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Psychological investigations for adults with type 1 diabetes.

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A: Overview

This portfolio thesis consists of three parts: a systematic literature review, an empirical report and appendices including a reflective statement.

Part one is a systematic literature review investigating the impact psychological interventions have on aiding glycaemic control in adults with type 1 diabetes. This review systematically searched 6 databases to find 10 randomised control trials which met the requirements of the inclusion and exclusion criteria. A meta-analysis was employed to assess whether glycaemic control improved in the group using psychological interventions compared to individuals receiving usual diabetes care. The results of the investigation are reported along with limitations to the review, and a discussion of study quality and clinical implications.

Part two is an empirical paper which reports the findings of an investigation into objective memory functioning, subjective memory, and differences between objective memory and subjective memory in adults with type 1 diabetes. Objective memory was measured using the BMIPB, whilst subjective memory was assessed using the Memory Functioning Questionnaire. Potential covariates were measured, which included mood, anxiety and information processing speed, to investigate whether they influenced any potential differences between objective and subjective memory. There were three groups of participants used, which were people with poorly-controlled diabetes, people with well-controlled diabetes, and a healthy control group. The results from the study, along with a discussion of clinical implications have been reported.

Part three is comprised of the appendices of supporting information from the empirical paper and systematic literature review, as well as a reflective statement.

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PART 1: Systematic Literature Review

This paper is written in the format ready for submission to the British Journal of Health Psychology. Please see Appendix 2.1 for the ‘‘Author Guidelines’’.

Word count: 4997 (excluding references and tables)

How effective are psychological interventions in aiding glycaemic control in adults with type 1 diabetes? A systematic review and meta-analysis

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Abstract

Type 1 diabetes is a chronic health condition which is managed by multi-disciplinary teams. Psychological interventions as part of a multi-disciplinary approach have proved to be effective in improving quality of life and reducing symptoms in other chronic health conditions. There is currently a growing literature regarding psychological interventions to aid improvement in glycaemic control in adults with type 1 diabetes. The aim of this systematic review was to assess, using a meta-analysis, the effect of psychological interventions on management of glycaemic control. Studies used in this intervention were randomised control trials. A systematic literature search was conducted using six databases. There were 10 studies identified as suitable to be included in the meta-analysis. The participants were aged between 16-80 years old, with varying levels of glycaemic control and duration of illness. The result of the meta-analysis provided evidence that psychological interventions provided a small improvement in glycaemic control compared to usual diabetes care only. The review highlighted some issues with the randomised control trials that were included in the meta-analysis. The studies reviewed were mainly based on cognitive behavioural interventions. Current psychological approaches in chronic health conditions are moving towards mindfulness and acceptance and commitment therapy interventions. There are currently limited randomised control trials investigating the effects of these therapies on glycaemic control in type 1 diabetes. Therefore, more varying psychological investigations should be undertaken before further systematic reviews in this area are completed.

Keywords: type 1 diabetes, glycaemic control, psychological interventions.

Introduction

Diabetes mellitus is a chronic health condition which is characterised by blood sugar levels rising to abnormally high levels as a result of a lack of insulin, a hormone responsible for assisting glucose to enter the bloodstream (Diabetes UK, 2014). There are two types of diabetes mellitus, type 1 diabetes (T1DM) or insulin-dependent diabetes, and type 2 diabetes (T2DM). Insulin-dependent diabetes is distinguished by the person afflicted by the condition being unable to produce insulin due to the beta cells in the pancreas responsible for insulin production having been destroyed (Ismail, Maissi, Thomas et al., 2010). Patients with T2DM are still able to produce insulin, but it is at a reduced level (Diabetes UK, 2014). Symptoms associated with T1DM include increased urination and thirst, weight loss, changes in vision, and fatigue (Ismail et al., 2010). Currently in the United Kingdom, it is estimated that there are 2.9 million people diagnosed with diabetes, with approximately 400,000 of these diagnosed individuals having the insulin-dependent variation (NHS Choices, 2014). Currently the incidence of diagnosis of T1DM is increasing between 2-5% yearly (Najmi, Marasi, Hashemipour, Hovsepian & Ghasemi, 2013).

People with T1DM at times experience abnormally low blood sugar levels (hypoglycaemia) and high blood sugar levels (hyperglycaemia). Hypoglycaemia is commonly associated with over administration of insulin, excessive exercise and reduced food intake. Hyperglycaemia is when blood sugar levels become too high. This occurs because the body cannot convert the glucose into energy and builds up in the blood stream (NHS Choices, 2014). There are a number of complications people with T1DM are at greater risk for, associated with poor blood glucose control or glycaemic control. These complications include visual and renal problems,

nephropathy, neuropathy, and vascular complications (Nathan, Cleary, Backlund et al., 2005). It is therefore important for patients with T1DM to manage their chronic health condition as effectively as possible. Glycaemic control is assessed by measuring a person's glycated haemoglobin (HbA_{1c}). HbA_{1c} provides an indication of the amount of circulatory glucose in the blood over a 120 day period. The ideal percentage of glycated haemoglobin is below 7.5% (Alam, Sturt, Lall, & Winkley, 2009). Every 1% reduction in HbA_{1c} is related to a reduction in complications associated with T1DM (Alam et al., 2009).

There is no cure for T1DM, and therefore providing strategies to manage the condition as effectively as possible is the focus of healthcare providers. Current management of T1DM for adults utilises a multi-disciplinary team (MDT) approach. The management techniques include dietary management and education, insulin therapy, blood glucose self-monitoring training and advice, education about physical activity, and support and therapeutic interventions to help manage complications associated with diabetes (NICE, 2004). Constant attention to diet, blood glucose monitoring, physical exercise, and insulin adherence to achieve optimal glycaemic control is associated with increased levels of stress in individuals with insulin-dependent diabetes (Attari, Sartippour, Amini, & Haghighi, 2006).

It is reported that one third of people with diabetes experience a clinical depressive disorder (Lloyd, 2010), with anxiety and other mental health problems common. People with diabetes are twice as likely to experience depression, anxiety, or other serious psychological distress as people without diabetes (Li, Ford, Zhao, Balluz, Berry, & Mokdad, 2010). In addition to this, mood and psychosocial factors can exert influence on glycaemic control (Cramer, 2004). These psychological factors associated with less effective blood glucose control have evidence to suggest that

they interfere with self-care behaviour (Ridge, Treasure, Forbes, Thomas, & Ismail, 2012) and adherence to medication (Markowitz, 2012), and therefore in turn affect blood glucose levels. According to Ridge and colleagues (2012), only a third of patients with T1DM achieve an HbA_{1c} of 7.5% or below.

As previously discussed, the current NICE (2004) guidelines recommend an MDT approach to effective self-management of T1DM, but psychological therapies are not recommended currently. In other chronic health conditions psychological interventions have demonstrated efficacy in improving physical symptoms associated with the conditions. For patients with a chronic pain condition, psychological interventions focusing on self-management, behavioural change and cognitive change, with regular care have led to people feeling more in control of their pain, and being more active in the management of it (Roditi & Robinson, 2011). For adults experiencing chronic lower back pain, psychological intervention has evidence to support that it is an effective pain relief (Ostelo, van Tulder, Vlaeyen, Linton, Morley, &Assendelft, 2005). Psychological treatment to help reduce symptoms and improve quality of life with people experiencing irritable bowel syndrome (IBS) have evidence for efficacy as well (Zijdenbos, de Wit, van der Heijden, Rubin, & Quartero, 2009).

To date, only one systematic review regarding psychological interventions for adults with T1DM exclusively has been produced (Winkley, Landau, Eisler, & Ismail, 2006). Winkley and colleagues (2006) produced a meta-analysis of randomised control trials (RCTs) investigating psychological interventions and their effectiveness in improving blood glucose control in adults and children with T1DM. They analysed the mean changes in glycaemic control from baseline measures to follow up in both the intervention and non-psychological intervention groups. The

results of their study found evidence to support psychological therapies improving glycaemic control in children and adolescents, but not in adults. However, at that time, psychological interventions aimed at adults with T1DM were infrequent and still developing. Therefore, this review aimed to investigate the effects of the psychological interventions on glycaemic control in adults with T1DM. It is important that the effect of psychological interventions are analysed, because it is clear that they are beneficial in other health conditions, and potentially providing evidence for their effectiveness could lead to better outcomes and less complications for adults with T1DM.

Method

Search Strategy

An initial search using The Cochrane Library and Scopus was undertaken to investigate whether any additional meta-analyses or systematic literature reviews had been undertaken to assess effectiveness of psychological interventions in aiding glycaemic control in adults with T1DM. The only other review, in addition to Winkley and colleagues (2006) that had been conducted was by Elliott (2011), but focused on cognitive behaviour therapy, and was not exclusive to T1DM. A systematic literature search was employed in January 2014. The search utilised 6 different internet databases in an attempt to provide as comprehensive a search as possible. The databases used were: PsycInfo, PsycArticles, Medline, Scopus, Cinahl, and Pub Med. These databases were chosen because they contained up to date journal articles, and with many articles from more than 40 years previous. The databases also present abstracts from the journal articles, allowing the researcher to assess the content of each article found.

Search Terms

The search terms were chosen after reading articles regarding glycaemic control in both T1DM and T2DM. Key words, journal titles and abstracts were searched utilising the following search terms: (type 1 diabetes OR insulin#dependent diabetes OR T1DM OR iddm OR type 1 diabetes mellitus OR insulin#dependent diabetes mellitus) AND (psycholo* therap* OR psycholo* interven* OR psychology* treatment OR psycho* education OR mindfulness OR psychodynamic psychotherap* OR cognitive#behavio#r therap* OR CBT OR famil* therap* OR system* thearp* OR acceptance commitment therap* OR compassion#focused therap* OR compassionate mind OR cognitive#analytic* therap* OR ACT OR CFT OR CAT) AND glyc#emic control OR metabol* control OR h#emoglobin A1c OR HbA1c OR A1C).

There were 2 notable characters used in the search; (*) and (#). The (*) was used due to many of the words having multiple possible endings, and this character allowed all possible words with the word prior to the (*) to be searched. The (#) allowed words to be searched more effectively which may have extra letters or a hyphen. The (#) was used to replace a potential letter or hyphen so the results which contained the extra letter or hyphen would be included.

Search Limits

Where options were available specific search limits were applied whilst searching databases. The search limits were placed to restrict the number of potential articles which did not meet the inclusion criteria or research question. The limits used were peer-reviewed journals, randomised control trials human subjects, adult participants

(over 16 years old), and articles written in English language only. No time limits were applied to the database searches.

The criteria for inclusion within this review are described below in Table 1.

Criteria	Rationale
Studies that utilised a randomised control trial method.	Randomised control trials are the gold standard in treatment efficacy research.
Studies which included adult participants only (aged 16 years and over).	Using 18 as a guide would have limited the number of RCTs because some included 16 year olds.
Studies where a clear distinction between T1DM and T2DM data was reported.	If T2DM data were to be included this would have contaminated the data.
Studies which utilised a psychological intervention.	Psychological interventions were the variables investigated.
Studies which outcome measures included the HbA_{1c} for both pre and post intervention data, and reported standard deviations for pre and post intervention.	A meta-analysis calculation could not be completed without all of this data.
Studies published in peer-reviewed journals.	Studies published in peer-reviewed journals have had their quality, validity, and reliability assessed. They have used good scientific methods.
Studies published in the English language.	The researcher was not able to read in any other language but English.

Table 1. Study inclusion criteria and rationale for the meta-analysis.

Exclusion Criteria

The criteria for studies to be excluded from this review are described below in Table 2.

Criteria	Rationale
Systematic literature reviews.	They would not provide the data appropriate for a meta-analysis calculation.
Case reports.	They would not provide the data appropriate for a meta-analysis calculation.

Studies including participants under 16 years old.	The study focused on adults. People under 16 are not adults.
Studies not reporting pre and post HbA1c data or standard deviations.	They would not provide the data appropriate for a meta-analysis calculation.
Studies not using psychological methods as the main intervention.	Psychological interventions were the focus of the research.
Studies not published in the English language.	The researcher was not able to read articles in any other language but English.
Studies where the available HbA1c data was not distinct between T1DM and T2DM when both forms of diabetes mellitus were investigated.	Including T2DM data would contaminate the data for the meta-analysis calculation.

Table 2. Study exclusion criteria and rationale for the meta-analysis.

Results of the Systematic Search Strategy

After the search 193 articles were identified as potentially suitable. The researcher then assessed all study titles to look for duplicates. There were 29 duplicates were identified, leaving a total of 164 abstracts to be read. The abstracts were assessed to see if they met the inclusion and exclusion criteria for the review, and whether they were appropriate to the question being investigated. A further 147 studies were rejected from the research at this stage. Full text journal articles which met the inclusion and exclusion criteria after abstract review were obtained (n=18). These full articles were reviewed further to identify the articles which would be suitable for the meta-analysis. There were 2 articles rejected at this stage because the intervention used was not a psychological intervention. The remaining studies were quality assessed (n= 16). Google Scholar and a reference list search were utilised after this process in an attempt to identify any further potential studies, which the previous searches had not identified. This search did not find any further studies after searching the various psychological therapies individually. Key authors were contacted from 2 potential studies to enquire if T1DM information only could be

shared due to their studies incorporating both T1DM and T2DM information as one value in the analysis. The authors kindly shared this information. A further author was contacted to enquire if they had collected data from a proposed pilot study which had been retrieved in the database search. Unfortunately the author was still awaiting their data to be published at the time the current researcher was analysing the data found. There were a further 6 authors contacted to enquire about standard deviation data which were not reported in their published journal articles. Unfortunately the contact was not reciprocated. The process is demonstrated in Figure 1. The key information from the appropriate articles was extracted using a data extraction form, which had been adapted to meet the current review's aims (Appendix 3.1).

Assessment of Methodological Quality

To assess the methodological quality of the studies included in the review, an adapted quality checklist based upon the Downs and Black Checklist (1998) and Schultz, Altman and Moher Checklist (2010) was used. The two checklists adapted were selected because they were specifically developed for assessing quality of healthcare interventions (Downs & Black, 1998; Schulz, Altman, & Moher, 2010). The adapted checklist incorporated items to assess overall quality of the study, the methodology, the results, and discussion, taking into account the reliability and validity of the outcome of the studies, and assessing the characteristics of the participants. The previous meta-analysis (Winkley et al., 2006) did not assess study blindness in the quality assessment, which is an area that is important for validity (Cochrane Collaboration, 2002). However, their rationale stated that blinding participants in psychological intervention RCTs was not possible, and so the current author did not include blinding of participants in the quality checklist. The adapted

checklist was comprised of 28 items, all of which were considered to be appropriate for assessing the studies in this review. The checklist had a maximum score of 28, which would mean the study had exceptional design quality due to it meeting all the standards set. Therefore, the higher the score achieved, the better the quality of the study. Please see Appendix 3.2 for a copy.

There were 16 studies included in the quality assessment, although as already stated only 10 were included in the meta-analysis. This was because the assessment was undertaken whilst the author awaited information regarding standard deviations from authors of the already completed studies. The researcher and an independent rater experienced in psychological research assessed the studies to ensure the ratings were reliable. The second rater assessed 53% of studies (n=9). Appendix 3.3 provides an overview of the ratings provided and the level of agreement between raters. Inter-rating agreement was high, with 23 of the 28 categories receiving 100% agreement. The lowest percentage of agreement was 82%, which was regarding random variability in the data. The raters discussed these differences. The author of this review did not give a favourable rating on each of the differing occasions because there were standard deviations missing from parts of the results section, which would be needed for the analysis. The inter-rater reliability was .975, which is an exceptionally high rate. This high rate may have been due to the studies all being RCTs, with clear goals and the same measurement of glycaemic control used. These studies were all excluded at meta-analysis stage because all the random variability (standard deviations) had not been reported, and therefore did not meet the inclusion criteria.

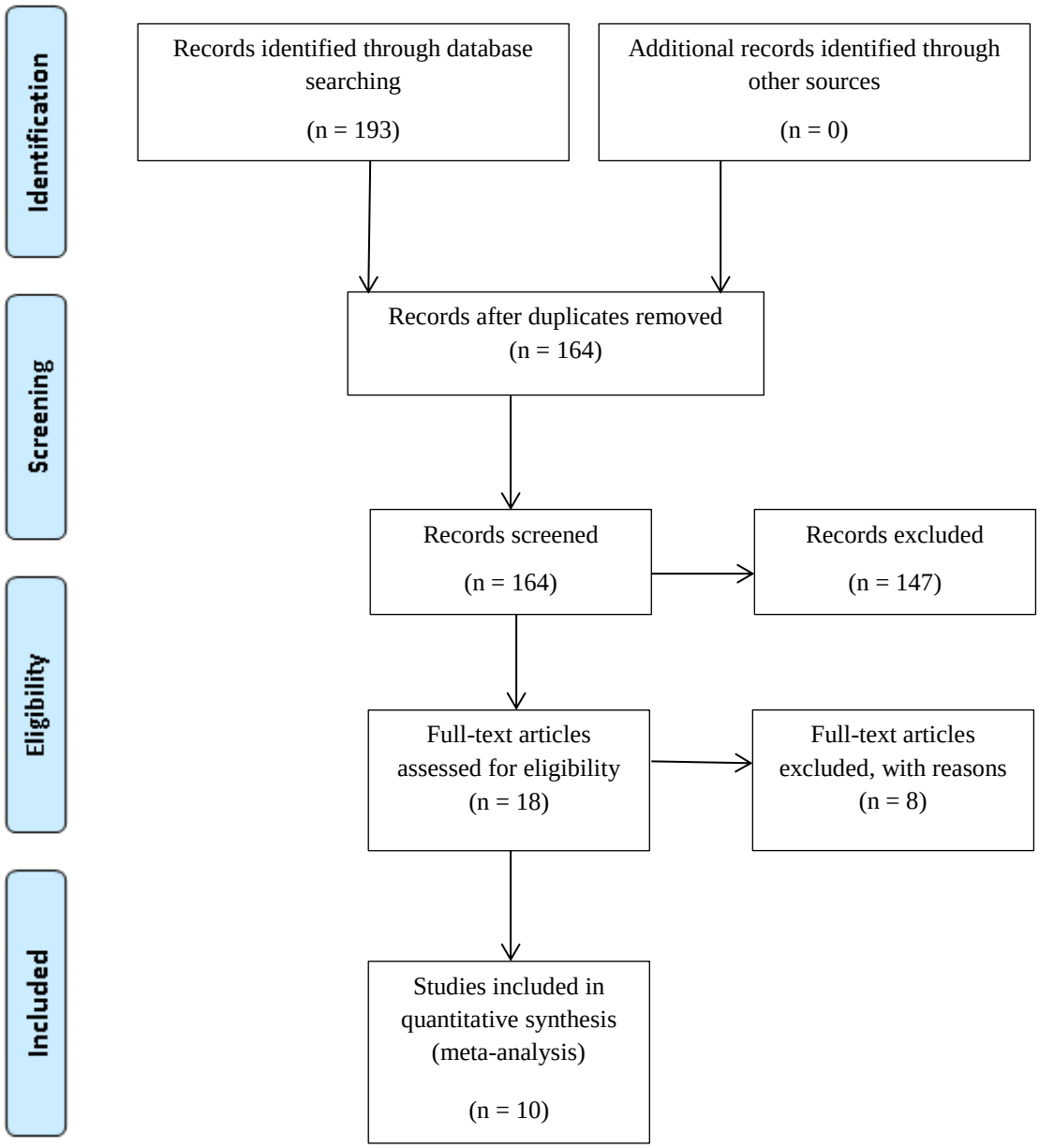

Figure 1. Summary of Study Selection Process

Data Analysis

The data in this study was analysed using a meta-analysis. A meta-analysis was implemented because it allowed several individual studies to be integrated together and statistically analysed simultaneously using study weightings (Cochrane Collaboration, 2012). A meta-analysis provides an objective appraisal of the research findings provided (if they have the same outcome measure), and demonstrate a more precise treatment effect (Egger, Smith, & Philips, 1997). A

meta-analysis is also top of the hierarchy of evidence when assessing effectiveness of interventions in medical studies (Haidich, 2010).

The meta-analysis was conducted using Review Manager Version 5.2 computer software (Review Manager 5.2, 2012). The analysis was conducted on all studies identified through the systematic search procedure which met the inclusion criteria. The mean post HbA_{1c} and standard deviations for both the intervention and control groups were required to complete the calculation. Analysing the difference between the pre and post HbA_{1c} measures was not possible, because there were no standard deviations for the differences. The most recent post intervention HbA_{1c} measures were the figures used in the calculation.

Intervention sub-groups were not created because the majority of the interventions were CBT/psychoeducation approaches, with a handful of other types of interventions which are noted in an overview of the study information (Appendix 3.4). In addition to this, the primary focus of some of the studies was not to assess the effect of the intervention on glycaemic control, although they did investigate this.

Results

A table containing all the information extracted from the 16 studies identified as potentially contributing to the meta-analysis can be found in Appendix 3.4. A table with information regarding excluded studies can be found in Appendix 3.5.

The key information extracted from the 10 included studies is presented below:

Participants

A total of 345 intervention participants were included in the meta-analysis, with a mean average of 34.5 participants per study (SD= 29.46). The number of participants in each group ranged from 10 (Feinglos, Hastedt, & Surwit, 1987; Fosbury, Bosley, Ryle, Sonksen & Judd, 1997) to 106 (Ismail, Thomas, Malssi et al., 2008). The total number of control participants across studies was 370, with a mean average of 37 per study (SD= 32.76). The number of participants in this group ranged from 10 (Feinglos et al., 1987) to 121 (Ismail et al., 2008). This shows that there was great variance between the numbers participating across studies. The studies included minimum ages of participants from 16 years old, with the oldest participants up to 80 years old. The average age of participants in the intervention groups based on studies averages was 38.28 (SD=9.85), with a mean of 39.87 (SD=10.21) in the control participants. The mean average age range from 19.7 (Attari et al., 2006) to 56 (van Son, Nyklicek, Pop, Blonk, Erdtsieck, Spooren et al., 2013) in the intervention group, and 20.8 (Attari et al., 2006) to 57 (van Son et al., 2013) in the control group. This shows that there were large variances between ages of participants receiving psychological interventions across studies. The average percentage of male participants in the intervention group was 43 (SD=10.15), with an average of 46.6 (SD=15.89) in the control group. Only 7 out of 10 the studies reported gender information.

Only two studies reported ethnicity data. Both of these studies were completed in the United Kingdom. One study reported that 100% of participants in the intervention group were white, with 81% of control participants being of white of origin. The other control participants were 13% Afro-Caribbean and 6% Asian in origin (Fosbury et al., 1997). Ismail and colleagues (2008) reported that 83% of

participants in the intervention group were of white origin with 17% of participants being described as of black origin. The control group in this study reported 73% white and 27% black origin. The results suggest that more people of white origin participated in these studies. Due to only 2 studies reporting figures regarding ethnic backgrounds, it is not possible to know the ethnic diversity for all the studies. However, 9 of the 10 studies were conducted in countries which are predominantly white in ethnic origin, and therefore it is likely that these figures would be similar in the other studies, with the exception of the study by Feinglos and colleagues (1987) which was conducted in North America. One study was conducted in Iran (Attari, et al., 2006), with the majority of the participants likely to be of Iranian origin.

The information related to glycaemic control was used in the meta-analysis and is reported in the meta-analysis section. For this section it would relevant to report the duration of diagnosis of T1DM for the participants. The average length of duration in the intervention group was 17.43 years (SD= 8.43), with an average duration of 16.73 years (SD= 6.78) in the control participants. The standard deviations were quite high in relation to the means, which would suggest there was great variance in the duration of diagnosis across studies. Indeed, Attari and colleagues (2006) reported a mean duration of illness of their participants for both groups to be 2.1 years. The study by Schachinger and colleagues (2005) reported long duration of illness for both intervention and control group (33.1 years and 22.7 years respectively). The average HbA_{1c} measure recorded for the intervention group at baseline was 9.39% (SD=2.04). The average HbA_{1c} for the control group at baseline was measured at 9.24% (SD=2.06). This demonstrates that between the groups across the studies, the participants' baseline glycaemic control was well matched. The ranges in baselines were similar too with 12.6 and 13.1 the highest

recorded for both groups at baseline (Feinglos et al., 1987), and 6.93 and 6.91 the lowest recorded at baseline (Schachinger, Hegor, Hermanns, Strauman, Keller, Wolfsdorf et al., 2005). The participants did vary at the end of the treatment, with the intervention group reporting a HbA_{1c} of 8.74% (SD= 1.75), compared to the control group's 9.12% (1.78).

Aims of the Studies

All the studies included in the meta-analysis provided baseline and post-intervention measures of glycaemic control. However, not all the studies exclusive aim was to make glycaemic control more effective. Van Basterlaar and colleagues (2011) had the primary aim of assessing the effectiveness of web-based cognitive behaviour therapy (CBT) on depression in adults with diabetes. There were four studies investigating psychological therapy effectiveness on mood and glycaemic control (Didjurgeit, Kruse, Schmitz, Stückenschneider & Sawicki,2002; Fosbury et al., 1997; Ismail et al., 2008; van Son et al., 2013). The remaining five studies were concerned with glycaemic control as their primary aim of the investigation.

Inclusion/Exclusion Criteria

The studies used various inclusion criteria, with regular items including ages of participants, duration of illness, and control of blood sugar. Some studies required participants to be able to speak and read the language of the country of the study (Halford, Goodall & Nicholson, 1997; Ismail et al., 2008; van der Ven, Hosenelst, Tromp-Wever, Twisk, van der Ploeg, Heine, & Snoek, 2004; Van Son et al., 2013). The remaining inclusion criteria varied greatly with participants included if they were inpatients (Feinglos et al., 1987), and had access to the internet (van Basterlaar, Pouwer, Cuijpers, Riper & Snoek, 2011), for example.

The exclusion criteria had common themes which included severe diabetic complications, substance use and dependence, being pregnant, presence of severe mental illness (e.g. psychosis and major depression), and a serious illness or comorbid health problem (e.g. cancer, heart problems, renal failure). Exclusion criteria were not included for 3 studies (Feinglos et al., 1987; Fosbury et al., 1997; Halford et al., 1997).

Participant Treatment

The interventions the participants received varied. There were many studies using some cognitive behavioural techniques. The approaches utilised did differ with a web-based approached used (van Basterlaar et al., 2011), CBT with motivational enhancement group therapy (Ismail et al., 2008), a CBT group (Schachinger et al., 2005; van der Ven et al., 2004), group problems solving training (Halford et al., 1997), and group relaxation training (Attari et al., 2006; Feinglos et al., 1987). The remaining therapeutic approaches involved group mindfulness (van Son et al., 2013), individual Cognitive Analytic Therapy (Fosbury et al., 1997), and individual problem orientated psychotherapy (Didjurgeit et al., 2002). All the therapists involved in the interventions received specialist training or were in line with their professional duties. Information for therapist profession was not supplied in the study conducted by Feinglos and colleagues (1987).

The control groups used across the studies demonstrated little variance compared to the intervention groups. The control groups used mainly regular diabetes care and education. No psychological interventions were used in the control groups.

Key Findings

Improvements in glycaemic control were reported in some of the studies, although statistically significant improvements compared to the control group was reported in the study by Attari and colleagues (2006) only. Small improvements were reported by 5 studies (van Basterlaar et al., 2011; Feiglos et al., 1987; Halford et al., 1997; Schachinger et al 2005; van der Ven et al., 2004).

Quality Assessment

The quality assessment of the studies used in the meta-analysis would suggest that the studies were of a good standard. The maximum score achievable was 28. There were 6 out of the final 10 studies quality assessed by both raters. The average rating was 24.8 (SD= 2.78). The range of quality scores was between 20 (Attari et al., 2006; Feinglos et al., 1987) and 28 (van Bastelaar et al., 2011). The issues with the studies which have impacted on their quality have been concerned with the lack of reporting of participant drop out, missing sample size calculations, and limitations to the studies not being acknowledged. However, in general the studies were of good quality. The participants were recruited randomly, without bias. Intervention and control groups were also well balanced, with similar demographic features. Appropriate statistical analysis techniques were employed.

Meta-analysis

The results of the meta-analysis are shown in Figure 2.

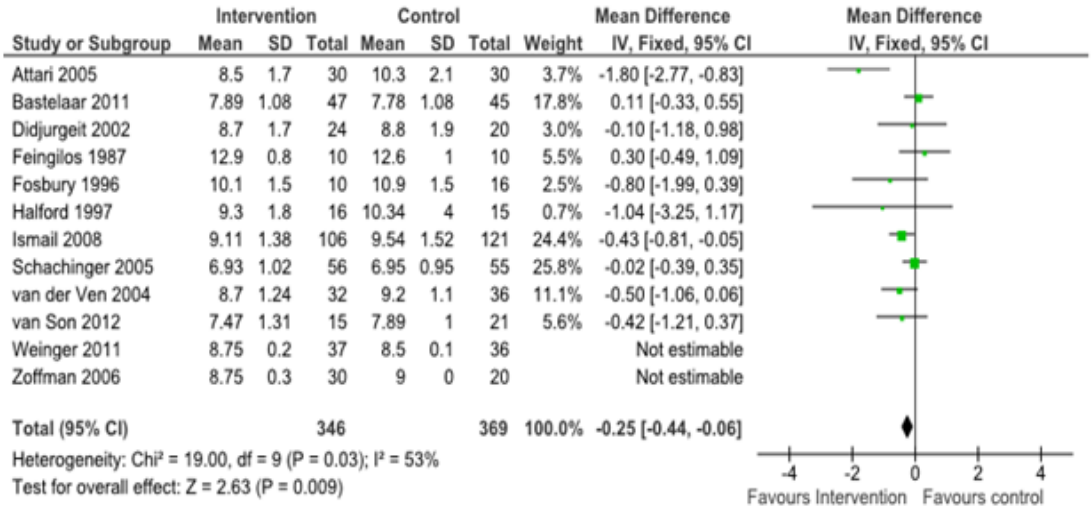

Figure 2. Effects of psychological interventions on glycated haemoglobin in adults.

The results of the meta-analysis indicate that the overall effect of psychological interventions improve glycaemic control in adults with T1DM. This improvement is a small improvement with an overall benefit of a reduction of 0.25% in HbA_{1c} in favour of the psychological intervention. This result has been calculated as statistically significant ($p<0.05$). The variability between the studies has been calculated to be a good level ($I^2= 53\%$) which is statistically significant ($p<0.05$). Although this data is positive, the results show that the majority of the weight of the calculation depends on three studies to account for 68% of it (van Basterlaar, 2011; Ismail, 2008; Schachinger, 2005). The results also demonstrate that the confidence intervals were very large for four of the studies (Attari, 2006; Didjurgeit, 2002; Fosbury, 1997; Halford, 1997), which indicate that their results were less precise, and therefore potentially reduced the overall effect.

Publication bias was important to investigate in the meta-analysis. Many studies receive publication because they are interesting, have large funding, have a higher quality of methodology, or produced significant results. Sometimes studies are not published because they do not meet any of the above criteria. This is known as publication bias. Publication bias can lead to conclusions in a meta-analysis being invalidated (Sutton, Dual, Tweedie, Abrams, & Jones, 2000). The effect of potential publication bias was assessed using a funnel plot analysis. A funnel plot is a scatter graph which demonstrates the effect of treatment against study size. A study with no publication bias has a relatively symmetrical funnel. A funnel with the majority of the studies on one side of the average would suggest publication bias (Egger, et al., 1997). The results are shown in Figure 3. The funnel plot indicates that there was no publication bias, with symmetry displayed in the funnel plot. This means that there is confidence that no bias has been incorporated into the results or search.

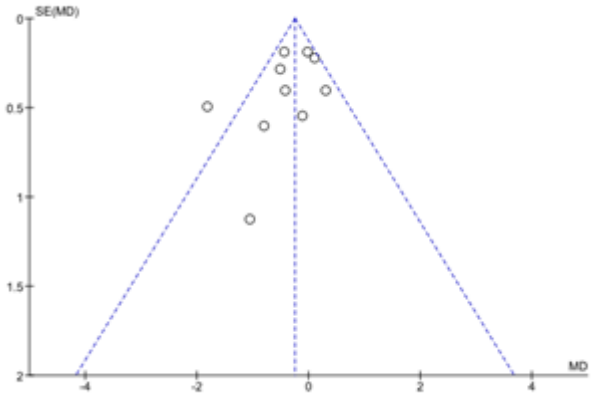

Figure 3. Publication bias in the randomised control trials of psychological interventions in adults with T1DM.

Discussion

The result of this meta-analysis provides evidence to support the use of psychological interventions as a part of the treatment for adults with T1DM. The statistics found evidence for a small improvement in glycaemic control compared to treatment without psychological intervention (HbA_{1c} =0.25%). However, the results demonstrated that there were large confidence intervals for 4 out of the 10 studies. This may have reduced the effect size, and therefore reduced the level of improvement in HbA_{1c}.

Quality of the studies

A thorough quality assessment was conducted in the study. All studies included inclusion criteria, they did not report bias, and tested the relevant population, which could generalise the findings to the population they tested. The two studies which scored the lowest on the quality assessment (Attari et al., 2006; Feinglos et al., 1987) both failed to calculate sample sizes, report drop outs or discuss them, and their participants were not seen as representative of the population. These studies may have affected the results of the study due to their reduced quality. In general, most studies lost points in the quality assessment for missing out on reporting limitations, not suggesting future directions to research, or not generalising the findings to the population. Although this is an issue of quality of the report, it is not a quality issue in terms of the study design.

Limitations

There were a number of limitations to this study. Firstly, six studies had to be rejected because they did not report the standard deviations to the mean HbA_{1c}

information required for the meta-analysis calculation. Three of these studies had a quality rating which exceeded the actual mean quality rating, with all the other rejected studies scoring within the range from the accepted studies. The inclusion of these studies could have provided data which may have changed the outcome of the meta-analysis calculation.

A second limitation to this study is that the meta-analysis calculation was based on the post-intervention HbA_{1c} for both the psychological intervention group and the control group. A calculation investigating the differences between the baseline and post-intervention HbA_{1c} data may have been more appropriate to the current research question. This is because the calculation in this study compared the outcome HbA_{1c} level. It did not take into account the amount of change between baseline measures. The study by Attari and colleagues (2006) demonstrates that the baseline measures between the intervention and control had nearly 1% difference. After the intervention, the HbA_{1c} reduced by 3.2% compared to just 0.6% in the control group. Investigating these figures may have produced a calculation that reported a larger improvement in glycaemic control than 0.25% in favour of the psychological intervention group. Unfortunately, the studies did not report the figures necessary to produce the calculation.

A third limitation to this investigation is that no lower limits were used in regards to the glycaemic control figures reported in the studies. The optimal level desired is a HbA_{1c} of 7.5% (NICE, 2009), but some studies included participants with already well-controlled T1DM according the mean HbA_{1c} levels provided (Halford et al., 1997; Schachinger et al., 2005). The participants may have already reached their optimal control, and therefore the psychological intervention may not have been effective or beneficial for them.

A final limitation to the study is that there were large variations between the participants used in the various studies. Participant age is an example of these differences, with an age range of 16 to 80 years. This may have impacted the overall findings of the meta-analysis because of the different life stages affecting how someone will engage with therapy. A 16 year old may not want to engage with psychological support because of stigma that may be attached to it, especially at a time when someone is finding their identity. This may affect their ability to engage fully with the therapy, and therefore the outcome might be compromised. With older adults they may want to engage in the psychological support, but cognitive decline may lead to difficulties using these techniques, and therefore impacting on the effectiveness of the therapy. The large range of duration of illness reported in the studies may also have had an effect on the outcome. The range of duration of illness was between 2 and 32 years. The length of time suffering with the disease could impact upon the psychological presentation. Patients who had suffered with T1DM for 2 years may present with grief related problems, where as someone with long term T1DM may experience depressive symptoms. These presentations may receive different psychological treatment. Therefore, this may have impacted the data as well.

Future Research

The studies included in this review have mainly used psychological approaches, which were based upon cognitive behavioural approaches. Although cognitive behaviour therapy has good evidence for effectiveness in chronic health conditions (Hofmann, Asnaani, Vonk, Sawyer & Fang, 2012), different psychological approaches are being used effectively in physical health services, including Acceptance and Commitment Therapy (ACT) and mindfulness (McCracken, 2011).

A study currently in press (Tovote, Fleer, Snippe, Bas, Links, Emmelkamp et al., In Press) has compared the effectiveness of mindfulness-based therapy against CBT in glycaemic control. The results show that mindfulness was more effective than CBT in reducing HbA_{1c} in the participants with T1DM. This would suggest that there is a need for randomised control trials to investigate the effect of mindfulness-based interventions on glycaemic control compared to regular T1DM care.

Further studies investigating psychodynamic and cognitive analytic therapy (CAT) may also find evidence for effectiveness in glycaemic control, with only one study regarding CAT being reported so far.

Conclusions

The review has found evidence to support the effectiveness of psychological therapies on glycaemic control compare to usual diabetes care only. Although an improvement has been identified, it is only a small improvement. However, many studies which were suitable and reported good quality were excluded from the meta-analysis because they had data missing essential for the calculation. This may have had an impact on the results, with improved evidence for or reduced evidence for the findings. In addition to this, CBT has been shown to be the dominant therapeutic approach to the psychological intervention. A recent study (Tovote et al., In Press) has evidence to show that mindfulness-based therapy is more effective than CBT in glycaemic control in adults, and therefore more research is needed.

At this time, the results should be interpreted with caution, and reviewed again when more psychological approaches, especially mindfulness and ACT, have been studied. Despite the caution, psychological therapies should be offered to patients with T1DM because they have improved glycaemic control.

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PART 2: Empirical Research

This paper is written in the format ready for submission to the Journal of Neuropsychology. Please see Appendix 2.2 for the ‘‘Author Guidelines’’.

Word count 5, 987 (excluding references and tables).

Do adults with type 1 diabetes under estimate their memory functioning?

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Word count (exc. figures/tables): 5987

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Abstract

Memory functioning has been investigated for adults with type 1 diabetes mellitus (T1DM), but studies have not concurred with the effects diabetes potentially has on memory. Subjective memory has received limited research to date for people with T1DM. In a different population, subjective and objective memory discrepancies have been reported, with information processing speed the covariate measure facilitating this difference. The current study aimed at investigating objective memory performance, subjective memory report, and differences between the two measures when controlling the covariates of information processing speed and depressive symptomology. The study investigated whether a difference between poorly and well-controlled T1DM was associated with these findings. Better objective memory was observed in the healthy control group, but this was not statistically significant. People with T1DM reported poorer memory functioning than healthy controls. Differences between objective and subjective memory were not observed between the experimental groups. Statistically significant differences were reported between objective and subjective memory for the whole test sample, which were associated with depressive symptomology.

The results of the study would suggest that adults with T1DM report greater memory problems, but actually perform as well as healthy controls on memory tests. Subjective and objective memory discrepancies were not caused by the condition T1DM. Increased depressive symptomology results in underestimation of memory compared to actual memory in all the participants. This finding could be used to help guide clinicians into enquiring about mood more with patients if they report memory problems. In a condition like T1DM treating depressive symptoms may lead to better glycaemic control.

Introduction

Diabetes Mellitus is a chronic physical health condition which causes high blood sugar levels due to dysregulation of insulin in the blood. It is estimated that 2.9 million people in the United Kingdom have a diagnosis of diabetes. Approximately 10 % have the insulin-dependent form of the disease known as T1DM. People with T1DM are not able to produce insulin, a hormone produced by the pancreas which helps to convert glucose into energy in the circulatory system, due to auto-immune destruction of the beta cells in the pancreas. Without insulin, various tissues in the body will not be able to use glucose and the blood glucose level increase. People with T1DM need lifelong exogenous insulin administration for maintaining blood glucose and survival (Diabetes, UK, 2014).

People with T1DM are at greater risk of experiencing hypoglycaemia and hyperglycaemia. Hypoglycaemia is defined as abnormally low levels of glucose in the blood, which can be associated with injecting a greater quantity of insulin than needed, skipping meals, or over exertion in people with T1DM. Hyperglycaemia is when blood sugar levels become too high. This occurs because the body cannot convert the glucose into energy and the glucose builds up in the blood stream (NHS, 2014). If the high blood glucose levels are not controlled this can lead to serious complications which include nerve damage, retinopathy, kidney disease, foot problems, sexual dysfunction, and an increased risk of heart disease and stroke. Furthermore, the damage to the blood vessels increases the risk of developing vascular dementia as a person gets older (NHS, 2014).

Diabetes and Mental Health

It is reported that one third of people with diabetes experience a clinical depressive disorder (Lloyd, 2010). Other mental health problems including anxiety disorders are also common. People with diabetes are twice as likely to experience depression, anxiety, or other serious psychological distress as people without diabetes (Li, Ford, Zhao, Balluz, Berry, & Mokdad, 2010). It is reported that when depression and diabetes are comorbid, they are experienced as more distressing compared to when they are experienced in isolation (Lloyd, 2010). This may be due to the reported lack of medical adherence of people with diabetes and mental health problems, which leads to further complications (Piette, Richardson, & Valestein, 2004).

Type 1 diabetes and Cognitive Deficits

Cognitive deficits in T1DM have been investigated in numerous studies. A notable deficit in many people with T1DM is information processing speed, which has been concluded in many studies (Kodl & Seaquist, 2008). Psychomotor efficiency is another cognitive function with evidence to suggest that it is impaired compared to the non-diabetes population (Asvold, Sand, Hestad & Bjorgaas, 2009).

The length of duration and onset of T1DM at a young age are strong predictors of cognitive impairment. Earlier onset has been associated with mild cerebral damage and reduced cognitive performance compared to patients with T1DM with later onset of the disease (Ferguson, Blane, Wardlaw, Frier, Perros, McCrimmon, et al., 2005). However, there is conflicting research regarding the number of previous hypoglycaemic events having an effect on cognitive performance. One study has found evidence that chronic hypoglycaemia does not affect cognitive performance in adults with T1DM (Brismar, 2007). Further studies have shown that chronic

hypoglycaemia can lead to cognitive difficulties (Kodl & Seaquist, 2008) and neurological damage (Warren & Frier, 2004). Chronic hyperglycaemia is reported to affect information processing and attention (Ferguson, Blane, Perros, McCrimmon, Best, Wardlaw et al., 2003; Kodl & Seaquist, 2008).

Type 1 diabetes and Neurological Changes

Numerous neurological factors have been proposed to explain why these deficits occur. Firstly, numerous repeated episodes of severe hypoglycaemia and severe hyperglycaemia can affect neurological function (Brand, Biessels, de Haan, Kappell & Kessels, 2005). Hypoglycaemia leads to decreased availability of glucose to be metabolised therefore preventing adequate respiration in the dentate gyrus of the hippocampus, resulting in necrosis and subsequent memory impairment (Auer, 2004). Hypoglycaemia can also lead to an increase in glutamate released by cells. Glutamate is neuro toxic (Northam, Rankin, Lin, Wellard, Pell, Finch, et al., 2009). It accumulates outside of the nerve cells, resulting in damage, and eventual death of the cell. This can lead to a significant decrease in blood flow in the brain, potentially leading to strokes and seizures (Jacobson, Ryan, Cleary, Waberski, Weinger, Musen, et al., 2011). Chronic hyperglycaemia is associated with microvascular and macrovascular incidents which can lead to damage in the brain (Northam et al., 2009). Peripheral arterial disease is a macrovascular complication which is signified by the peripheral arteries becoming damaged, and potentially leading to large areas of the brain not receiving blood, and therefore not receiving oxygen. Strokes are another macrovascular complication which could result in large areas of the brain becoming damaged by both oxygen deprivation and through damage caused by blood vessels rupturing (Fowler, 2008). Mild cerebral atrophy in people with a long duration of insulin-dependent diabetes has been found in Magnetic Resonance

Imaging (MRI) studies (Lobnig, Kromeke, Optenheistert-Porst , & Wolft, 2006). Reduction in grey matter in the left superior temporal region has been associated with severe hypoglycaemia exposure; whereas severe hyperglycaemia has been associated with grey matter volume reduction in the right cunea and precunea, and white matter reduction in the right posterior parietal region (Perantie, Wu, Koller et al., 2007). This white matter volume reduction has been associated with impaired performance on information processing and visuospatial tasks (Wessels, Rombouts, Remijns, Boom, Scheltens, Barkhof et al., 2007). However, approximately half the participants utilised in this study had proliferative retinopathy, which may have impacted on the performance of visuospatial tasks.

Memory and Type 1 diabetes

Investigations into memory difficulties in people with T1DM have varied in their findings. Some studies have found evidence that adults with T1DM perform as well as matched controls on memory tasks (Bade-White & Obrzut, 2009; Ryan & Williams, 1993). Research into cognitive changes in children with T1DM would appear to have received greater research to date. Two recent meta-analyses have investigated cognitive function in children with T1DM. One found evidence to suggest that children with early onset diabetes performed poorly on visual and verbal memory tasks compared to healthy controls, and to children with late onset diabetes (Gaudieri, Chen, Greer, & Holmes, 2008). The second of these meta-analyses suggested that children with a history of severe hypoglycaemic episodes would show impairment on short-term verbal memory tasks compared to healthy controls (Naguib, Kulinskaya, Lomax, & Garralda, 2009). A more recent study however, has found evidence to suggest that children with T1DM and diabetic ketoacidosis (DKA) perform at a lower level on memory tasks compared to children with T1DM

without DKA (Ghetti, Lee, Sims, Demaster & Glaser, 2010). DKA is the process when the body converts fat stores into energy due to the lack of insulin that would normally allow glucose to be converted into energy. If DKA is left untreated it can lead to severe complications including swelling of the brain, coma, or even death (NHS Choices, 2014).

In adults it has been suggested that working memory difficulties can be the result of complications in T1DM, and these difficulties have remained when depression and anxiety have been controlled, which suggest that it is a neurological impairment (Macander, Talarowski, Galecki, Moczulsk, & Lewinski, 2011). Verbal memory deficits in comparison to healthy controls has been reported in people with T1DM (Weinger, Jacobson, Musen, Lyoo, Ryan, Jimerson, & Renshaw, 2008), but there have been relatively few studies concerned with this impairment in this client group. It would appear that research into chronic memory difficulties for people with diabetes and over 18 years old is limited at this time. It is important to understand objective memory difficulties in adults with T1DM because they may interfere with self-management of the condition.

Subjective Memory

Metamemory is the term used to describe the self-report of cognitive ability and memory functioning (Randolph, Arnett, & Friske, 2004). Metamemory is important because it allows an individual to know their own strengths and weaknesses, make judgements about their own memory, and it helps people to learn and utilise their own memory abilities. Metamemory failure can be the result of a traumatic brain injury, illness, stroke or a mental health problem (Metcalfe & Dunlosky, 2008).

Metamemory is typically measured using self-report or subjective memory measures.

Subjective memory in patients with diabetes has not been researched to date. There is conflicting evidence in other patient populations that differences between objective and subjective memory exists. In Multiple Sclerosis (MS), there have been three notable investigations into subjective and objective memory. The three studies have all found evidence for a correlation between objective and subjective memory (Matotek, Saling, Gates, & Sedel, 2001; Bruce, Bruce, Hancock & Lynch, 2010; Randolph et al., 2004), but only one of these studies found this correlation to exist when depressive symptoms had not been included in the analysis (Matotek et al., 2001). These findings have been observed in the Parkinson's disease and Posttraumatic Stress Disorder populations as well (Silek, Soltan, Wieczorek, Robowski & Slawk, 2011; Roca & Freeman, 2001; Carlozzi, Reese-Melancon & Thomas, 2010). This would partly suggest that overestimating memory problems is associated with emotional difficulties in these populations, which is believed to be the result of a tendency to exaggerate difficulties when people are experiencing depressive symptoms (Fritsch, McClendon, Wallendal, Hyde, & Larsen, 2014).

Broome and Rogish (2012) found evidence to suggest that subjective memory and objective memory correlated significantly in people with multiple sclerosis. However, when information processing speed was factored into the analysis, greater variance between objective and subjective memory was reported with difficulties in processing speed being associated with perceived difficulties in subjective memory but not objective memory. This finding has also been observed in similar studies which have factored information processing speed into the analysis (Higginson, Arnett, & Voss, 2000). From a clinical perspective it is common for patients to

complain of memory problems, but not actually having difficulties with encoding or recall. The problem does seem to arise from slower speed of information processing, and because of that they can believe that they are experiencing memory problems. Memory performance can be impacted by slower than average information processing speed, but if the rate of information coming in is controlled to compensate for diminished information processing speed, actual memory performance can be within the normal limits (Salthouse, 1996).

Subjective Cognition in type 1 diabetes

People with T1DM report having poor memory (Diabetes UK, 2014). However, there are no studies which have exclusively investigated self-report of memory in adults with T1DM, and therefore a lack of evidence to support this. Wessels and colleagues (2007) have investigated self-reported cognitive failure in T1DM and T2DM. The study utilised 55 participants with T1DM, 100 with T2DM, and 100 controls. No objective cognitive measures were administered, but each participant completed a Patient Health Questionnaire 9 items (PHQ9), and a Cognitive Failures Questionnaire (CFQ). The results of the test suggest there are no differences in self-report of cognitive functions between T1DM and T2DM participants, and between type 1 and control participants. For all participants a strong positive association was observed between depression symptomatology and frequency of self-reported cognitive complaint. This would suggest that when someone is experiencing emotional distress they report more cognitive complaints regardless of their health condition, and therefore T1DM does not impact a person's self-perception of their cognitive functioning (Wessels, Pouwer, Geelhoed-Duijvestijn, et al, 2007).

Current research

People with T1DM are reported to under evaluate their memory functioning. In addition to this memory functioning in adults with T1DM has been studied, but findings from these studies have not been conclusive. There is however evidence to suggest that information processing speed is compromised in adults with T1DM. In other clinical populations reduced information processing speed has been associated with over estimation of memory difficulties. Over estimation in memory difficulties has also been associated with an increase in depressive symptoms. With reduced information processing speed and the increased possibility of experiencing depressive symptoms in adults with T1DM it would seem appropriate for diabetes services to understand if processing speed or depressive symptoms have an impact on self-evaluation of memory. Beliefs about having poor memory can increase levels of stress, which can in turn impact upon diabetes management. Normalising this experience and providing psychoeducation could make a difference to glycaemic control. In addition to this knowing more about actual memory functioning in adults with T1DM is important. If remembering to follow diabetes self-care is compromised, this could have potentially fatal consequences. Therefore this information could add to the knowledge base already established.

There were no studies investigating subjective and objective memory in T1DM. This study investigated this gap in scientific knowledge regarding objective and subjective memory in adults with T1DM. There were three participant groups, one with well-controlled T1DM, one with poorly-controlled T1DM, and a control group of healthy participants. Participants completed tests to measure objective memory performance, subjective memory, information processing speed, and emotional distress.

Based on the previously described findings the hypotheses to this study were:

- Adults without a chronic health condition will perform better on the objective memory tasks compared to adults with T1DM. The adults with well-controlled T1DM will perform better than patients with poorly controlled T1DM.
- The poorly controlled diabetes group will report greater subjective memory difficulties than the well-controlled T1DM group and the healthy controls.
- Greater differences between subjective and objective memory will be observed in the diabetes groups, especially the poorly controlled group. Due to people with T1DM reportedly having slower speed of information processing, it was predicted that differences between subjective and objective memory would be associated with information processing speed. Subjective memory would be poorer with reduced slower information processing speed.

Method

Design

A between-subjects design was employed in this study.

The dependent variables (DVs) measured were:

- The objective memory scores were measured by the achieved scores on each component of the BIRT Memory and Information Processing Battery BMIPB. (Coughlan, Oddy, & Crawford, 2007).

- The subjective memory scores were measured by participant self-report on the Memory Functioning Questionnaire (MFQ) (Gilweski, Zelinski, & Warner-Schaie, 1990).

- A derived DV involving the calculated difference between standardised objective and subjective memory scores.

The independent variable (IV) investigated was the participation group. There were three participation groups: participants with well-controlled T1DM, participants with poorly-controlled T1DM, and a healthy control group. How the participants were defined as well-controlled or poorly-controlled is outlined in the participant section.

Covariates were also measured in this investigation. The covariates measures were information processing speed, and symptomology of anxiety and depression.

Power Analysis

A power analysis was difficult to calculate due to a lack of studies comparing subjective and objective memory in any clinical population. In the studies discussed above no significant Pearson r2 values had been calculated. Therefore, based on using a one-way ANOVA with 80% power, with an effect size of 0.40, it was calculated that comparing 3 different groups would require 66 participants, with 22 in each group. This calculation was produced using GPower Version 3.1 software (Faul, Buchner, & Erdfelder 2009). The results of this study may help to establish an effect size for future studies regarding objective and subjective memory.

Participants

Both clinical and non-clinical participants were recruited in this sample. The participants with T1DM were recruited from local NHS specialist diabetes services

and a local university. The healthy control group were recruited through leisure centres, Women's Institutes, Working Men's Clubs, church halls, and students from a local. Participants were identified as presenting with well-controlled or poorly-controlled T1DM using the glycated haemoglobin concentration (HbA_{1c}) percentage. A HbA_{1c} exceeding 7.5% is considered to indicate difficulties managing diabetes (NICE, 2004). The poorly-controlled diabetes group reported a HbA_{1c} above 7.5%.

The inclusion criteria to participate were:

- A diagnosis of T1DM for at least 5 years. Evidence has been found to suggest that cognitive changes are detected in people who have had a diagnosis of T1DM for approximately 5 years (Ferguson et al., 2005).
- Be able to speak, read and write fluently in the English language,
- Aged between 18 and 69 years of age. The BMIPB has normative data for this age range only.

The exclusion criteria were:

- History of significant head trauma.
- Heart disease, stroke or hypertension (defined as 180/80).[1]
- Currently experiencing severe mental health problems i.e., eating disorder, psychosis, moderate- severe depression and taking psychiatric medication.
- Neurological impairment, i.e., epilepsy, dementia.

[1] Blood pressure above 180/80 is defined as hypertension. The pressure of the blood when the heart beats is 180, whereas the pressure of the blood when the heart is at rest is 80. The difference between the two measures is the pulse pressure. 100 is considered to be very high and at a potentially dangerous level (NHS Choices, 2014).

- Other significant health problems, i.e., cancer, inflammatory bowel disease.
- Significant visual or auditory impairment.

Measures

Demographics Form (Appendix 4.1)

The demographics form provided a measure of age, gender, years of education, employment status, physical health, mental health, and diabetes specific questions. The demographics information provided the researcher with information about differences in the independent variable sample populations.

Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). (Appendix 4.2)

The HADS is a short measure of mood and anxiety. It consists of 14 items, with 7 items assessing anxiety and 7 items assessing depression. Each item has 4 possible answers, which are scored on a 4 point rating scale. A total score of 21 can be reported for both anxiety and depression. The higher the score, the greater the experience of depression and/or anxiety. It is reported to have good internal consistency and validity (Herman, 1997). The HADS was utilised to establish whether the participant was presenting with levels of anxiety and depression which could potentially impact cognitive functioning. The HADS was used as the covariate measure of depression.

Memory Functioning Questionnaire (MFQ). (Appendix 4.3)

The MFQ is a measure of subjective memory which is frequently used in clinical work (Randolph et al, 2004). This inventory assesses four constructs. These

constructs are general frequency of forgetting, seriousness of forgetting, retrospective functioning, and mnemonics usage. There are 64 items in the questionnaire, with 33 aimed at frequency of forgetting, 18 at seriousness of forgetting, 5 for retrospective functioning, and 8 for mnemonics usage. Gilweski and colleagues (1990) reported that the scale has very good reliability. Only the section regarding frequency of forgetting was used in this study because it provided a self-report measure of perception of memory ability.

BIRT Memory and Information Processing Battery (BMIPB)

The BMIPB was been chosen because it provides measures of objective memory functions and information processing, with good inter-rater reliability, and construct validity (Coughlan et al., 2007). The test has four parallel forms for retest ability; however, the same form was used across all participants in this study. The test consists of verbal and visual memory subtests, which assess immediate and delayed memory functioning as well as recognition ability. Information processing speed and hand motor speed are also assessed. There is no overall memory score, but aged norms for each subtest are provided which enables strengths and weaknesses to be identified.

Procedure

The specialist nurses provided potential suitable participants with invitation sheets. (Appendix 4.4) The nurses approached both poorly managed and well managed individuals with T1DM using the glycated haemoglobin concentration criteria. In addition to this the university's email system was used, posters (Appendix 4.5) were placed around the university's campus, local leisure centres, church halls, Women's Institutes, and Working Men's clubs, with the aim of recruiting 22 healthy controls

and adults with T1DM. Once participants had contacted the researcher they were screened to ensure they met the inclusion criteria. (Appendix 4.6) The researcher then arranged to meet the participant at their home, the diabetes clinic, or a research room at the university in accordance with the local NHS Trust's and the university's lone worker policies. The researcher provided the participants with the Participant Information Sheet (Appendix 4.7) at least 24 hours prior to gaining consent. The researcher obtained informed consent (Appendix 4.8) from the participant once they had discussed consent, confidentiality and the right to withdraw from the study. Participants then completed the HADS, MFQ and the demographics sheet before completing the BMIPB. The researcher administered the BMIPB to all the participants in this study. The process of completing the questionnaires and the BMIPB required approximately 1 hour. Participants received a results sheet highlighting the main findings of the study and were provided with compensation for travelling and parking costs.

Data Analysis

A mixture of statistical analysis procedures were used in the data analysis stage of the investigation. Analysis of Variance (ANOVA) was employed to assess the statistical significance of the data relevant to the 3 hypotheses. The planned additional data analysis strategy for hypothesis 3 was to use a Multivariate Analysis of Covariance (MANCOVA) in addition to the ANOVA. A MANCOVA would allow the various DVs to be analysed simultaneously, whilst analysing the effect the covariates have on the relationship between the IV and DVs.

The BMIPB and MFQ did not convert scores into scaled scores (Howell, 2009), and so z-scores were calculated for these tests to put the subjective and objective scores

onto the same scale. Then the difference between standardised subjective and objective scores could be interpreted as a discrepancy between objective and subjective memory, this enabled the results to be processed using a multivariate analysis. The z-scores for the BMIPB data were calculated using the age specific means and standard deviations for each subtest from the normative data in the BMIPB manual. Z-scores for the MFQ were calculated using an overall mean and standard deviation from the participating sample. No normative mean or standard deviation information was available for an overall adult population of the MFQ.

Results

There were 60 participants recruited in total. Table 1 provides data regarding the participant numbers and demographic information. The table clearly demonstrates that there were differences between the 3 experimental groups in numbers participating, mean age of participants, and employment status. The 3 experimental groups were all well matched in terms of their gender. For the participants with diabetes there was a distinct difference between duration of illness (16.56 years for well-controlled compared to 25.82 for poorly-controlled). The differences are considered in the Discussion section of this report. In addition to duration of disease, there was nearly a 2% difference between the HbA_{1c} levels between the T1DM groups. Weekly experiences of hyper or hypoglycaemic episodes were very similar between the 2 groups, but the poorly-controlled group reported complications associated with diabetes compared to no complications reported by the well-controlled group. Depression levels as measured by the HADS were all low levels, although the poorly-controlled T1DM group reported slightly higher levels.

Table 3. Demographic Information

Variable	Well-managed type 1 diabetes	Poorly managed type 1 diabetes	Control Group	Total Sample
Number of participants (n)	16	22	22	60
Gender % (n)				
Male	37.5 (6)	40.9 (9)	40.9 (9)	40 (24)
Female	62.5 (10)	59.1(13)	59.1 (13)	60 (36)
Age, mean (SD)	32.19 (12.83)	42.91 (13.04)	37.36 (14.265)	38.02 (13.89)
Min-max	19-58	19-69	20-66	19-69
Years of Education mean % (SD)	15.63 (2.68)	15.45 (3.14)	17.18 (2.70)	16.13 (2.93)
Employment status % (n)				
Employed	50(8)	68.2 (15)	45.5 (10)	55 (33)
Unemployed	0	13.6 (3)	0	5 (3)
Retired	0	4.5 (1)	4.5 (1)	3.3 (2)
Student	50(8)	13.6 (3)	50 (11)	36.7 (22)
Ethnicity %(n)				
White British	87.5(14)	95.5 (21)	86.5 (19)	90 (54)
White Euro	6.3(1)	4.5 (1)	9 (2)	5.8 (4)
White Other	6.3(1)	0	0	1.7 (1)
Middle Eastern	0	0	4.5 (1)	1.7 (1)
Duration of disease, mean % (SD)	16.56 (11.69)	25.82 (10.59)	NA	21.92 (11.86)
HbA1c, mean (SD)	7.1 (.238)	8.88 (1.15)	NA	8.14 (1.25)
Participants with diabetic complications disclosed (n)	0	8	NA	NA
Participants experiencing weekly hypo/hyper episodes (n)	6	7	NA	NA
HADS Anxiety, mean (SD)	4.63 (2.06)	7.05 (3.05)	5.45 (2.15)	5.82 (2.65)
Depression, mean, (SD)	1.87 (1.41)	3.23 (3.1)	1.95 (2.26)	2.40 (2.48)

Hypothesis 1

The z-scores calculated for the participants' BMIPB performance are summarised in Table 2. The results indicate that the healthy control group's memory performance on the BMIPB was at a higher standard throughout the test, with exception to the

Design Identification task, which the poorly-managed diabetes group performance was superior.

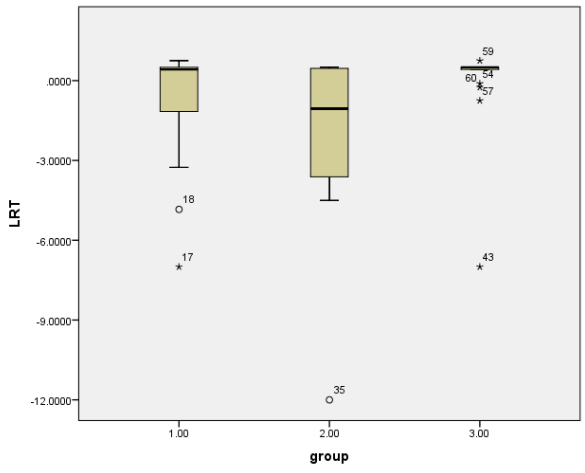
A one-way ANOVA to investigate the statistical significance of these findings was calculated. Statistical significance was found to exist for the difference between the mean scores on the Story Recall Immediate task (F (2,57) 5.345, p= 0.007) and the List Recognition task (F (2,57) 3.545, p=0.035).

A Bonferroni post-hoc test was performed to compare the differences between the means scored on the 2 tasks where statistical significance was reported. After the Bonferroni tests, a statistically significant difference was found between the poorly-controlled diabetes group and the healthy control group performance on the Story Recall Immediate task (p=0.010). No statistically significant differences were reported between the other pairwise comparisons for the Story Recall Immediate task. After the Bonferroni correction for the List Recognition task a statistical significance difference was found between the well-controlled diabetes and healthy control group (p=0.030). No statistically significant difference was reported between the other pairwise comparisons on the List Recognition task. However, further analysis using a Stem and Leaf Plot (Figure 1) shows that outliers existed for all 3 experimental groups, with the healthy control group having a minute variance for the majority of the participants. The healthy participant group had a large amount of outliers, compared to the diabetes groups. In addition to this, the well-controlled group had greater variation in the participant's performance, and had an outlier with a greater difference compared to the other performances in the group. This may reduce the significance of the results. Therefore the groups differ in other ways apart from differences between the means. The Stem and Leaf Plots for the other BMIPB tasks did not demonstrate such extreme data.

Table 4. z-scores of BMIPB performance for all experimental groups.

BMIPB Test	Well Controlled type 1 diabetes group (n=16)	Poorly Controlled type 1 diabetes group (n=22)	Control group (n=22)	Total Sample (n=60)
Story Recall Immediate, mean (SD)	-.885 (.521)	-1.032 (1.577)	-.054 (.583) ***	-.634 (1.13)
Story Recall Delayed, mean (SD)	-.506 (.567)	-.622 (1.413)	.0195 (.548)	-.356 (.992)
Figure Recall Immediate, mean (SD)	-.286 (1.217)	-.203 (1.544)	.000 (.873)	-.151 (1.229)
Figure Recall Delayed, mean (SD)	-.020 (.861)	-.308 (1.828)	.091 (.809)	-.84 (1.281)
List Learning, mean (SD)	-.972 (1.176)	-1.150 (.967)	-1.070 (.895)	-1.073 (.988)
Word Recognition, mean (SD)	-1.902 (1.961)	-1.683 (2.605)	-1.283 (1.697)	-1.594 (2.117)
List Recognition, mean (SD)	-1.976 (3.298)	-.733 (2.014)	.372 (1.605) ***	-.782 (2.40)
Design Learning, mean (SD)	-.470 (1.166)	-.673 (1.655)	-.355 (1.024)	-.502 (1.309)
Design Recognition, mean (SD)	-.118 (.841)	-.0741 (.827)	-.0877 (.856)	-.091 (.827)
Design Identification, mean (SD)	-.388 (1.080)	-.359 (1.372)	-.530 (1.375)	-429 (1.283)
Adjusted Information Processing Speed, mean (SD)	-.0393 (.954)	-.663 (.949)	-.258 (1.187)	-.348 (1.039)

***= statistical significant difference between group means.



Key

Group 1- Poorly-controlled

Group 2- Well-controlled

Group 3- Healthy controls

Figure 4. Participant variation on the List Recall Task performance.

Although the healthy control group performed better in general on the BMIPB tasks, statistically significant differences between the group means were only calculated for two of the BMIPB tasks. In addition to this, the Stem and Leaf Plot for one of the tasks with statistical significance clearly showed that the participant's performances varied greatly in all groups, but especially between the well-controlled diabetes participants and healthy control group, where a post-hoc statistically significant difference was observed.

Hypothesis 2

The z-scores calculated for the participants' MFQ performance are summarised in Table 3. The results show the healthy control group reporting to have less concerns about their memory functioning. There was little difference in concerns about memory between the well-controlled and poorly-controlled diabetes groups.

Table 5. Memory Functioning Questionnaire scores.

Variable	Well-controlled diabetes	Poorly-controlled diabetes	Healthy control	Total
Memory Functioning Questionnaire, mean (SD)	151.81 (43.12)	152.73 (26.54)	172.59 (14.79) ***	161.70 (23.27)

***= statistical significant difference between groups.

A one-way ANOVA to investigate the statistical significance of these findings was calculated. This showed statistically significance differences between groups (F (2,57) 4.662, p =0.013).

The Bonferroni correction was used to investigate potential pairwise comparisons. This showed a statistically significant difference between the poorly-controlled diabetes group and the healthy control group (p= 0.012). However, statistical significance was not calculated when comparing the diabetes groups with one

another, or when comparing the well-controlled diabetes group with the healthy control group. This was probably because the well-controlled diabetes group's standard deviation was larger.

Hypothesis 3

Hypothesis 3 predicted there would be a greater difference between BMIPB performance and MFQ rating in the diabetes groups, especially the poorly-controlled group due to a predicted reduction in information processing speed in the poorly-controlled group. Table 2 demonstrates that poorly-controlled participants with diabetes had reduced information processing speed compared to the healthy controls and well-controlled diabetes group. The well-controlled diabetes group demonstrated faster information processing speed than the healthy control group. A one-way ANOVA did not support this finding, with no statistical significant differences between the means calculated.

The mean z-scores calculated to investigate differences between objective memory performance and subjective memory are displayed in Table 4. The results do not support the hypothesis that there would be greater differences between objective and subjective memory in the poorly-controlled diabetes group compared to the healthy controls and well-controlled diabetes group. The results demonstrated that no individual group had a more accurate self-report of memory in relation to their objective memory scores. A one-way ANOVA revealed that no statistically significant differences existed between the mean z-score differences between BMIPB performance and self-reported memory.

Table 6. Mean differences between objective memory performance and subjective memory.

Difference between BMIPB and MFQ z-scores	Well Controlled type 1 diabetes group (n=16)	Poorly Controlled type 1 diabetes group (n=22)	Control group (n=22)	Total Sample (n=60)
Story Recall Immediate, mean (SD)	-.7717 (1.25)	-.6467 (1.84)	-.5221 (.91)	-.6343 (1.38)
Story Recall Delayed, mean (SD)	-.3923 (1.15)	-.2362 (1.72)	-.4485 (.73)	-.3557 (1.26)
Figure Recall Immediate, mean (SD)	-.1729 (1.79)	.1828 (1.55)	-.4680 (0.98)	-.1507 (1.45)
Figure Recall Delayed, mean (SD)	.0933 (1.35)	.0774 (1.74)	-.3766 (0.93)	-.0848 (1.37)
List Learning, mean (SD)	-.972 (1.176)	-1.150 (.967)	-1.070 (.895)	-1.073 (.988)
Word Recognition, mean (SD)	-1.7885 (2.19)	-1.2972 (2.63)	-1.7512 (1.84)	-1.5947 (2.22)
List Recognition, mean (SD)	-1.8623 (3.12)	-.3476 (2.088)	-.4307 (1.438)	-.7820 (2.28)
Design Learning, mean (SD)	-.3567 (1.75)	-.2872 (1.70)	-.8230 (1.07)	-.5022 (1.51)
Design Recognition, mean (SD)	-.0042 (1.25)	.3115 (1.39)	-1.5947 (2.22)	-.0907 (1.24)
Design Identification, mean (SD)	-.2748 (1.385)	.0260 (1.759)	-.9985 (1.385)	-.4298 (1.573)

A Multivariate Analysis of Covariance (MANCOVA) was planned to be used as the statistical technique to analyse the data to support that information processing speed would account for differences between objective and subjective differences as outlined in Hypothesis 3. However, a Pearson r^2 correlation calculation was used to assess the strength of the correlations between the BMIPB subtest z-scores and standardised MFQ z-scores differences. There were strong positive correlations identified between Figure Recall Immediate (FRI) and MFQ difference and Figure Recall Delayed (FRD) and MFQ difference ($r^2 = .857$, $p<0.001$), Story Recall Immediate (SRI) and MFQ and Story Recall Delayed (SRD) and MFQ ($r^2= .825$. $p<0.001$), Design Learning Task (DLT) and MFQ and FRD and MFQ ($r^2= .688$,

$p<0.001$), and FRI and MFQ and DLT and MFQ ($r^2= .672$, $p<0.001$). Due to these strong correlations, Tabachnick and Fidell (2006), recommended using a univariate analysis as opposed to the planned MANCOVA. An Analysis of Covariance (ANCOVA) was subsequently employed to tests for group differences on the z-score differences, controlling for the covariates of information processing speed, anxiety, and depressive symptoms.

The results of the ANCOVA show that information processing speed and experimental group did not affect the differences between the objective and subjective memory performances. However, on 8 of the differences between BMIPB z-scores and standardised MFQ z-score, increased depressive symptomology was associated with statistically significant differences between the objective and subjective memory scores. This would suggest that depressive symptomology is associated with reduced beliefs about memory. The two differences between BMIPB z-score and MFQ standardised z-score where this was not observed were the Word Recognition Task (WRT) and the List Recognition Task (LRT). Further analysis of the WRT and LRT tasks using Stem and Leaf plots did not identify any unusual data. There were two outliers for the healthy controls, but there were outliers in all Stem and Leaf plots. The outliers were not the same participants for each BMIPB task.

These results do not support hypothesis 3. Firstly, no statistical significant difference between information processing speed, or differences between objective and subjective memory were calculated. In addition to this, when an ANCOVA was calculated to look at the covariate's impact on the relationship between the experimental group and the objective and subjective memory difference, information processing speed did not have an effect. Depressive symptomology appears to have

an influence on the difference between objective memory performance and subjective memory, but this is for all participants regardless of experimental group.

Discussion

The results of this investigation have not found evidence to support all the hypotheses. Hypothesis 1 predicted that adults with T1DM would have less effective memory functioning on the BMIPB subtests than the healthy controls. The z-score data did suggest that this may be apparent, but when statistical techniques were employed, the performance only the Story Recall Immediate task was found to be statistically significant. This test is the first task in the BMIPB. The healthy controls performance may be statistically significant due to the some of the control participants already knowing the researcher, which may have reduced any test anxiety. The T1DM groups may have experienced worry at first due to stranger anxiety, and therefore this may have affected their performance in this test. In addition to this, the task is potentially anxiety provoking due to the length of information to be recalled.

Further results suggest that the healthy controls reported statistically significant better memory functioning than both T1DM groups, which supports the prediction made in hypothesis 2. The reason for this is unclear, but approximately a third of participants who volunteered to participate in the study from the two diabetes groups disclosed concern that they had problems with their memory. Very few of the healthy control participants expressed concerns regarding their memory. This would suggest that poorer subjective memory is associated with health concerns in the clinical groups. A possible explanation for this finding is that the

participants with T1DM may catastrophize physical symptoms due to their experience of having a chronic health condition. T1DM is usually diagnosed in childhood and can be traumatic for families, which can have a lasting effect on the patient (Yafi, 2014). Parent's behaviour can influence the patient's thinking styles, which may result in catastrophizing when a physical experience may not seem normal. Vervoort and colleagues (2011) investigated the effects of catastrophizing thoughts by children with T1DM before having a pin prick on their perception of pain from the pin prick. The results showed that higher catastrophizing was correlated with increased pain perception. As an adult, if the patient with T1DM forgets something, they may catastrophize this experience, leading to over estimating memory problems. Catastrophizing is a negative thinking style. Enduring this type of thinking style can lead to depression or depressive symptomology. As previously stated, people experiencing depressive symptoms have a tendency to exaggerate their difficulties (Fritsch et al., 2014).

The results of hypothesis 3 do not support the prediction that there would be a) reduced information processing speed in the poorly-controlled diabetes group; b) that there would be a greater difference between subjective and objective memory functioning in the poorly-controlled group; and c) the difference between subjective and objective memory would be the effect of the reduced information processing speed covariate. There was reduced information processing speed in the poorly-controlled group, but difference did not reach statistical significance. Differences between subjective and objective memory were also not identified for any specific group. This will be discussed along with other limitations. The only covariate which had an effect on the difference between subjective memory and objective memory was depressive symptomatology, which was not isolated to one experimental group.

This may suggest that emotional disturbances have an effect on subjective memory. In this study, any emotional disturbances were in the low range, because current psychiatric medication was an exclusion criterion, and the highest HADS depression score reported was 10/21. As previously stated people with diabetes are twice as likely to experience depression compared to people without a health condition (Li et al., 2010).

Unlike the other measurements of objective memory, the differences between subjective memory and LRT and WRT performance were not influenced by depressive symptomology. People experiencing depression often perform better on recognition than recall tasks (Smith, Mullally, McLoughlin & O'Mara, 2014). These two tasks require less cognitive resources to facilitate performance, compared to the visual recognition task on the BMIPB. The LRT and WRT are more ecologically valid tests (Helmstaedter, Hauff & Elger, 1998) because recognising verbally presented information is more common in daily life compared to having to remember where lines are positioned in an abstract array of non-verbally encodable designs. The visual tests require considerably more effort processing too. Effort and concentration are typically described as being affected by depressive symptoms (Haines, Norris, & Kashy, 1996).

Main findings

The results from this study have found evidence to support that a person's subjective memory may be affected by their experience of depressive symptoms regardless of whether they are actually depressed or experiencing some of the symptomology associated with depression. This is not isolated to the participants with diabetes, but the healthy control participants as well. These findings are not a

new discovery. As previously discussed in the Introduction section, other studies have found evidence to support that depressive symptomology influences self-report of memory (Silek, Soltan, Wieczorek, Robowski & Slawk, 2011; Roca & Freeman, 2001; Carlozzi, Reese-Melancon & Thomas, 2010).

The results also show that people with diabetes report their memory functioning to be less effective than a person without a health condition. This supports the idea that people with T1DM report memory problems. This finding was generic to the T1DM participants, with no differences reported between the poorly-controlled and well-controlled groups. An explanation for this finding has already been provided.

Limitations

There were a number of limitations to the study, which although the best possible effort to control was applied, some extraneous variables proved difficult to control. Firstly, the three experimental groups had big differences in the mean average of ages. This may have affected the outcome data because age has an effect on cognitive functioning. The difference in ages was not a large difference, and the mean average ages were at a middle adult age, not at the age when cognitive decline is faster (over 60 years of age) (Deary, Corley, Gow, Harris, Houlihan, Marioni, et al., 2009).

A major limitation to the study was the criteria defining control of diabetes. In this study HbA_{1c} exceeding 7.5% was used to diagnose poorly-controlled diabetes as per NICE guidance (2004). A participant may have controlled their HbA_{1c} below 7.5% for 20 years, with no diabetes related complications, but in the last 6 months had changes in their lifestyle or habits, which affected their glycaemic control,

resulting with an increased in blood glucose concentration, and therefore defined as poorly-controlled. Very few participants reported diabetes related complications, with mild retinopathy the only symptoms disclosed. This would suggest that most participants had controlled their blood glucose effectively over time, and therefore should be considered as having well-controlled T1DM. In addition to this, neurological changes may not have occurred if the participants had managed their condition well, and so the results from this study should be interpreted with caution.

In addition to the above point, the groups were not even in terms of number of participants. Fewer well-controlled participants completed the study compared to both the poorly-controlled participants and the healthy controls. There were 6 less well-controlled participants compared to the other groups. This also reduced the statistical power of the sample because 22 participants were calculated to be required for each participant group. Therefore, the statistical significant results should be interpreted with caution.

The sample population of people with T1DM may not have been representative of the population. There were only white European participants with T1DM used. This was a result of only this group volunteering, but there are other ethnic groups who report T1DM, although people of European origin are the ethnic group where T1DM is reported most frequently (Diabetes UK, 2011). In addition to this, the sample relied heavily upon university students, with 50% of the well-managed diabetes participants in this employment category. If demographic information was available for the United Kingdom's T1DM patients' employment status, it is highly unlikely that half of the adult population are students. In 2012, there were 2.3 million university students in the UK (Higher Education Statistics Agency, 2014), which is only 5% of the adult population of the UK between 18- 70

years old. The fact that students participated may have affected the outcome due to students utilising their memory functioning more often and put greater loads on memory due to the requirements of intense learning and repeated practice in evaluative processes. This sample had a total of 60 participants, which was not necessarily representative of the United Kingdom's population.

A critique of the objective and subjective memory tests should also be considered when interpreting the study findings. Although both report good validity and reliability, the normative data for both tests is not ideal. The BMIPB data is based on a normative sample of 300 (Coughlan et al., 2007), compared to the Wechsler Memory Scale Fourth Edition (Wechsler, 2009), which has normative data based on a sample of 900 adults across age ranges (British Psychological Society, 2012). In addition to this, the MFQ does not have normative data for adults under 65 years old. It was therefore not possible to standardised the subjective memory scores using the older adult data, resulting in standardised MFQ data being calculated from the current studies' mean score and standard deviation.

Clinical Implications

The main findings from this study suggest that subjective memory is influenced by the experience of depressive symptoms, and not the effects of information processing speed. This is useful for professionals working with patients with T1DM because no effect of T1DM was connected to a difference between objective and subjective functioning due to the disease. The difference between the memory functioning was influenced by depressive symptomatology. Due to patients with T1DM being at greater risk of experiencing major depressive disorder, professionals working with patients with T1DM would benefit from discussing emotions with

their patients and screen for depression, as well as the typical physical experiences of the condition. Clinicians could use this information for education programmes, which could normalise the experience of believing that memory functioning is poorer, providing reassurance that this is an effect of depressive symptomology rather than the effect of the health condition.

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Part 3: Reflective Statement

The research journey has been a long ride, with many twists and turns, with little indication that the destination was close by. As I finally approach the end, I can see that there have been many experiences that have been valuable for learning. Each stage of this research project has presented different challenges, with different rewards. I am very grateful to have been given this opportunity.

Designing the Study

In January 2012 I began planning an empirical study, which was going to look at attachment styles and cognitive functioning. However, I couldn't find an area that would be possible to investigate for a doctoral thesis. I then started planning a study investigating post-traumatic stress disorder and subjective memory, which I was very excited by, as I have a keen interest in both subjects. Unfortunately, I spent a long period of time trying to get different services to provide me with potential numbers of participants for the study, and started to run short of time, with an ethics application to undertake. In July, 2013, I felt that I needed to change the clinical group because I could see that I would not get the 20 participants the power calculation had suggested.

I decided that I could look at a population of people where recruitment may not be as difficult. I thought that people with T1DM would be a suitable group to adapt my previous research question to because they were a population who received less psychological research compared to other chronic illness groups, especially T2DM. I began to find momentum from this point, and designing the study picked up pace. I spoke to a colleague who had T1DM about the study. We discussed the rationale, design and the importance of the research. My colleague thought that the study was

an excellent idea and well thought through. On reflection, this was just one opinion from a healthcare professional with an interest in research. I think I should have consulted with more people with T1DM who were not healthcare professionals. They might have focused on smaller details which may have been important. These details could have been what constitutes as effective control versus poorly controlled.

Application to NHS Ethics and Research & Development

My application did not have any ethical issues and was a straight forward design. I applied for a Proportionate Ethics Review. I did not see any difficulties with the application not progressing. Unfortunately, the application was felt to have issues with the design, namely the measure to define poorly-controlled T1DM. A previous trainee had used a measure to look at kidney functioning which is damaged when diabetes has had management difficulties for long periods. However, the medical member of the ethics panel decided this was not suitable for the study. I therefore had to find a different method of assessing diabetes control. I decided to consult the medical school at the university, who suggested I use glycaemic control. I realised that I should have taken this step before submitting the application, because now I had to wait 6 weeks to meet an ethics committee, which had halted my progress. On reflection, this could have been avoided by spending more time with service users before. Spending that time would have saved me a lot of time in the end. If I decide to undertake research in the future I will definitely make sure I focus on the participant group to a greater extent.

I eventually gained ethical approval on 23rd December, and started the process of applying for Research and Development (R&D) approval. This was an incredibly

frustrating experience. Many people were on annual leave in January and February, so I had to wait for people to return from their leave before receiving approval. I was able to start recruiting and testing both control participants and participants with T1DM from the university population whilst I was waiting. Awaiting R&D approval was very frustrating because documents kept going missing even though they were being emailed to departments! I was glad when I was finally granted approval by all R&D departments I applied to. I have learnt through this experience that sending emails with an acknowledgement of receipt can help to save a lot of time.

Recruitment of Testing of Participants

I thoroughly enjoyed this experience. I worked alongside some excellent departments and individual staff members to gain valuable knowledge regarding T1DM, and to recruit participants for the study. I realised early in the recruitment stage after gaining R&D approval that certain services would be more helpful in recruitment because they had positive attitudes and did not seem to be overwhelmed by my request to hand out invitation letters to potential participants. Many staff members were excited to be involved, and they kept my motivation high, when it may have begun to fall after having difficulty to recruit participants at times. This experience has taught me to spend more time with the services beforehand to see what potential barriers may be in place, and how I may be able to overcome them, or help to overcome them.

The testing phase of the research was by far the best stage. I thoroughly enjoyed meeting many different people across all three of the experimental groups. People were keen to share their experiences of services and living with their condition, which at times made me think a qualitative study investigating experience of

diabetes services and professionals may have been a better study to have undertaken due to the passion the participants spoke about their experiences. However, I can recognise my limits in research, and I am certainly not someone who would be able to embrace this type of research due to the lengthy analysis and focus on words. I like numbers because they are fairly straight forward to analyse, and patterns easier to identify. On reflection, I do think I missed an opportunity to really test myself with qualitative research. I will never get better at it if I do not attempt it. This may be something to consider in potential future research.

Testing sessions could vary in length because some participants were keen to talk about experiences and have someone to talk to in general. I really enjoyed this aspect of the research, because although I do not believe I would be a good qualitative researcher, I find listening to people's stories fascinating, which is one reason why I have chosen to pursue a career in clinical psychology. Sitting with people and talking about their lives before testing their memory was by far the best part of the research for me. It meant that I tested less people each day because I spent a lot of time just listening to participants, but what I lost in time, I gained in knowledge about type 1 diabetes and how it has had a positive effect on people's lives, rather than the negative effects which generally receive more attention.

Data Analysis

This process was difficult due to the complexity of the design. I was very lucky that the statistician in the department was approachable and cared about my research. I had to refresh my own memory about statistical analysis and the different vocabulary I had not encountered since my undergraduate dissertation. I think that I left looking at the statistics late, and if done earlier I would have understood the

results in greater detail. I also could have ran preliminary analysis to get me use to interpreting the data. This is something I will try to do in future research.

Report writing

I did not expect that writing a 6000 word and a 5000 report would take so much time and cause so much stress! I am usually a last minute person when writing assignments, and although not the most successful at times, I get a job done. Unfortunately, I have caused myself needless stress, to levels I never thought possible! The report writing needs focus on many different areas, especially trying to meet journal specifications. I had to change my SLR journal very late due to the specifications proving too difficult to achieve. In retrospect, I did not look at the guidelines in as much detail as I should, and this has impacted on the report writing.

Summary

I have learnt a great deal from this research experience, and having had time to think about it, I have enjoyed it. Would I do a thesis again by choice? Yes! Although I have found that I have spent too much time thinking about research whilst I should have been enjoying life or getting on with the research, I would do it again, using the experiences I have gained to change certain things so I could be more efficient. I feel that my strengths are not in research, which may have led to avoiding it at times, which then fulfils the prophecy, because I do not do as well as I could potentially do. I do hope to undertake further research in my clinical practice, and this experience has taught me a lot. It will stay with me forever.

Part 4: Appendices

Appendix 1.1 NHS Ethical Provisional Opinion Letter

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Appendix 1.1 NHS Ethical Provisional Opinion Letter

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Appendix 1.2 NHS Ethical Favourable Opinion Letter

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Appendix 1.2 NHS Ethical Favourable Opinion Letter

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Appendix 1.2 NHS Ethical Favourable Opinion Letter

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Appendix 1.2 NHS Ethical Favourable Opinion Letter

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Appendix 1.3: Hull and East Yorkshire Hospital NHS Trust R&D Approval

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Appendix 1.3: Hull and East Yorkshire Hospital NHS Trust R&D Approval

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Appendix 1.4: Humber NHS Foundation Trust R&D Approval

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Appendix 1.4: Humber NHS Foundation Trust R&D Approval

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Appendix 1.5: North Lincs and Goole NHS Trust R&D Approval.

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Appendix 1.5: North Lincs and Goole NHS Trust R&D Approval.

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Appendix 1.6: York NHS Foundation Trust R&D Approval.

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Appendix 2.1: British Journal of Health Psychology Author Guidelines

The aim of the British Journal of Health Psychology is to provide a forum for high quality research relating to health and illness. The scope of the journal includes all areas of health psychology across the life span, ranging from experimental and clinical research on aetiology and the management of acute and chronic illness, responses to ill-health, screening and medical procedures, to research on health behaviour and psychological aspects of prevention. Research carried out at the individual, group and community levels is welcome, and submissions concerning clinical applications and interventions are particularly encouraged.

The types of paper invited are:

• papers reporting original empirical investigations, using either quantitative or qualitative methods;

• theoretical papers which may be analyses or commentaries on established theories in health psychology, or presentations of theoretical innovations;

• review papers, which should aim to provide systematic overviews, evaluations and interpretations of research in a given field of health psychology; and

• methodological papers dealing with methodological issues of particular relevance to health psychology.

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers should normally be no more than 5000 words (excluding the abstract, reference list, tables and figures), although the Editor retains discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length.

3. Editorial policy

The Journal receives a large volume of papers to review each year, and in order to make the process as efficient as possible for authors and editors alike, all papers are initially examined by the Editors to ascertain whether the article is suitable for full peer review. In order to qualify for full review, papers must meet the following criteria:

• the content of the paper falls within the scope of the Journal

• the methods and/or sample size are appropriate for the questions being addressed

• research with student populations is appropriately justified

• the word count is within the stated limit for the Journal (i.e. 5000 words)

4. Submission and reviewing

All manuscripts must be submitted via Editorial Manager. You may like to use the Submission Checklist to help you prepare your manuscript. The Journal operates a policy of anonymous peer review. Authors must suggest three reviewers when submitting their manuscript, who may or may not be approached by the Associate Editor dealing with the paper. Before submitting, please read the terms and conditions of submission and the declaration of competing interests.

5. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded from here.

• Statement of Contribution: All authors are required to provide a clear summary of ‘what is already known on this subject?’ and ‘what does this study add?’. Authors should identify existing research knowledge relating to the specific research question and give a summary of the new knowledge added by your study. Under each of these headings, please provide 2-3 (maximum) clear outcome statements (not process statements of what the paper does); the statements for 'what does this study add?' should be presented as bullet points of no more than 100 characters each. The Statement of Contribution should be a separate file.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript with their approximate locations indicated in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.

• For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide doi numbers where possible for journal articles. For example:

Author, A., Author, B., & Author, C. (1995). Title of book. City, Country: Publisher.

Author, A. (2013). Title of journal article. Name of journal, 1, 1-16. doi: 10.1111/bjep.12031

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright. For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.

• Manuscripts describing clinical trials are encouraged to submit in accordance with the CONSORT statement on reporting randomised controlled trials.

6. Supporting information

Supporting Information can be a useful way for an author to include important but ancillary information with the online version of an article. Examples of Supporting Information include appendices, additional tables, data sets, figures, movie files, audio clips, and other related nonessential multimedia files. Supporting Information should be cited within the article text, and a descriptive legend should be included. Please indicate clearly on submission which material is for online only publication. It is published as supplied by the author, and a proof is not made available prior to publication; for these reasons, authors should provide any Supporting Information in the desired final format.

For further information on recommended file types and requirements for submission, please visit the Supporting Information page on Author Services.

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10. Colour illustrations

Colour illustrations can be accepted for publication online. These would be reproduced in greyscale in the print version. If authors would like these figures to be reproduced in colour in print at their expense they should request this by completing a Colour Work Agreement form upon acceptance of the paper.

11. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found in Author Services. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

12. The Later Stages

The corresponding author will receive an email alert containing a link to a web site. A working e-mail address must therefore be provided for the corresponding author. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from Adobe's web site. This will enable the file to be opened, read on screen and annotated direct in the PDF. Corrections can also be supplied by hard copy if preferred. Further instructions will be sent with the proof. Hard copy proofs will be posted if no e-mail address is available. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately.

13. Early View

British Journal of Health Psychology is covered by the Early View service on Wiley Online Library. Early View articles are complete full-text articles published online

in advance of their publication in a printed issue. Articles are therefore available as soon as they are ready, rather than having to wait for the next scheduled print issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and issue or pagination information. Eg Jones, A.B. (2010). Human rights Issues. Journal of Human Rights. Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x

Appendix 2.2: Journal of Neuropsychology Author Guidelines

The Journal of Neuropsychology publishes theory-driven patient studies. The central brief is to learn more from patients with brain dysfunctions to gain a better understanding of brain-behaviour relationships and to help future patients. Important developments in neuropsychology will follow from a multidisciplinary approach embracing neighbouring fields such as developmental psychology, neurology, psychiatry, physiology, endocrinology, pharmacology and imaging science. The journal publishes group and case studies addressing fundamental issues concerning the cognitive architecture of the brain. In addition, the journal includes theory-driven studies regarding the epidemiology of specific deficits, new assessment tools, and the evaluation of treatment regimes.

The journal is committed to a fast and efficient turn-around of papers, aiming to complete reviewing in under 90 days. Submissions are processed via a web-based system and reviewers are required to complete their referee report within 28 days.

Papers will be evaluated by the Editorial Board and referees in terms of scientific merit, readability, and interest to a general readership.

1. Quality Control

The content, format, quality and ambition of the JNP as a major outlet for theory-driven neuropsychological studies is under constant review by the Consulting Editors:

• Kenneth M. Heilman (University of Florida College of Medicine, Gainesville, USA)

• Donald T. Stuss (Rotman Research Institute, Baycrest, University of Toronto, Canada)

• Giuseppe Vallar (University of Milan-Bicocca, Italy)

• Elizabeth Warrington (National Hospital for Neurology and Neurosurgery, London, UK)

2. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

3. Paper formats and length

Research papers are full-length reports of original scientific investigations. Papers should normally be no more than 6000 words excluding abstract (maximum 250 words) and references. Multiple citations for a single point are usually duplicative

and authors are urged to cite the best reference. The Editor retains discretion to publish longer papers.

Theoretical or review articles are full-length reviews of, or opinion statements regarding, the literature in a specific scientific area. They need not be exhaustive but should give an interpretation of the state of research in a given field. They should normally be no more than 4000 words excluding abstract (maximum is 250 words) and references. The number of references should not exceed 40-45. Multiple citations for a single point are usually duplicative and authors are urged to cite the best reference. The Editor retains discretion to publish longer papers.

Brief communications are short reports of original research or case reports. They contain no more than 1500 words excluding abstract (maximum is 80 words), references, a total of up to three tables or figures, and no more than 10 references.

Fast-track papers are timely and relevant reports that, to the discretion of the Editor, are included in the issue following acceptance. Authors may ask that their submitted manuscripts are considered for fast-track.

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• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form

consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.

• All articles should be preceded by an Abstract (see point 3 for guidelines), giving a concise statement of the intention, results or conclusions of the article.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide DOI numbers where possible for journal articles.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

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Appendix 3.1: Data Extraction Form.

General Information Date of extraction Journal article author(s) Article title Journal	
Study Information Aims of research Design	
Participants Groups Number in each group Duration of disease HbA_{1c} limits used Age Gender Ethnicity Geographical region	
Participant Recruitment How recruited? Inclusion criteria Exclusion criteria	

Type of Intervention Individual therapy? Group therapy? Who delivered the intervention?	
Results Improvement in HbA_{1c}? Mean HbA_{1c} reported? Standard deviations reported? Statistical test used Results of main statistical test	
Conclusions Interpretation of results Generalisations from results Limitations Further research	

Appendix 3.2: Quality Assessment Checklist for the Studies

Section	Question	Yes (1)	No (0)	Unclear (0)
Abstract	1. Is there a structured summary of trial design, methods, results, and conclusions?			
Introduction	2. Is the scientific background and rationale clear? 3. Are the hypotheses/aims/objective of the study clear?			
Method	4. Are the main outcomes to be measured clearly described in the Introduction or Methods section? 5. Are the characteristics of the patients included in the study clearly described? 6. Are the interventions of interest clearly described? 7. Were the primary and secondary measures clearly described? 8. Are the distributions of principal confounders in each group of subjects to be compared clearly described? 9. Were the subjects asked to participate in the study representative of the entire population from which they were recruited? 10. Were those subjects who were prepared to participate representative of the entire population from which they were recruited? 11. Were the patients in different intervention groups recruited from the same population? 12. Were study subjects in different intervention groups recruited over the same period of time? 13. Were study subjects randomised to intervention groups? 14. Was a sample size determined following a power calculation? 15. Were the statistical methods used for analysing the primary and secondary outcomes clearly described?			

Results	16. Was baseline demographic and clinically relevant information provided? 17. Are the main findings of the study clearly described? 18. Were the statistical tests used to assess the main outcomes appropriate? 19. Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001? 20. Does the study provide estimates of the random variability in the data for the main outcomes? 21. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? 22. Was compliance with the intervention/s reliable? 23. Were losses of patients to follow-up taken into account? 24. Have the characteristics of patients lost to follow-up been described?	
Discussion	25. Did the study summarise key results with reference to the study objectives? 26. Were limitations to the study reported? 27. Did the discussion address the generalisibility of the study and clinical relevance? 28. Did the discussion identify areas of further research?	

Appendix 3.3: Quality Assessment by Rater A (and Rater B) for All Studies.

Authors	Item														
	Abstract	Introduction		Method											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Amsberg et al., 2009	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)
Attari et al., 2006	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)	1(1)	0(0)	0(0)	1(1)
Bastelaar et al., 2011	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Didjurgeit et al., 2002	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)
Feingilos et al., 1987	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)	1(1)	1(1)	0(0)	0(0)
Fosbury et al., 1996	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)	1(1)	1(1)	0(0)	1(1)
George et al., 2008	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)
Halford et al., 1997	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1
Ismail et al., 2008	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Schachinger et al., 2005	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Snoek et al., 2008	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(0)	1(1)

Authors	Item													Total Score
	Results								Discussion					
	16	17	18	19	20	21	22	23	24	25	26	27	28	
Amsberg et al., 2009	1(1)	1(1)	1(1)	1(1)	0(1)	1(1)	1(1)	0(0)	0(0)	1(1)	1(1)	1(1)	1(1)	23(24)
Attari et al., 2006	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	0(0)	0(0)	1(1)	0(0)	1(1)	0(0)	20(20)
Bastelaar et al., 2011	1	1	1	1	1	1	1	1	1	1	1	1	1	28
Didjurgeit et al., 2002	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)	1(1)	1(1)	0(0)	25(25)
Feingilos et al., 1987	1(1)	1(1)	0(0)	0(0)	1(1)	1(1)	1(1)	0(0)	0(0)	1(1)	0(0)	1(1)	1(1)	20(20)
Fosbury et al., 1996	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)	0(0)	24(24)
George et al., 2008	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	27(27)
Halford et al., 1997	1	1	1	1	1	1	1	1	1	1	1	1	1	27
Ismail et al., 2008	1	1	1	1	1	1	1	1	1	1	1	1	0	27
Schachinger et al., 2005	1	1	1	1	1	1	1	0	0	1	1	1	0	25
Snoek et al., 2008	1(1)	1(1)	1(1)	1(1)	0(1)	1(1)	1(0)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	27(26)

Authors	Item														
	Abstract	Introduction		Method											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Stenstrom et al., 2003	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1
Van der Ven et al., 2004	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1
Van Son et al., 2012	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(0)	1(1)	1(0)	1(1)	1(1)	1(1)	0(0)	1(1)
Weinger et al., 2011	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	1(1)
Zoffman & Lauritzen, 2006	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Percentage Agreement	100%	100%	100%	100%	100%	100%	100%	94%	100%	94%	100%	100%	100%	94%	100%

Authors	Item													Total Score
	Results								Discussion					
	16	17	18	19	20	21	22	23	24	25	26	27	28	
Stenstrom et al., 2003	1	1	1	0	0	1	1	0	0	1	0	1	0	20
Van der Ven et al., 2004	1	1	1	1	1	1	1	1	0	1	1	1	1	26
Van Son et al., 2012	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	27 (25)
Weinger et al., 2011	1(1)	1(1)	1(1)	1(1)	0(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	1(1)	0(0)	25(26)
Zoffman & Lauritzen, 2006	1	1	1	0	0	1	1	1	1	1	0	1	0	24
Percentage Agreement	100%	100%	100%	100%	82%	100%	94%	100%	100%	100%	100%	100%	100%	

Appendix 3.4: Data Extracted from the Journal Articles.

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
Amsberg et al., 2009. **EXCLUDED**	Investigate the impact a CBT –based intervention has upon HbA_{1c}, self-care behaviours and psychosocial factors in adults with poorly-controlled type 1 diabetes.	94 patients randomised to control or intervention group. 69 completed study. **Intervention.** N= 32. Mean age= 41.4 years Male %= 42% **Control** N=37 Mean age= 41.1 years. Male% = 55% Research conducted in Sweden. No ethnicity data provided.	**Inclusion**: • diagnosis for at least 2 years. • Aged between 18-65 years. • HbA_{1c} exceeding 7.5%. • Sufficient reading and comprehension skill. **Exclusion**: • Pregnant • Diagnosed with a psychiatric disorder, • Substance misuse.	**Intervention**: Group-based CBT, with between 4-6 participants in each group. 8 weekly sessions looking at behaviours. Subsequent 40 weeks focusing on maintained behavioural change. Intervention carried out by psychologist and diabetes specialist nurses trained in CBT. **Control:** Regular diabetes management.	**Intervention group**: duration of diabetes 19.9 years. Baseline HbA_{1c} 8.5% (0.9). HbA_{1c} at 48 weeks 7.72 (No SD). **Control group:** duration of diabetes 23.2 years. Baseline HbA_{1c} 8.5% (0.8). HbA_{1c} at 48 weeks 8.21 (No SD)	CBT is a promising approach to blood glucose control management in adults with type 1 diabetes. Mood was reported to improve. Hypoglycaemic events reduced/	23.5
Attari et al., 2006.	Investigate the effect of stress management training on glycaemic control in adults with type 1 diabetes.	60 participants randomised to intervention or control group. All 60 completed study. **Intervention:** N= 30. Mean age= 19.7 years. N= 30 **Control:** Mean age= 20.8 years. No information about gender or ethnicity. Study completed in Finland.	**Inclusion:** • Aged between 16- 30. • At least 1 year diagnosed. **Exclusion:** • Severe complications • Psychoactive drug use.	**Intervention:** Group therapy for 8 weeks lasting 2 hours. 10-15 in each group. Psychiatrist led focusing on psychoeducation about different stressors, and encouraging physical activity and stress reduction techniques. **Control:** Regular insulin therapy.	**Intervention group**: duration of diabetes 2.1 years. Baseline HbA1c 11.7% (2.9). HbA1c after intervention 8.5 (1.7). **Control group:** duration of diabetes 2.14 years. Baseline HbA1c 10.9% (2.1). HbA1c at end of group 10.3 (2.1)	Results show a clinically significant beneficial effect of stress management training on glycaemic control in adults with type 1 diabetes.	20

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
van Bastelaar et al., 2011	Evaluate the effectiveness of web-based CBT for depression in adults with diabetes. Glycaemic control is a secondary measure.	92 type 1 diabetes randomised into intervention and control groups. **Intervention:** N= 47 Mean age= 48 years. Male %= 38% **Control:** N= 45 Mean age= 51 years Male %= 44% No ethnicity information provided. Research undertaken in Holland.	**Inclusion:** • An email address and internet access. • A score of above or equal to 16 on the Centre for Epidemiological Studies Depression Scale. **Exclusion:** • History of attempted suicide. • Psychosis diagnosis. • Pregnant. • Recent loss.	**Intervention:** 8 weekly web-based CBT lessons. Homework tasks provided too. Therapy conducted by a health psychologist. **Control:** Usual diabetes care.	**Intervention group**: Baseline HbA1c 8.11% (1.3). HbA1c at end 7.89 (1.08). **Control group:** Baseline HbA1c 7.72% (1.04). HbA1c at end 7.78 (1.08) Average duration for diagnosis was 20 years for the entire sample.	Web-based CBT does not appear to effective in improving glycaemic control. Intervention is reported to have a positive effect on mood.	28
Didjurgeit et al., 2002	Assess time-limited problem-orientated psychotherapy on self-defined psychological problems and metabolic control in adults with type 1 diabetes and microvascular problems.	44 participants were randomly assigned to a medical management control group and individual psychotherapy. All inpatients. **Intervention:** N= 23 Mean age= 36 years. Male %= 60 %. **Control:** N= 21 Mean age= 41 years. Male %= 66% No ethnicity data. Research completed in Germany.	**Inclusion:** • Presence of self-reported psychological problems. • At least one diabetic microvascular problem. • Previous self-management insulin therapy. **No exclusion criteria.**	**Intervention:** 1:1 brief-problem orientated psychotherapy delivered by a psychotherapist. **Control:** Medical care only.	**Intervention:** Duration of illness= 23 years. Baseline HbA_{1c} 9(2.0). HbA_{1c} 6 month follow up- 8.7(1.7). **Control:** Duration of illness= 25 years. Baseline HbA_{1c} 8.7 (1.7) HbA_{1c} at 6 month follow up- 8.8 (1.9).	A time-limited structured, problem-orientated psychotherapy intervention improves metabolic control.	25

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
Feinglos et al., 1987	Assess the effect relaxation therapy has on blood glucose training in type 1 diabetes.	20 participants randomly assigned to control or intervention group. All participants were inpatients. **Intervention:** N= 10 Mean age= 36 years. **Control:** N=10 Mean age= 38 years. No gender or ethnicity information supplied. Study completed in America.	**Inclusion:** • History of diabetic ketoacidosis. • Poorly controlled (not defined). • Inpatients **No exclusion criteria.**	**Intervention:** Group modified progressive muscle relaxation training. No information regarding profession of therapist. **Control:** Regular diabetes management.	**Intervention:** Baseline HbA_{1c} 12.6 (0.7). Post HbA_{1c} 12.9 (0.8). **Control:** Baseline HbA_{1c} 13.1 (1.0). Post HbA_{1c} 12.6 (1.0). An overall mean duration of illness was 11 years.	Relaxation therapy is not effective in enhancing blood glucose control in patients with type 1 diabetes.	20
Fosbury et al., 1996	Compare Cognitive Analytic Therapy (CAT) with diabetes specialist nurse education (DSNE) in glycaemic control and interpersonal functioning.	26 participants randomly assigned to CAT or DSNE. **Intervention:** N= 10. Mean age= 30.5 years. Male %= 30%. Ethnicity: 100% white. **Control:** N=16 Mean age= 32 years. Male %= 69% Ethnicity= 81% white 13% Afro- Caribbean 6% Asian. Study conducted in England.	**Inclusion:** • Aged 18-55 • Consistently poorly-controlled HbA_{1c} (over 9%). **No exclusion criteria.**	**Intervention:** CAT therapy for 16 weeks led by a CAT therapist. **Control:** Teaching and advice regarding diabetes management. Led by diabetes specialist nurses.	**Intervention:** Duration of illness= 15 years. Baseline HbA_{1c} 12.12 (1.3). Post intervention HbA_{1c} 10.1 (1.5) **Control:** Duration of illness= 17 years. Baseline HbA_{1c} 11.76 (1.88) Post intervention HbA_{1c} 10.9 (1.5). Post intervention measured after 9 months.	CAT prolonged the effect on glycaemic control compared to DSNE, but not statistically different. CAT improves interpersonal functioning.	24

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
George et al., 2008 **EXCLUDED**	Assess the effectiveness of 2.5 days psycho-educational intervention Vs usual control on glycaemic control and hypoglycaemia awareness.	114 participants randomised to psychoeducation or usual care. **Intervention:** N= 54 Mean age= 41 years. Male %= 50% **Control:** N= 60 Mean age= 41 years. Male %= 40% No ethnicity data provided. Study completed in England.	**Inclusion:** • At least 1 year diagnosed with condition. • Be involved with a specialist diabetes service. • Receiving multiple injection therapy. • Aged over 18 years. • Can read and write. **No exclusion criteria.**	**Intervention:** 2.5 consecutive days group psychoeducation. Intervention led by diabetes specialist nurses and dieticians. **Control:** Usual care.	**Intervention:** Duration of illness= 19.7 years. Baseline $HbA1_c$ 8.7 (1.51). 12 month follow-up HbA_{1c} 8.4 (No SD) **Control:** Duration of illness= 19.4 years. Baseline HbA_{1c} 8.7 (1.3). 12 month follow-up HbA_{1c} 8.4 (No SD).	The 2.5 day psychoeducation did not contribute to a reduction in HbA_{1c} or hypoglycaemic events compared to usual care.	27
Halford et al., 1997	Assess the effect of problem regarding dietary management on glycaemic control and frequency of hypoglycaemia.	31 participants were randomly assigned to the intervention or control group. **Intervention:** N= 16 **Control:** N= 15. Gender information and mean age is for the entire sample. Mean age= 37.2 years. Male%= 45 %. No ethnicity information. Study completed in Australia.	**Inclusion:** • At least 1 year diagnosis of condition. • HbA_{1c} above 6.5%. • Aged over 16 years. • Able to read English. **No exclusion criteria.**	**Intervention:** Psychology led intervention. Group based over 6 weekly sessions. Dietary management, followed by high risk dietary problem solving techniques. **Control:** Regular diabetes management.	Overall duration of illness for both groups was 16.1 years. **Intervention:** Baseline HbA_{1c} 7.4 (1.1). End of intervention HbA_{1c} 7.1 (0.9). **Control:** Baseline HbA1c 7.2 (0.9). End of intervention HbA1c 7.2 (0.8).	HbA1c was not affected by the intervention. Hypoglycaemic events reduced significantly.	27

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
Ismail et al., 2008.	Assess the effectiveness of group Motivational Enhancement Therapy (MET) with CBT relative to usual diabetes care for emotional distress and glycaemic control.	344 participants randomly assigned to 3 groups. Purpose of the review, will report main psychological intervention and control. **Intervention:** N= 106 Mean Age= 36.6 years. Male %= 34% Ethnicity= 88 white. 22 black **Control:** N= 121 Mean age= 36 years Male %= 24%. Ethnicity= 88 white. 29 black. Study completed in England.	**Inclusion:** • Aged 18-65 • Diagnosis for over 2 years. • Disease onset before 35. • Persistent suboptimal HbA_{1c} (8-15%). **Exclusion:** • Unable to speak English. • Pregnant. • Serious medical illness. • Advanced diabetic complications- blind. • Psychiatric disorder. • Alcohol dependency. • In therapy.	**Intervention:** 4 sessions of MET over 2 months. Plus 8 sessions of CBT over 4 months. All individualised. Nurse led intervention, trained in the intervention techniques. **Control:** Usual care- education and insulin pump clinics.	**Intervention:** Duration of illness= 18.6 years. Baseline HbA_{1c} 9.25 (1.2). 12 month follow up HbA_{1c} 9.11 (1.38). **Control:** Duration of illness= 18.7 years. Baseline HbA_{1c} 9.4 (1.3). 12 month follow up HbA_{1c} 9.54 (1.52)	MET+CBT can lead to small improvements in HbA_{1c} compared to usual care controls, but change is not huge or to the recommended level.	27

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
Schachinger et al., 2005.	Assess the effect of blood glucose awareness training (BGAT) on management of extreme blood glucose levels.	111 participants randomly assigned to the intervention or control group. **Intervention:** N= 56. Mean age= 45 years. Male %= 44%. **Control:** N= 55. Mean age= 47.9 years, Male %= 38%. No ethnicity data reported. Study completed in Germany and Switzerland.	**Inclusion:** • Over 18 years. • Have type 1 diabetes, **Exclusion:** • Heart or vascular condition. • Mental health problems. • Substance dependency.	**Intervention:** Group psychoeducation regarding physical symptoms to extreme blood glucose levels, cognitive and motor problems, education about exercise and food consumption. 2 hour sessions for 8 weeks. Physician and psychologist led. **Control:** Physician guided self-help. 5-12 participants in group. 3 times over 1 month.	**Intervention:** Duration of illness= 33.1 years. Baseline HbA_{1c} 6.93 (0.82). End of intervention HbA_{1c} 6.93 (1.02). **Control:** Duration of illness= 22.7 years. Baseline HbA1c 6.91 (0.94). End of intervention HbA1c 6.95 (0.98).	BGAT reduces severe hypoglycaemic events, but no impact on $HbA_{1c.}$	25
Snoek et al., 2008. **EXCLUDED**	Assess long-term effectiveness of CBT over BGAT for glycaemic control with comorbid depression in adults with type 1 diabetes.	86 participants randomly assigned to the CBT or BGAT groups. **Intervention:** N= 45 Mean age= 38.1 years. Male %= 48.9%. **Control:** N= 41 Mean age= 37.4 years. Male %= 34.1 % No ethnicity data reported. Study completed in Holland.	**Inclusion:** • 2 consecutive HbA_{1c} tests above 8%. • Diagnosed for over 1 year at least. **Exclusion:** • Pregnant. • Visual impairment. • A learning disability. • Substance misuse. • History of severe mental health problems.	**Intervention:** Group intervention over 6 weekly sessions aimed at helping to identify psychological barriers and to challenge negative beliefs about their illness. Diabetes specialist nurses and psychologist led. **Control:** Group intervention to help identify symptoms of changing blood glucose levels to allow correcting early enough.	**Intervention:** Duration of illness= 17.8 years. Baseline HbA_{1c} 9.5 (No SD). 12 month follow up HbA_{1c} 8.8 (No SD). **Control:** Duration of illness= 18.8 years. Baseline HbA1c 9.5 (No SD). 12 month follow up HbA1c 9.4 (No SD).	Group CBT enabled a slight improvement regarding glycaemic control compared to the BGAT intervention. Improvement in mood also.	26.5

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
Strenstrom et al., 2003. **EXCLUDED**	To assess the effectiveness of stress management training and relaxation training on glycaemic control and mood.	31 participants randomly assigned to the intervention and control groups. **Intervention:** N= 17. Mean age= 40.4 years. Male%= 41% **Control:** N= 14. Mean age= 41.4 years. Male %= 35% No ethnicity information reported. Research completed in Sweden.	**No inclusion or exclusion criteria provided.**	**Intervention:** 14 weekly group sessions. Sessions focused on stress management strategies and muscle relaxation training. **Control:** Usual care.	**Intervention:** Duration of illness= 16.2 years. Baseline HbA_{1c} 7.3 (1.7). End of intervention HbA_{1c} 7.2 (1.4). **Control:** Duration of illness= 17.3 years. Baseline HbA1c 7.2 (1.0). End of intervention HbA_{1c} not reported.	Intervention improved mood of participants, but did not affect $HbA_{1c.}$	20
van der Ven et al., 2004.	Assess the effects of group CBT training on glycaemic control and diabetes self-efficacy in persistent poor glycaemic control.	78 participants randomly assigned to the intervention and control groups. **Intervention:** N=32 **Control:** N=36 Overall mean age= 37.8 years. Overall male %= 52% No ethnicity information reported. Study completed in Holland.	**Inclusion:** • Diagnosis for more than 1 year. • HbA_{1c} over 8% on last two tests. **Exclusion:** • Pregnancy • Comorbid health problem. • Visually impaired. • Unable to read Dutch language efficiently. • Psychiatric diagnosis.	**Intervention:** Group CBT over 6 weekly sessions lasting 2 hours. 6-8 participants in a group. Therapy focuses on cognitive restructuring, goal setting, and relationships. Intervention psychologist led. **Control:** Training from diabetes specialist nurses to prevent and correct extreme blood glucose fluctuations.	**Intervention:** Baseline HbA_{1c} 8.9 (1.14). 3 month follow up HbA_{1c} 8.7 (1.24). **Control:** Baseline HbA1c 8.9 (.92). 3 month follow up HbA1c 9.2 (1.10). A mean duration of illness for the entire sample was 18 years.	No significant improvements in glycaemic control after intervention.	26

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
van Son et al., 2013	Assess the effectiveness of group Mindfulness Based-Cognitive Therapy relative to usual care for patients with emotional distress and poor glycaemic control.	A type 1 and type 2 diabetes study. 36 participants with type 1 diabetes were randomly assigned to the intervention or control groups. **Intervention:** N= 15. Mean age= 56 years. **Control:** N= 21. Mean age= 57, Gender and ethnicity information reported. Study completed in Holland.	**Inclusion:** • Dutch speaker. • Low-levels of emotional well-being. • Aged 18-80. **Exclusion:** • Suicidal. • Psychotic. • Comorbid physical condition. • Insufficient reading ability. • Substance misuse.	**Intervention:** 8 week group-based Mindfulness therapy intervention. Sessions 2 hours long. 3 month 2 hour booster. **Control:** Usual diabetes care. Waitlist for mood therapy.	**Intervention:** Baseline HbA_{1c} 7.9 (1.12). 3 month follow-up HbA_{1c} 7.47 (1.31). **Control:** Baseline HbA1c 7.82 (1.0). 3 month follow-up HbA1c 7.89 (1.12). Duration of illness information not available.	Mindfulness –based cognitive therapy showed some benefits in helping improve glycaemic control and mood.	26
Weinger at al., 2011 **EXCLUDED**	Assess the effectiveness of a cognitive behaviour program on glycaemic control in adults with long-duration type 1 diabetes.	Both type 1 and type 2 diabetes were included. 56 participants with type 1 diabetes were randomised into an intervention or control group. **Intervention:** N= 28. **Control:** N= 28. Overall mean age was 46.6 years. Overall male % was 38%. No ethnicity information disclosed. Study completed in America.	**Inclusion:** • Aged 18-70. • Diagnosis for at least 2 years. • Free of severe complications. • HbA_{1c} greater than 7.5%. **Exclusion:** • Inability to read or speak English. • Pregnant. • Severe mental illness. • Unstable depression. • Untreated proliferative	**Intervention:** Five 2 hour sessions over a 6 week period. Behaviour based group work reviewing exercise, diet, medication use. Problem-solving. Exploring barriers against self-care. Dietician and diabetes specialist nurse led. **Control:** 1:1 education sessions led by diabetes specialist nurses and dieticians.	**Intervention:** Baseline HbA_{1c} 9.12 (No SD). Post intervention HbA_{1c} 8.75 (No SD). **Control:** Baseline HbA1c 8.70 (No SD). Post intervention HbA1c 8.50 (No SD). An overall mean duration of illness was reported as 23.7 years.	The cognitive behaviour program was slightly more effective in glycaemic control than the control group.	25.5

Study	Aim	Participants (Age, gender, ethnicity)	Inclusion/ Exclusion criteria	Treatment	Diabetes information	Key Findings	Quality Rating
Zoffman & Lauritzen, 2006. **EXCLUDED**	Assess long-term effectiveness of guided self-determination training to improve life skills and glycaemic control for adults with type 1 diabetes.	Participants randomly assigned to the intervention or control. **Intervention:** N=30 Mean age= 36.8 years. Male %= 46.5% **Control:** N= 20. Mean age= 35.7 years. Male%= 50%. No ethnicity information reported. Study completed in Denmark.	**Inclusion:** • Persistent poor glycaemic control (over 8%). • Illness duration of at least 2 years. • Onset of condition before 40. **No exclusion criteria reported.**	**Intervention:** Group based, with 10 participants in each group. Sessions lasted 2 hours over 8 weeks. The content was developing problem-solving skills, with some individual problems solving-skills set as goals. Diabetes management education provide too. DSN led intervention. **Control:** Usual diabetes care.	**Intervention:** Baseline HbA1c 9.01 (No SD). Post intervention (1 year) HbA1c 8.75 (No SD). **Control:** Baseline HbA1c 9.05 (No SD). Post intervention (1 year) HbA1c 9.00 (No SD). No duration of illness data reported.	The intervention improved life skills in the intervention group, and marginally improve glycaemic control.	24

Appendix 3.5: Studies Excluded from the Meta-Analysis

Study	Reason for Exclusion
Amsberg, Anderbro, Wredling, Lisspers, Lins, Adamson & Johansson, 2009.	Standard deviation data was not provided for post intervention mean HbA_{1c} scores for the control group.
George, Valdovinos, Russell, Dromgoole, Lomax, Torgerson, Wells & Thow, 2008.	Standard deviations were not reported for the control group HbA_{1c} means.
Snoek, van der Ven, Twisk, Hogenelst, Tromp-Wever, van der Ploeg & Heine, 2008.	Standard deviations were not provided for pre and post intervention mean HbA1c scores for both intervention and control groups.
Stenstrom, Goth, Carlsson & Anderson, 2005.	Standard deviation data was not provided for post intervention mean HbA1c scores for the control group.
Weinger, Beverley, Lee, Sitnokov, Ganda & Caballero, 2011.	Confidence intervals were reported as opposed to standard deviations which were essential for the meta-analysis calculation.
Zoffman & Lauritzen, 2006.	Confidence intervals were reported as opposed to standard deviations which were essential for the meta-analysis calculation.

References

Amsberg, S, Anderbro, T, Wredling, R, Lisspers, J, Lins, P, Adamson, U & Johansson, U (2009). A cognitive behavior therapy-based intervention among poorly controlled adult type 1 diabetes patients—A randomized controlled trial. Patient Education and Counseling. 77. 72–80.

George, J.T, Valdovinos, A.P, Russell, I, Dromgoole, P, Lomax, S, Torgerson, D.J, Wells, T & Thow, J,C (2008). Education and Psychological Care Clinical effectiveness of a brief educational intervention in Type 1 diabetes: results

from the BITES (Brief Intervention in Type 1 diabetes, Education for Self - efficacy) trial. Diabet. Med. 25, 1447–1453.

Snoek, F.J, van der Ven, N.C.W, Twisk, J.W.R, Hogenelst, M.H.E, Tromp-Wever, A.M.E, van der Ploeg, H.M & Heine, R.J (2008). Cognitive behavioural therapy (CBT) compared with blood glucose awareness training (BGAT) in poorly controlled Type 1 diabetic patients: long-term effects on HbA_{1c} moderated by depression. A randomized controlled trial. Diabet. Med. 25. 1337–1342.

Stenstrom, U, Goth, A, Carlsson, C & Anderson, P (2005). Stress management training as related to glycemic control and mood in adults with Type 1 diabetes mellitus. Diabetes Research and Clinical Practice. 60. 147-152.

Weinger, K, Beverley, E.A, Lee, Y, Sitnokov, L, Ganda, O.P & Caballero, A.E (2011). The Effect of a Structured Behavioral Intervention on Poorly Controlled Diabetes. A Randomized Controlled Trial. Arch Intern Med. 171(22).1990-1999.

Zoffman, V & Lauritzen, T. (2006). Guided self-determination improves life skills with Type 1 diabetes and A1C in randomized controlled trial. Patient Education and Counseling. 64. 78–86.

Appendix 4.1: Demographics Form

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Participant Number…….

Gender ……

Date of Birth ……..

Marital Status …….

Years of Education ……

Employment Status ……

Do you have Type 1 Diabetes? Yes…… No…….

How long have you had a diagnosis of Type 1 Diabetes? ……..

Have you had any complications related to your diabetes? Yes…… No…….

If yes, what complications have you endured?
……
……
……
……
……

Have you experienced episodes of hypoglycaemia or hyperglycaemia? Yes……...
No…….

If yes, how often have you experienced hypo or hyperglycaemia?
……
……
……
……

Do you have any other physical health problems? Yes…….. No……

What is the nature of your problems?
……
……
……
……

Do you currently use any prescribed medications? Yes……. No ……

Please list any medications you are currently using

……
……
……
…….

Have you ever had a head injury? Yes …….. No……..

What was the nature of your head injury/ injuries?

……
……
……
……

Have you ever experienced a traumatic event? Yes…… No……..

Have you had involvement with any mental health services before? Yes……..
No……

What are the details of this involvement?

.....
.....
.....
.....

Are you currently receiving support from a mental health team? Yes…….
No……..

Are you currently prescribed medication for depression or anxiety? Yes……
No…….

Thank you for completing this questionnaire.

Appendix 4.2: Hospital Anxiety and Depression Scale.

HAD SCALE

Name: ..... Date:.....

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.

This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

Tick only one box in each section.

I feel tense or 'wound up: Most of the time ..... A lot of the time ..... Time to time, occasionally. Not at all		**I feel as if I am slowed down:** Nearly all the time ..... Very often ..... Sometimes ..... Not at all	
I still enjoy the things I used to enjoy: Definitely as much ..... Not quite so much ..... Only a little ..... Hardly at all		**I get a sort of frightened feeling like 'butterflies' in the stomach:** Not at all .... Occasionally ..... Quite often ..... Very often	
I get a sort of frightened feeling as if something awful is about to happen: Very definitely & quite badly Yes, but not too badly ..... A little, but it doesn't worry me. Not at all		**I have lost interest in my appearance:** Definitely .... I don't take so much care as I should I may not take quite as much care I take just as much care as ever	
I can laugh and see the funny side of things: As much as I always could Not quite so much now .... Definitely not so much now Not at all		**I feel restless as if I have to be on the move:** Very much indeed ..... Quite a lot ..... Not very much ..... Not at all	
Worrying thoughts go through my mind: A great deal of the time .... A lot of the time ..... From time to time but not too often ..... Only occasionally		**I look forward with enjoyment to things:** As much as ever I did ..... Rather less than I used to ..... Definitely less than I used to ... Hardly at all	
I feel cheerful: Not at all .... Not often ..... Sometimes ..... Most of the time		**I get sudden feelings of panic:** Very often indeed ..... Quite often ..... Not very often ..... Not at all	
I can sit at ease and feel relaxed: Definitely .... Usually..... ..... Not often ..... Not at all		**I can enjoy a good book or radio or TV programme:** Often .... Sometimes ..... Not often ..... Very seldom	

Do not write below this line

A - (8-10) .....

D - (8-10) .....

Appendix 4.3: Memory Functioning Questionnaire

Memory Functioning Questionnaire

This is a questionnaire about how you remember information. There are no right or wrong answers. Circle a number between 1 and 7 that best reflects your judgment about your memory. Think carefully about your responses, and try to be as realistic as possible when you make them. Please answer all questions.

General Frequency of Forgetting

How would you rate your memory in terms of the kinds of problems that you have?

major problems			*some minor problems*			*no problems*
1	2	3	4	5	6	7

How often do these present a problem for you?

	always			*sometimes*			*never*
a. names	1	2	3	4	5	6	7
b. faces	1	2	3	4	5	6	7
c. appointments	1	2	3	4	5	6	7
d. where you put things (e.g., keys)	1	2	3	4	5	6	7
e. performing household chores	1	2	3	4	5	6	7
f. directions to places	1	2	3	4	5	6	7
g. phone numbers you've just checked	1	2	3	4	5	6	7
h. phone numbers you use frequently	1	2	3	4	5	6	7
i. things people tell you	1	2	3	4	5	6	7
j. keeping up correspondence	1	2	3	4	5	6	7
k. personal dates (e.g., birthdays)	1	2	3	4	5	6	7
l. words	1	2	3	4	5	6	7
m. going to the store and forgetting what you wanted to buy	1	2	3	4	5	6	7
n. taking a test	1	2	3	4	5	6	7
o. beginning to do something and forgetting what you were doing	1	2	3	4	5	6	7
p. losing the thread of thought in conversation	1	2	3	4	5	6	7
q. losing the thread of thought in public speaking	1	2	3	4	5	6	7
r. knowing whether you've already told someone something	1	2	3	4	5	6	7

As you are reading a novel, how often do you have trouble remembering what you have read . . .

	always			*sometimes*			*never*
a. in the opening chapters, once you have finished the book	1	2	3	4	5	6	7
b. three or four chapters before the one you are currently reading	1	2	3	4	5	6	7
c. the chapter before the one you are currently reading	1	2	3	4	5	6	7
d. the paragraph just before the one you are currently reading	1	2	3	4	5	6	7
e. the sentence before the one you are currently reading	1	2	3	4	5	6	7

When you are reading a newspaper or magazine article, how often do you have trouble remembering what you have read . . .

	always			*sometimes*			*never*
a. in the opening paragraphs, once you have finished the article	1	2	3	4	5	6	7
b. three or four paragraphs before the one you are currently reading	1	2	3	4	5	6	7
c. the paragraph before the one you are currently reading	1	2	3	4	5	6	7
d. three or four sentences before the one you are currently reading	1	2	3	4	5	6	7
e. the sentence before the one you are currently reading	1	2	3	4	5	6	7

Appendix 4.4: Invitation Letter

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Department of Clinical Psychology
University of Hull
Hertford Building
Cottingham Road
Hull
HU6 7RX

Email: r.p.pearson@2008.hull.ac.uk

Telephone number: 07599800044

Hello,

I am a trainee clinical psychologist currently studying my Doctorate in Clinical Psychology at the University of Hull. I am conducting research into memory functioning and beliefs about our own memories in adults with type 1 diabetes.

I am looking for participants to complete some memory testing, and fill in some forms about their mood and anxiety and beliefs about their own memory. The testing time will take approximately 60 minutes in total. No payment can be offered for participating in this study, but I can refund the cost of travel expenses. The information generated may lead to better support and education for people with type 1 diabetes in the future.

If you are interested in participating please contact me using the above email address or telephone number.

Yours sincerely

Richard Pearson
Trainee Clinical Psychologist

Appendix 4.5: Study Advertisement Poster

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Type 1 Diabetes Psychology Study

The University of Hull's Department of Clinical Psychology and Psychological Therapies is currently studying how Type 1 Diabetes can influence a person's memory performance and beliefs about their own memory.

The Person

- **Have you had a diagnosis of Type 1 Diabetes for at least 5 years?**
- **Are you at least 18 years old?**

What is involved?

- **2 questionnaires and a memory test.**
- **Approximately 60 minutes of your time.**
  Travel costs for participating will be reimbursed.

If you are interested in participating in this study, or would like more information please feel free to contact myself by email. My email address is: r.p.pearson@2008.hull.ac.uk.

Alternatively you can call me on: Telephone number TBC

Richard Pearson, Trainee Clinical Psychologist.

Appendix 4.6: Telephone Screening Sheet

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Initial Telephone Contact Information Sheet

1. Do you have Type 1 Diabetes? Yes……. No…….

2. Do you currently have any mental health difficulties which you receive care from a mental health team and/or receiving medication to help reduce the symptoms?

Yes…… No…….

3. Are you receiving or have ever received professional involvement in regards to a neurological condition or brain injury? Yes…….. No……..

4. Do you have any other health difficulties? Yes…….
No……

Thank you for your time.

Appendix 4.7: Participant Information Sheet

Participant Information Sheet

PROJECT TITLE
The Effect of Type 1 Diabetes on Actual and Self-Report of Memory

INVITATION
I would like to invite you to take part in this research study. Before you decide I would like you to understand why the research is being done and what it would involve for you. I will go through the information sheet with you and answer any questions you have. I suggest this should take about 5 minutes.

PURPOSE
The purpose of this study is to investigate the effect the condition Type 1 Diabetes has on a person's actual memory functioning, and their own beliefs about their memory.

WHY HAVE YOU BEEN INVITED TO PARTICIPATE?
You have been invited to participate in this study because you have a diagnosis of Type 1 Diabetes or currently have no health concerns at this time. The study requires a comparison to be made between adults with Type 1 Diabetes and adults without a medical condition to see if memory performance and memory beliefs are different between the two groups, and therefore if Type 1 Diabetes is associated with memory difficulties. The study will aim to assess memory in 22 adults without a medical condition, and 44 adults with Type 1 Diabetes.

DO I HAVE TO TAKE PART?
It is up to you to decide to join the study. I will describe the study and go through this information sheet with you. If you agree to take part, I will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

WHAT WILL HAPPEN TO ME IF I TAKE PART?
In this study, you will be asked to complete the very short Hospital Anxiety and Depression Scale, and the Memory Functioning Questionnaire. The final task will be a memory assessment using a test called the Brain Injury Rehabilitation Trust Memory and Information Processing Battery (BMIPB). The findings from the research will be presented to all participants in the form of a letter when the study has been completed. The study typically takes approximately 1 hour 10 minutes to complete. All the information provided in this study is confidential with only the researcher to know the results of individual tests. If the tests reveal any potential

mood problems, you will be informed, and with your consent, your GP will also be informed.

EXPENSES AND PAYMENTS
Your participation in this study is voluntary. However, you will be offered reimbursement for travel expenses, which will be provided at the meeting.

WHAT ARE THE POSSIBLE BENEFITS FOR TAKING PART?
There are no known benefits for your participation in this study, but the information gained in the project may help to improve knowledge about Type 1 Diabetes, and therefore improve therapies for managing the condition.

WHAT IF THERE IS A PROBLEM?
If your experience is not satisfactory or you have concerns about any aspect of this study you can contact Dr Miles Rogish (m.rogish@hull.ac.uk/ (01482) 464008) at The University of Hull, or contacts the local NHS Patient Advice and Liaison Service (PALS). PALS can be contacted by telephone (01482 303966), in writing at 296 Cottingham Road, Hull, East Yorkshire, HU6 8QA, or via email at pals@humber.nhs.uk. Complaints will not affect your treatment offered by your NHS service.

WILL TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?
Information obtained in this study will only be used for this study. All information is stored securely, and will remain so for 5 years and then destroyed. Information is collected by myself only, and participants will not be identified by name at any point during this study. All information is anonymised.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?
The information that is collected in this study will be presented in a doctoral thesis, a presentation of the results, and a journal publication. No individual participant will be identified in the presentation of the data.

WHO HAS REVIEWED THIS STUDY?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by South Yorkshire NHS Research Ethics Committee.

This participant information sheet is for you keep. In addition you will also receive a copy of the consent form should you wish to consent to participating in this research.

FOR FURTHER INFORMATION
Mr Richard Pearson and Dr Miles Rogish will be glad to answer your questions about this study at any time. You may contact them at: Emails; r.p.pearson@2008.hull.ac.uk and m.rogish@hull.ac.uk, or Richard Pearson/Dr Miles Rogish, Department of Psychological Therapies, University of Hull, Cottingham Road, Hull, HU6 7RX

Appendix 4.8: Consent Form

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Participant Identification Number for this trial:

CONSENT FORM

Title of Project: The Effect of Type 1 Diabetes on Actual and Self-Report of Memory

Name of Researcher: Richard Pearson, Trainee Clinical Psychologist

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 21/12/2013 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 is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to my GP being informed if any of the results from the tests give cause for concern. ☐

4. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature

Name of Person taking consent	Date	Signature