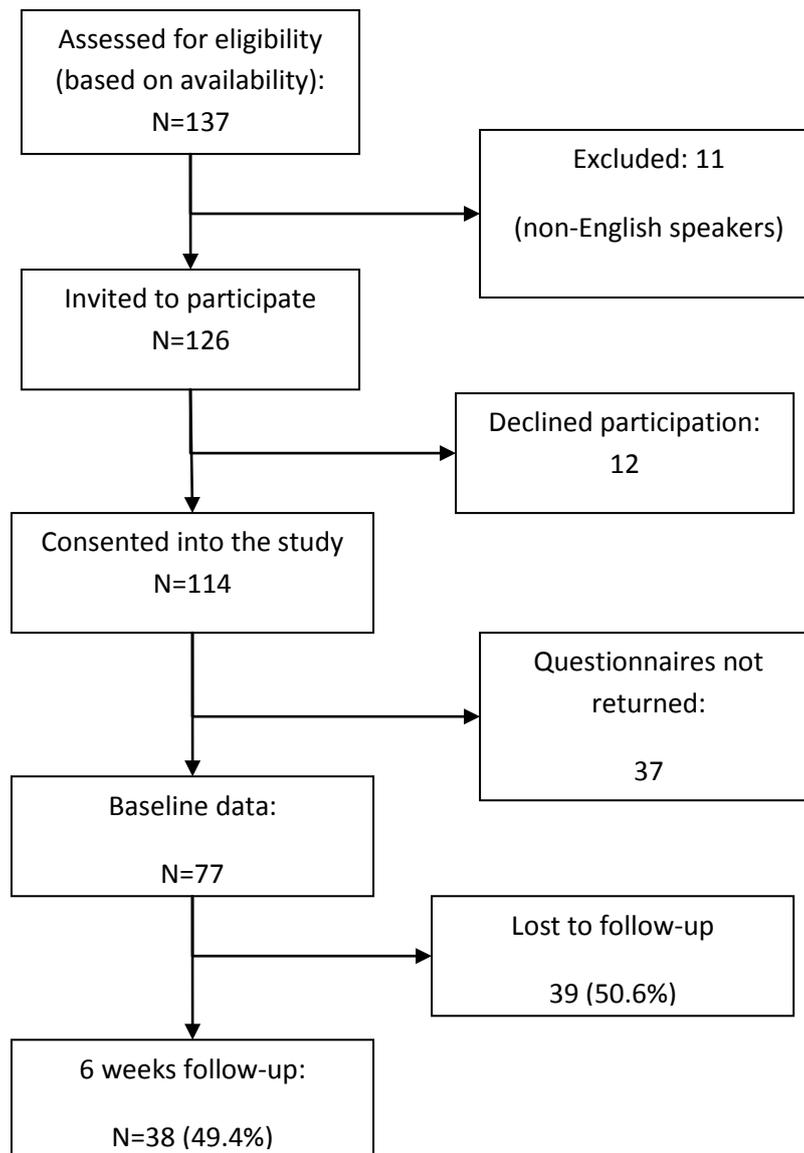
Sample size was determined using a 'rule of thumb' suggested by Tabachnick and Fidell (2007), which states that the number of participants required when using a multiple regression analysis is at least  $50 + 8 \times$  the number of predictor variables being entered into the regression. In the current study, the number of predictor variables was 13, and therefore the sample size requirement was 154 participants ( $50 + 8 \times 13 = 154$ ).

## **2.5. Statistical methods**

Descriptive methods were used to describe participant's characteristics. Independent samples t-tests, Mann-Whitney U tests (where there were violations to the assumption of a normal distribution), and chi-square analyses were used to compare between participants who were followed up at six weeks postnatal with the ones who dropped out of the study. Hierarchical multiple regression was used to examine the relationship between potential risk factors and postnatal depression.

## **RESULTS**

137 women (based on availability) were invited to participate in the study. 11 did not meet the eligibility criteria (i.e. non-English speakers). 12 declined to participate. 114 consented to participate and 77 returned baseline questionnaires. 38 (49.4%) participants returned the six week follow-up questionnaires and 39 (50.6%) were lost to follow-up (see Figure 1 below).



**Figure 1.** Study sample recruitment

The baseline sociodemographic and clinical characteristics of participants who completed the baseline questionnaire (N=77) are presented in the table 1 below.

**Table 1.** Baseline demographic and clinical characteristics for all participants

<b>Characteristics</b>	<b>Total sample (N=77)</b>
<b>Age</b>	
Range	22-42
Mean ( <i>SD</i> )	32.3 (4.8)
<b>Marital status N (%)</b>	
Single/separated/divorced/widowed	4 (5.2%)
Married/cohabiting	73 (94.8%)
<b>Number of children (range)</b>	
	0-4
<b>Ethnicity N (%)</b>	
White British	45 (58.4%)
White other	7 (9.1%)
British Asian	16 (20.8%)
British Black African	1 (1.3%)
Other	5 (6.5%)
<b>SES (deprivation scores)<sup>a</sup></b>	
Range	2.2- 71.6
Mean ( <i>SD</i> )	20.4 (16.5)
<b>Education – 1<sup>st</sup> degree and above N (%)</b>	
	41 (53.2%)
<b>Pregnancy planned N (%)</b>	
Yes	54 (70.1%)
No	23 (29.9%)
<b>Pregnancy wanted N (%)</b>	
Yes	77 (100%)
<b>History of depression N (%)</b>	
Yes	25 (32.5%)
No	52 (67.5%)

Characteristics	Total sample (N=77)
<b>Antenatal depression (HADS-D) N (%)</b>	
Yes	6 (7.8%)
No	69 (89.6%)
<b>Antenatal anxiety (HADS-A) N (%)</b>	
Yes	6 (7.8%)
No	70 (9.1)

<sup>a</sup>Deprivation scores were computed using the National Statistics Postcode Directory (available at [www.census.ac.uk](http://www.census.ac.uk))

Out of the 77 women who completed the baseline questionnaires, 38 women (49.4%) completed the six weeks follow-up questionnaires. Table 2 describes the comparisons between participants who were followed-up with the ones who were lost to follow-up on sociodemographic and clinical characteristics.

**Table 2.** Comparison between participants who returned the six weeks questionnaires and the ones who were lost at follow-up

Characteristics	Follow-up N=38	Drop-out N=39	<i>p</i> values
<b>Age</b>			
Range	22-42	23-42	
Mean ( <i>SD</i> )	32.3 (4.7)	32.4 (4.9)	ns
<b>Marital status N (%)</b>			
Single/separated/divorced/widowed	2 (5.3%)	2 (5.1%)	
Married/cohabiting	36 (94.7%)	37 (94.9%)	ns
<b>Number of children (range)</b>	0-4	0-4	ns
<b>Ethnicity N (%)</b>			
White British	25 (65.8%)	20 (51.3%)	

<b>Characteristics</b>	<b>Follow-up N=38</b>	<b>Drop-out N=39</b>	<b><i>p</i> values</b>
White other	4 (10.5%)	3 (7.7%)	
British Asian	6 (15.8%)	10 (25.6%)	
British Black African	1 (2.6%)	-	
Other	1 (2.6%)	4 (10.3%)	ns
<b>SES (deprivation scores)</b>			
Range	2.6-71.6	2.2-63.6	
Median	17.51	16.05	ns
<b>Education –1<sup>st</sup> degree and above N (%)</b>	24 (63.2%)	17 (43.6%)	ns
<b>Pregnancy planned N (%)</b>			
Yes	28 (73.7%)	26 (66.7%)	
No	10 (26.3%)	13 (33.3%)	ns
<b>Pregnancy wanted N (%)</b>			
Yes	38 (100%)	39 (100%)	N/A
<b>History of depression N (%)</b>			
Yes	9 (23.7%)	16 (41.1%)	
No	29 (76.3%)	23 (58.9%)	ns
<b>Antenatal depression (HADS-D) N (%)</b>			
Yes	2 (5.3%)	4 (10.3%)	
No	35 (92.1%)	34 (87.2%)	ns
<b>Antenatal anxiety (HADS-A) N (%)</b>			
Yes	1 (2.6%)	5 (12.8%)	
No	36 (94.7%)	34 (87.2%)	ns
<b>Delivery outcome N (%)</b>			
Live baby	32 (84.2%)	27 (69.2%)	
Special care	3 (7.9%)	2 (5.1%)	
Transferred out	1 (2.6%)	-	ns

<b>Characteristics</b>	<b>Follow-up N=38</b>	<b>Drop-out N=39</b>	<b>p values</b>
<b>Mode of delivery N (%)</b>			
Normal vaginal delivery	12 (31.6%)	16 (41.1%)	
Instrumental delivery	6 (15.8%)	1 (2.6%)	
Elective caesarean	8 (21.1%)	7 (17.9%)	
Caesarean section in labour	10 (26.3%)	5 (12.8%)	ns
<b>Preterm N (%)</b>	2 (5.3%)	2 (5.1%)	ns

ns=not significant; N/A=not applicable

There were no significant differences on demographic characteristics, obstetric outcomes, history of depression, antenatal depression, or antenatal anxiety between the women who returned the six week follow-up questionnaires and the ones who were lost at follow-up.

### ***Incidence and prevalence of postnatal depression***

Incidence rates refer to the number of new cases of depression, measured at six weeks postnatal. Prevalence rates refer to the total number of women with depression at six weeks postnatal (i.e. it includes women with antenatal depression). The incidence and prevalence of postnatal depression was assessed using the EPDS (EPDS score > 9) at six weeks postnatal. The incidence of postnatal depression in the current study was 11.5%. The prevalence of postnatal depression in the current study was 15.8%.

### ***Risk factors for postnatal depression in women with gestational diabetes***

Variables of interest were first examined for normality. The Kolmogorov-Smirnov test of normality indicated that antenatal anxiety, antenatal depression, diabetes distress and diabetes severity were normally distributed ( $p>0.05$ , Appendix 1). The remaining variables (child care stress, infant temperament, life stress, social support, marital satisfaction, deprivation scores,

diabetes social support, and diabetes interference) were not normally distributed ( $p < 0.05$ , Appendix 8). Independent samples t-tests, Mann-Whitney U tests (where there were violations to the assumption of a normal distribution), and chi square tests (with Yates Continuity Correction) were used in order to compare women with postnatal depressive symptoms at six weeks postnatal (EPDS > 9) with women without postnatal depressive symptoms (EPDS ≤ 9) on various known risk factors for postnatal depression (Beck, 2001; Roberston et al., 2004). The results are presented in Table 3 below.

Table 3. Comparisons between depressed and non-depressed women

<b>Variables</b>	<b>No postnatal depression</b>	<b>Postnatal depression</b>	<b>t, z or <math>\chi^2</math></b>
Antenatal anxiety (HADS-A) <i>Mean (SD)</i>	4.45(3.19)	8.67(2.07)	-3.09**
Antenatal depression (HADS-D) <i>Mean (SD)</i>	4.58(2.85)	7.67(2.94)	-2.42*
Child care stress (PPDI-R)	0.00	1.50	-1.93*
Infant temperament (PPDI-R)	0.00	0.50	-1.07
Life stress (PPDI-R)	0.00	1.00	-2.90**
Social support (PPDI-R)	0.00	2.00	-1.93*
Marital satisfaction (PPDI-R)	0.00	0.00	-0.62
Deprivation scores	17.8	17.14	-0.02
Diabetes distress (PAID) M(SD)	21.99(17.66)	36.04(16.29)	-1.74
Diabetes social support (MDQ)	4.88	3.00	2.15*
Diabetes severity (MDQ) M(SD)	2.54(1.36)	3.61(1.51)	-1.81
Diabetes interference (MDQ)	0.83	2.33	-1.95*
History of depression <i>N (%)</i>	7(21.9)	2(33.3)	0.01

Data are median scores unless otherwise indicated; \* $p < 0.05$ ; \*\* $p < 0.01$

Antenatal anxiety, antenatal depression, social support, life stress, child care stress, diabetes social support, and diabetes interference significantly differed between women with and without postnatal depression symptoms at six weeks postnatal.

A correlation matrix containing all antenatal variables is presented in Table 4 below.

Table 4. Correlation matrix between study variables

<b>Variables</b>	Antenatal depression	Antenatal anxiety	Social support	Life stress	Diabetes social support	Diabetes interference
Antenatal depression	1.00	0.57***	0.20	0.15	-0.22*	0.50***
Antenatal anxiety	0.57***	1.00	0.19	0.19	-0.29*	0.42***
Social support	0.20	0.19	1.00	0.36***	-0.20	0.15
Life stress	0.15	0.19	0.36***	1.00	-0.15	0.17
Diabetes social support	-0.22*	-0.29*	-0.20	-0.15	1.00	-0.34**
Diabetes interference	0.50**	0.42***	0.15	0.17	-0.34**	1.00

All data represent Spearman's *rho* correlation coefficient; \* $p < 0.05$ ; \*\* $p < 0.01$ , \*\*\* $p < 0.001$

Variables that were not normally distributed (social support, life stress, child care stress, diabetes social support, and diabetes interference) were transformed in order to achieve normal distribution before entering them in a hierarchical multiple regression. Different types of transformations were performed, as recommended by Tabachnick & Fidell (2007); social support, life stress and child care stress did not improve, and were therefore entered in the regression in their original format (Tabachnick & Fidell 2007); for diabetes social support a 'reflect and square root' transformation was used [new variable=SQRT(K-old variable),

K=largest possible value +1], while diabetes interference was transformed using a ‘square root’ transformation [new variable=SQRT(old variable)], (Tabachnick & Fidell 2007).

All variables were entered in a hierarchical multiple regression in order to assess whether diabetes-specific factors (diabetes social support, diabetes interference) were able to predict depressive symptoms, after controlling for known postnatal depression risk-factors (antenatal anxiety, antenatal depression, social support, life stress, child care stress). (Appendix 9)

Data was checked for collinearity. Tolerance values were greater than 0.1 and VIF values were less than 10. The data was also checked for outliers, inspecting the Mahalanobis distances; the critical value was 15.14, which was less than 24.32 (the maximum critical value for seven independent variables, Tabachnick & Fidell, 2007).

Antenatal depression, antenatal anxiety, social support, and life stress were entered at Step 1 (model 1), explaining 41% of the variance in postnatal depressive symptoms. Antenatal anxiety was a significant predictor for postnatal depression. After entry of child care stress at Step 2 (model 2), the total variance explained by the model as a whole was 48%,  $F(5,15)=2.79, p<0.05$ . Child care stress explained an additional 7% of the variance in depressive symptoms,  $R$  square change=0.07,  $F$  change (1,15)=1.99,  $p=0.18$ . In model 2, antenatal anxiety was a significant predictor for postnatal depression. However, the  $R$  square change was not significant, meaning that the additional variable (child care stress) did not add a significant amount of variance to the first model.

Diabetes distress and diabetes-specific social support were entered at Step 3 (model 3). The total variance explained by the model was 59%,  $F(7,13)=2.77, p<0.05$ . The two variables explained an additional 11% of the variance in depressive symptoms,  $R$  square change=0.11,

$F$  change (2, 13)=1.89,  $p$ =0.19. Adding diabetes social support and diabetes interference to the model did not lead to a better prediction model ( $R$  square change not significant).

Table 5. Predictors of postnatal depressive symptoms in women with gestational diabetes

Model	Predictors	$\beta$	$F$	$R^2$	$R^2$ change	$F$ change
1	Antenatal depression	0.04	2.82*	0.41	0.41	2.8
	Antenatal anxiety	0.52*				
	Social support	0.13				
	Life stress	0.14				
2	Antenatal depression	-0.004	2.79*	0.48	0.07	1.98
	Antenatal anxiety	0.50*				
	Social support	0.09				
	Life stress	0.09				
	Child care stress	0.28				
3	Antenatal depression	-0.08	2.77*	0.59	0.11	1.88
	Antenatal anxiety	0.43				
	Social support	0.01				
	Life stress	0.12				
	Child care stress	0.33				
	Diabetes social support	-0.20				
	Diabetes interference	0.22				

\* $p$ <0.05

# Discussion

## 4.1. Summary of findings

The first aim of the current study was to investigate the incidence and prevalence of postnatal depression in women with gestational diabetes in a general hospital UK population. The incidence was 11.5%. The prevalence of postnatal depression was 15.8%. The incidence rate of postnatal depression in this study was lower than the prevalence rate, indicating that the majority of women depressed postnatally were also depressed antenatally. The incidence rate in this study was slightly higher than the one found by the Backes Kozhimanhil study (Backes Kozhimanhil, Pereira, & Harlow, 2009), which reported a 9.6% incidence of depression amongst women with diabetes during pregnancy. The prevalence rate in this study (15.8%) is higher than the prevalence rate of the Backes Kozhimanhil study (Backes Kozhimanhil Pereira, & Harlow, 2009); they reported a 13.4% prevalence of postnatal depression amongst women with diabetes (pre-gestational or gestational diabetes). The difference in findings could be attributed to several factors. First, the Backes Kozhimanhil study was conducted in the US, while the current study was conducted in the UK. Second, in more recent years, postnatal depression has had some media popularity with a variety of well known celebrities admitting to have suffered from it, perhaps leading to an increased awareness of the illness, which in turn facilitates help-seeking behaviour (Highet, Gemmill & Milgrom, 2011; Sword, Busser, Ganann, McMillan & Swinton, 2008).

The second aim of the current study was to investigate whether known risk factors for postnatal depression in the general population predict postnatal depression in women with gestational diabetes. Current study findings showed that antenatal anxiety was the only factor that significantly contributed to the prediction of postnatal depression in women with

gestational diabetes. The model also included antenatal depression, social support, and life stress, and explained 41% of the variance in depressive symptoms. The findings are consistent with the results of a meta-analysis conducted by Beck (2001), showing a moderate effect of antenatal anxiety in the prediction of postnatal depression in the general population (effect size  $r=0.45$ ). The findings are also consistent with a systematic review conducted by Robertson and colleagues, which showed that anxiety during pregnancy was a predictor for postnatal depression (Robertson et al., 2004). Coelho and colleagues explored in greater detail the relationship between various forms of anxiety (generalized anxiety disorder, social phobia) and postnatal depression, and found that a diagnosis of antenatal generalized anxiety disorder independently predicted depression after delivery (Coelho, Murray, Royal-Lawson & Cooper, 2011). Further research is needed to investigate whether reducing the level of anxiety during pregnancy would lead to a reduction in postnatal depression.

It is surprising that antenatal depression was not a significant predictor for postnatal depression, considering that most women who were depressed antenatally continued to be depressed postnatally (see incident and prevalence rates above). This could be attributed to the small sample size relative to the number of variables entered in the regression, and to the high level of inter-correlation between antenatal anxiety and antenatal depression (Spearman's  $\rho=0.57$ ,  $p<0.001$ ).

When child care stress was added to the model (model 2), the model explained 48% of the variance, but model change was not significant. Child care stress was not found to be a significant predictor of postnatal depression. Antenatal anxiety continued to be a significant predictor of postnatal depression. The findings are not consistent with the results of a meta-analysis conducted by Beck (2001), which showed a moderate effect of child care stress in the prediction of postnatal depression in the general population (effect size  $r=0.46$ ). At the same

time, in contrast with the findings of the Beck (2001) meta-analysis, the findings of the current study showed that antenatal depression, social support, and life stress were not significant predictors of postnatal depression. This could be attributed to the small sample size relative to the number of variables entered in the regression, and to the high level of inter-correlation between these variables. Also, antenatal social support, life stress and child care stress were measured using a subscale of the PPDI-R. The subscale uses only 'yes' or 'no' answers, leading to a limited range of scores.

The third aim of the study was to investigate whether diabetes-specific risk factors predict depression in women with gestational diabetes, over and above general risk factors. Diabetes-specific social support during pregnancy and diabetes interference were not significant predictors of postnatal depression, when controlling for known risk factors. In the third regression model, the two variables explained an additional 11% of the variance, bringing the total variance explained by the model to 59% (but no significant difference in variance between model 2 and model 3). Antenatal anxiety was no longer a significant predictor of postnatal depression. This is perhaps an indication that the effect of antenatal anxiety on postnatal depression is moderated by diabetes social support and diabetes interference.

Two dominant models were proposed to explain the process through which social support has an effect on physical and psychological well-being: the direct or main-effect model and the buffering model. The direct effect model suggests that social support is beneficial all the time, irrespective whether the person is under stress (i.e. there is a direct, linear relationship between social support and well-being). The buffering model posits that support is related to well-being when the person is under stress; social support 'buffers' oneself from the pathogenic influence of stressful events (Cohen & Wills, 1985). The wider literature suggests that there is evidence supporting both models (Taylor, 2011). The results of the current study

(i.e. the effect of antenatal anxiety on postnatal depression is potentially mediated by diabetes social support – see previous paragraph) would support the latter model, i.e. that diabetes-specific social support could act as a ‘buffer’ between antenatal anxiety and postnatal depression; women receiving adequate diabetes-specific social support are potentially less likely to develop postnatal depression.

In the wider literature exploring the relationship between diabetes and depression in the general population, people living with both diabetes and depression were less likely to report receiving needed social support than people with diabetes and no depression (Egede, Grubaugh, & Ellis, 2010). A qualitative meta-synthesis examining patients’ experience of living with diabetes and depression (Gask, MacDonald & Bower, 2011) found that diabetes specific social support from health care professionals, social networks and family members could buffer the consequences of living with diabetes or create further difficulties. Social support affected self-care behaviours amongst people living with diabetes, with people receiving adequate social support being more likely to control their weight and to exercise (Bai, Chiou, & Chang, 2009; Rees, Karter, & Young, 2010). At the same time, diabetes interference was found to be significantly associated with depressive symptomatology in people with type 2 diabetes (Talbot et al., 1999).

Further research is needed to explore the relationship between diabetes-specific factors and postnatal depression. Previous literature showed that individualized diabetes management plans (e.g. dietary advice, blood glucose monitoring, insulin therapy-as needed) for pregnant women with gestational diabetes reduced the rate of serious perinatal outcomes (such as death, shoulder dystocia, bone fracture, nerve palsy), macrosomic babies, and the incidence of postnatal depression (Crowther, Hiller, Moss, McPhee, Jeffries, & Robinson, 2005).

## **4.2. Limitations of the study**

The incidence and prevalence rates for postnatal depression that were found in this study should be interpreted with caution, as data were collected using participants from a relatively small geographical area (i.e. not nationwide data). The present study had a high percentage of lost to follow-up participants. The relatively small number of participants could have led to the study having insufficient power to detect important associations. Also, there was no control group of women without diabetes. A decision was taken not to have a control group, due to the small scale of the current student project.

The study used a self-report measure for the identification of depressive symptoms (i.e. EPDS). Although the scale has high sensitivity and specificity (Cox et al., 1987) and its psychometric assessment was conducted on a sample of new mothers, it is only a screening tool, rather than providing a clinical diagnosis of postnatal depression.

Diabetes-related distress (i.e. psychosocial adjustment to diabetes, and in particular diabetes-related emotional distress) was measured using the PAID. Although the scale has good psychometric properties and it is widely used when studying diabetes in the general population, the PAID is not a specific scale for gestational diabetes. A diagnosis of gestational diabetes presents different challenges from type 1 or type 2 diabetes. Women with gestational diabetes tend to be worried about the impact it might have on the pregnancy and the baby (i.e. stillborn, premature birth, macrosomic babies) and the increased risk for themselves of developing diabetes in later life (Hjelm et al., 2005). People living with type 1 and type 2 diabetes tend to be worried about the development of serious diabetes-related complications, such as coronary artery disease, stroke, amputations etc (Miller, 2011). Further research is needed for the development and validation of a gestational diabetes-specific scale.

No data was collected on diabetes management (i.e. levels of glycaemic control) due to unavailability of hospital files. There is a known link between depression and hyperglycaemia in people living with type 1 or type 2 diabetes (Lustman, Anderson, Freedland, de Groot, Carney, & Clouse, 2000). Langer & Langer (2000) showed that women (with gestational diabetes) with well controlled diabetes were significantly less distressed than those with poor glycaemic control.

The strength of the present study lies in the prospective longitudinal investigation of the relationship between gestational diabetes and postnatal depression. However, the study did not demonstrate that there are diabetes-specific risk factors that predict postnatal depression in women with gestational diabetes, over and above known risk factors. Further research using a larger sample size is required in order to further investigate the relationship between psychosocial variables related to gestational diabetes and postnatal depression.

The current research project is ongoing. A third hospital in the West Midlands has recently joined the study and recruitment has begun in April 2012. We will continue to recruit women with gestational diabetes, in order to increase our study sample. At the same time, women identified at risk of developing gestational diabetes, but with a negative OGTT test result will be recruited and act as a control group for the study.

### **4.3. Clinical implications of the study**

The antenatal period is a time when women are highly scrutinized, with a wide range of professionals available for consultation. It is an ideal time for women to access support. Screening for antenatal depression is important, as the vast majority of women who are depressed in the antenatal period continue to be depressed in the postnatal period. Screening

for antenatal anxiety is also important, as it is a strong predictor for postnatal depression (as well as postnatal anxiety), (Beck, 2001; Coelho et. al., 2011; Robertson et. al., 2004).

Philipp and Carr (2001) proposed the psychological model of normal pregnancy. They suggest that once conception occurs, women pass through three distinct psychological phases. They loosely correspond to the three trimesters of pregnancy and are triggered by biological, psychological and cultural factors. The first stage (0-18 weeks gestation) is characterized by *ambivalence* about the pregnancy and is dominated by bodily needs (e.g. food) and fear of miscarriage. The second stage (18-34 weeks gestation) is the time when fetal movements begin to be felt by the expectant mother, and is a time of relative *peace*. Attachment to the fetus takes place in this stage, as illustrated by behaviours such as talking to the fetus, calling the fetus a particular pet name etc. The third stage (after 34 weeks gestation) is dominated by physical *discomfort* and the mother's sense that her fetus is viable (Philipp and Carr, 2001).

Women are tested for gestational diabetes around 28 weeks, which corresponds with the second psychological stage of normal pregnancy. A diagnosis of gestational diabetes means that their pregnancy is now considered a high-risk pregnancy, leading to increased levels of anxiety about the wellbeing and survival of the fetus. The label of high risk may interfere with the process of attachment, in the presence of a threat to the survival of the fetus. The knowledge of an 'imperfect' pregnancy may affect the mother's self-esteem, and lead to feelings of failure (Philipp and Carr, 2001, p.23).

Validated questionnaires such as the Hospital Anxiety and Depression Scale (HADS) could be used to identify antenatal anxiety and depressive symptoms in women diagnosed with gestational diabetes. These women could then be offered additional support from midwives, GPs, and mental health services.

In line with the NICE guidelines for antenatal and postnatal mental health (NICE, 2007), appropriate interventions are needed to support women with gestational diabetes diagnosed with antenatal anxiety, including good support for diabetes management. The World Health Organisation (WHO) principles of perinatal care stipulate the importance of involving women in the decision making process and referral to appropriate education classes, as well providing an individualised approach to care at all times (Chalmers, Mangiaterra, & Porter, 2001).

During the postnatal period (once the baby is born) the support from maternity care professionals tends to wind down, and generally becomes limited to several meetings with the health visitor. However, health visitors have a remit for ongoing support to women with children in the 0-5 age group and therefore are ideally placed to offer more support such as listening visits, referral to GP and mental health services. Gestational diabetes could be flagged to health visitors, so that they are aware of the increased risk of developing postnatal depression. Repeat screening for postnatal depression is recommended, so that women get the appropriate help in order to ensure good baby development.

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Public Domain Briefing Paper

**INCIDENCE, PREVALENCE, AND RISK FACTORS FOR  
POSTNATAL DEPRESSION IN WOMEN  
WITH GESTATIONAL DIABETES**

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## **Introduction**

Postnatal depression is a common affective disorder following childbirth, affecting around 13% of women. Studies have shown that postnatal depression tends to affect both the mother and her baby, leading to relationship difficulties between the mother and her baby, as well as affecting the normal development of the child, particularly for boys from disadvantaged backgrounds. Risk factors for postnatal depression include: history of depression, antenatal depression, antenatal anxiety, life stress, socioeconomic status, social support, marital satisfaction, child care stress, and infant temperament.

There is a known link between depression and diabetes in the general population. Scientists are also interested in the link between diabetes during pregnancy and the mental health of the mother around the time of the birth. A large study conducted by Backes Kozhimanhil and colleagues in 2009 showed that women with diabetes during pregnancy (gestational diabetes and pre-existing diabetes) were almost twice as likely to experience depression as women without diabetes.

## **Aims of the study**

The study aimed to: 1) establish the percentage of women with gestational diabetes newly diagnosed with depression, measured at six weeks postnatal; 2) to establish the total percentage of women who were depressed at six weeks postnatal (including women who were depressed in the antenatal period); 3) to investigate whether known risk factors of postnatal depression predict depression in women with gestational diabetes; 4) to investigate whether diabetes specific risk factors (e.g. diabetes distress, diabetes interference, diabetes social support) predict depression in women with gestational diabetes over and above general risk factors.

## **Method**

The current study used a longitudinal design, which involved collecting data at two points in time. Women with a diagnosis of gestational diabetes who attended a joint antenatal/diabetes clinic in the third trimester of pregnancy were invited to participate in the study and asked to complete a questionnaire pack. They were followed-up by post at six weeks after childbirth.

## **Results**

77 women consented to participate in the study and filled in the questionnaire pack. Out of the 77 women, 38 also completed the follow-up questionnaire at six weeks following childbirth. Overall, 15.8% of women had depressive symptoms; 11.5% of women had not had depressive symptoms in the antenatal period. This shows that the majority of women who were depressed in the postnatal period were also depressed in the antenatal period.

Women who had antenatal anxiety were significantly more likely to have postnatal depression. Diabetes-specific factors were not significant predictors for postnatal depression.

## **Study limitations**

Depressive symptoms were measured using a self-report questionnaire (as opposed to a formal medical diagnosis). The analyses were based on a relatively small sample size, and therefore important associations were potentially missed. However, the research project is ongoing, and we are collecting more data in order to strengthen our results.

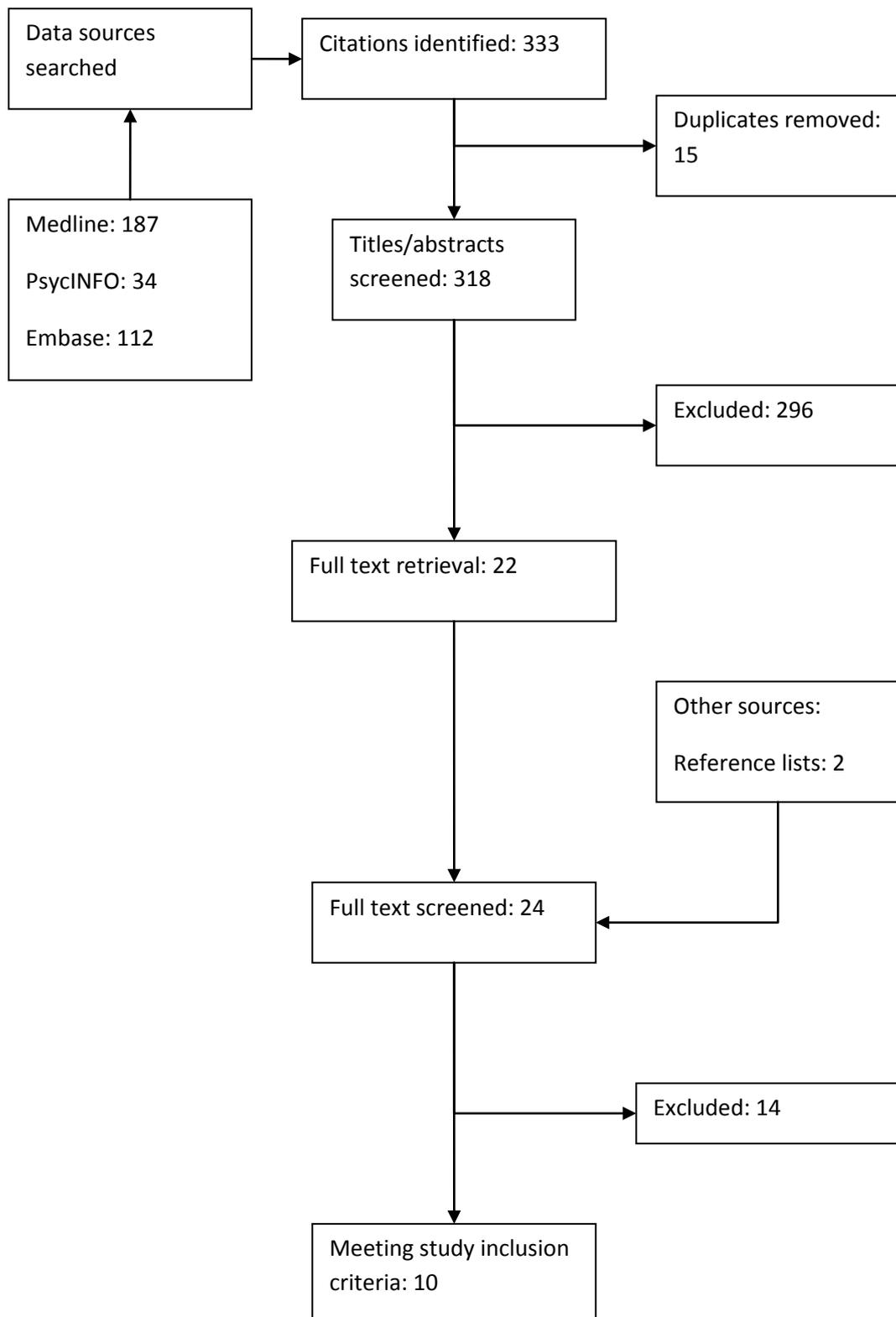
## **Clinical implications**

It is important to identify women with antenatal depression and anxiety, in order to provide them with appropriate care, and potentially reduce the number of women who are newly

diagnosed with depression in the postnatal period. Further research is needed to explore the role of diabetes-specific factors in the occurrence of postnatal depression in women with gestational diabetes.

## Systematic review –

### Appendix 1 Search flowchart



## Appendix 2 Selected characteristics of included studies

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
<b>USA: Orchard et al, 2003</b>	Prospective cohort study	603	600	28 (8-47) years old 51% men	Type 1 19 (7-37)	10	BDI>14  (≥18 years of age)	Medical records	ECG ischemia: Minnesota Code; Angina: Pittsburgh EDC study physician diagnosis; Hard CAD: angiographic stenosis ≥ 50%; revascularisation procedure; Q waves (MC 1.1-1.2), nonfatal MI or CAD death	Depressive symptoms predicted angina  HR=1.40  95% CI=1.06-1.84  p<0.05  Depressive symptoms did not predict hard CAD events (e.g. myocardial infarction) or total CAD.
<b>USA: Black et al, 2003</b>	Prospective population study	2830	2092	65+ years old 41.4% men	Type 2	7	CESD>16 at baseline and CIDI/DSM-IV at 2-year follow up	Self-report	Nephropathy, retinopathy, neuropathy (microvascular): self-report.  CAD, stroke, kidney disease (macrovascular)-	Depressive symptoms predicted:  1) microvascular complications:  HR=8.63  95%CI=5.40-13.79

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
									self-report.	<p>2) macrovascular complications:</p> <p>HR=2.40 95%CI=1.71-3.36</p> <p>Lifetime depression predicted:</p> <p>a) microvascular complications:</p> <p>HR=11.32 95%CI=8.76-15.43</p> <p>b) macrovascular complications:</p> <p>HR=2.64 95%CI=1.73-4.04</p> <p>p&lt;0.05</p>
<b>Australia: Bruce et al, 2005</b>	Prospective observational study	1273	369 deaths 152 cardiac deaths	64.1 (52-73) years old 48.7% men	Type 2 4 (1-9)	7.8±2.4	GHS (presence of two or more symptoms was seen as indicative of	Fasting blood glucose levels	Peripheral sensory neuropathy: Michigan Neuropathy Screening	Depressive symptoms did not predict CHD mortality after adjustment for diabetes

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
							depression)		Instrument Retinopathy: direct and/or indirect ophthalmoscopy CVD: self-reported stroke or TIA CHD: self-reported/hospital history of MI, angina, coronary artery bypass grafting, angioplasty PAD: ABI≤0.9. or the presence of a diabetes-related amputation	complications: HR=1.15 95%CI=0.80-1.68 P=0.45
<b>USA: Roy, Peng &amp; Roy, 2007</b>	Prospective cohort study	725	483	27.5±10.8 years old 40.4% men	Type 1 10.4±8.6	6.1±0.5	BDI>14	Medical records	CAD: medical records Stroke: medical records Peripheral	Depressive symptoms predicted incidence of any CVD (CAD or stroke) OR=1.04

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
									neuropathy: self-report  Retinopathy: Airlie House classification of diabetic retinopathy	95%CI=1.001-1.08  p<0.05
<b>USA: Roy, Roy &amp; Affouf, 2007</b>	Prospective cohort study	725	483	27.5±10.8 years old  40.4% men	Type 1	6.1±0.5	BDI>14	Medical records	Retinopathy: Airlie House classification of diabetic retinopathy	Depressive symptoms predicted:  1) Diabetic retinopathy (DR):  OR=2.44  95%CI=1.01-5.88  2) Proliferative DR:  OR=3.19  95%CI=1.30-7.87  p<0.05
<b>USA: Katon et</b>	Prospective cohort study	4239	2909	55.1% > 60 years of age	Type 1 – 4.8%	5	PHQ-9 for baseline and follow-up	Medical records	Medical records (ICD-9 diagnosis)	1) Retinopathy did not predict depression:

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
al, 2009				50.8% men	Type 2 – 95.2% 9±6		depression  ICD-9 codes for history of depression	(ICD-9 diagnosis codes)	codes and CPT codes)	OR=0.69 CI=0.40-1.21 p>0.05  2) Nephropathy did not predict depression:  OR=1.06 CI=0.65-1.71 P>0.05  3) number of microvascular events did not predict depression:  OR=0.88 CI=0.64-1.21 p>0.05  4) number of macrovascular events

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
										<p>or procedures predicted depression:</p> <p>OR=1.39</p> <p>95%CI=1.02-1.88</p> <p>p&lt;0.05</p> <p>5) Coronary procedures predicted depression:</p> <p>OR=1.92</p> <p>95%CI=1.14-3.25</p> <p>p&lt;0.05</p>
<b>USA: Vileikyte et al, 2009</b>	Prospective cohort study	Baseline: 495 9 months: 376 18 months: 338	61.87±11.01 years old 70.7% men	Type 1 (27%) or Type 2 (73%)	1.5	HADS	N/A	Neuropathy: DPN severity: VPT>25 V NDS>3 DPN somatic experiences (symptoms and	Increased depression scores were predicted by: 1) Baseline NDS $\beta=0.10$ , p<0.05 2) baseline unsteadiness	

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
									foot ulceration): NeuroQoL  DPN psychological consequences (restrictions in ADL and social self-perception): NeuroQoL	β=0.16, p<0.01  3) baseline ADL restrictions β=0.16, p<0.01  4) changes in social self-perception  β=0.13, p<0.01
<b>USA: Gonzales et al, 2010</b>	Prospective cohort study	Baseline: 333  During follow up 63 participants developed foot ulcers	62.2±11.1 years old  70.6% men	Type 1 (27%) or Type 2 (73%)  17.0±11.5	1.5	HADS	N/A	Neuropathy:  VPT≥25 V  NDS≥3  Foot ulcers: self-report	Depressive symptoms predicted first foot ulcers  HR=1.68  95% CI=1.20-2.35	
<b>USA: Lin et al, 2010</b>	Prospective cohort study	4623      3723	64.3±12.5 years old  52.1% men	Type 2  8.8±8.4	5	PHQ-9	Medical records  ICD-9 diagnosis codes	Medical records  ICD-9 diagnosis codes	Major depression predicted:  1) microvascular complications  HR=1.36	

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
										95% CI=1.05-1.76 2) macrovascular complications HR=1.25 95%CI=1.00-1.54 P<0.05
<b>USA: Sieu et al, 2011</b>	Prospective cohort study	2359	2355	63.9±12.9 years old 52.2% men	Type 2 8.1±8.1	5	PHQ-9	Medical records (ICD-9 diagnosis codes)	Medical records (ICD-9 diagnosis codes)	Depressive symptoms predicted an increased risk of incident retinopathy OR=1.026 95%CI=1.002-1.051 P<0.05 Depressive symptoms were associated with time to incident retinopathy HR=1.025

Study	Design	No of participants		Age at baseline mean±SD (range) & Gender (% male)	Type of diabetes/ Duration mean±SD (range)	Length of follow up (years)	Depression assessment method	Diabetes assessment method	Complications: assessment method	Results
		Baseline	Follow up							
										95%CI=1.009-1.041

## **Acronyms**

ABI = Ankle brachial index

ADL = activities of daily living

BDI= Beck Depression Inventory

CAD= Coronary artery disease

CESD = Centre for Epidemiologic Studies Depression Scale

CHD = coronary heart disease

CI = Confidence interval

CIDI/DSM-IV = Composite International Diagnostic Interview / Diagnostic and Statistical Manual of Mental Disorders, 4<sup>th</sup> edition

CPT codes = Current Procedural Terminology Codes

CVD = cerebrovascular disease

DN = diabetic neuropathy

DN-DA = diabetic neuropathy with co-morbid depression or anxiety

DPN = diabetic peripheral neuropathy

DR = diabetic retinopathy

EDC = Epidemiology of diabetes complications

GHS = General Health status questionnaire

HADS = Hospital Anxiety and Depression Scale

HR = Hazard ratio

ICD-9 = International Classification of Diseases, 9<sup>th</sup> Revision

N/A = not available

MI = Myocardial Infarction

NDS = neuropathy disability score

NeuroQoL = Neuropathy and Foot Ulcer-specific Quality of Life Instrument

PAD = peripheral arterial disease

PHQ-9 = Patient Health Questionnaire – 9

OR = Odds ratio

TIA = Transient ischaemic attack

VPT = vibration perception threshold

UNIVERSITY OF  
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[Enter Date]

## Mood States and Diabetes in Pregnancy study

Dear [enter Name]

Researchers from the University of Birmingham and health care professionals at Warwick Hospital and University Hospital, Coventry are working together to try to develop ways to help mothers experiencing gestational diabetes.

We have enclosed an Information Sheet, which provides further details about the study and what taking part would involve.

We would like to invite you to take part in the research. If you agreed to take part, any information that you provided to the researcher would be treated as strictly confidential, and your identity would not be revealed to anybody outside the study.

We will contact you in one week to find out whether you have any further questions, and to hear your decision about whether you wish to take part. If you agreed to take part, we would ask you to sign one copy of the enclosed consent forms and return it to us in the reply prepaid envelope. The second consent form would be for you to keep. If you decided that you did not wish to take part you could tell the researcher when she contacted you.

Whether or not you decide to take part we would like to thank you for taking the time to find out more about the research study.

With best wishes

Dr. Isabela Caramlau  
Study researcher  
School of Psychology  
University of Birmingham  
Edgbaston, Birmingham  
B15 2TT

### Appendix 3 Quality assessment of included studies

Study	Choice of outcome measure (depression only)	Description of study population	Control for confounding variables (age, gender, SES, education)	Blinding of baseline assessment data - diabetes diagnosis only	Description of follow-up numbers	Description of drop-out rates	Comparison of drop-out rates on key variables	Sufficient follow-up period
Orchard et al, 2003	Adequate	Adequate	Adequate	N/A	Adequate	Inadequate	Inadequate	Adequate
Black et al, 2003	Adequate	Adequate	Adequate	Not reported	Adequate	Inadequate	Inadequate	Adequate
Bruce et al, 2005	Inadequate	Adequate	Adequate	N/A	Adequate	Inadequate	Inadequate	Adequate
Roy, Peng & Roy, 2007	Adequate	Adequate	Inadequate	N/A	Adequate	Adequate	Inadequate	Adequate
Roy, Roy & Affouf, 2007	Adequate	Adequate	Adequate	N/A	Adequate	Adequate	Inadequate	Adequate
Katon et al, 2009	Adequate	Adequate	Adequate	N/A	Adequate	Adequate	Adequate	Adequate
Vileikyte et al, 2009	Adequate	Adequate	Adequate	N/A	Adequate	Adequate	Adequate	Inadequate
Gonzales et al, 2010	Adequate	Adequate	Inadequate	N/A	Inadequate	Inadequate	Inadequate	Inadequate

<b>Study</b>	<b>Choice of outcome measure (depression only)</b>	<b>Description of study population</b>	<b>Control for confounding variables (age, gender, SES, education)</b>	<b>Blinding of baseline assessment data - diabetes diagnosis only</b>	<b>Description of follow-up numbers</b>	<b>Description of drop-out rates</b>	<b>Comparison of drop-out rates on key variables</b>	<b>Sufficient follow-up period</b>
<b>Lin et al, 2010</b>	Adequate	Adequate	Adequate	N/A	Adequate	Adequate	Inadequate	Adequate
<b>Sieu et al, 2011</b>	Adequate	Adequate	Adequate	N/A	Adequate	Adequate	Inadequate	Adequate

N/A = not applicable; SES = socioeconomic status

UNIVERSITY OF  
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## Study Title: Mood states and diabetes in pregnancy Participant Information Sheet



Research Ethics Committee reference number [REDACTED]

We are inviting you to take part in a research study, which is being undertaken as part of a clinical psychology training programme.

Before you decide whether you want to take part, it is important for you to understand why the research is being done, and what it will involve. We would be grateful if you could take the time to read the following information carefully. Please feel free to discuss it with friends, relatives, midwife and your family doctor (GP) if you wish. If there is anything that is not clear, or if you would like more information, please contact the study researcher, Isabela Caramlau, whose contact details you will find at the end of this information sheet.

We would be grateful if you were able to take a decision within the next week.

### **What is the purpose of the study?**

The aim of this study is to investigate the occurrence of postnatal depression (PND) and identify factors that may increase the risk for developing PND among women with diabetes in pregnancy. Specifically, we aim to investigate: i) whether known risk factors of PND predict depression in women with gestational diabetes; ii) whether diabetes specific risk factors (e.g. problems with diabetes control, management, etc.) predict depression in women with gestational diabetes over and above general risk factors.

## **Why have I been selected to take part in the study?**

All women who have been invited to undergo a glucose tolerance test during pregnancy will be invited to participate in the study.

## **Do I have to take part?**

It is up to you to decide whether or not to take part. This information sheet is provided to help you to make that decision. Even if you decided to take part, you would still be free to withdraw at any time and would not have to give a reason. This would not affect the care you receive.

## **What would taking part in the study involve?**

If you agree to take part in the study, you will be asked to fill in a questionnaire pack at three different points in time: 3<sup>rd</sup> trimester of your pregnancy, 6 weeks postnatal and 3 months postnatal. The questionnaires will take about 45 minutes to complete. You could do this while at the hospital for tests or when seeing the doctor/midwife. The follow-up questionnaires will be posted to you. If we do not hear from you, we will send you a reminder letter, followed by a phone call. We would also like to have access to your medical records in order to find information about your pregnancy and outcome, height, weight, and blood glucose diary.

Any information you provided would be treated as confidential and anonymous. Your participation in this study would not affect any support or care that you were receiving.

## **Who would know about me taking part in the study?**

The research team would know whether you had agreed to take part in the study. We would also like to let your GP and your midwife know that you are taking part. Should you prefer that this information remains confidential, please let us know. When writing up the findings of the study the researchers would take care to ensure that they did not reveal the identity of participants. All information that you provide to us will be treated as confidential and will not be shared with anyone outside the research team unless required by law under the terms of the Children Act (1989). This refers to any information about risk to a child that is brought to the attention of a researcher.

## **What are the benefits of taking part?**

The study could lead to the early identification of emotional distress. If you require professional help, we will discuss this with you first and suggest that you contact your GP for treatment and support. It could also have a significant impact on the wellbeing of the baby, by improving your mental health and functioning. It might also help to improve and refine the NHS service for future mothers.

## **What are the possible disadvantages and risks of taking part?**

There are no risks involved. However, if you become distressed as a result of your participation, please let us know using the contact details below. In the first instance we will discuss the difficulties that arose. If you require professional help, we will discuss this with you first and suggest that you contact your GP.

If the answers that you give to the well-being questionnaires cause us concern about your well-being, we will contact you and may suggest that you contact your GP or your diabetes care providers for further advice.

## **What if something goes wrong?**

Once again, if participating in this research project distresses you, you should let us know by using the contact information at the end of this sheet. In the first instance, we will discuss your difficulties with you. If you need professional help, we will speak to you about this and you may then want to contact your GP or Doctor at clinic.

Contact for complaints:

Dr Jan Oyeboode

ClinPsyD course director

Faculty of Psychology

University of Birmingham

Edgbaston, Birmingham

B15 2TT

Tel: 0121 4147124

*There are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you.*

## **What if I have special needs?**

We will make every effort to ensure that there are no barriers for you if you wish to take part. If you have communication problems due to a disability - e.g. hearing impairment / visual impairment/ dyslexia, you are asked to contact us using the details below. If you have difficulties with reading, please inform us. The researcher may be able to offer you more time to complete the study and will assist you in reading the questionnaires. If you can think of any other difficulties, please contact the researcher and every effort will be made to make things easier for you.

## **What would happen to the information I provide in the questionnaires?**

The questionnaires will be stored in a locked cabinet and would only be identifiable via the study number. The responses would only be used for the purposes of this study, and would be destroyed after a period of five years.

## **What will happen to the results of the research study?**

The results of the study will be written up in a final report and the results may also be written up in professional journals. If you are interested, we will be happy to provide you with a copy of the report. All participants' information will be completely anonymised and no-one will be able to identify you from the report or article.

## **Who is organising and funding the research?**

Researchers from Birmingham University together with midwives and diabetes specialist nurses from Warwick Hospital, University Hospital, Coventry, and Birmingham Women's Hospital are organising and conducting the study. The study is being conducted under the direction of Dr Arie Nouwen, Senior Lecturer at the University of Birmingham and Dr Kirstie McKenzie-McHarg, Clinical Psychologist at Warwick Hospital. The study researcher is Dr. Isabela Caramlau.

## **Who has reviewed the study?**

The study has been reviewed and approved by the NHS Research Ethics Committee.

## **What if I want further information about the study?**

If you want any further information about the study you can contact the study researcher **Isabela Caramlau** at [IOC913@bham.ac.uk](mailto:IOC913@bham.ac.uk).

\* \* \* \* \*

## Mood States and Diabetes in Pregnancy Research Study

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Research Ethics committee number [REDACTED]

### Consent form for research participants

(Please tick each box)

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
  
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time during the research, without giving any reason, and without my care being affected.
  
3. I understand that the information which I provide will be treated in confidence and that it will not be shared with any person outside of the research team.
  
4. I give permission for my medical records to be accessed by the research team
  
5. I confirm that I am willing to take part in this research study

.....  
Name of participant

.....  
Date

.....  
Signature

.....  
Name of researcher

.....  
Date

.....  
Signature

UNIVERSITY OF  
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Study Title: Mood states and  
diabetes in pregnancy



Dear [Name]

A few weeks ago you have kindly agreed to take part in the Mood States and Diabetes in Pregnancy research study.

The aim of this study is to investigate the occurrence of postnatal depression (PND) and identify factors that may increase the risk for developing PND among women with diabetes in pregnancy.

We enclose the 1<sup>st</sup> follow up questionnaire pack. We would be grateful if you could complete and return the questionnaire pack within the next two weeks.

Should you require further information or assistance with completing the questionnaire pack, please do not hesitate to contact me.

Your contribution to the success of this study will be greatly appreciated.

Yours sincerely

Dr. Isabela Caramlau  
Study researcher  
School of Psychology  
University of Birmingham  
Edgbaston, Birmingham  
B15 2TT



## Mood States and Diabetes in Pregnancy

Please read the following information before you answer the questions:

### A: Instructions

1. This questionnaire is divided into 8 sections, labelled Form 1-8.
2. Please answer all of the questions in each section in the order they appear in the questionnaire.
3. There are no 'right' or 'wrong' answers, so please answer the questions as honestly as you can.
4. Please read the instructions at the beginning of each section and circle the response which you feel is the most relevant to you.
5. Although some statements may seem similar to others, no two are exactly the same.
6. Please take your time to read and understand the questions thoroughly.
7. If there is anything you do not understand, please ask the researcher for help.

### B: Confidentiality

1. Your name will not be put on the questionnaire. The researchers have given each questionnaire a code number, known only to them.
2. All information stored on computer is compliant with the Data Protection Act.
3. The information you provide in this questionnaire is confidential and will not be shared with anyone outside the research team unless required by law under the terms of the Children's Act (1989).

If you have any queries please contact:

Isabela Caramlau on 

Questionnaire type: BD

Date of receipt.....

Participant no.....

# Form 1

Please place a tick in the column that describes you best:

	Tick one	
Marital Status		
1. Single	<input type="checkbox"/>	<input type="checkbox"/>
2. Married/cohabiting	<input type="checkbox"/>	<input type="checkbox"/>
3. Separated	<input type="checkbox"/>	<input type="checkbox"/>
4. Divorced	<input type="checkbox"/>	<input type="checkbox"/>
5. Widowed	<input type="checkbox"/>	<input type="checkbox"/>
6. Partnered	<input type="checkbox"/>	<input type="checkbox"/>
Socioeconomic Status		
Low	<input type="checkbox"/>	<input type="checkbox"/>
Middle	<input type="checkbox"/>	<input type="checkbox"/>
High	<input type="checkbox"/>	<input type="checkbox"/>
Self-esteem	Yes	No
Do you feel good about yourself as a person?	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel worthwhile?	<input type="checkbox"/>	<input type="checkbox"/>
Do you feel you have a number of good qualities as a person?	<input type="checkbox"/>	<input type="checkbox"/>
Prenatal Depression	Yes	No
1. Have you ever felt depressed during your pregnancy?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, when and how long have you been feeling this way?		
If yes, how mild or severe would you consider your depression?		
Prenatal Anxiety	Yes	No
1. Have you ever felt anxious during your pregnancy?	<input type="checkbox"/>	<input type="checkbox"/>
If yes, how long have you been feeling this way?		
Views on pregnancy	Yes	No
Was the pregnancy planned?	<input type="checkbox"/>	<input type="checkbox"/>
Is the pregnancy wanted?	<input type="checkbox"/>	<input type="checkbox"/>

History of previous depression	Yes	No
1. Before this pregnancy, have you ever been depressed?	[ ]	[ ]
If yes, when did you experience this depression?		
If yes, have you been under a GP's care for this past depression?		
If yes, did the GP prescribe any medication for your depression?		

Social Support	Yes	No
1. Do you feel you receive adequate support from your partner?	[ ]	[ ]
2. Do you feel you receive adequate practical support from your partner? (e.g. help with household chores or babysitting)	[ ]	[ ]
3. Do you feel you can rely on your partner when you need help?	[ ]	[ ]
4. Do you feel you can confide in your partner?	[ ]	[ ]
1. Do you feel you receive adequate support from your family?	[ ]	[ ]
2. Do you feel you receive adequate practical support from your family? (e.g. help with household chores or babysitting)	[ ]	[ ]
3. Do you feel you can rely on your family when you need help?	[ ]	[ ]
4. Do you feel you can confide in your family?	[ ]	[ ]
1. Do you feel you receive adequate support from your friends?	[ ]	[ ]
2. Do you feel you receive adequate practical support from your friends? (e.g. help with household chores or babysitting)	[ ]	[ ]
3. Do you feel you can rely on your friends when you need help?	[ ]	[ ]
4. Do you feel you can confide in your friends?	[ ]	[ ]

Marital Satisfaction	Yes	No
1. Are you satisfied with your marriage (or living arrangements)?	[ ]	[ ]
2. Are you currently experiencing any marital problems?	[ ]	[ ]
3. Are things going well between you and your partner?	[ ]	[ ]

Life stress	Yes	No
1. Are you currently experiencing any stressful events in your life such as:		
• Financial problems	[ ]	[ ]
• Marital problems	[ ]	[ ]
• Death in the family	[ ]	[ ]
• Serious illness in the family	[ ]	[ ]
• Moving	[ ]	[ ]
• Unemployment	[ ]	[ ]
• Job change	[ ]	[ ]

## Form 2

For each question, please write the number that best describes how you feel:

1 – Not at all or never

2 – Somewhat or sometimes

3 – Moderately or most of the time

4 – Very much or almost all the time

1. I am confident of having a normal childbirth	
2. I think my labour and delivery will go normally	
3. I have a lot of fear regarding the health of my baby	
4. I am worried that the baby could be abnormal	
5. I am afraid that I will be harmed during delivery	
6. I am concerned (worried) about how the baby is growing and developing inside me	
7. I am concerned (worried) about losing the baby	
8. I am concerned (worried) about having a hard or difficult labour and delivery	
9. I am concerned (worried) about taking care of a new baby	
10. I am concerned (worried) about developing medical problems during my pregnancy	

### Form 3

Please place a tick in the column that describes you best:

	Yes definitely	Yes sometimes	No, not much	No, not at all
1. I wake early and then sleep badly for the rest of the night.				
2. I get very frightened or have panic feelings for apparently no reason at all.				
3. I feel miserable and sad.				
4. I feel anxious when I go out of the house on my own.				
5. I have lost interest in things.				
6. I get palpitations, or sensations of 'butterflies' in my stomach or chest.				
7. I have a good appetite.				
8. I feel scared or frightened.				
9. I feel life is not worth living.				
10. I still enjoy the things I used to.				
11. I am restless and can't keep still.				
12. I am more irritable than usual.				
13. I feel as if I have slowed down.				
14. Worrying thoughts constantly go through my mind.				

## Form 4

Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3.

Over the last two weeks	All of the time 5	Most of the time 4	More than half of the time 3	Less than half of the time 2	Some of the time 1	At no time 0
1. I have felt cheerful and in good spirits						
2. I have felt calm and relaxed						
3. I have felt active and vigorous						
4. I woke up feeling fresh and rested						
5. My daily life has been filled with things that interest me						

Form 5

For each question, please circle the number that best describes you:

A. Have you been able to talk about your feelings and problems with at least one friend during the last month?

1. I could always talk freely about my feelings
2. I usually could talk about my feelings
3. About half the time I felt able to talk about my feelings
4. I usually was not able to talk about my feelings
5. I was never able to talk about my feelings

B. Have you been able to talk about your feelings and problems with at least one of your relatives in the last month?

1. I could always talk freely about my feelings
2. I usually could talk about my feelings
3. About half the time I felt able to talk about my feelings
4. I usually was not able to talk about my feelings
5. I was never able to talk about my feelings

C. Have you been able to talk about your feelings and problems with your spouse or partner in the last month?

1. I could always talk freely about my feelings
2. I usually could talk about my feelings
3. About half the time I felt able to talk about my feelings
4. I usually was not able to talk about my feelings
5. I was never able to talk about my feelings

## Form 6

Which of the following diabetes issues are currently a problem for you?

Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
<b>1. Not having clear and concrete goals for your diabetes care</b>	0	1	2	3	4
<b>2. Feeling discouraged with your diabetes treatment plan</b>	0	1	2	3	4
<b>3. Feeling scared when you think about living with diabetes</b>	0	1	2	3	4
<b>4. Uncomfortable social situations related to your diabetes care (e.g. people telling you what to eat)?</b>	0	1	2	3	4
<b>5. Feelings of deprivation regarding food and meals</b>	0	1	2	3	4
<b>6. Feeling depressed when you think about living with diabetes</b>	0	1	2	3	4
<b>7. Not knowing if your mood or feelings are related to your diabetes</b>	0	1	2	3	4
<b>8. Feeling overwhelmed by your diabetes</b>	0	1	2	3	4
<b>9. Worrying about low blood sugar reactions</b>	0	1	2	3	4
<b>10. Feeling angry when you think about living with diabetes</b>	0	1	2	3	4
<b>11. Feeling constantly concerned about food and eating</b>	0	1	2	3	4
<b>12. Worrying about the future and the possibility of serious complications</b>	0	1	2	3	4

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
<b>13. Feelings of guilt or anxiety when you get off track with your diabetes management</b>	0	1	2	3	4
<b>14. Not "accepting" your diabetes</b>	0	1	2	3	4
<b>15. Feeling unsatisfied with your diabetes physician</b>	0	1	2	3	4
<b>16. Feeling that diabetes is taking up too much of your mental and physical energy every day</b>	0	1	2	3	4
<b>17. Feeling alone with your diabetes</b>	0	1	2	3	4
<b>18. Feeling that your friends and family are not supportive of your diabetes management efforts</b>	0	1	2	3	4
<b>19. Coping with complications of diabetes</b>	0	1	2	3	4
<b>20. Feeling "burned out" by the constant effort needed to manage diabetes</b>	0	1	2	3	4

## Form 7

We are interested to learn more about your diabetes and the way it affects your life.

### Section I: For each question please circle the number that corresponds best to your situation

	Not at all						Extremely	
1. To what extent does your diabetes interfere with your daily activities?	0	1	2	3	4	5	6	
2. To what extent does your partner support you with your diabetes? (_____ Tick here you live alone)	0	1	2	3	4	5	6	
3. To what extent do you consider your diabetes to be a severe health problem?	0	1	2	3	4	5	6	
4. To what extent does your diabetes decrease your satisfaction or pleasure from social or recreational activities?	0	1	2	3	4	5	6	
5. To what extent do your family and friends support you or help with your diabetes?	0	1	2	3	4	5	6	
6. To what extent do you worry about long-term complications of diabetes?	0	1	2	3	4	5	6	
7. To what extent does your diabetes interfere with your effectiveness at work?	0	1	2	3	4	5	6	
8. To what extent does your diabetes interfere with your relationship with your partner? (_____ Tick here if you live alone)	0	1	2	3	4	5	6	
9. To what extent do you worry about your diabetes?	0	1	2	3	4	5	6	
10. To what extent does your partner pay attention to you because of your diabetes? (_____ Tick here if you live alone)	0	1	2	3	4	5	6	
11. To what extent does your diabetes prevent you from traveling as much as you would like?	0	1	2	3	4	5	6	
12. To what extent does your doctor or health care team support you or help you with your diabetes?	0	1	2	3	4	5	6	
13. To what extent does your diabetes interfere with your ability to participate in social or recreational activities?	0	1	2	3	4	5	6	

14. To what extent does your diabetes interfere with your ability to plan your activities?	0	1	2	3	4	5	6
15. To what extent does your diabetes prevent you from being as active as you would like?	0	1	2	3	4	5	6
16. To what extent does your diabetes prevent you from having a schedule that you like (e.g. to sleep late)?	0	1	2	3	4	5	6
<b>Section II: We are interested to learn about the way your partner responds to you concerning your self-care program. For each question please circle the number that best indicates how often they respond to you in that particular way.</b>							
<b>My partner:</b>	<b>Never</b>						<b>Very often</b>
1. Congratulates me when I follow my diet	0	1	2	3	4	5	6
2. Hassles me about my diabetes medication (pills, insulin) (____ Tick here if you do not take medication for your diabetes)	0	1	2	3	4	5	6
3. Congratulates me for regularly measuring my blood glucose level. (____ Tick here if self-monitoring of blood sugar levels has NOT been recommended)	0	1	2	3	4	5	6
4. Hassles me about exercise. (____ Tick here if you have been advised NOT to exercise)	0	1	2	3	4	5	6
5. Reminds me to take care of my feet. (____ Tick here if foot care has not been recommended)	0	1	2	3	4	5	6
6. Congratulates me when I follow my meal schedule (meals and snacks).	0	1	2	3	4	5	6
7. Reminds me to take my diabetes medication (pills, insulin) (____ Tick here if you do NOT take medication for your diabetes).	0	1	2	3	4	5	6
8. Helps me to adjust my food intake when I exercise. (____ Tick here if you have been advised NOT to exercise).	0	1	2	3	4	5	6
9. Hassles me about my diet.	0	1	2	3	4	5	6
10. Plans family activities in a way that allows me to take my medication at the right time. (____ Tick here if you do NOT take medication for your diabetes)	0	1	2	3	4	5	6
11. Hassles me about measuring my blood sugar. (____ Tick here if self-monitoring of blood sugar levels has NOT been recommended)	0	1	2	3	4	5	6

12. Encourages me to exercise. ( _____ Tick here if you have been advised NOT to exercise)	0	1	2	3	4	5	6
<p><b>Section III: Treatment of diabetes involves several self-care activities (e.g. diet, exercise etc.). People sometimes find it difficult, or do not see the importance of following one or more of these self-care activities. We would like to know how this applies to you. Read each question carefully and circle the number that corresponds best to your situation.</b></p> <p style="text-align: center;">Not at all confident <span style="float: right;">Very confident</span></p>							
1. How confident are you in your ability to follow your diet.	0	1	2	3	4	5	6
2. How confident are you in your ability to test your blood sugar at the recommended frequency? ( _____ Tick here if measuring of blood sugar levels has NOT been recommended)	0	1	2	3	4	5	6
3. How confident are you in your ability to exercise regularly? ( _____ Tick here if you have been advised NOT to exercise)	0	1	2	3	4	5	6
4. How confident are you in your ability to keep your weight under control?	0	1	2	3	4	5	6
5. How confident are you in your ability to keep your blood sugar level under control?	0	1	2	3	4	5	6
6. How confident are you in your ability to resist food temptations?	0	1	2	3	4	5	6
7. How confident are you in your ability to follow your diabetes treatment (diet, medication, blood sugar testing, physical activities)?	0	1	2	3	4	5	5
8. To what extent do you think that following your diet is important for controlling your diabetes?	0	1	2	3	4	5	6
9. To what extent do you think that taking your medication as recommended (pills, insulin) is important for controlling your diabetes? ( _____ Tick here if you do NOT take medication for your diabetes).	0	1	2	3	4	5	6
10. To what extent do you think that exercise is important for controlling your diabetes? ( _____ Tick here if you have been advised NOT to exercise)	0	1	2	3	4	5	6
11. To what extent do you think that measuring your blood sugar is important for controlling your diabetes? ( _____ Tick here if self-monitoring of blood sugar levels has NOT been recommended)	0	1	2	3	4	5	6

<b>12. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for controlling your diabetes?</b>	0	1	2	3	4	5	6
<b>12. To what extent do you think that following your diabetes treatment (diet, medication, blood sugar testing, exercise) is important for delaying and/or preventing long-term diabetes complications (problems related to eyes, kidneys, heart or feet)?</b>	0	1	2	3	4	5	6

Form 8

DEMOGRAPHIC QUESTIONNAIRE

Please answer the questions below:

1. Your age:

2. YOUR HEIGHT:

3. YOUR WEIGHT:

4. NUMBER OF CHILDREN:

5. What type of work do/did you do?

---

---

6. What is the **highest** level of qualification that you have?

---

8. Which of these groups do you consider yourself to belong to (please tick one):

**White British**

**White Irish**

**White Other**

**Indian**

**Pakistani**

**Bangladeshi**

<input type="checkbox"/>

**Black African**

**Black**

**Caribbean**

**Black Other**

**Chinese**

**Other**

<input type="checkbox"/>

## Mood States and Diabetes in Pregnancy

Please read the following information before you answer the questions:

### A: Instructions

1. This questionnaire is divided into 5 sections, labelled Form 1-5.
2. Please answer all of the questions in each section in the order they appear in the questionnaire.
3. There are no 'right' or 'wrong' answers, so please answer the questions as honestly as you can.
4. Please read the instructions at the beginning of each section and circle the response which you feel is the most relevant to you.
5. Although some statements may seem similar to others, no two are exactly the same.
6. Please take your time to read and understand the questions thoroughly.
7. If there is anything you do not understand, please ask the researcher for help.

### B: Confidentiality

1. Your name will not be put on the questionnaire. The researchers have given each questionnaire a code number, known only to them.
2. All information stored on computer is compliant with the Data Protection Act.
3. The information you provide in this questionnaire is confidential and will not be shared with anyone outside the research team unless required by law under the terms of the Children's Act (1989).

If you have any queries please contact:

Isabela Caramlau on 

---

Questionnaire type: AD

Date of receipt.....

Participant no.....

# Form 1

Please place a tick in the column that describes you best:

	Tick one	
<b>Marital Status</b>		
1. Single	[ ]	[ ]
2. Married/cohabiting	[ ]	[ ]
3. Separated	[ ]	[ ]
4. Divorced	[ ]	[ ]
5. Widowed	[ ]	[ ]
6. Partnered	[ ]	[ ]
<b>Socioeconomic Status</b>		
Low	[ ]	[ ]
Middle	[ ]	[ ]
High	[ ]	[ ]
<b>Self-esteem</b>	Yes	No
Do you feel good about yourself as a person?	[ ]	[ ]
Do you feel worthwhile?	[ ]	[ ]
Do you feel you have a number of good qualities as a person?	[ ]	[ ]
<b>Prenatal Depression</b>	Yes	No
1. Have you ever felt depressed during your pregnancy?	[ ]	[ ]
If yes, when and how long have you been feeling this way?		
If yes, how mild or severe would you consider your depression?		
<b>Prenatal Anxiety</b>	Yes	No
1. Have you ever felt anxious during your pregnancy?	[ ]	[ ]
If yes, how long have you been feeling this way?		
<b>Views on pregnancy</b>	Yes	No
Was the pregnancy planned?	[ ]	[ ]
Is the pregnancy wanted?	[ ]	[ ]

History of previous depression	Yes	No
1. Before this pregnancy, have you ever been depressed?	[ ]	[ ]
If yes, when did you experience this depression?		
If yes, have you been under a GP's care for this past depression		
If yes, did the GP prescribe any medication for your depression?		
Social Support	Yes	No
1. Do you feel you receive adequate support from your partner?	[ ]	[ ]
2. Do you feel you receive adequate practical support from your partner? (e.g. help with household chores or babysitting)	[ ]	[ ]
3. Do you feel you can rely on your partner when you need help?	[ ]	[ ]
4. Do you feel you can confide in your partner?	[ ]	[ ]
1. Do you feel you receive adequate support from your family?	[ ]	[ ]
2. Do you feel you receive adequate practical support from your family? (e.g. help with household chores or babysitting)	[ ]	[ ]
3. Do you feel you can rely on your family when you need help?	[ ]	[ ]
4. Do you feel you can confide in your family?	[ ]	[ ]
1. Do you feel you receive adequate support from your friends?	[ ]	[ ]
2. Do you feel you receive adequate practical support from your friends? (e.g. help with household chores or babysitting)	[ ]	[ ]
3. Do you feel you can rely on your friends when you need help?	[ ]	[ ]
4. Do you feel you can confide in your friends?	[ ]	[ ]
Marital Satisfaction	Yes	No
1. Are you satisfied with your marriage (or living arrangements)?	[ ]	[ ]
2. Are you currently experiencing any marital problems?	[ ]	[ ]
3. Are things going well between you and your partner?	[ ]	[ ]

Life stress	Yes	No
1. Are you currently experiencing any stressful events in your life such as:		
• Financial problems	[ ]	[ ]
• Marital problems	[ ]	[ ]
• Death in the family	[ ]	[ ]
• Serious illness in the family	[ ]	[ ]
• Moving	[ ]	[ ]
• Unemployment	[ ]	[ ]
• Job change	[ ]	[ ]
Child care stress	Yes	No
1. Is your infant experiencing any health problems?	[ ]	[ ]
2. Are you having problems with your baby feeding?	[ ]	[ ]
3. Are you having problems with your baby sleeping?	[ ]	[ ]
Infant temperament	Yes	No
1. Would you consider your baby irritable or fussy?	[ ]	[ ]
2. Does your baby cry a lot?	[ ]	[ ]
3. Is your baby difficult to console or soothe?	[ ]	[ ]
Maternity blues	Yes	No
1. Did you experience a brief period of tearfulness and mood swings during the first week after delivery?	[ ]	[ ]

## Form 2

Please place a tick in the column that describes you best:

	Yes definitely	Yes sometimes	No, not much	No, not at all
1. I wake early and then sleep badly for the rest of the night.				
2. I get very frightened or have panic feelings for apparently no reason at all.				
3. I feel miserable and sad.				
4. I feel anxious when I go out of the house on my own.				
5. I have lost interest in things.				
6. I get palpitations, or sensations of 'butterflies' in my stomach or chest.				
7. I have a good appetite.				
8. I feel scared or frightened.				
9. I feel life is not worth living.				
10. I still enjoy the things I used to.				
11. I am restless and can't keep still.				
12. I am more irritable than usual.				
13. I feel as if I have slowed down.				
14. Worrying thoughts constantly go through my mind.				

### Form 3

Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3.

Over the last two weeks	All of the time 5	Most of the time 4	More than half of the time 3	Less than half of the time 2	Some of the time 1	At no time 0
1. I have felt cheerful and in good spirits						
2. I have felt calm and relaxed						
3. I have felt active and vigorous						
4. I woke up feeling fresh and rested						
5. My daily life has been filled with things that interest me						

Form 4

For each question, please circle the number that best describes you:

A. Have you been able to talk about your feelings and problems with at least one friend during the last month?

1. I could always talk freely about my feelings
2. I usually could talk about my feelings
3. About half the time I felt able to talk about my feelings
4. I usually was not able to talk about my feelings
5. I was never able to talk about my feelings

B. Have you been able to talk about your feelings and problems with at least one of your relatives in the last month?

1. I could always talk freely about my feelings
2. I usually could talk about my feelings
3. About half the time I felt able to talk about my feelings
4. I usually was not able to talk about my feelings
5. I was never able to talk about my feelings

C. Have you been able to talk about your feelings and problems with your spouse or partner in the last month?

1. I could always talk freely about my feelings
2. I usually could talk about my feelings
3. About half the time I felt able to talk about my feelings
4. I usually was not able to talk about my feelings
5. I was never able to talk about my feelings

## Form 5

Please tick and **UNDERLINE** the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

1. I have been able to laugh and see the funny side of things.
  - As much as I always could
  - Not quite so much now
  - Definitely not
  - Not at all
2. I have looked forward with enjoyment to things.
  - As much as I ever did
  - Rather less than I used to
  - Definitely less than I used to
  - Hardly at all
3. I have felt scared or panicky for no very good reason.
  - Yes, quite a lot
  - Yes, sometimes
  - No, not much
  - No, not at all
4. Things have been getting on top of me.
  - Yes, most of the time I haven't been able to cope at all
  - Yes, sometimes I haven't been coping as well as usual
  - No, most of the time I have coped quite well
  - No, I have been coping as well as ever
5. I have been so unhappy that I have had difficulty sleeping.
  - Yes, most of the time
  - Yes, sometimes
  - Not very often
  - No, not at all
6. I have blamed myself unnecessarily when things went wrong.
  - Yes, most of the time
  - Yes, some of the time
  - Not very often
  - No, never
7. I have been anxious or worried for no good reason.
  - No, not at all
  - Hardly ever
  - Yes, sometimes
  - Yes, very often
8. I have felt sad or miserable.
  - Yes, most of the time
  - Yes, quite often
  - Not very often
  - No, not at all
9. I have been so unhappy that I have been crying.
  - Yes, most of the time
  - Yes, quite often
  - Only occasionally
  - No, never
10. The thought of harming myself has occurred to me.
  - Yes, quite often
  - Sometimes
  - Hardly ever
  - Never

## Appendix 8 – Test of normality

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
baseline HADS total depression	.105	37	.200 <sup>*</sup>	.963	37	.258
baseline HADS total anxiety	.125	37	.158	.950	37	.100
baseline marital satisfaction	.539	38	.000	.237	38	.000
six weeks infant temperament	.417	38	.000	.648	38	.000
AD1 EPDS total score	.145	38	.041	.898	38	.002
deprivation index score	.174	38	.005	.854	38	.000
six weeks child care stress total score	.362	38	.000	.711	38	.000
baseline life stress	.371	38	.000	.692	38	.000
baseline social support	.310	38	.000	.549	38	.000
PAID total score	.113	38	.200 <sup>*</sup>	.931	38	.021
MDQ_interf	.172	38	.006	.881	38	.001
MDQ_sev	.113	38	.200 <sup>*</sup>	.979	38	.677
MDQ_socsup	.151	38	.028	.927	38	.016

## Regression

**Descriptive Statistics**

	Mean	Std. Deviation	N
squarerootEPDS	2.3170	.90043	38
baseline HADS total depression	5.5333	3.12934	75
baseline HADS total anxiety	5.6316	3.72681	76
baseline life stress	.7403	1.20746	77
baseline social support	1.5714	3.04107	77
six weeks child care stress total score	.5526	.79517	38
Reflect SQRT MDQ Social Support	1.5309	.37441	38
SQRT MDQ Interference Time1	.9722	.62836	38

**Correlations**

	squarerootEPDS	baseline HADS total depression	baseline HADS total anxiety	baseline life stress	baseline social support	six weeks child care stress total score	Reflect SQRT MDQ Social Support	SQRT MDQ Interference Time1	
Pearson Correlation	squarerootEPDS	1.000	.419	.610	.242	.328	.444	-.349	-.428
	baseline HADS total depression	.419	1.000	.610	.112	.315	.276	-.173	-.109
	baseline HADS total anxiety	.610	.610	1.000	.138	.309	.246	-.084	-.317
	baseline life stress	.242	.112	.138	1.000	.195	.211	-.011	.037
	baseline social support	.328	.315	.309	.195	1.000	.220	-.285	-.159
	six weeks child care stress total score	.444	.276	.246	.211	.220	1.000	-.002	.070
	Reflect SQRT MDQ Social Support	-.349	-.173	-.084	-.011	-.285	-.002	1.000	.503
	SQRT MDQ Interference Time1	-.428	-.109	-.317	.037	-.159	.070	.503	1.000
	Sig. (1-tailed)	squarerootEPDS	.	.005	.000	.071	.022	.003	.060
baseline HADS total depression		.005	.	.000	.169	.003	.049	.156	.263
baseline HADS total anxiety		.000	.000	.	.117	.003	.071	.311	.028
baseline life stress		.071	.169	.117	.	.045	.102	.474	.413
baseline social support		.022	.003	.003	.045	.	.092	.041	.170
six weeks child care stress total score		.003	.049	.071	.102	.092	.	.497	.382
Reflect SQRT MDQ Social Support		.060	.156	.311	.474	.041	.497	.	.001
SQRT MDQ Interference Time1		.027	.263	.028	.413	.170	.382	.001	.
N		squarerootEPDS	38	37	37	38	38	38	21
	baseline HADS total depression	37	75	75	75	75	37	36	36
	baseline HADS total anxiety	37	75	76	76	76	37	37	37
	baseline life stress	38	75	76	77	77	38	38	38
	baseline social support	38	75	76	77	77	38	38	38
	six weeks child care stress total score	38	37	37	38	38	38	21	21
	Reflect SQRT MDQ Social Support	21	36	37	38	38	21	38	38
	SQRT MDQ Interference Time1	21	36	37	38	38	21	38	38

**Variables Entered/Removed<sup>a</sup>**

Model	Variables Entered	Variables Removed	Method
1	baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression <sup>b</sup>		Enter
2	six weeks child care stress total score <sup>b</sup>		Enter
3	Reflect SQRT MDQ Social Support, SQRT MDQ Interference Time1 <sup>b</sup>		Enter

a. Dependent Variable: squarerootEPDS

b. All requested variables entered.

**Model Summary<sup>d</sup>**

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.643 <sup>a</sup>	.414	.267	.77098	.414	2.820	4	16	.060
2	.694 <sup>b</sup>	.482	.310	.74822	.069	1.988	1	15	.179
3	.774 <sup>c</sup>	.598	.382	.70770	.116	1.884	2	13	.191

a. Predictors: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression

b. Predictors: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression, six weeks child care stress total score

c. Predictors: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression, six weeks child care stress total score, Reflect SQRT MDQ Social Support, SQRT MDQ Interference Time1

d. Dependent Variable: squarerootEPDS

ANOVA<sup>a</sup>

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	6.705	4	1.676	2.820	.060 <sup>b</sup>
	Residual	9.510	16	.594		
	Total	16.216	20			
2	Regression	7.818	5	1.564	2.793	.056 <sup>c</sup>
	Residual	8.398	15	.560		
	Total	16.216	20			
3	Regression	9.705	7	1.386	2.768	.054 <sup>d</sup>
	Residual	6.511	13	.501		
	Total	16.216	20			

a. Dependent Variable: squarerootEPDS

b. Predictors: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression

c. Predictors: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression, six weeks child care stress total score

d. Predictors: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression, six weeks child care stress total score, Reflect SQRT MDQ Social Support, SQRT MDQ Interference Time1

Coefficients<sup>a</sup>

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Correlations			Collinearity Statistics		
	B	Std. Error	Beta			Zero-order	Partial	Part	Tolerance	VIF	
1	(Constant)	1.397	.368		3.799	.002					
	baseline HADS total depression	.013	.071	.044	.180	.859	.419	.045	.034	.610	1.639
	baseline HADS total anxiety	.127	.059	.525	2.142	.048	.610	.472	.410	.610	1.638
	baseline life stress	.105	.146	.141	.717	.484	.242	.177	.137	.955	1.047
	baseline social support	.037	.061	.125	.603	.555	.328	.149	.116	.857	1.167
2	(Constant)	1.370	.357		3.833	.002					
	baseline HADS total depression	-.001	.069	-.004	-.017	.987	.419	-.004	-.003	.598	1.673
	baseline HADS total anxiety	.121	.058	.501	2.100	.053	.610	.477	.390	.607	1.647
	baseline life stress	.072	.144	.096	.498	.625	.242	.128	.093	.930	1.076
	baseline social support	.028	.060	.094	.468	.647	.328	.120	.087	.847	1.180
3	six weeks child care stress total score	.317	.225	.280	1.410	.179	.444	.342	.262	.874	1.144
	(Constant)	2.512	.800		3.142	.008					
	baseline HADS total depression	-.002	.067	-.008	-.032	.975	.419	-.009	-.006	.566	1.767
	baseline HADS total anxiety	.103	.060	.428	1.737	.106	.610	.434	.305	.509	1.965
	baseline life stress	.088	.136	.119	.649	.528	.242	.177	.114	.924	1.082
	baseline social support	.003	.059	.011	.057	.955	.328	.016	.010	.787	1.270
	six weeks child care stress total score	.371	.215	.328	1.724	.108	.444	.431	.303	.855	1.169
Reflect SQRT MDQ Social Support	-.482	.523	-.200	-.923	.373	-.349	-.248	-.162	.654	1.529	
SQRT MDQ Interference Time1	-.311	.319	-.217	-.975	.347	-.428	-.261	-.171	.621	1.609	

a. Dependent Variable: squarerootEPDS

Excluded Variables<sup>a</sup>

Model	Beta In	t	Sig.	Partial Correlation	Collinearity Statistics			
					Tolerance	VIF	Minimum Tolerance	
1	six weeks child care stress total score	.280 <sup>b</sup>	1.410	.179	.342	.874	1.144	.598
	Reflect SQRT MDQ Social Support	-.288 <sup>b</sup>	-1.484	.158	-.358	.904	1.106	.602
	SQRT MDQ Interference Time1	-.277 <sup>b</sup>	-1.389	.185	-.338	.873	1.146	.552
2	Reflect SQRT MDQ Social Support	-.311 <sup>c</sup>	-1.681	.115	-.410	.899	1.112	.588
	SQRT MDQ Interference Time1	-.325 <sup>c</sup>	-1.717	.108	-.417	.854	1.171	.544

a. Dependent Variable: squarerootEPDS

b. Predictors in the Model: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression

c. Predictors in the Model: (Constant), baseline social support, baseline life stress, baseline HADS total anxiety, baseline HADS total depression, six weeks child care stress total score

**Collinearity Diagnostics<sup>a</sup>**

Model	Dimension	Eigenvalue	Condition Index	Variance Proportions							
				(Constant)	baseline HADS total depression	baseline HADS total anxiety	baseline life stress	baseline social support	six weeks child care stress total score	Reflect SQRT MDQ Social Support	SQRT MDQ Interference Time1
1	1	3.504	1.000	.01	.01	.01	.03	.03			
	2	.633	2.353	.04	.02	.02	.30	.48			
	3	.612	2.394	.00	.00	.00	.65	.44			
	4	.155	4.750	.75	.01	.48	.01	.05			
	5	.096	6.031	.20	.96	.48	.00	.01			
2	1	3.993	1.000	.01	.01	.01	.02	.02	.02		
	2	.633	2.512	.04	.02	.02	.30	.47	.00		
	3	.614	2.551	.00	.00	.00	.58	.46	.02		
	4	.510	2.799	.02	.01	.01	.08	.00	.96		
	5	.155	5.072	.73	.01	.49	.01	.05	.00		
	6	.096	6.451	.20	.95	.47	.01	.01	.00		
3	1	5.432	1.000	.00	.00	.00	.01	.01	.01	.00	.00
	2	.849	2.530	.00	.00	.00	.07	.39	.04	.00	.03
	3	.619	2.963	.00	.01	.01	.80	.14	.01	.00	.00
	4	.521	3.229	.00	.00	.00	.10	.09	.89	.00	.00
	5	.360	3.886	.00	.04	.14	.02	.31	.01	.00	.16
	6	.117	6.825	.04	.56	.04	.00	.02	.02	.05	.23
	7	.084	8.056	.08	.27	.76	.00	.00	.01	.01	.43
	8	.019	16.768	.87	.12	.04	.00	.05	.00	.93	.14

a. Dependent Variable: squarerootEPDS

Residuals Statistics<sup>a</sup>

	Minimum	Maximum	Mean	Std. Deviation	N
Predicted Value	1.2884	3.6675	2.5085	.62510	20
Std. Predicted Value	-1.477	1.939	.275	.897	20
Standard Error of Predicted Value	.214	.635	.412	.122	20
Adjusted Predicted Value	1.0739	4.5064	2.5181	.85242	20
Residual	-1.49396	.90535	-.00906	.63465	20
Std. Residual	-2.111	1.279	-.013	.897	20
Stud. Residual	-3.037	2.348	-.026	1.246	20
Deleted Residual	-3.09215	3.04917	-.01862	1.29583	20
Stud. Deleted Residual	-5.414	2.972	-.130	1.680	20
Mahal. Distance	.871	15.139	6.403	4.141	20
Cook's Distance	.004	1.631	.214	.442	20
Centered Leverage Value	.044	.757	.320	.207	20

a. Dependent Variable: squarerootEPDS

## Charts

Normal P-P Plot of Regression Standardized Residual

Dependent Variable: squarerootEPDS

