

**The Impact of a Web-Based Self-Management Programme on the  
Psychological Well-Being of Adults with Type 2 Diabetes**

**Megan Cockburn**

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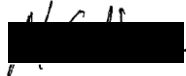
**University College London**

## UCL Doctorate in Clinical Psychology

### Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signature:



Name: Megan Cockburn

Date: 11<sup>th</sup> June 2014

## Overview

Psychological distress in people living with type 2 diabetes is associated with lowered glycaemic control and an increased risk of serious health complications. Therefore, interventions capable of improving the psychological well-being of people with diabetes may also positively affect physical health and quality of life. This thesis explores the impact of diabetes interventions on psychological well-being.

Part one is a literature review of the efficacy of interventions at reducing diabetes-related distress. Twenty papers were included in the review and three types of intervention were identified: self-management, educational and psychological. Five self-management interventions and two psychological interventions showed a reduction in diabetes-related distress compared to the control group, indicating that the interventions were capable of improving psychological well-being.

Part two is an empirical study of the impact of a web-based, self-management programme, called HeLP-Diabetes, on the psychological well-being of adults with type 2 diabetes. This study used a mixed method, quantitative and qualitative design with 18 participants. The qualitative data suggested that the participants felt some important psychological benefits from using the programme, although the quantitative data did not show any significant findings.

Finally, part three is a critical appraisal of the research process. In particular, it examines how the researcher's background and experiences affected the study approach. Methodological issues, such as the decision to use a mixed method design, are expanded upon from the discussion in part two. It concludes with a reflection on the personal impact of the study on the researcher.

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## **Part 1: Literature Review**

### **The Efficacy of Interventions for Reducing Diabetes-Related Distress**



## **Abstract**

*Aim:* Depression is associated with poor glycaemic control and an increased risk of health complications in people with diabetes. Diabetes-related distress may have an even greater negative impact on clinical outcomes than depression. This review aimed to identify intervention studies which have shown efficacy in reducing diabetes-related distress.

*Method:* A review of the literature was systematically conducted using 'MEDLINE (Ovid)', 'PsycINFO', 'EMBASE' and 'CINAHL Plus' databases and manual searches of bibliographies. The inclusion criteria consisted of adults with type 2 diabetes; educational, psychological or self-management interventions; an RCT design; and an outcome measure of diabetes-related distress. Data was analysed based on the statistical significance of the outcomes relating to diabetes-related distress. The quality of the study methodologies was assessed using the Quality Assessment Tool for Quantitative Studies from the Effective Public Health Practice Project (EPHPP).

*Results:* Twenty studies met the inclusion criteria. Three types of interventions were identified: self-management (14), educational (3) and psychological (3). The overall quality of the studies was good with ten studies achieving moderate ratings and eight being rated as strong. Five self-management interventions and two psychological interventions showed a statistically significant reduction in diabetes-related distress compared to the control group, indicating that the intervention was beneficial.

*Conclusions:* The findings of this review indicate that interventions can be effective in reducing diabetes-related distress. Self-management and psychological interventions may be more effective than educational interventions in targeting this area of difficulty. Future research is required to establish the active components of an intervention which impact diabetes-related distress.

The emotional needs of people with diabetes are complex and challenging. Diabetes mellitus is a chronic metabolic disorder which requires careful self-management to reduce the risk of physical complications. The provision of educational and psychological interventions that facilitate self-management is the cornerstone of effective diabetes care (Department of Health, 2001).

Diabetes is characterised by raised glucose levels in the blood. Type 2 diabetes mellitus involves a background of insulin insensitivity plus a failure of pancreatic insulin secretion to compensate for this (National Collaborating Centre for Chronic Conditions, 2008). It is distinct from type 1 diabetes in which there is an absolute insulin deficiency due to destruction of islet cells in the pancreas. The number of people diagnosed with diabetes in the UK is around 2.9 million (Diabetes UK, 2012), 90% of whom have type 2 diabetes. By 2025, it is estimated that 5 million people in the UK (8% of the population) will have diabetes. The World Health Organisation has described diabetes as a “growing epidemic” (World Health Organisation, 2002).

Diabetes can have a profound impact on a person’s psychological well-being. The complex nature of the condition means that effective self-management is critical to achieve healthy, flexible and independent day-to-day living. The key to preventing painful, distressing and life-threatening complications such as neuropathy and blindness is control of blood sugar levels. The “gold standard” measure of blood sugar control is the level of glycated haemoglobin, known as HbA1c. Controlling blood sugar levels often requires substantial behaviour change by individuals affected, in terms of altering their diet, levels of physical activity and adherence to medications. This can put a considerable amount of pressure on an individual. Psychological well-being can be compromised when an individual feels unable to meet the demands of the self-care routine or their efforts are not successful. People with diabetes may have difficulty in accepting their diagnosis and

experience a range of other difficult emotions, including anger, guilt, frustration, denial, fear of hypoglycaemia and loneliness (Polonksy et al., 1995).

Studies have found that depression prevalence is approximately twice as high in people with diabetes as in the general population (e.g. Anderson, Freedland, Clouse, & Lustman, 2001). Depression in people with diabetes is associated with worse clinical outcomes and increased health complications (Black, Markides & Ray, 2003; de Groot, Anderson, Freedland, Clouse & Lustman, 2001). However, it is unclear whether targeting the depression improves outcomes. Some investigators have found moderate but significant associations between depression and glycaemic control (e.g. Eaton et al., 1992; Lustman et al., 2000; Van der Does et al., 1996), whereas others have found none (Georgiades et al., 2007; Katon et al., 2004; Lin et al., 2006).

Recent studies have highlighted the conceptual and empirical distinction between depression and diabetes-related distress (DRD; Aikens, 2012; Fisher et al., 2010; Gonzalez, Fisher & William, 2011; Polonsky et al., 1995; van Bastelaar et al., 2010). DRD refers to significant negative psychological reactions that are specific to having diabetes, including the diagnosis, potential or actual complications, self-management burdens, difficult patient-provider relationships, and problematic interpersonal relationships (Gonzalez et al., 2011). The illness-specific nature of DRD distinguishes it from depression. In a survey of 8596 adults with type 2 diabetes across 17 countries, 44.6% reported experiencing DRD (Nicolucci et al., 2013). DRD has been found to be about twice as prevalent as major depressive disorder in people with diabetes and more closely related to diabetes-related variables such as self-management behaviours, BMI and complications (Fisher et al., 2007).

Recent studies have shown that DRD may have a greater impact on glycaemic control than depression. Zagarins, Allen, Garb and Welch (2012) and Aikens (2012) found that DRD was associated with changes in glycaemic control,

whereas depression was not. Aikens (2012) hypothesised that a reduction in DRD may have led to increased medication adherence. Another study (Fisher et al., 2010) also found that out of DRD, major depressive disorder and depressive symptoms, only DRD was significantly associated with HbA1c. Further studies have found similar findings (van Bastelaar et al., 2010) and have suggested that DRD may be the mediator between depression and glycaemic control. This differential impact on glycaemic control, further supports the idea that DRD is conceptually and empirically distinct from depressive symptoms or major depressive disorder in people with diabetes.

### **Aims of the Literature Review**

The finding that DRD is more closely associated with glycaemic control than depression, highlights the need for effective treatment of DRD. People with DRD experience significant emotional difficulties but their symptoms are not severe enough to merit a diagnosis of depression. They are therefore easily overlooked by their health care systems and may continue with poor self-management and increased risk of complications. Effort therefore needs to be made to identify and address DRD in people living with diabetes. Diabetes self-management interventions have been shown to have a beneficial impact on DRD (e.g. Welch, Garb, Zagarins, Lendel & Gabbay, 2010). However, this is a relatively new area of interest in the diabetes literature and the types of interventions that are effective in reducing DRD remain unclear. In order to address this gap in knowledge, the current review aimed to identify intervention studies which have included DRD as an outcome measure and, from these studies, to establish which interventions were effective in reducing DRD.

### **Method**

#### *Inclusion and Exclusion Criteria*

The inclusion and exclusion criteria for the review are presented in Table 1.

Table 1

*Inclusion and Exclusion Criteria*

	<b>Inclusion</b>	<b>Exclusion</b>
<b>Participants</b>	Adults with type 2 diabetes	Adults with type 1 diabetes  Mixed type 1 and type 2 diabetes studies with more than 50% of participants with type 1 diabetes
<b>Intervention</b>	Educational, self-management or psychological interventions  Group or individual  Telephone, online or face-to-face	Pharmacological interventions
<b>Comparator</b>	Treatment as usual or active control	
<b>Outcome measures</b>	Diabetes-related distress (as a primary or secondary outcome)	Depression, anxiety or quality of life measures only
<b>Study Design</b>	Randomised controlled trials (RCTs)	Study designs that are not RCTs, including qualitative studies or case studies  Studies with samples of fewer than 15 in each participant group (intervention and control)
<b>General</b>	Peer reviewed  Published prior to September 2013	

*Search Strategy*

Four databases were used in the search: MEDLINE (Ovid), PsycINFO, EMBASE and CINAHL Plus. Reference lists of retrieved articles were also searched for relevant studies. Results were limited to peer-reviewed journal articles published prior to September 2013. No language restriction was applied.

An initial scope of the literature was conducted in order to identify relevant search terms for the participants, interventions and outcomes. 'OR' was used to combine the terms within each of these areas and then 'AND' was used to combine the concepts. Truncated terms were used in order to allow for variations in key words (e.g. treat/ treated/ treatment).

Subject headings were used to identify studies which used 'Type 2 Diabetes Mellitus' as a descriptor of participants. In order to include recent studies which may not have yet assigned subject headings to their journal article, 'Diabet\*', limited to 2013, was also searched. Search terms relating to interventions included: 'treat\*', 'train\*', 'coach\*', 'self-management', 'program\*', 'education', 'intervention'. The terms used to identify relevant outcomes were: 'diabetes-related distress', 'diabetes-related emotional distress', 'diabetes-specific distress', 'diabetes distress', 'diabetes-specific emotional distress', 'diabetes-related psychosocial distress', 'diabetes-specific psychosocial distress', 'emotional adjustment to diabetes' and 'psychosocial adjustment to diabetes'. Additionally, an 'ADJ//N' operator was used to find 'diabet\*' and 'distress' in any order and with three words (or fewer) between them (see Appendix A for Medline search strategy in full).

### *Data Extraction*

Key data was extracted from each of the studies included in the review. This data included author, year and country of publication, research aim, study design, sample characteristics, intervention type, outcome measure for diabetes-related distress, follow up, changes to glycaemic control and findings related to diabetes-related distress. Interventions were categorised into three types: self-management, educational and psychological. Self-management interventions aim to increase knowledge and additionally provide behavioural skills training, such as goal setting and problem solving. They may also try to identify beliefs or cognitions which are creating barriers to self-care. Educational interventions simply aim to increase diabetes-related knowledge in order to improve regimen adherence and clinical

outcomes. Psychological interventions target emotional states such as depression, anxiety, low self-esteem, through approaches based on psychological theory, e.g. Cognitive Behavioural Therapy (CBT). These classifications have been used within previous research looking at diabetes interventions (Steed, Cooke & Newman, 2003).

#### *Analysis Strategy*

The studies were analysed based on the statistical change in their outcome for diabetes-related-distress over time, as reported in the study. Studies that showed a significant reduction in diabetes-related distress compared to the control group (i.e. a group by time interaction effect) were considered to be effective. It was also noted when studies showed a significant reduction in diabetes-related distress over time but not significantly more so than the control group (i.e. a main effect).

#### *Assessment of Methodological Quality*

The Quality Assessment Tool for Quantitative Studies, developed by the Effective Public Health Practice Project (EPHPP; Thomas, Ciliska, Dobbins & Micucci, 2004), was used to assess the quality of the studies included. This tool is targeted towards systematic reviews of public health interventions (Jackson & Waters, 2005) and was therefore suitable for the current review. It is also considered appropriate for reviews of intervention effectiveness (Deeks et al., 2003). The content and construct validity have also been established (Thomas et al., 2004).

The EPHPP quality assessment tool includes the following six components: sample selection, study design, identification and treatment of confounders, blinding of outcome assessors and of participants, reliability and validity of data collection methods and withdrawals and dropouts. These various components are assigned a rating of strong, moderate or weak, according to a standardized guide and dictionary, as outlined in Table 2 (Thomas et al., 2004). Studies with at least four components rated as strong and none rated as weak, are classified as strong

overall. Studies with fewer than four components rated as strong and one component rated as weak are classified as moderate. If the study has two or more components that are rated as weak then they are considered to be weak overall. The tool also considers the integrity of the interventions and whether appropriate data analysis was used. Following the guidelines in Table 2, the six components for each paper was assigned a rating. A global rating for each paper was then established.

Table 2

*Quality Assessment Components and Ratings for EPHPP Tool*

<b>Component</b>	<b>Strong Rating</b>	<b>Moderate Rating</b>	<b>Weak Rating</b>
Selection bias	Very likely to be representative of the target population and greater than 80% participation rate	Somewhat likely to be representative of the target population and 60-79% participations rate	All other responses or not stated
Study design	RCTs and CTTs	Cohort analytic, case control, cohort or an interrupted time series	All other designs or design not stated
Confounders	Controlled for at least 80% of confounders	Controlled for 60-79% of confounders	Confounders not controlled for, or not stated
Blinding	Blinding of outcome assessor and study participants to intervention status and/or research question	Blinding of either outcome assessor or study participants	Outcome assessor and study participants are aware of intervention status and/or research question
Data collection and methods	Tools are valid and reliable	Tools are valid but reliability not described	No evidence of validity or reliability
Withdrawals and dropouts	Follow-up rate of >80% of participants	Follow-up rate of 60-79% of participants	Follow-up rate of <60% of participants or withdrawals and dropouts not described.

*Note.* RCTs = randomised controlled trials; CCTs = controlled clinical trials



## Results

The study selection process is outlined as a PRISMA flowchart in Figure 1. The initial search elicited 435 papers from four databases. These articles were screened for duplicates and 215 articles were excluded. The articles were then screened by their titles and abstracts and subsequently a further 179 papers were excluded. The full text of the remaining 41 papers were read and a further 23 papers were excluded in accordance with the inclusion and exclusion criteria (see Figure 1 for further detail). Reference lists of the remaining 18 papers were examined and a further two papers were identified which met the inclusion criteria. The total number of papers selected for review was therefore 20. One of these papers was from a Mexican journal and written in Spanish (Lerman et al., 2009) and was therefore translated for the review.

Out of the 20 included studies, 14 used self-management interventions, three used educational interventions and three used psychological interventions. The majority of studies (15) were conducted since 2010. Most (14) were conducted in the United States of America; the others were conducted in the United Kingdom, Germany or The Netherlands. The majority of interventions (11) involved working with the participant individually, whilst five of the interventions used a group format and four included a combination. Eleven of the 20 studies used a face-to-face approach, six involved use of the telephone, two involved use of the internet and one involved both the telephone and internet. Fifteen of the studies involved only participants with type 2 diabetes, whereas five studies included participants with both type 1 and type 2 diabetes (with over 50% having type 2 diabetes in each study).

The construct of DRD was captured by two different measures. Eighteen used the Problem Areas in Diabetes Scale (PAID; Polonsky et al., 1995) and two used the Diabetes Distress Scale (DSS; Polonsky et al., 2005).

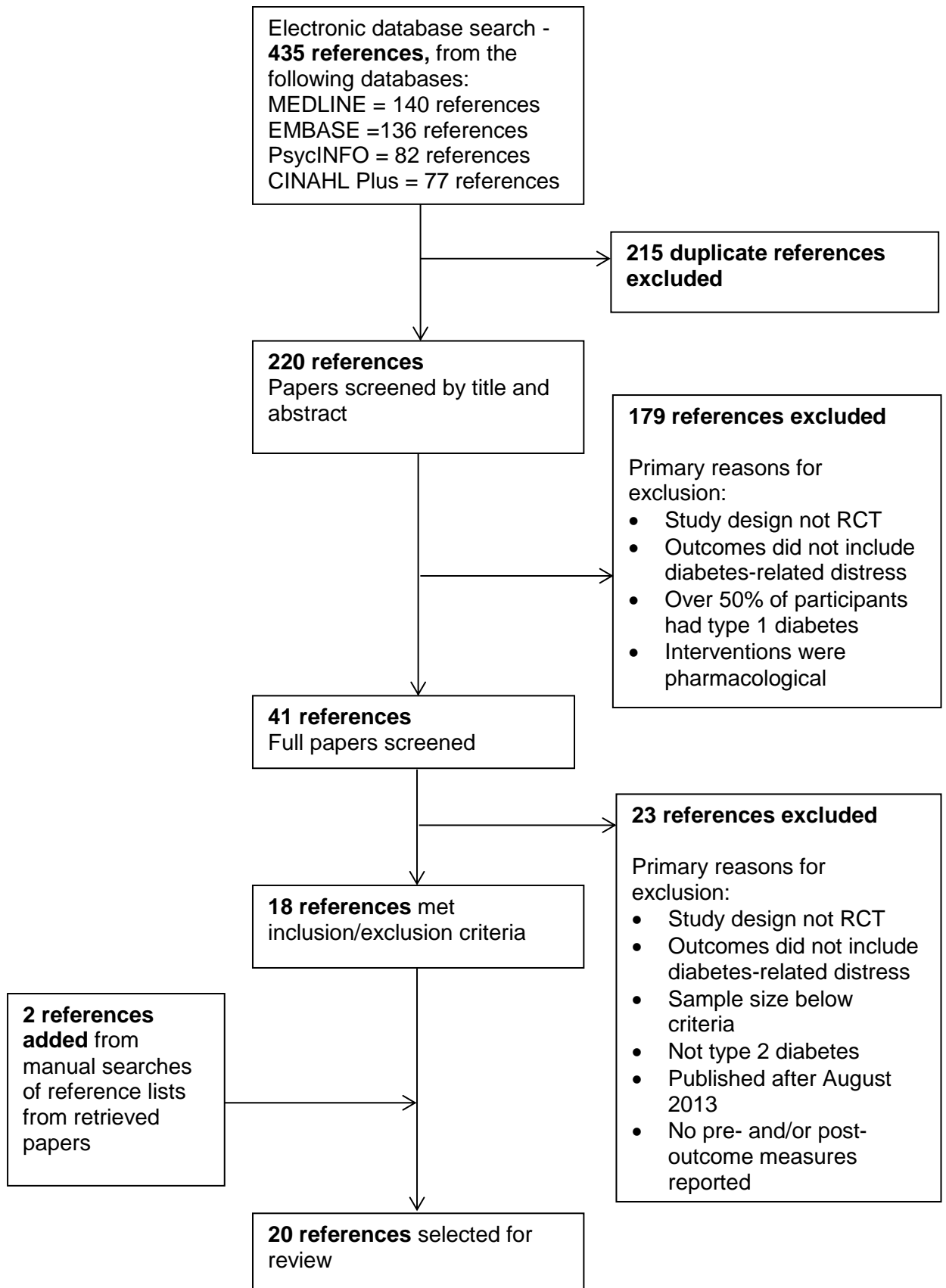


Figure 1. PRISMA Flowchart

Table 3  
*Characteristics of Included Studies*

<b>Author, Year and Country</b>	<b>Research Aim</b>	<b>Study Design</b>	<b>Sample Characteristics</b>	<b>Intervention Type</b>	<b>Outcome Measure for DRD</b>	<b>Follow-Up</b>	<b>Changes to Glycaemic Control</b>	<b>Findings Related to DRD</b>
<b><i>Self-Management Interventions</i></b>								
Beverly et al. (2013a) USA	To assess the value of reinforcing diabetes self-management for improving glycaemia and self-care among adults with type 2 diabetes who had at least 3 hours of prior diabetes education	Two-arm RCT; group educational attentional control	N = 134; mean age = 59.1; mean HbA1c= 8.4; mean diabetes duration: 13.3 years; 100% type 2 diabetes	<b>Self-management Group Face-to-face</b>  Four, one-hour group discussions about diabetes self-care and goal setting	PAID (secondary outcome)	12m	Improved at 3 months but not maintained at 6 and 12 months	Main time effect for experimental (p=0.003) and control conditions; no interaction effect

*Table 3 continues*

Table 3 continued

<b>Author, Year and Country</b>	<b>Research Aim</b>	<b>Study Design</b>	<b>Sample Characteristics</b>	<b>Intervention Type</b>	<b>Outcome Measure for DRD</b>	<b>Follow-Up</b>	<b>Changes to Glycaemic Control</b>	<b>Findings Related to DRD</b>
Beverly et al. (2013b) USA	To explore whether older adults (aged 60-75 years), with type 1 or type 2 diabetes, benefit from self-management interventions similarly to younger and middle-aged adults	Three-arm RCT (secondary analysis); two control conditions: 1) group educational attentional control 2) individual educational attentional control	N = 222; mean age =53; mean HbA1c = 9.0; mean diabetes duration = 18 years; 51% type 2 diabetes	<b>Self-management Group and individual Face-to-face</b>  A manual-based group programme of specific cognitive behavioural strategies and techniques for implementing self-care behaviours; five group sessions	PAID (secondary outcome)	12m	Improved over time for both older and younger participants	Main time effect for older and younger participants; no interaction effect
Dale et al. (2008) UK	To measure the effectiveness of a peer telephone intervention to enhance self-efficacy in type 2 diabetes	Three-arm RCT; usual care control	N = 231; 100% type 2 diabetes	<b>Self-management Individual Telephone</b>  Two experimental conditions: 1) one to six telephone calls over 150 days from diabetes specialist nurses; intended to motivate treatment adherence 2) the same intervention delivered by peer supporters	PAID (secondary outcome)	6m	No differences	Main time effect for diabetes specialist nurse condition; no interaction effect

Table 3 continues

Table 3 continued

Author, Year and Country	Research Aim	Study Design	Sample Characteristics	Intervention Type	Outcome Measure for DRD	Follow-Up	Changes to Glycaemic Control	Findings Related to DRD
D'Eramo Melkus et al. (2010) USA	To explore if a culturally relevant diabetes intervention will have greater impact on outcomes than conventional care in Black American women	Two-arm RCT; attentional group diabetes educational control	N=109; Black American women; mean age = 45 (control) & 47 (intervention); mean HbA1c = 8.3 (control) & 8.0 (intervention); 100% type 2 diabetes	<b>Self-management Group Face-to-face</b>  Twelve group sessions; culturally adapted intervention of diabetes self-management, coping skills training and diabetes care	PAID (secondary outcome)	24m	Improved over time in both the experimental and control groups	Time by group interaction effect (p =.01)
Gabbay et al. (2006) USA	To study the impact of nurse case management (NCM) on blood pressure, HbA1C and diabetes complication screening	Two-arm RCT; usual care control	N=332; Mean age = 64 (control) & 65 (intervention); Mean duration = 9 years (control) & 10 years (intervention); 95% type 2 diabetes	<b>Self-management Individual Face-to-face and telephone</b>  Sessions at least once every four months for a year; additional nurse case management, including self-management education, behavioural goal setting, establishing individualised plan, and phone calls to patient	PAID (secondary outcome)	12m	No differences	Main time effect for experimental condition; PAID scores not measured in control group; no interaction effect

Table 3 continues

Table 3 continued

Author, Year and Country	Research Aim	Study Design	Sample Characteristics	Intervention Type	Outcome Measure for DRD	Follow-Up	Changes to Glycaemic Control	Findings Related to DRD
Hermanns et al. (2012) Germany	To compare the effect of a diabetes education programme involving intensive insulin treatment for people with T2DM against an established education programme	Two-arm RCT; active comparator control	N=186; mean age = 63.9 (control) & 62 (intervention); mean diabetes duration = 13.6 (control) & 13.8 (intervention); 100% type 2 diabetes	<b>Self-management Group</b> <b>Face-to-face</b>  Ten group intervention sessions to help patients perform multiple injection insulin therapy and to adjust doses depending on different circumstances; addresses personal barriers (including attitudes and personal perceptions of diabetes) to treatment goals	PAID (primary outcome)	6m	Improved over time	Time by group interaction effect (p =.031)

Table 3 continues

Table 3 continued

<b>Author, Year and Country</b>	<b>Research Aim</b>	<b>Study Design</b>	<b>Sample Characteristics</b>	<b>Intervention Type</b>	<b>Outcome Measure for DRD</b>	<b>Follow-Up</b>	<b>Changes to Glycaemic Control</b>	<b>Findings Related to DRD</b>
Lerman et al. (2009) Mexico	To assess two different reinforcement strategies for diabetes self-care management, psychological distress and glycaemic control in a one year follow-up study	Three-arm RCT; usual care control	N= 70; age range = 30-75 years; 100% type 2 diabetes	<p><b>Self-management Group and individual Telephone and face-to-face</b></p> <p>Two experimental conditions:</p> <ol style="list-style-type: none"> <li>1) group reinforcement after six months: one, five-hour session with five to six patients to strengthen self-care behaviours, problem-solve, relate personal experiences and increase QOL</li> <li>2) monthly group reinforcement: contacted monthly over the telephone by doctor to promote self-care behaviours and problem solve</li> </ol>	PAID (secondary outcome)	12m	No differences	No main or interaction effects

Table 3 continues

Table 3 continued

<b>Author, Year and Country</b>	<b>Research Aim</b>	<b>Study Design</b>	<b>Sample Characteristics</b>	<b>Intervention Type</b>	<b>Outcome Measure for DRD</b>	<b>Follow-Up</b>	<b>Changes to Glycaemic Control</b>	<b>Findings Related to DRD</b>
Munshi et al. (2013) USA	To evaluate whether assessment of barriers to self-care and strategies to cope with these barriers in older adults with diabetes is superior to usual care	Three-arm RCT; attentional telephone call control	N=100; mean age = 75; mean duration = 21; 68% type 2 diabetes	<b>Self-management Individual Telephone and face-to-face</b>  Two experimental conditions: 1) Up to 11 telephone calls from diabetes educators, plus one home visit; helped patients to address and overcome barriers to self-care 2) One home visit and as many telephone calls as needed in 6 months to address and overcome barriers to self-care. Delivered by a non-health professional	PAID (secondary outcome)	12m	Improved over time	Main time effect for control group and both experimental conditions; no interaction effect

Table 3 continues



Table 3 continued

Author, Year and Country	Research Aim	Study Design	Sample Characteristics	Intervention Type	Outcome Measure for DRD	Follow-Up	Changes to Glycaemic Control	Findings Related to DRD
Sinclair et al. (2013) USA	To pilot test the effectiveness of a culturally adapted diabetes self-management intervention	Two-arm RCT; waiting list control	N=82; native Hawaiians and Pacific Islanders; mean age = 52 (intervention) & 55 (control); 100% type 2 diabetes	<b>Self-management Group</b> <b>Face-to-face</b>  Twelve group, culturally adapted intervention sessions aimed at increasing participants' understanding and practise of self-management activities, their self-efficacy and emotional coping; delivered by peer educators in the local language.	PAID (secondary outcome)	3m	Improved over time	Time by group interaction effect (p =.04) in complete case analysis
Sperl-Hillen et al. (2013) USA	To evaluate whether outcomes from diabetes self-management education for patients with suboptimal control were sustained	Three-arm RCT; usual care control  Individual education (IE), group education with US diabetes conversation maps (GE) or usual care (UC) with no education	N=623; mean age = 62; mean duration of diabetes = 11.7 years; 100% type 2 diabetes	<b>Self-management Individual/group sessions</b> <b>Face-to-face and computer</b>  Two experimental conditions: 1) Individual education: one hour sessions, one month apart; focused on needs, concerns, evaluation of progress and setting goals 2) Group education: four, two hour sessions, 1 week apart; aimed to help patients overcome barriers to self-management	PAID (secondary outcome)	10m	No differences	Main time effect for control group and both experimental conditions; no interaction effect

Table 3 continues

Table 3 continued

<b>Author, Year and Country</b>	<b>Research Aim</b>	<b>Study Design</b>	<b>Sample Characteristics</b>	<b>Intervention Type</b>	<b>Outcome Measure for DRD</b>	<b>Follow-Up</b>	<b>Changes to Glycaemic Control</b>	<b>Findings Related to DRD</b>
Van der Wulp et al. (2012) The Netherlands	To study the effectiveness of a peer-led self-management coaching intervention in recently diagnosed patients with type 2 diabetes	Two-arm RCT; usual care control	N = 332; mean age = 61; Duration of diabetes= 8 years; 100% type 2 diabetes	<b>Self-management Individual Face-to-face and telephone</b>  Coaching by expert patients; three monthly visits with telephone contact in-between; aimed to improve self-efficacy, physical activity and dietary habits; use of a script with discussion topics and exercises on lifestyle changes and diabetes; included goal setting and motivational interviewing	PAID (secondary)	6m	Not reported	No main or interaction effects
Weigner et al. (2011) USA	To test the efficacy of a behavioural diabetes intervention in improving glycaemia in long-duration poorly controlled diabetes	Three-arm RCT; two control conditions: 1) group educational attentional control 2) individual educational attentional control	N = 222; mean Age =53; Mean HbA1c = 9.0; mean diabetes duration = 18 years; 51% type 2 diabetes	<b>Self-management Group and individual Face-to-face</b>  A manual-based group programme of specific cognitive behavioural strategies and techniques for implementing self-care behaviours; five group sessions	PAID (secondary outcome)	12m	Improved over time in control and intervention groups	Main time effect for control and intervention groups; no interaction effect

Table 3 continues

Table 3 continued

<b>Author, Year and Country</b>	<b>Research Aim</b>	<b>Study Design</b>	<b>Sample Characteristics</b>	<b>Intervention Type</b>	<b>Outcome Measure for DRD</b>	<b>Follow-Up</b>	<b>Changes to Glycaemic Control</b>	<b>Findings Related to DRD</b>
Welch et al. (2011) USA	To evaluate the clinical usefulness of a nurse-led diabetes care programme (Comprehensive Diabetes Management) for poorly controlled Hispanic type 2 diabetes patients	Two-arm RCT; attentional control	N = 46; Hispanic; mean age = 55.8; diabetes duration = 11.9; 100% type 2 diabetes	<b>Self-management Individual Face-to-face and computer</b>  Seven, one-hour diabetes care visits over 12 months, conducted by bilingual team; use of an interactive web-based diabetes management tool to guide education and behaviour change; identifies psychosocial and attitudinal barriers to facilitate discussion	PAID (secondary outcome)	12m	Improved over time	Time by group interaction (P=.05)
Whittemore et al. (2004) USA	To determine the efficacy of a 6 month nurse coaching intervention that was provided after diabetes education for women with type 2 diabetes	Two-arm RCT; usual care control	N=53; mean age = 57.6; mean diabetes duration = 2.7; 100% type 2 diabetes	<b>Self-management Individual Face-to-face and telephone</b>  Nurse-coaching intervention. Six sessions over 6 months and two brief phone calls; educating, identifying barriers, problem solving, goal setting and providing psychosocial support	PAID (primary outcome)	6m	Improved over time	Time by group interaction (P<.01)

Table 3 continues

Table 3 continued

Author, Year and Country	Research Aim	Study Design	Sample Characteristics	Intervention Type	Outcome Measure for DRD	Follow-Up	Changes to Glycaemic Control	Findings Related to DRD
<b>Educational Interventions</b>								
Fisher et al. (2011) USA	To test whether a structured self-monitoring of blood glucose protocol reduces depression and diabetes-distress	Two-arm RCT; enhanced usual care control	N = 483; Mean age = 55.8; HbA1c = 8.9; Diabetes duration = 7.6 years; 100% type 2 diabetes	<b>Educational Individual Face-to-face</b>  Five individual visits in 12 months. A structured SMBG intervention; education glycaemic patterns and training on how to address them	DDS (primary outcome)	12m	Not reported	Main time effect for experimental and control conditions ( $p < 0.001$ ); no interaction effect
McMahon et al. (2012) USA	To investigate whether telephone or online care management improves diabetes-related outcomes	Three-arm RCT; usual care control supplemented with internet access and training	N=151; mean age = 60 100% type 2 diabetes	<b>Educational Individual Telephone and computer</b>  Two experimental conditions: 1) telephone-based care management: use of software to log and track results; biweekly calls to review progress, reinforce self-care 2) online care management: Asked to log-in to internet-based care management programme bi-weekly; reviewed online by care managers	PAID (secondary outcome)	12m	Improved over time	Main time effect for control group and telephone based care management; no interaction effect

Table 3 continues

Table 3 continued

<b>Author, Year and Country</b>	<b>Research Aim</b>	<b>Study Design</b>	<b>Sample Characteristics</b>	<b>Intervention Type</b>	<b>Outcome Measure for DRD</b>	<b>Follow-Up</b>	<b>Changes to Glycaemic Control</b>	<b>Findings Related to DRD</b>
Quinn et al. (2011) USA	To test whether adding mobile application coaching and patient/provider web portals to community primary care, compared with standard diabetes management, would reduce glycated haemoglobin levels in patients with type 2 diabetes	Four-arm RCT; usual care control	N = 163; mean age = 52.8; mean duration of diabetes: 8.2 years; 100% type 2 diabetes	<b>Educational Individual Telephone and computer</b>  Three experimental conditions: 1) coach only: use of a mobile-based diabetes coaching system 2) coach primary care provider (PCP) portal: use of an internet-based coaching system 3) coach PCP portal with decision support: use of internet-based system with access to evidence-based guidelines	DDS (secondary outcome)	12m	Improved over time	No main or interaction effects

Table 3 continues

Table 3 continued

Author, Year and Country	Research Aim	Study Design	Sample Characteristics	Intervention Type	Outcome Measure for DRD	Follow-Up	Changes to Glycaemic Control	Findings Related to DRD
<b>Psychological Interventions</b>								
Sturt et al. (2008) UK	To determine the effects of a diabetes manual on glycaemic control, diabetes-related distress and confidence to self-care of patients with type 2 diabetes	Two-arm RCT; 6 month delayed intervention control	N=245; mean age = 62; 100% type 2 diabetes	<b>Psychological Individual Face-to-face, telephone &amp; workbook</b>  15 minute face-to-face consultation followed by 12 weeks working through a diabetes manual with telephone support on week 3; manual was based on social learning theory and aimed to enhance strategies such as positive-experiences mastery, vicarious learning, emotional adjustment and verbal persuasion	PAID (primary outcome)	26 weeks	No differences	Time by group interaction (p=0.012)

Table 3 continues

Table 3 continued

Author, Year and Country	Research Aim	Study Design	Sample Characteristics	Intervention Type	Outcome Measure for DRD	Follow-Up	Changes to Glycaemic Control	Findings Related to DRD
van Bastelaar et al. (2011) The Netherlands	To evaluate the effectiveness of web-based CBT for depression treatment in adults with type 1 or type 2 diabetes, with minimal guidance	Two-arm RCT; waiting list control	N=255; mean age = 50; 55% type 2 diabetes	<b>Psychological Individual Computer</b>  Web-based CBT: eight sessions of written and spoken information; skill development in relaxation, cognitive restructuring, positive reinforcement, communication skills and increasing pleasant activities; Health psychologists provided feedback on homework assignments	PAID (secondary)	1m	No differences	Time by group interaction (P<0.001)
van Son et al. (2013) The Netherlands	To determine the effectiveness of group therapy with Mindfulness-Based Cognitive Therapy (MBCT), relative to usual care for patients with diabetes	Two arm RCT; waiting list control	N=139; mean age = 56 (intervention) & 57 (control); HbA1c = 7.5 (intervention) & 7.6 (control); 69.7% type 2 diabetes	<b>Psychological Group Face to face</b>  Eight weekly, two hour sessions; four to ten participants; based on mindfulness-based stress reduction and cognitive therapy programmes; aimed at developing mindfulness with meditation exercises	PAID (primary outcome)	8 weeks	No differences	Main time effect for intervention group; no interaction effect

Note: DRD = Diabetes-related Distress; PAID = Problem Areas in Diabetes Scale; DDS = Diabetes Distress Scale

## **Quality Assessment of Included Studies**

Table 4 displays the results of the EPHPP quality ratings of the included studies. The overall quality of the studies was good with ten studies achieving a moderate rating and eight being rated as strong. The ratings given for selection bias showed that the selected individuals in the majority of the studies (80%) were at least somewhat likely to be representative of the target population and generally more than 60% of the individuals agreed to participate. Most of these studies selected participants using systematic referrals from a clinic or GP practice. Six studies included individuals that were not likely to be representative of the target population, either because they self-referred into the study or because more than 40% of them declined to participate. Only one study was rated strong in relation to selection bias and this was because they randomly selected from a comprehensive list of individuals in the target population.

In accordance with the inclusion criteria, all 20 studies used a randomised control trial (RCT) design. However, two of the studies did not describe their method of randomisation and therefore achieved a study design rating of weak. The remaining 18 studies were rated as strong. The studies were also rated on whether the authors reported important differences between groups prior to the intervention and what percentage of these confounders was controlled for. Ten of the studies reported and controlled for over 80% of cofounders and were rated as strong. Four of the studies were rated as moderate as they only controlled for some of the cofounders; and six studies achieved a weak rating as they controlled for 60% or less of the cofounders.

All of the studies achieved a moderate rating with regards to the 'blinding' component. All except for three studies made no mention of blinding and, in the three that did mention it, they either mentioned blinding of the assessor or study participants but not both. All of the studies were rated strong in the 'data collection



Table 4

*Quality Assessment of Reviewed Studies*

<b>Study</b>	<b>Selection Bias</b>	<b>Study Design</b>	<b>Confounders</b>	<b>Blinding</b>	<b>Data Collection Methods</b>	<b>Withdrawals and Drop-Outs</b>	<b>Total Score</b>	<b>Global Rating</b>
<b><i>Self-Management Interventions</i></b>								
Beverley et al. (2013a)	Moderate	Strong	Weak	Moderate	Strong	Strong	1.67	Moderate
Beverley et al (2013b)	Moderate	Strong	Strong	Moderate	Strong	Strong	1.33	Strong
Dale et al. (2009)	Moderate	Strong	Weak	Moderate	Strong	Strong	1.67	Moderate
D'Eramo Melkus et al. (2010)	Strong	Strong	Weak	Moderate	Strong	Moderate	1.67	Moderate
Gabbay et al. (2006)	Moderate	Strong	Weak	Moderate	Strong	Weak	2.00	Weak
Hermanns et al. (2012)	Moderate	Strong	Moderate	Moderate	Strong	Strong	1.50	Strong
Lerman et al. (2009)	Moderate	Weak	Weak	Moderate	Strong	Strong	2.00	Weak
Munshi, et al. (2013)	Moderate	Strong	Strong	Moderate	Strong	Strong	1.33	Strong
Sinclair, et al. (2013)	Weak	Strong	Strong	Moderate	Strong	Moderate	1.67	Moderate
Sperl-Hillen et al. (2013)	Weak	Strong	Strong	Moderate	Strong	Strong	1.5	Moderate
Van der Wulp et al. (2012)	Weak	Strong	Moderate	Moderate	Strong	Strong	1.67	Moderate
Weigner et al. (2011)	Moderate	Strong	Strong	Moderate	Strong	Strong	1.33	Strong
Welch et al. (2011)	Moderate	Strong	Weak	Moderate	Strong	Strong	1.67	Moderate
Whittemore et al. (2004)	Moderate	Weak	Strong	Moderate	Strong	Strong	1.67	Moderate
<b><i>Educational Interventions</i></b>								
Fisher et al. (2011)	Moderate	Strong	Strong	Moderate	Strong	Moderate	1.50	Strong
McMahon et al. (2012)	Moderate	Strong	Moderate	Moderate	Strong	Strong	1.50	Strong
Quinn, et al. (2011)	Weak	Strong	Strong	Moderate	Strong	Moderate	1.67	Moderate
<b><i>Psychological Interventions</i></b>								
Sturt et al. (2008)	Moderate	Strong	Strong	Moderate	Strong	Weak	1.67	Moderate
van Bastelaar et al. (2011)	Weak	Strong	Moderate	Moderate	Strong	Moderate	1.83	Moderate
van Son et al. (2013)	Weak	Strong	Strong	Moderate	Strong	Strong	1.50	Moderate

*Note.* Total score average of six domain scores, maximum = 3; Higher = weaker quality

methods' component as the majority of outcome measures used were shown to be valid and reliable. In relation to withdrawals and drop-outs, the majority of the studies did very well. The follow-up rate for 13 of the studies was 80% or greater, and for five studies it was between 60-79%. Only two studies achieved a rating of weak in this component as their follow-up rate was less than 60%.

The EPHPP quality assessment tool also takes into account intervention integrity by considering the percentage of participants who received the allocated intervention and the consistency of the intervention measured. Thirteen studies reported that 80% or more of their participants received the complete intervention. Twelve studies described a method of measuring consistency of the delivery of the intervention. None reported contamination of the intervention that may have influenced the results. Finally, all of the studies used a quantitative analysis that was appropriate to the research question being asked and thirteen studies included an intention-to-treat analysis.

### **Self-Management Interventions**

Out of the 14 self-management intervention studies, five showed a reduction in diabetes-related distress over time which was superior to the control group (i.e. a group by time interaction), indicating that the intervention was beneficial. Seven studies showed a reduction over time of DRD but no differences from the control group (i.e. a main effect). Two studies showed neither main nor group by time interaction effects.

#### *Group Interventions*

Out of the four group-based self-management interventions, three showed that their interventions were superior to the control and one showed that it reduced DRD but not more so than the control. One group intervention involved educating participants around intensive insulin treatment for people with type 2 diabetes (Hermanns, Kulzer, Maier, Mahr & Haak, 2012). As well as providing information on

insulin therapy, they also helped to problem-solve barriers to treatment goals and addressed problematic attitudes towards their diabetes treatment. This intervention showed superiority compared to the active comparator condition group in reducing DRD. Another study, by D'Eramo Melkus et al. (2010), looked at whether a 12 week, culturally adapted, self-management and coping skills group could produce better outcomes in Black American women than conventional care. They found that the intervention group participants sustained lower levels of DRD at 24 months follow-up compared to the control group participants. Sinclair et al. (2013) also used a culturally adapted group intervention for Native Hawaiians and Pacific Islanders. This Intervention used techniques based on social cognitive theory to help participants build self-efficacy in relation to their self-management capabilities. In a completed case analysis only, this intervention group showed a significant reduction in DRD in comparison to a waiting-list control group.

The self-management group intervention which failed to show a superior reduction in DRD to the control group was by Beverley et al. (2013a). This study used a structured group programme to reinforce the knowledge that participants had already gained on a prior diabetes educational course. The intervention group consisted of four one-hour sessions and educators facilitated discussions around diabetes self-care and goal setting. The control group consisted of an education group on blood pressure and cholesterol. Both groups showed a reduction in DRD.

#### *Individual Interventions*

Six self-management interventions were delivered on an individual basis, two of which showed reductions in DRD over time which were superior to the control group (i.e. a group by time interaction effect), three showed reductions over time in DRD but with no differences from the control group (i.e. a main effect) and one showed neither a main nor interaction effect.

The two individual interventions which showed a group by time interaction were both supplemented by the use of a telephone or computer. In another culturally adapted study by Welch et al. (2011), bilingual nurses visited Hispanic participants at home and used an interactive web-based diabetes management tool with them. The tool aggregated and displayed clinical data and helped to guide treatment decisions. It also identified psychosocial barriers in order to facilitate educational discussions. The other individual format intervention included six one-to-one self-management coaching sessions with a nurse and two telephone calls over a six month period (Whittemore, D'Eramo Melkus, Sullivan & Grey, 2004).

The three individual interventions which only showed a main effect and no interaction effect, all made use of telephone communication. One of these interventions involved using telephone support delivered either by a peer or a diabetes specialist nurse (Dale, Caramlau, Sturt, Friede & Walker, 2009). The support aimed to motivate adherence to advice from the GP and enhance self-efficacy. The control group just received calls from a researcher and were informed they were in the routine care group. Only the diabetes specialist nurse telephone intervention group showed a reduction in DRD, though the p value was not reported and there were no significant differences between the control or peer support group. Another study described an individual intervention aimed at older adults (Munshi et al. 2013). Members from a geriatric diabetes team helped patients to identify barriers and optimise abilities in self-care. The intervention was either delivered over the telephone or in face-to-face home visits. The control group received phone calls from an educator but only discussed non-diabetes-related life events. There was a statistically significant reduction in DRD in the control group and the two intervention groups and no differences between groups. The final individual intervention study involved participants with both type 2 (95%) and type 1 diabetes and explored the impact of the addition of nurse case-management to usual care (Gabbay et al.,

2006). The nurse had face-to-face and telephone contact with the participant to educate them regarding self-management and also to help set goals, establish plans and make onward referrals where necessary. The control group received usual care and did not complete measures of DRD, which was a serious weakness in the study's methodology. The intervention group was reported as showing a statistically significant reduction in their distress, though p values were not reported. This study received an overall weak rating in the EPHP quality assessment as it did not report any control of confounding variables or any details of drop-outs.

One individual intervention study showed no significant difference in the participants' levels of distress. This study compared a peer-led self-management coaching intervention to care as usual (Van der Wulp, de Leeuw, Gorter & Rutten 2012). Participants reported low levels of DRD at baseline, which limited the change that could have occurred.

#### *Group and Individual Interventions*

Four studies combined both group and individual approaches in their intervention. Sperl-Hillen et al. (2013) compared individual diabetes education, group diabetes education and usual care with no education (control). All three groups showed a reduction in DRD, with no significant differences between groups. Similarly, Weigner et al. (2011) compared a structured group intervention with CBT strategies to individual nurse and dietician education sessions and an attention control group education programme. This study included participants with both type 1 (49%) and type 2 diabetes. Again, all three groups showed a reduction in DRD that was not superior to the control. Beverley et al. (2013b) conducted a secondary analysis based on the RCT by Weigner et al. (2011) and explored the difference in outcomes between the older and younger participants. Both older and younger participants showed a significant reduction in DRD and there was no difference between the age groups.

One study which combined individual and group interventions showed no main or group by time interaction effects. The study by Lerman et al. (2009) looked at interventions involving two different types of reinforcement strategies following diabetes education. One intervention arm involved a group session lasting 5 hours and the other arm involved monthly phone contacts for six months. No significant changes occurred to the participants' levels of DRD. This study was rated weak overall in the EPHPP quality assessment as the authors did not describe their method of randomisation and confounders were not controlled for.

In summary, 14 self-management intervention studies were identified. Four of these interventions were group-based, three of which showed a reduction in DRD which was superior to the control group. Six were individual interventions, two of which showed superiority to the control group. Out of the four interventions which combined both group and individual approaches, none showed reductions in DRD that were superior to the control.

### **Educational Interventions**

The three educational interventions were all based on an individual approach. Two showed a main effect but no differences with the control group and one showed neither a main nor group by time interaction effect. One study by Fisher, et al. (2011) tested whether educating people on how to follow a structured regime of self-monitoring blood glucose could reduce DRD. Participants were taught to identify problematic glycaemic patterns and how to address them. The control group received the same enhanced usual care pattern but without the training around self-monitoring of blood glucose. Both the experimental and control group showed a reduction in DRD but no superiority to the control. However, the authors did report that the participants in their experimental group with elevated distress at baseline showed a greater reduction in DRD than their control participants, which may indicate a regression to the mean.

McMahon, Fonda, Gomes, Alexis and Conlin (2012) compared online- and telephone-based care management with a control group which consisted of internet training alone. Both the online and telephone care management techniques involved monitoring glucose readings with participants and educating them on lifestyle and medication modifications. There was a reduction in DRD in the control group and the telephone case-management group but no interaction effects. The final educational study did not show a reduction in diabetes distress. Quinn et al. (2011) tested whether adding a mobile coaching application and patient/provider web portals to community primary care could reduce glycosylated haemoglobin levels compared to standard diabetes management. This four arm RCT, consisted of a usual care control group, a coach only group, a coach with patient/provider web portal group and a coach with patient/provider web portal with additional decision support group. The patient/provider web portal allowed self-care data to be entered and automated relevant educational messages to be sent back to the patient. None of the groups showed a reduction in DRD.

In summary, three individual educational interventions were identified; two showed a main effect of time but no superiority to the control group and one showed no reductions in DRD.

## **Psychological Interventions**

### *Group Interventions*

Three studies used psychological interventions. One used a group approach (van Son et al., 2013). The aim of the study was to determine the effectiveness of group therapy with Mindfulness-Based Cognitive Therapy (MBCT) compared to usual care. MBCT involves the development of mindfulness through practising meditation exercises. The intervention group showed a reduction in DRD but no difference from the control group.

### *Individual Interventions*

Two of the psychological studies used an individual approach and showed a reduction in DRD which was superior to the control. An intervention used by Sturt et al. (2008) involved a diabetes manual based on social learning theory and aimed at enhancing self-efficacy. Strategies in the manual included positive experiences mastery, vicarious learning and emotional adjustment. The control consisted of a six month delayed intervention group. At follow up, DRD scores were lower in the intervention group compared with the control group. Another psychological intervention by van Bastelaar, Pouter, Cuijpers, Riper and Snoek (2011) evaluated the effectiveness of a web-based CBT for depression treatment in adults with type 1 and type 2 diabetes (55%). Compared to a 12 week waiting list control group, the intervention group showed a significant reduction in DRD.

In summary, three psychological interventions were identified. One used a group approach and did not show a superior reduction in DRD compared to the control group; and two used individual approaches and both did show a greater reduction in DRD compared to the control group.

### **Summary**

Out of the 14 self-management intervention studies, five showed a reduction in DRD which was superior to the control group (i.e. a group by time interaction effect). Four out of these five interventions were group-based and one was individualised. Three of these successful self-management interventions were culturally adapted. None of the educational interventions showed a reduction in DRD which was superior to the control. Out of the three psychological interventions, the two that showed greater reductions in DRD compared to the control group both used individual, rather than group approaches. None of the interventions showed evidence of negative effects on the participants.



## Discussion

Seven out of the 20 studies reported a greater reduction in DRD compared to a control group (i.e. a group by time interaction effect). Ten of the remaining studies showed a reduction in DRD over time but showed no difference to the control group (a main effect) and three studies did not show any differences in DRD scores. From the seven studies that showed an interaction effect, five used group or individual self-management interventions and two used individual psychological interventions. The evidence suggests that these types of interventions may reduce DRD. However, it is difficult to draw conclusions regarding the specific components of the interventions which impacted DRD, as this was not described by any of the studies.

One factor that distinguished three of the successful interventions was that they were culturally adapted. Several previous reviews have demonstrated the efficacy of culturally enhanced health interventions for improving diabetes outcomes (e.g. Hawthorne, Robles, Cannings-John & Edward, 2010; Sarkisian, Brown, Norris, Wintz & Mangione, 2003). In a systematic review of diabetes interventions for socially disadvantaged populations, the authors concluded that cultural enhancement was associated with positive outcomes such as improved HbA1c levels, lipids and blood pressure (Glazier, Bajcar, Kenne & Wilson, 2006). However, previous reviews have not looked specifically at the effect of cultural adaptation on DRD.

Within the group self-management interventions, one factor that may have influenced the reduction of DRD was the duration of the group. The three studies which showed a group by time interaction all involved groups which ran for 10 to 12 weeks (D'Eramo Malkus et al., 2010; Sinclair et al., 2013; Hermanns et al., 2012). The one group self-management intervention which did not produce an interaction effect, only a main effect, only ran four one-hour sessions (Beverley et al., 2013a).

A similar pattern was found within the individual self-management interventions. The two interventions which showed an interaction effect involved seven one-hour visits (Welch et al., 2011) and six face-to-face sessions plus two telephone calls (Whittemore, et al., 2004). The self-management interventions which showed a main effect only, involved shorter or fewer contacts. One involved six calls of approximately 13 minutes on average over 150 days (Dale et al, 2008); one offered up to 11 calls of approximately 12 minutes duration over six months (Munshi, et al., 2013); and another only offered 4 sessions in one year (Gabbay, et al, 2006). The individual self-management intervention which did not show any significant findings only offered three one-hour home visits (van der Wulp et al, 2012).

In relation to the content of the self-management interventions, similar techniques were used within both the interventions which showed an interaction effect and the interventions that showed only a main effect. They all involved elements of goal setting and identifying and addressing barriers to self-care. Within the group self-management interventions, the three studies which showed an interaction effect all aimed to increase the participant's self-efficacy in relation to their diabetes management and involved an element of addressing emotional coping. The one group intervention that did not show an interaction effect, did not address self-efficacy or coping skills. Ten out of the 14 self-management interventions included a focus on psychosocial factors relating to diabetes management, e.g. self-efficacy, social support, motivation. The four studies that did not report addressing psychosocial factors all showed a main effect but not an interaction effect (Gabbay et al., 2006; Beverley et al. 2013; Weigner et al, 2011; Beverley et al. 2013). All of the psychological interventions and none of the educational interventions addressed psychosocial factors and none of the educational interventions reported an interaction effect.

All of the self-management interventions which showed an interaction effect also showed a significant improvement in glycaemic control. It is not possible to discern from the studies whether an improvement in control is related to a reduction in DRD. However, based on previously mentioned research, one could hypothesise that this may be the case (Zagarins et al., 2012). Interestingly the psychological interventions which showed an interaction effect did not produce any changes in glycaemic control. One may therefore hypothesise that a different mechanism of change took place within these interventions.

Out of the 10 studies which found a main effect but no interaction effect, seven of them reported that their control group showed a reduction in DRD. Out of these seven studies, five used attentional control or enhanced usual care groups, rather than treatment as usual. The provision of increased contact with health professionals, regardless of the nature of the contact, seemed to be enough to reduce DRD. This may relate to gaining an increased sense of social support.

### **Methodological Quality**

Overall the studies had good quality methodologies, which allowed for greater confidence in the findings described above. The review included RCT designs only, which is the 'gold standard' design within outcome research. However, most of the studies (18) showed at least one area of design weakness. For 12 of the studies this weakness was found in either their selection bias and or their apparent lack of control of confounders. Six of the studies were rated as weak for selection bias as the participants were not likely to be representative of the target population, due to self-referring or more than 40% declining to participate. The existence of a selection bias may pose a threat to the studies' internal validity. Another six studies either did not mention any strategies for controlling confounders or seemed to control for fewer than 60% of them. It is therefore less clear whether the outcomes from these studies were due to the intervention and or other associated variables.

Future studies could therefore be improved by reducing selection bias and control of confounders.

Another area of methodological concern relates to the intervention integrity. Only 11 of the 20 studies reported methods of monitoring the consistency of the intervention being delivered. This is an important aspect of the methodology as it increases the likelihood that the participants are receiving the same intervention. Future work should include monitoring of intervention delivery and strategies to ensure consistency.

Despite these areas of weakness, the majority of studies reported randomisation strategies (18), used intention to treat analyses (13), described response and dropout rates (19) and outlined and used appropriate outcome measures and statistical methods (20). The EPHP critical appraisal tool allowed for each of these areas to be assessed systematically. There were, however, limitations to this tool, which meant that it did not cover all aspects of method quality assessment. As the outcome of interest, DRD, was measured as a secondary outcome in 13 of the studies, it was not always reported in full detail. One study (Beverley et al., 2013a) did not report scores from their PAID outcome measure for their control group. Another study did not collect DRD scores from their control group (Gabbay et al., 2006). Furthermore, the EPHPP did not consider study follow-up periods, making it harder to assess the long-term impact of an intervention. Sixteen of the studies had a follow up-period of 6 months or greater. However, four studies had follow-up periods of less than 6 months and one study only followed up after one month. Future research should ensure a sufficient follow-up period.

### **Limitations of the Review and Areas for Future Research**

The current review aimed to explore the type of interventions that could effectively reduce DRD. The review has shown that a number of different types of interventions can do this, including self-management and psychological, group and

individual, face-to-face and over-the-internet or telephone. However, due to the heterogeneous nature of the interventions, it has been difficult to draw conclusions regarding specific aspects of the interventions which impact DRD. None of the studies made hypotheses regarding the mechanisms of action that may have caused the DRD of their participants to decrease. This is related to the fact that distress was not the primary outcome of interest in any of the studies.

The review was also limited by the small number of RCT studies looking at reducing DRD. This is a relatively new construct and area of research. Due to the limited number of intervention studies, the inclusion criteria were relatively broad and therefore increased heterogeneity. With the emergence of further studies looking at DRD, it would be beneficial for future reviews to focus on particular types of interventions (e.g. self-management) and to explore the potential active components within them.

Another limitation of this review was that it did not report the effect sizes of the various interventions. As two different types of measures were used to capture DRD, this would have provided a means to compare the changes in scores reported by the different studies. However, six of the studies did not report the raw distress outcome scores for pre- and post- intervention for both the control and experimental groups. Therefore it would not have been possible to calculate effect sizes for these studies. Future studies could report effect sizes to allow for easier comparison of the interventions.

### **Clinical Implications**

DRD may be more influential than other mental states (e.g. depression) in predicting diabetes treatment adherence and metabolic control. It is therefore important to understand the types of interventions that may be effective in reducing DRD.

The current review has examined intervention studies which have included DRD as an outcome measure. The majority of the studies focused on metabolic markers (e.g. HbA1c) as a primary outcome measure and DRD as secondary. The interventions were therefore not specifically targeted towards distress.

Nevertheless, DRD was shown to reduce in 17 of the studies and group by time interaction effects were found in seven studies. We may therefore conclude that diabetes interventions can reduce DRD. Psychological and self-management interventions may be particularly effective, having produced interaction effects.

All of the self-management interventions that were successful in reducing DRD compared to the control group also showed a significant improvement in glycaemic control; whereas the psychological interventions which produced an interaction effect did not show any changes in glycaemic control. Although reduced DRD may positively impact a person's well-being, without improved glycaemic control, high or low blood sugar levels are likely to eventually impact a person's functioning, mood and also lead to future physical health complications (Katon et al., 2004). Reduced DRD may be an important first step for people to feel better able to manage their diabetes. However, the self-management interventions in the current review have shown that it is possible to improve both levels of DRD and glycaemic control concurrently. This may suggest that people with diabetes could benefit more from self-management interventions compared to psychological interventions.

Unfortunately the studies did not report hypotheses of which aspects of the interventions may have impacted DRD. Intervention patterns highlighted in this review suggest that factors associated with reduced DRD could include cultural adaption, intervention duration, targeting of psychosocial factors, improved glycaemic control and increased sense of social support. Further research should aim to elucidate the specific aspects of interventions which may reduce distress and thereby potentially reduce the risk of diabetes-related complications.

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## **Part 2: Empirical Paper**

### **The Impact of a Web-Based Self-Management Programme on the Psychological Well-Being of Adults with Type 2 Diabetes**



## **Abstract**

*Aim:* The psychological distress caused by living with type 2 diabetes is associated with an increased risk of long term health complications. Information and emotional support through diabetes self-management programmes are vital in helping adults with type 2 diabetes improve their quality of life. However, relatively few people attend these programmes. The current study aimed to explore the impact of a web-based, self-management programme on the psychological well-being of adults with type 2 diabetes.

*Method:* The study used a mixed method, quantitative and qualitative approach with eighteen participants. The quantitative aspect involved a pre-test, post-test, uncontrolled design, with measurement points at baseline and six-week follow-up. Diabetes-related distress was measured as a primary outcome. Secondary measures included anxiety, depression, diabetes-related self-efficacy, perceived social support and diabetes-related beliefs. Semi-structured interviews were conducted at both measurement points and analysed using thematic analysis.

*Results:* The quantitative measures did not show any differences in pre- and post- intervention scores in any of the measures. However, in the qualitative interviews, participants reported many psychological benefits gained from using the website. Reported improvements included increased diabetes-related self-efficacy, greater diabetes awareness and taking the condition more seriously.

*Conclusions:* The participant reports from the qualitative interviews suggest that a web-based self-management intervention can positively impact the psychological well-being of adults with type 2 diabetes. However, possibly due to the study's lack of statistical power, these psychological benefits were not captured by the quantitative measures. The psychological shifts described in the participant interviews, may improve glycaemic control and reduce the risk of diabetes-related complications.

Type 2 diabetes is a complex and challenging condition. In order to avoid serious physical complications, people living with diabetes have to meet constant behavioural demands (Russell, Suh & Safford, 2005). However the psychological burden of living with diabetes can create significant barriers to managing these demands and achieving treatment goals (Anderson et al., 2002; Peyrot, McMurry & Kruger, 1999). Facilitating diabetes self-management through provision of information and emotional support is an essential part of diabetes care (Marrero et al., 2013; Norris, Engelgau & Narayan, 2001).

Type 2 diabetes is a chronic metabolic disorder where the body does not produce enough insulin or the insulin that is produced does not work properly. It is distinct from type 1 diabetes in which the body is unable to produce any insulin. In people with untreated diabetes, glucose remains in the blood-stream rather than being absorbed by cells. High blood glucose levels can lead to long-term physical health complications such as cardiovascular diseases and renal failure. In 1996, the number of people in the UK diagnosed with both types of diabetes was 1.4 million; in 2012 this figure had more than doubled to three million (Diabetes UK, 2012). Possible causes may include increasingly sedentary lifestyles and rises in obesity. It is estimated that by 2025 five million people in the UK will have diabetes. Type 2 is the most common form of diabetes (approximately 90% of cases), and treatment involves a combination of lifestyle changes, weight loss, tablets and injections.

### **Psychological Impact of Diabetes**

The burden of living with type 2 diabetes can have a considerable impact on a person's psychological well-being (Hosoya, Matsushima, Nukariya & Utsunmiya, 2012). This may be particularly true in relation to receiving the diagnosis, starting on insulin injections and developing complications (Katon et al., 2004). People with diabetes are likely to feel under pressure to make substantial behavioural and lifestyle changes in order to meet treatment goals (Whittemore, Bak, Melkus & Grey,

2003). If overwhelmed by this pressure, one response may be to deny the condition or push it to one side, which may lead to a reduction in knowledge, awareness and skills needed to manage their diabetes (Garay-Sevilla, Malacara, Gutierrez-Roa & Gonzalez, 1999). Numerous studies have found that the prevalence of psychological difficulties such as anxiety and eating disorders are higher in people with diabetes than the general population (Grigsby, Anderson, Freedland, Clouse & Lustman, 2002; Lustman et al., 2000). The prevalence of depression is approximately twice as high (e.g. Anderson, Freedland, Clouse & Lustman, 2001).

The psychological well-being of people with type 2 diabetes can also be impacted by the progression of the condition. Type 2 diabetes can cause severe physical complications and reduce life expectancy by up to 10 years (Department of Health, 2001). People with diabetes have twice the risk of developing a range of cardiovascular diseases (ERFC, 2010) and twice the risk of stroke within the first five years of diagnosis compared with the general population (Jeerakathil, Johnson, Simpson & Majumdar, 2007). Diabetes is also the leading cause of renal failure (Ritz, Rychlik, Locatelli & Halimi, 1999) and blindness in people of working age (Arun, Ngugi, Lovelock & Taylor, 2003). It is the second most common cause of lower limb amputation (Department of Health, 2001). The National Diabetes Audit (The NHS Information Centre, 2011) showed that between 2009 and 2010, over 800,000 people in the UK with diabetes were at high risk of future complications due to glucose control not meeting the recommended levels.

Poor psychological well-being in people with diabetes is associated with suboptimal glycaemic control and increased risk of complications (e.g. Lustman et al., 2000; Polonsky et al., 1995). It is also associated with lower medication adherence, greater difficulties managing medical care and lost productivity (Das-Munshi et al., 2007). These findings highlight the importance of improving psychological well-being in people with type 2 diabetes. However, a survey called

'Minding the Gap' (Trigwell et al., 2008) showed 85% of people with diabetes in the UK have either no defined access to professional psychological help or at best have access to a local generic mental health service. The same survey showed that 41% of people with diabetes experience poor psychological well-being but do not meet the criteria for a referral to a psychology service or a formal mental health diagnosis. Similarly, another study showed that 44.6% of participants reported significant diabetes-related distress, but only 23.7% reported that their health care team had asked them how their diabetes impacted their life (Nicolucci et al., 2013). Self-management programmes provide an alternative approach to helping people with type 2 diabetes improve their psychological well-being (Clement, 1995).

### **Self-Management Programmes**

Self-management of long term conditions has become increasingly important in improving quality of life and maintaining independence. The evidence base of the effectiveness of self-care support for diabetes has recently been documented in NHS policy (Department of Health, 2005; 2007). In 2008, NICE advised that the delivery of structured self-management programmes (SMPs) within diabetes treatment was to be a key priority (National Collaborating Centre for Chronic Conditions, 2008).

The aims of structured education and SMPs are improving outcomes through addressing the individual's beliefs, improving quality of life, reducing depression, facilitating behaviour change, optimising metabolic control, addressing cardiovascular risk factors, and facilitating communication with health professionals (National Collaborating Centre for Chronic Conditions, 2008). Diabetes SMPs have shown to improve emotional well-being, quality of life and diabetes self-efficacy as well as other clinical outcomes such as glycaemic control (Fonda, McMahon, Gomes, Hicson & Conlin, 2009; Rubin, Peyrot & Saudek, 1989; Tankova, Dakovska

& Koev, 2004). They have also been found to lead to a four-fold reduction in the risk of complications (Nicolucci et al., 1996).

Examples of current SMPs in the UK include DESMOND (Davies et al., 2008), DAFNE (DAFNE study group, 2002) and X-PERT (Deakin, Cade, Williams & Greenwood, 2006). These face-to-face programmes have all shown to improve quality of life in the people who attend them. The DESMOND intervention has shown to lead to an increase in quality of life through a proposed mechanism of changing the attendees' beliefs about diabetes and the perception of their own self-efficacy to self-manage their condition (Skinner, et al. 2006). This intervention is based on Leventhal's Common Sense Theory (Leventhal, Brissette & Leventhal, 2003) and Social Learning Theory (Bandura, 1997). The DAFNE intervention proposed that increased dietary freedom is the active component in improving the attendee's quality of life. X-PERT did not define their active components relating to the improved psychological adjustment in their participants. They suggested that improvements could be due to a number of factors including the skills and motivation of the educator, peer support, visual aids and/or the 12 hour contact time the participants received (Deakin, Cade, Williams & Greenwood 2006).

The length, content and style of diabetes educational programmes can vary widely. Most educational programmes are unstructured and few have been formally evaluated (Deakin et al., 2006). For the structured programmes that have been evaluated, the outcomes are encouraging with regards to both psychological well-being and metabolic control. However, in 2006 only 11% of people with Type 2 diabetes reported being offered structured education (Healthcare Commission, 2007). This suggests that health care providers are encountering difficulties implementing and resourcing quality education programmes. Web-based SMPs may serve as one solution to this problem.

## **Web-Based Self-Management Programmes**

Web-based SMPs have been proposed as an effective manner of delivering high quality and low cost health services (Wanless, 2002). This is reflected in mainstream NHS policy (Department of Health, 2002; 2004) and the use of a number of SMPs within NHS Choices (the NHS's online health information service for the public). With approximately 73% of UK households having access to the internet (Dutton & Blank, 2011), web-based SMPs offer an accessible and convenient approach to facilitating diabetes self-management.

Advantages to web-based SMPs include being able to present information accessibly in simple graphics or audio-visual clips and to easily update information with the latest research available. They can also provide structured and on-going support to facilitate behaviour change, including individual assessment, goal setting, monitoring and feedback. This support is readily available in times of need, for example a change in medication regime or when struggling emotionally. Online support groups, as part of web-based SMPs for long term conditions, can help people normalise negative emotions such as depression and boost positive emotions like hope, self-efficacy and motivation. Additionally, sharing personal stories on line has been found to relieve social isolation, provide information in a meaningful way and increase coping ability (Murray, Kerr, Stevenson, Gore & Nazareth, 2007). Also, several studies have shown that diabetes specific web-based SMPs can improve health behaviours, clinical outcomes and psychological well-being (Glasgow, Boles, McKay, Feil & Barrera, 2003; Lorig et al., 2010; Wangberg, 2008).

## **Present Study**

The present mixed method study was centred around a newly developed, web-based, diabetes SMP, called HeLP-Diabetes (Healthy Living for People with type 2 Diabetes). This programme was developed by the E-Health Unit (EHU) at

UCL. It was part of a series of studies being conducted by the EHU to refine, trial and implement the programme. The project structure was based on the Medical Research Council (MRC) framework for designing and evaluating complex interventions to improve health care (Craig et al., 2008).

The HeLP-Diabetes research programme from EHU aimed to apply two NHS priority policies: the promotion of self-management by patients and the use of information and communication technologies to enhance quality and cost-effectiveness of care. The intervention has been informed by three main theoretical frameworks: self-management, behaviour change and Normalisation Process Theory. The self-management theoretical framework is based on a model of learning to live with a long term condition from Corbin and Strauss (1988). They describe three tasks required for this process: 1) medical/behavioural management, 2) role management, and 3) emotional management. The theoretical framework for behaviour change was developed by Abraham and Michie (2008). They advised categorising the determinants that drive health behaviour according to twelve domains and then selecting techniques with empirical support for each domain identified. Finally, Normalisation Process Theory focuses on work that individuals or groups have to do for an intervention to become normalised, or thoroughly embedded in routine practice (May et al., 2009).

### **The HeLP-Diabetes Programme**

HeLP-Diabetes is a web-based self-management programme aimed at helping people to look after themselves and take control of their diabetes so they can live healthier and happier lives ([www.help-diabetes.org.uk](http://www.help-diabetes.org.uk); see Appendix B for screen shots of the website). It was developed by a team of professionals in diabetes care and research, including General Practitioners (GPs), Psychologists, Sociologists, Researchers, Diabetes Nurses, Consultants and Dieticians. The programme consists of eight modules (see Table 1).

Table 1

*Help-Diabetes Module Names and Descriptions*

<b>Module Names</b>	<b>Descriptions</b>
Understanding Diabetes Treating Diabetes Living and Working with Diabetes	Three modules aimed at increasing the user's knowledge and skills, including how to gain and use social support.
Staying Healthy	Focused on behaviour change and aims to build self-efficacy with regards to diet, physical activity, taking medicine, reducing smoking and alcohol consumption and working with a diabetes care team.
Getting Help	Includes an interactive forum and personal stories of real people with type 2 diabetes. It aims to change illness representations through normalisation and the forum aims to increase support by facilitating communication between users.
My Health Record	A module that interacts with the user's health professional and contains the user's personal information.
Managing my Feelings	Contains a computerised cognitive behavioural therapy course called 'Living life to the full', which was adapted for people with diabetes by Dr Chris Williams (2014). This module aims to provide strategies to manage symptoms of anxiety and depression. It also contains information on mindfulness techniques.
News and Research	Provides the latest news articles, research trials and advice on media coverage about type 2 diabetes.

**Study Aims and Hypotheses**

The aim of the study was to explore the impact of the HeLP-Diabetes programme on the psychological well-being of adults with type 2 diabetes.

Specific study hypotheses and their theoretical rationale were as follows:

- 1) The knowledge and support gained from the HeLP-Diabetes programme would reduce the participants' diabetes-related distress. People living with diabetes



may experience distress around their diagnosis, potential and actual health complications, self-management burdens, difficult patient–provider relationships and many other aspects of their condition (Gonzalez et al., 2011). Diabetes-related distress refers to the emotional adjustment to these practical and psychosocial aspects of living with diabetes (Polonsky et al., 1995) and has been found to be associated with quality of life and glycaemic control (Aikens, 2012; Fisher et al., 2010; Zagarins, Allen, Garb & Welch, 2012).

2) The contents of HeLP-Diabetes, including personal accounts from people living with type 2 diabetes, would impact the beliefs or representations that the participants had about their condition. Leventhal’s Common Sense Model of Illness (Leventhal, Brissette & Levental, 2003) suggests that these are key determinants of people’s behavioural and emotional responses to their health condition. In a trial of the DESMOND intervention, participants’ beliefs and understanding of diabetes was shown to change and this was associated with improved quality of life and metabolic control (Skinner et al., 2006).

3) The information within the programme, and the manner in which it is conveyed, would help patients to gain a greater sense of control and self-efficacy over their diabetes. Social Learning Theory (Bandura, 1997) proposes that behavioural change is made possible by a personal sense of control and ‘the belief in one’s capabilities to organise and execute the course of action’ (Bandura, 1997). Increased self-efficacy in people with diabetes following intervention has also been found to be associated with improved quality of life and psychological well-being (Kuijjer & De Ridder, 2003; Rose, Fliege, Hildebrandt, Schirop & Klapp, 2002; Rubin, Peyrot & Saudek, 1989).

4) Techniques from Cognitive Behavioural Therapy (CBT; Beck, 1976) which are described in the website, would help participants to reduce levels of anxiety and/or depression. CBT has been recommended by the National Institute for Health

and Clinical Excellence as the treatment of choice for both of these mental health difficulties (NICE, 2009, 2011). A systematic review and meta-analysis of RCTs of psychological interventions showed that CBT for people with type 2 diabetes is effective in reducing psychological distress (Ismail, Winkley & Rabe-Hesketh, 2004).

5) The participants in the present study would benefit emotionally from an increase in perceived social support from the website. The Stress-Buffering Model of Social Support (Cohen, 2004) suggests that social support helps individuals cope with stress by reducing the stress-illness link and buffering the individual from the stressor. Social support for diabetic adults has shown to improve self-management and quality of life (Goz, Karaoz, Goz, Ekiz & Cetin, 2007; van Dam et al., 2005). A qualitative study reported that patients with type 2 diabetes believed that social support was a critical component of effective diabetes management (Miller & Davis, 2005).

## **Method**

### **Overview**

The study used a mixed method, quantitative and qualitative approach. The quantitative aspect involved a pre-test, post-test, uncontrolled design, with measurement points at baseline and 6 week follow up. Semi-structured interviews were conducted at the same two measurement points.

### **Participants and Setting**

Nineteen participants (six women and thirteen men) were recruited from three inner-city General Practices. Table 2 presents demographic, medical and computer usage information for the 19 participants who took part in the pre-intervention interview. The majority of participants were male (68%), White-British (42%), well-educated (86%) and had diabetes for over 5 years (74%). The mean age was 63.5 years, with a range of 41 to 83 years. Individual demographic details can be found in Table 3.

Table 2

*Demographic, Medical and Computer Usage Information*

<b>Variable</b>	<b>Mean (SD) or Frequency (%)</b>
<b>Demographics</b>	
<b>Age (years)</b>	63.5 (10.7), range 41-83
<b>Gender</b>	32% Female 68% Male
<b>Ethnicity</b>	
White British	8 (42%)
White Irish	3 (16%)
White Other	2 (11%)
Bangladeshi	2 (11%)
African	1 (5%)
Caribbean	1 (5%)
Chinese	1 (5%)
Other Asian	1 (5%)
<b>Highest Level Qualification</b>	
Secondary School	1 (5%)
GCSE's	1 (5%)
A-levels	1 (5%)
Further Qualifications (e.g. diploma)	7 (38%)
Undergraduate Degree	2 (11%)
Postgraduate Degree	7 (37%)
<b>Marital Status</b>	
Married	9 (47%)
Single	5 (26%)
Divorced	4 (21%)
Preferred not to state	1 (5%)
<b>First Language</b>	
English	15 (79%)
Spanish	1 (5%)
French	1 (5%)
Swahili	1 (5%)
Mandarin	1 (5%)
<b>Medical</b>	
<b>Time since diagnosis</b>	
0-6 months	1 (5%)
1-2 years	1 (5%)
2-5 years	3 (16%)
5-10 years	6 (32%)
10+ years	8 (42%)
<b>Current or previous diabetes-related complications</b>	
Yes	8 (42%)
No	11 (58%)

*Table 2 continues*

Table 2 continued

<b>Current Treatment</b>		
A Healthy, Balanced Diet		14 (74%)
Regular Physical Activity		11 (76%)
Other Lifestyle Changes		11 (76%)
Metformin		14 (74%)
Insulin		6 (32%)
Other Diabetes-Related Medications		5 (26%)
Blood Sugar Testing		13 (68%)
Blood Pressure Monitoring		13 (68%)
<b>Previous Attendance at a Diabetes Self-Management Course</b>		
Yes		8 (42%)
No		9 (47%)
No Response		2 (11%)
<b>Computer Usage</b>		
<b>Place of Access</b>		
Home		16 (84%)
Public Access		1 (5%)
Both Home and Public		2 (11%)
<b>Computer Skills</b>		
Advanced		7 (39%)
Intermediate		7 (39%)
Basic		5 (26%)

Table 3

*Individual Demographic Details*

Participant	Gender	Age	Ethnicity	Time since diagnosis	Previous or current complications	Computer skills
1	Female	40s	African	10+ yrs	No	Advanced
2	Female	60s	Caribbean	0-6 months	Yes	Basic
3	Female	60s	Bangladeshi	10+ yrs	Yes	Advanced
4	Female	70s	White British	10+ yrs	Yes	Intermediate
5	Male	60s	White British	2-5 yrs	No	Intermediate
6	Male	80s	White British	10+ yrs	Yes	Basic
7	Male	40s	White British	2-5 yrs	No	Intermediate
8	Male	60s	White British	10+ yrs	Yes	Advanced
9	Male	60s	White British	2-5 yrs	No	Advanced
10	Male	60s	Other Asian background	5-10 yrs	No	Advanced
11	Female	70s	White British	1-2 yrs	No	Intermediate
12	Male	50s	White Irish	5-10 yrs	No	Basic
13	Male	40s	Bangladeshi	5-10 yrs	Yes	Advanced
14	Male	60s	White British	10+ yrs	Yes	Basic
15	Female	70s	White (other)	5-10 yrs	No	Intermediate
16	Male	70s	White (other)	10+ yrs	No	Intermediate
17	Male	70s	White Irish	5-10 yrs	No	Basic
18	Male	50s	Chinese	10+ yrs	Yes	Advanced
19	Male	60s	White Irish	5-10 yrs	No	Intermediate

Note. yrs = years

## **Inclusion and Exclusion Criteria**

The inclusion criteria specified patients registered at participating General Practices who had been diagnosed with type 2 diabetes and were 18 or older. They were also required to have internet access either at their home, work or a public access point, e.g. a library or an internet café.

The exclusion criteria were participants who 1) were unable to provide informed consent (e.g. due to psychosis, dementia, severe learning difficulties); 2) were terminally ill with less than 12 months life expectancy; 3) were unable to use a computer or mobile phone due to severe mental or physical impairment; 4) had spoken or written English language skills that were insufficient to use the intervention; and 5) were concurrently participating in a trial of a different self-management programme. Additional exclusion criteria were if the participant was actively suicidal or severely depressed (score above 11 on HAD-D scale); or if they were receiving psychological therapy or counselling at the same time as the study.

During the interviews, three participants (8, 16 and 19) disclosed that they were currently receiving psychological therapy for issues that were separate to their diabetes. In the follow-up interviews, these participants did not express that the therapy had impacted their mood, their diabetes or their use of HeLP-Diabetes. It was therefore decided that the data from these participants would be included in the analysis.

## **Ethical Approval**

Ethical approval for the study was granted by the National Research Ethics Committee North West - Greater Manchester North (see Appendix C) and the local NHS R & D department (see Appendix D). Participants were given time to read, understand and ask questions regarding the participant information sheet (see Appendix E). Written, informed consent was obtained from all participants (see

Appendix F). The study posed minimal risk and had some potential benefits for participants.

## **Procedure**

### *Practice Recruitment*

Three General Practices in an urban setting were approached by the researcher in March 2013 and were invited to take part in the study. One practice was selected through the researcher's previous professional relationship with them. The other two were selected with assistance from the local NHS R & D department. Within the selected practices, a lead clinician (GP or Practice Nurse) was asked to be the main liaison for the study. This clinician was recommended by the Practice Manager in all three practices.

### *Patient Recruitment*

A verbal explanation and written summary of the study's inclusion and exclusion criteria were given to the lead clinicians of each Practice. Prior to routine diabetes-related appointments, the clinician was asked to check a patient's medical records in order to verify their eligibility for the study. If eligible, the clinician was asked to discuss the HeLP-Diabetes website with the patient, to give them a leaflet about the study (see Appendix G) and to gauge their interest in taking part. Interested patients were asked to give permission for the clinician to complete a referral form that would be passed to the study researcher.

The researcher collected the referral forms in person from the three Practices. Contact was then made with the interested patients via their preferred mode of communication, as indicated on the referral form. The researcher explained the study further and answered any questions. If they continued to express interest in taking part then they were invited to attend a facilitation appointment with the researcher at their General Practice.

One General Practice tried the patient recruitment strategy described above for a couple of weeks and then felt that a more effective method would be to send out study invitation letters. The GP therefore identified 40 patients who met the study's inclusion and exclusion criteria from the patient database and sent them a letter about the study asking them to contact the researcher for further information. On contacting the researcher, the interested patients were invited to a facilitation appointment. This strategy yielded 13 patients, compared to six patients from the other two practices combined.

The facilitation appointment lasted approximately 90 minutes. The first task involved discussing the study further and going through the participant information sheet (see Appendix E), which participants were sent in advance of the appointment. Those who agreed to participate were asked to sign a written consent form (see Appendix F).

On agreeing to participate in the study, the participants were then registered on the HeLP-Diabetes website and shown how to log-on using their username and password. The researcher demonstrated different parts of the programme and suggested areas they may wish to focus on based on their self-management and emotional needs. Participants were also given a printed guide to using HeLP-Diabetes at home (see Appendix H), on which they were encouraged to note their HeLP-Diabetes username and a hint to their password.

The final task of the facilitation appointment consisted of a 30-minute semi-structured interview (see below). On completion, participants were informed that they would be sent an e-mail with a link to an online questionnaire. They were provided with a unique identification number to enter into the questionnaire and asked to complete this as soon as possible. Four of the participants asked to complete the questionnaire within the facilitation appointment.

### *Follow-up Appointment*

Six weeks following the baseline appointment, participants were invited to attend a follow-up appointment. This session consisted of a 30-minute semi-structured interview and the completion of the same set of questionnaires as completed at baseline. Participants were informed that they would have continued access to the HeLP-Diabetes website despite concluding their involvement in the study. A letter was then sent to the lead clinician of the General Practice to inform them of the conclusion of the participant's involvement in the study (See Appendix I).

### **Intervention**

The HeLP-Diabetes programme is described above in the introduction. Participants were asked to use the programme at least once or twice a week for six weeks. They were given the option of receiving weekly phone calls, texts or e-mails from the researcher to remind them to use the website and all participants accepted this offer. On registering on the website they were also automatically signed up to a weekly HeLP-Diabetes e-mail, which encouraged use of various aspects of the programme.

### **Power Analysis**

The primary focus of the study was on detailing the psychological changes that occurred as a result of using the HeLP-Diabetes programme, using both quantitative and qualitative methods. Using G\*Power, it was calculated that a sample of 16, with an alpha of 0.05, would give 80% power to detect an effect size of  $d=0.75$ . A sample size of 24 would give 80% power to detect an effect of 0.6.

### **Quantitative Data Collection**

Participants were asked to complete questionnaires at baseline and at a six week follow-up. The questionnaires were administered in an online survey through a system called Opinio (Object Planet, 2014). In order to complete the questionnaires



at baseline, the majority of participants were sent an email with a link to access the survey. For the follow-up, the majority completed the questionnaire in the follow-up appointment at their General Practice. During the completion of the follow-up questionnaire at the Practice, the researcher sat on the other side of the room, unable to see the computer screen.

### **Quantitative Measures**

The primary outcome measure was The Problem Areas in Diabetes Scale (PAID; Polonsky et al., 1995) which is a measure of diabetes-related distress and psychological adjustment. This primary outcome reflects the aims of the HeLP-Diabetes website – to reduce diabetes-related distress. It was also chosen as it is congruent with other diabetes psychological intervention studies (e.g. Sturt et al., 2008; van Son et al., 2013) and a recent literature review from the current author (see Part 1 of this thesis). The PAID has 20 items focusing on areas that cause difficulty for people living with diabetes, including social situations, food, friends and family, diabetes treatment, emotions, relationships with health care professionals and social support. An example item is ‘worrying about low blood sugar reactions’. Each item is scored from 0= “Not a problem” to 4= “Serious problem”. The scores are added up and multiplied by 1.25 to generate a score between 0-100, with higher levels indicating elevated emotional distress. A cut off of 40 has been recommended to indicate severe levels of distress (Hermanns et al., 2006; van Bastelaar et al., 2011). The PAID has been widely used to evaluate SMPs for people with type 2 diabetes (e.g. van Bastelaar et al, 2011), including web-based SMPs (Fonda et al., 2009). It is an easy-to-administer instrument with high internal consistency (Polonsky et al., 1995), good validity and responsiveness to change (Eigenmann, Colagiuri, Skinner, & Trevena, 2009).

The following questionnaires were also included in the online survey:

A background questionnaire to determine age, gender, ethnicity, first language, time since diagnosis, current treatment, education attainment, computer literacy, access to the internet, presence of diabetes-related complications and previous experience of self-management programmes was included in the baseline survey and omitted from the follow-up survey (see Appendix J) .

The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983) is a self-report measure consisting of 14 items with two subscales measuring depression (HADS-D) and anxiety (HADS-A). It was chosen for the current study as it does not contain any items that measure somatic symptomatology so symptoms of psychological distress cannot be confounded with the physical symptoms of uncontrolled diabetes. An example item is 'I get sudden feelings of panic'. The items can be scored from 0 = "No, not at all" to 3 = "Yes definitely", with reverse coding on 5 of the items. Score ranges for the subscales are suggested for indicating a non-case (0-7), a mild case (8-10), a moderate case (11-15) and a severe case ( $\geq 16$ ) (Snaith & Zigmond, 1994). It is a well validated questionnaire and has been used extensively in chronic disease populations, including type 2 diabetes (e.g. Kohen, Burgess, Catalan & Lant, 1998; Lloyd, Dyert & Barnett, 2000). However, a recent systematic review reported that the HADS's ability to assess anxiety and depression is uncertain but it is an effective tool in identifying emotional distress (Cosco, Doyle, Ward & McGee 2012). The HADS has been found to have good reliability and validity and is well accepted by patients and non-patients alike (Herrmann, 1997).

The Diabetes Management Self-Efficacy Scale UK (DMSES UK; Sturt, Hearnshaw & Wakelin, 2010) consists of 15 items measuring self-efficacy expectations for engaging in different type 2 diabetes self-management activities, e.g. 'I am confident that I am able to remedy too high blood sugars'. Respondents rate their confidence on a scale ranging from 0= "Can't do it at all" to 10= "Certain can do". Principal component analyses have supported the reporting of DMSES as

one overall score, rather than several subscales (Sturt et al., 2010). The score range is therefore 0-150 with higher scores indicating higher self-efficacy. The DMSES has been used previously in evaluating diabetes SMPs (Sturt et al., 2008). It has been shown to have good internal consistency, construct validity and test-retest reliability (Sturt et al, 2010).

Medical Outcomes Study Social Support Survey Scale (MOSSSS; Sherbourne & Stewart, 1991) consists of 19 items and measures four categories of functional support: tangible support, affectionate support, positive social interaction and emotional/information support. An example item is 'Someone who understands your problems'. Responses are on a five point scale from 1= "None of the time" to 5= "All of the time". An overall 'support index' is obtained by calculating the average of the scores across the 19 items. Scores range from 1-5 with higher average scores indicating a higher degree of perceived social support. The MOSSSS was developed for use with people with chronic illness. It has also been used to explore social support as a determinant of well-being in patients with type 2 diabetes (Westaway, Seager, Rheeder & van Zyl, 2007). Sherbourne and Stewart (1991) demonstrated that it has good internal consistency and test-retest reliability. Their factor analysis showed that the four subscales were distinct from each other but an overall support index, supporting a common higher order structure, could also be constructed.

The Illness Perception Questionnaire - Revised (IPQ-R; Moss-Morris et al., 2002) was used to assess health beliefs relating to diabetes. According to Leventhal's Common Sense Model of Illness, patients cluster their ideas about an illness around various themes or dimensions, which together make up the patient's perception of their illness (Leventhal and Diefenbach, 1991). The IPQ-R consists of 9 dimensions: identity, cause, timeline cyclical, timeline acute/chronic, consequences, treatment cure/control, illness coherence and emotional

representation. An example item within the treatment cure/control dimension is 'My treatment will be effective in curing my diabetes'. Each subscale uses a 5-point likert scale ranging from 1= "Strongly disagree" to 5= "Strongly agree". Most subscales have one or more negatively worded items with reverse scoring. As the timeline, consequences, personal control, treatment control and emotional representations subscales each contain six items, the scores on these subscales will range from 6 – 30. The Illness coherence subscale contains 5 items and scores therefore ranged from 5 – 25. The timeline cyclical subscale has 4 items and the scores range from 4 – 20. High subscale scores represent more strongly held beliefs about the dimension. The questionnaire has been widely used and adapted for chronic illness populations, including diabetes (e.g. Griva, Myers & Newman, 2000; Paschalides et al., 2004). The IPQ-R has shown to have good internal reliability and test-retest reliability, as well as sound discriminant, known group and predictive validity (Moss-Morris et al., 2002)

### **Qualitative Data Collection**

Semi structured interviews were conducted in the participant's General Practice at baseline and at a 6 week follow-up. The baseline interview was brief, with the aim of getting a picture of the participants' current difficulties with their diabetes and what they would like to get out of the HeLP-Diabetes programme (see Appendix K for baseline interview schedule). The follow-up interview explored whether the programme made any difference to the participants' psychological well-being and which parts of the programme they found helpful or unhelpful (see Appendix L for follow-up interview schedule). The interview schedules were developed in conjunction with two experienced researchers and the questions were based on the aims of the current study. All interviews were recorded with the respondent's consent, transcribed and edited to ensure anonymity of the respondent.

## **Qualitative Data Analysis**

The transcripts were subjected to a thematic analysis (Braun & Clarke, 2006). This method identifies, analyses and reports patterns or themes within a data set. A thematic analysis approach, above other qualitative research approaches, was chosen as it fitted with the aim of the study - to elicit central ideas and themes occurring within participant interview data about experiences of diabetes and the HeLP-Diabetes website. Braune and Clarke's thematic analysis framework was chosen above other frameworks such as Interpretative Phenomenological Analysis (IPA; Smith, Flowers & Larkin, 2009) and Grounded Theory (Strauss & Corbin, 1990). IPA is tied to the particular theoretical position of phenomenology, which did not seem relevant to evaluation data regarding the website. Grounded theory aims to generate theory that is "grounded in" the data and this did not reflect the aim of the current study. Braune and Clarke's approach offered the advantages of being flexible and not tied to a particular theory or epistemology. It could therefore be applied across a range of theoretical approaches and could be linked to the psychological constructs of interest in the present study, e.g. diabetes-related distress (Polonsky et al., 1995). Potential disadvantages of this approach, including lack of apparent structure and reliability, were controlled for by using a staged analytical procedure and implementing quality practice criteria.

The qualitative research software NVivo 10 (QSR International Pty Ltd, 2012) was used to carry out the thematic analysis. This software provides a workspace that allows researchers to classify, sort and arrange information in an efficient manner.

The analytical procedure can be summarised in five stages which were followed in a recursive, rather than a linear, fashion. The stages were as follows:

Stage 1: The transcripts were read repeatedly in order to become familiar with the contents and to check back against the original audio recording to ensure

accuracy. Preliminary notes were written manually in the left hand margin of each page to highlight anything interesting or significant or as a reminder of any thoughts that may have been provoked during the interview (see Appendix M for an example of thematic analysis).

Stage 2: The transcripts were uploaded onto NVivo 10. Initial codes were then created, which captured the essence of what was found in the text. At the end of the first transcript an initial list of codes was established. This list was referred to and added to when repeating the procedure for all the other transcripts.

Stage 3: The researcher combined the codes that had come out of stage two in order to form overarching themes. Some codes clearly clustered together whilst others appeared as superordinate themes. Codes were dropped at this point if they did not appear to connect well to any themes or if they did not have sufficient evidence within the transcript. During this process, constant referral back to the transcripts assured the researcher that the clusters being made were still relevant to the original data.

Stage 4: Themes were reviewed and refined by checking the collated extracts under each theme for relevance and reviewing whether the themes were appropriate to the data set. A master list of main themes and nested sub-themes were decided and put into table format. Themes were not chosen for their frequency or prevalence within the text but instead for their richness, salience and significance to the participants' experiences. Overarching domains were noted and added to the table.

Stage 5: The themes were translated into a narrative account which was supported by verbatim extracts from each of the participants. This stage is presented in the results section below.

The study followed good practice criteria in qualitative research (Mays & Pope, 2000). This included respondent validation, in which a summary of the results

from the study was e-mailed to the participants to establish their validity (see Appendix N). Four participants responded and expressed that they felt the results were an accurate reflection of their experience. Two experienced researchers examined the initial coding from randomly selected data, comparing the codes to preliminary themes, and also audited the structure of the themes (Barker & Pistrang, 2005; Elliott, Fischer & Rennie, 1999). Finally, the researcher used reflexivity to consider the ways in which the research process, and also the prior experience and assumptions of the research, may have shaped the study outcomes.

### **Researcher Background and Perspectives**

Making clear the researcher values and beliefs is necessary to establish a basis for validity in qualitative research (Barker et al. 2005; Elliott et al., 1999). I am a white, British, woman in my early thirties. I conducted this research for a doctorate course in Clinical Psychology. I have type 1 diabetes, which was diagnosed at the age of six. Based on my own experience, I believe that the psychological burden of diabetes can strongly impact a person's ability to self-manage their condition, and I also feel that the psychological aspects of diabetes are often over-looked by health care providers. In line with qualitative research guidelines, I attempted to 'bracket' these beliefs while conducting the research (Strauss & Corbin, 1990). I decided not to disclose my diabetes to any of the participants in case it may have impacted on the participants' willingness to talk honestly about their feelings towards their own diabetes.

## **Results**

### **Data Screening**

The data were screened to check whether normality assumptions were met. Six variables showed a deviation from normality, therefore the data were analysed using the non-parametric equivalent of the repeated measures t-test – the Wilcoxon

signed rank test. This was a two-tailed test. Due to multiple testing and the increased probability of a type 1 error, a significance level of 0.01 was used.

Both pre-and post-intervention questionnaires were completed by 18 participants. One participant completed the pre-intervention questionnaire and then dropped out of the study without giving any reasons for this decision. Their data is therefore not included in this analysis. Due to the format of the online questionnaires, there are no missing items from the data.

### **Baseline Population Characteristics**

The baseline PAID scores indicated that the sample had moderate levels of diabetes-related distress on entering the study (see Table 4). The scores on the HADS also indicated that the sample on average did not feel anxious or depressed. The other measures suggested that on average, the sample felt quite well supported (MOSSSS), they had a reasonable level of self-efficacy regarding their diabetes management (DMSES) and they did not hold extreme views or beliefs regarding their diabetes (IPQ-R). They showed some beliefs in the chronicity of the illness, the negative consequences of the condition, the controllability of their diabetes, the cyclical nature of the condition and the emotional reactions related to their condition. The IPQ-R also indicated that the sample felt slightly uncertain about the level of control they had over their treatment and also their understanding of their diabetes.

### **Pre-Post Comparisons**

Table 4 displays the results from the pre- and post- intervention data comparisons. The results from the questionnaires show that there were no significant changes between the pre- and post-intervention data. The measures that showed the most change were the PAID, HADS and the DMSES, which all approached statistical significance. There was a decrease of approximately 6 points on the PAID scale, with a small to moderate effect size, which may indicate a



reduction in diabetes-related distress. The average HADS score increased by approximately 1.5 points, indicating a slight raise in anxiety. However, the post-intervention average score on the HADS stayed within the 'non-case' category and therefore was not clinically meaningful. The depression scale of the HADS decreased by approximately 1 point. The DMSES showed an average increase of 12 points, indicating an increase in diabetes-related self-efficacy, however this result was not found to be significant.

Table 4

*Means, Standard Deviations, Wilcoxon Signed Rank Results and Effect Sizes*

<b>Measure</b>	<b>Pre M (SD)</b>	<b>Post M(SD)</b>	<b>Wilcoxon Signed Ranks Sig</b>	<b>Cohen's d</b>
<b>PAID</b>	26.32 (20.88)	20.97 (16.53)	.04	0.28
<b>MOSSSS – Overall Average</b>	3.15 (1.31)	3.07 (1.24)	.94	0.06
Tangible Support	2.90 (1.61)	2.82 (1.36)	.95	0.05
Emotional/ Informational	2.99 (1.30)	3.07 (1.19)	.72	0.06
Affectionate	3.11 (1.36)	3.14 (1.33)	.68	0.02
Positive Social	3.12 (1.30)	2.89 (1.41)	.50	0.12
<b>IPQ-R</b>				
Timeline	19.11 (3.79)	18.94 (1.95)	.68	0.05
Consequences	17.72 (3.46)	18.11 (3.58)	.60	0.11
Personal Control	19.39 (2.48)	20.10 (2.29)	.20	0.30
Treatment Control	13.78 (3.10)	14.39 (2.77)	.39	0.21
Illness Coherence	12.00 (3.58)	12.11 (2.64)	.72	0.03
Timeline Cyclical	10.61 (3.90)	10.22 (3.64)	.75	0.10
Emotional Representations	16.50 (4.81)	15.94 (5.03)	.63	0.11
<b>HADS – Overall</b>	12.33 (10.15)	12.78 (11.20)	.38	0.04
Anxiety	6.50 (5.53)	7.67 (5.91)	.04	0.20
Depression	6.00 (5.34)	5.11 (5.70)	.07	0.16
<b>DMSES</b>	90.67 (20.17)	102.78 (26.66)	.06	0.51

*Notes:* PAID = Problem Areas In Diabetes scale. MOSSSS = Medical Outcomes Study Social Support Survey Scale. IPQR = The Illness Perception Questionnaire – Revised. HADS = Hospital Anxiety and Depression scale. DMSES = Diabetes Management Self-Efficacy Scale UK. Please refer to the method section for an explanation of direction and range of each scale. Level of significance = 0.01

## Pre-Intervention Interview Data

The qualitative data from the pre-intervention interviews were organised into two domains: 'Difficulties of living with diabetes' and 'Hopes for HeLP-Diabetes'. The participants provided a large amount of detail on their experiences of living with diabetes and the daily difficulties that they faced. These difficulties are summarised in tabular form in the current paper, as they are described in more depth in other literature (e.g. Mathew, Gucciardi, De Melo & Barata, 2012). The 'Difficulties' domain was organised into three main themes: 'Impact on psychological well-being', 'Difficulties with self-management' and 'Social pressures and impact on social roles'. Each of these themes contained several sub-themes. The 'Hopes for HeLP-Diabetes' domain was divided into five main themes: 'Changing diet and losing weight', 'Changing level of exercise', 'Help with moods', 'Learning from other people with diabetes' and 'Wanting to learn more about diabetes'. The domains, main themes and sub-themes, as well as illustrative quotes are presented in table 5. The participants are described by their identification number and further details can be found in table 3.

Table 5

### *Domains, Themes, Sub-themes and Illustrative Quotes for the Pre-Intervention Data*

<b>Domains, Themes and Sub-themes</b>	<b>Illustrative Quotes</b>	<b>Prevalence</b>
<b>Difficulties of Living with Diabetes</b>		
<i>a) Impact on Psychological Well-Being</i>		
i) Worries about long term complications	"I ask God, you want to take something, take a leg but let me have my eyes." (4)	Common
ii) Concerns about medication and related side-effects	"you take medication, they treat one thing, they give you complications and the others, so... there's other things that play up in my mind as well. Knowing, okay, this is treating these, but there's side-effects as well." (1)	Common

*Table 5 continues*

*Table 5 continued*

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iii) Desire for normality	“that’s part of wanting to feel as normal as possible and to feel as normal as possible could involve a degree of pushing to one side what actually one needs to do to remain stable and to manage one’s condition.” (5)	Common
iv) Managing by minimising concerns	“it’s not treated at a deadly serious level, it’s treated lightly probably to disguise what’s going on underneath.” (14)	General
v) Anger and self-criticism	“I could be quite bad-tempered sometimes, and possibly...it might have been caused by...the thought of the diabetes. I could lose my temper.” (6)	General
vi) Feeling depressed and apathetic	“... I’m not a depressing type of person, but it can make you feel down sometimes. “ (17)	Common
<i>b) Difficulties with Self-Management</i>		
i) Battles with eating and weight	“It’s a bit tricky because I like food and I like cooking, and so it’s...yes, it’s quite a challenge” (11)	Common
ii) Difficulty controlling blood sugar levels	“It has taken an awful long time, not to take too much insulin and therefore get hypos and/or, not take enough and my diabetes goes up.” (3)	Variant
iii) Lack of control or predictability	“There are mysteries and disconnect between the prescribed treatment and the result.” (14)	Variant
iv) Difficulty sticking to a regime	“And so my main problem - apart from the odd lapses when I completely forget to take my medication, is how to stick to a regime which is going to have a positive impact on my health. (5)	Variant
<i>c) Social Pressures and Impact on Social Roles</i>		
i) Pressure from others	“My children are very supportive; they just said, dad, you can’t have that, or they will ask at a restaurant, and now it’s...got too much sugar in, you just can’t have it. So, it’s quite nice. Sometimes a bit of a pain in the butt” (8)	Variant

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*Table 5 continues*

*Table 5 continued*

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ii) Impact on role in family	“It contributes to one’s constant feeling of failure as a father, that you’re not bringing up your child properly, but... if you can’t rush out and do things.” (7)	Variant
iii) Impact on work role and hobbies	“We both love going to museums and art galleries and stuff and now I can’t. I cannot walk round an exhibition, I’m too tired.” (4)	Common
iv) Impact on social life and society	“Often I’m faced with big meals and lots of drink, and often you can get away with it. Often you’d find you’d be giving offence if you don’t.” (9)	Variant

## **2) Hopes for HeLP-Diabetes**

a) Changing diet and losing weight	“Hints on how I can lose weight and control my diabetes more.” (3)	General
b) Changing level of exercise	“That’s my battle. If I could get that, that would be very nice, yes. Even for a walk, just to go walking about. Maybe I can start that.” (1)	Common
c) Help with moods	“That, Managing my Feelings – that looked quite interesting. That was something that has made me feel quite happy, actually.” (19)	Common
d) Learning from other people with diabetes	“The forum, if I go there, they have the same situation, so we can share, we can give some information, we can help each other.” (13)	Variant
e) Wanting to learn more about diabetes	“Because I want to learn more, learn what I can do, the effects of it and whatever, you know, because I don’t to be ignorant or that, I want to know about this thing and know as much as I can about it.” (2)	Common

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*Notes:* General = theme applies to 13-18 participants. Common = theme applies to 7-12 participants. Variant = theme applies to 4-6 participants.

## **Difficulties of Living with Diabetes**

### *Impact on Psychological Well-Being*

Participants voiced their fears concerning diabetes-related, long-term health complications. Specifically, participants expressed concerns about complications

involving their kidneys, eyes, legs, feet, nerves and circulation and the impact this would have on their quality of life.

Concerns were also raised regarding their diabetes medication and the associated side-effects. Specific concerns included putting on weight, the impact on kidneys, becoming dependent on them, losing consciousness and constipation, as well as other possible complications. Other participants were more concerned about having to take large tablets that looked like they were “*designed for horses*” (7) and also having to inject insulin.

Participants expressed their desire to feel as “*normal as possible*” (5). This was described as a “*battle*” between doing what was best for their health but also wanting to live life to the full and not feel restricted. However, despite acknowledging the need for this balance, it seemed that participants remained very aware that avoiding the necessary self-management behaviours or “*pushing [their diabetes] to one side*” (5) could lead to diabetes-related complications. In another sub-theme, participants described how they managed their concerns around complications, by minimising them or “*treating [the diabetes] lightly*”. The majority of participants described using this coping strategy to prevent them from becoming “*paranoid*” (4), “*obsessed*” (7) or “*consumed*” (16).

The presence of anger in association with their diabetes was also described by the participants. This anger was either directed outwards to other people or seemed to be turned inwards and manifested in self-criticism and guilt. Externally directed anger was mainly attributed to when blood sugar levels were too high or too low. Some participants also attributed it to diabetes in general and felt that the condition had caused a shift in their temper e.g. “*I didn't used to be like that. It's fairly out of character*” (9). Self-blame and criticism were prevalent amongst the participants. Nine people spoke of feeling “*guilty*” (14), “*annoyed*” (5) and “*stupid*” (6)

about not being able to stick to their self-management regime. This seemed to be particularly common around the topic of losing or managing their weight.

The participants also spoke of feeling low in mood and apathetic as a result of their diabetes. For several, this took the form of lacking a “*get up and go*” (14) and feeling “*discouraged*” (16), “*useless*” (7) and “*hopeless*” (18). They also described a lack of energy and motivation relating to their diabetes, which impacted their enjoyment of activities and for one participant meant that she found herself constantly “*thinking how quickly [she could] go home and sit down again*” (5).

#### *Difficulties with Self-Management*

The difficulties of losing weight, maintaining weight loss or avoiding foods that they knew to be unhealthy, were common. They also described the difficulties in controlling their blood sugar levels. For some this meant experiencing high blood sugar levels and the unpleasant symptoms that this brought. Others described the difficulty in balancing medication intake, food and exercise in order to achieve the necessary blood sugar levels.

Participants talked about a lack of control or predictability associated with their diabetes. This impacted their day to day life by having to be constantly ready to control their blood sugar levels at any given point. It also required careful monitoring and patience to try and establish a treatment regime that worked for them. However, even when a regime was established, participants described difficulty in sticking to it - whether it was eating regularly, remembering to carry sugar in case of a hypo or remembering to take medication.

#### *Social Pressures and Impact on Social Roles*

The participants talked about the support they received from family and loved ones. This support often took the form of warning them about possible diabetes-related complications or trying to dissuade them from eating certain foods. Whilst the participants expressed understanding their loved ones concerns and

intentions, this type of support was generally considered to be “*a pain in the butt*” (8). One participant expressed “*I don’t like it. It makes me feel different and I’m not*” (12).

The perception of their role within their families seemed for many to be impacted by their diabetes. One third of participants spoke of sexual difficulties which affected their identity as a lover and partner. Others talked about the impact of their diabetes on their role as a parent, for example one participant spoke of feeling like a “*failure as a father*” (7).

The impact on work roles and hobbies were also described. Participants felt that their diabetes could affect their ability to do their job to their usual standards. They also expressed concern about how the diabetes might affect their prospects for promotion in their work place. Participants expressed that hobbies such as gardening, wine tasting, travelling, socialising and going to galleries were all hindered by their diabetes in various ways. This was commonly associated with a tiredness which they associated with their diabetes and which pervaded and restricted their day-to-day lives.

Social lives were also impacted by diabetes. Participants expressed their concerns about offending or boring people by not drinking or eating what was offered to them in a social setting. In relation to wider society, participants expressed concern about being a “*burden*” (16) and not being “*acceptable*” (14) in society due to their condition.

### **Hopes for HeLP-Diabetes**

Over two thirds of the participants expressed that they would like the website to assist them in changing their diet and eating habits in order to lose weight. One participant said that she would like to know “*how to control my diet, what the right things to eat are, what to leave out, what to look for in food*” (5). Others felt they needed help with “*willpower*” (9) and to “*be more aware of losing weight*” (16).

Several participants spoke about wanting to lose weight through doing more exercise. For many the difficulty with exercise was being able to find enough time to do it consistently. Others wanted to know “*what sort of exercises [they could] be doing*” so they could lose weight.

Another hope for the website was to ‘Learn from others with diabetes’. One participant expressed that they would like “*practical tips from people who have been there, done that*” (5). Participants commented on the benefit they felt they could gain from receiving tips and advice from other people living with type 2 diabetes. Several also felt it would be helpful to read about other people going through similar experiences as them so they would feel less isolated. Another theme was ‘Wanting to learn more about diabetes’ in which participants referred mainly to the general information about diabetes they could take from the website. By gaining more information, the participants hoped to be more aware of what to expect from their diabetes and thereby have a better understanding of how to manage it.

The final theme was ‘Help with moods’ in which participants spoke about wanting to feel a shift in their emotions, approach or attitude. Some participants expressed that they hoped the website could help them to feel more motivated. Other people wanted help with feelings such as anxiety, detachedness, mood swings, irritability, apathy and low moods.

### **Post-Intervention Interview Data**

#### *Usage and Engagement*

Eleven participants reported using the website more than once a week; seven reported using it less than once a week. The usage ranged from one participant only using the website once over the six week intervention period to another reporting using it at least once a day over this time.



Barriers to using the website included factors such as work, tiredness, being too busy, lack of familiarity with computers, other family members using the computer and being distracted.

*“Just the time barrier, that’s all; and sheer effort to go and sit there after a day of being tired.” (4)*

Conversely, facilitators to using the website were also discussed. Eight found systems and prompts that helped remind them to use the website. Such factors included establishing a routine of when they were going to use the website; leaving notes for themselves; receiving the weekly e-mail or phone call from the researcher; or just *“integrity”* (17) in wanting to keep to what they had agreed to do for the study.

Ten described the website as easy to navigate due to the way it was structured and presented. Conversely, twelve participants described some aspect of difficulty in using the site; seven of which spoke of problems with logging into the website.

*“I’m a bit impatient about getting in and passwords and all the rest of it and I don’t know if I didn’t spend long enough, but I seemed to have to get a password that wasn’t my password.” (11)*

Five people found the website difficult to navigate or to use due to only having basic knowledge of computers.

*“First of all, I’m 73 and I’m not IT – what’s the word – conversant.” (17)*

#### *Post-Intervention Interviews*

Following approximately six weeks of using the HeLP-Diabetes website, eighteen (of the nineteen) participants attended a follow-up interview. The post-intervention interview data was organised into three domains, each containing several themes as follows:

Table 6

*Outline of Domains and Themes for Post-Intervention Interviews*

<b>Domains and Themes</b>	<b>Prevalence</b>
<i>1) Positive Outcomes: Psychological</i>	
a) Feeling better informed and more aware	General
b) Taking diabetes more seriously	Common
c) Increased self-efficacy, control and confidence	Common
d) Help from social comparison and support	Common
e) Improved management of worries and low mood	Common
<i>2) Positive Outcomes: Behavioural</i>	
a) Changes to eating habits	Common
b) Changes to exercise	Variant
c) Other changes to self-management	Variant
<i>3) Negative Experiences of the Website</i>	
a) Finding the information to be not new or helpful	Common
b) Not feeling able to relate to the experiences of others	Variant
c) No changes to certain aspects of diabetes-related behaviour	Common
d) Technical frustrations	Common
e) Feeling guilty about not using the website	Variant

*Notes:* General = theme applies to 13-18 participants. Common = theme applies to 7-12 participants. Variant = theme applies to 4-6 participants.

**Positive Outcomes: Psychological***a) Feeling Better Informed and More Aware*

All but three participants reported feeling that the website had offered them new information regarding their diabetes or information they had previously learnt but felt it was beneficial to be reminded of. This new or updated information seemed to help the participants in different ways - from gaining a better understanding of their symptoms, to allowing them to feel more in control or more accepting of their condition.

*“So something I wasn’t aware of is that I really didn’t know that being constantly exhausted was part of diabetes; no one ever told me about.... Well, now I know why! All this time I was wondering why. When I know why, somehow it seems all right suddenly. I know why I feel like hell every day.”*  
(4)

Other participants spoke more of the practical information within the website.

The participants seemed to feel that new information, tips and ideas had the

potential to change their current behaviours in relation to their diabetes and therefore help them to gain more control over their condition.

*“It’s broadened my mind about everything. So, it’s opened things up to me that I wouldn’t have... if I’d have just gone on in my own little way, I would still be doing the same things so it has changed me, definitely, and I hope for the better.” (12)*

Participants expressed that their general awareness of their diabetes had increased from using the website. By bringing their condition closer to the forefront of their consciousness, it seemed to help them to make more healthy moment-to-moment decisions with regards to their self-management.

*“It’s reminding me about diabetes; the more I log on, you know, I’m not putting it out of my mind; that’s a sort of, prerequisite, or a prior condition to improving the confidence. You know, because if you’re kind of, fairly borderline like myself, it’s not always uppermost in your mind, and that’s dangerous work, you know, when you work it’s going to take you down the primrose path to over-indulgence.” (9)*

Participants also talked about the benefit of being able to refer back to the information on the website in times of need. This seemed to provide a level of comfort in knowing that the information and support was readily available to them. It also allowed them to read and digest the information at their own pace or to refer back to it if they had forgotten something. One participant felt this was helpful as it allowed him to be less reliant on his GP and the NHS.

*“It’s brilliant, it’s great because it means that if I have a particular concern or if I feel I’m going off track in any way, in any aspect of my living then I can refer back to that and it would, you know, on present experience it would probably give me the answer or point me in the right direction to an answer and make me less reliant on a GP appointment. And so that’s giving me instant input and giving the NHS less time to have to spend on concerns that can be answered in there.” (5)*

#### *b) Taking Diabetes More Seriously*

Another aspect of the website that seemed to impact on the participants’ intentions to change their behaviour was the description of diabetes-related complications. Seven participants reported feeling more aware of the “*dangers*” (2) of diabetes and consequently felt more motivated to improve their self-management.

The participants did not express that the information regarding complications had caused negative emotions, and this may have been because it was paired with information about taking action to prevent them from happening.

*“I suppose when you go into the risks and stuff about your body and different things that can happen but the main message that’s coming across is this is manageable, you can manage it, here are some things to do it, you know, why shouldn’t you manage it?” (7)*

Participants spoke about experiencing a shift in perception with regards to their diabetes. They talked about having previously viewed diabetes “a bit casually” (4) but in reading more about diabetes complications they felt they were taking their condition more seriously.

*“It made me aware and realise, hang on, all these years that I’ve played around and really I shouldn’t have, I should have taken it more seriously. And that was... so, put... it made me look at things in a different perspective – a better perspective....I should be doing more, and I should probably take it much more seriously, because perhaps I’m killing myself.” (6)*

For several participants, taking their condition more seriously came with an increased sense of responsibility and ownership over managing their condition. This could be viewed as an increased level of acceptance of what they have to do in order to manage their diabetes.

*“I have to look after myself because if you don’t look after yourself, who’s going to look after you? And then being on your own, you have to take the responsibility. You have to look after yourself, so that’s why I just look after myself now” (2)*

#### *c) Increased Self-Efficacy, Control and Confidence*

Seven participants reported feeling an increased sense of self-efficacy, control or confidence in managing their diabetes following using the website. The practical information on the website seemed to help the participants to feel that the steps they needed to take to gain more control over their diabetes were manageable and achievable.

*“I’m more aware of what is going on. I feel, like, I’m in control in a way.” (1)*

d) *Help from Social Comparison and Support*

Participants reported an increase in motivation and self-efficacy through seeing other people on the website who were managing their diabetes. Participants spoke about the benefits of relating to others with type 2 diabetes on the website.

*“You know, the people are just like me and they’re getting on with it... And they’re doing it at their age or whatever and there’s no excuse for me not to do it.” (7)*

As well as boosting self-efficacy, social comparison seemed to help the participants to feel less isolated in their experiences and helped them to normalise their feelings around diabetes self-management.

*“People often feel guilty about slipping up with their diet by indulging in something that they were trying not to eat, or putting off going for that swim they had planned; it was very useful to read that.” (9)*

Several participants spoke about the social support they took from the website. This seemed to help alleviate a general sense of isolation as well as providing a source of answers and information that they may not have felt was readily accessible elsewhere. One participant described that the people on the website now felt *“part of your support community” (7)*.

*“And sometimes, we need that, kind of, thing to not feel isolated, especially if you don’t have friends. Maybe you are alone, you can’t ask people questions, you can’t, so if you go in there, you see what you want to see and it directs you. So I think it’s a helpful website.” (1)*

Additionally, participants described feeling that it was beneficial to have advice from medical professionals available for when they needed it. This again may have helped to alleviate a sense of loneliness and uncertainty with regards to their condition.

*“I felt it was as though I was, sort of, face to face with a practitioner to the extent that that’s what they would tell me if I explained a certain symptom or a certain problem related to diabetes with them.” (5)*

e) *Improved Management of Worries and Low Mood*

Participants spoke about taking a new approach to managing their worries and low mood since using the website. Several participants seemed to find a new determination to acknowledge that “*life goes on*” (1) despite diabetes.

*“I think you can let your life be totally taken over by something like this kind of diagnosis and my inclination would be to not do that, but to just, sort of, be sensible.” (11)*

They also described feeling better able to manage their moods. This seemed mainly to come through finding an alternative way of thinking about their situation and trying to avoid worries unless they were necessary for managing their condition.

*“I’ve just accepted I’m a diabetic, and I’ve just got to live with it, so I don’t, sort of, get my knickers in a knot about it; the only time I sort of worry about it is when I start to feel faint or nauseous or something like that, then I check to see what my sugar is like.” (8)*

**Positive Outcomes: Behavioural**

All but four participants reported some aspect of behavioural shift following the use of the website. The behaviours reported changes to eating habits; changes to exercise; and other changes to self-management.

a) *Changes to Eating Habits*

Participants reported making changes to their eating habits in an effort to improve their diabetes self-management. Several participants started eating more fruits and vegetables.

*“Looking at it, it’s made me realise I have to change things. And I knew I had to change things, but not really how, but that has helped me to see, and one of the things I’m doing since is I’m getting a lot of fruit in. So I just leave the fruit lying around, whereas normally, what I would have done is just have some fruit when I felt like getting it.” (19)*

Other people reported becoming more aware of portion sizes, snacking and managing their intake of sugary foods.

*“I’m a bit more serious about it now, do you know? If I’m going to have sweets, I’m not going to have... I’m just going to do it a bit more sensible.” (12)*

*"I am much more conscious also of not snacking in between." (15)*

#### *b) Changes to Exercise*

Six participants reported that the website had highlighted to them *"that exercise is as important as anything"* (203), with regards to their diabetes self-management. A couple of participants spoke about using advice from the website to introduce exercise into their day-to-day lives, whether it was walking a bit further than usual or dancing while doing the housework.

*"Well, basically the website tells you to a bit more of exercise, walk here, 100 and... well, 90 or 150 minutes a week, doing this, that and the other, which I don't think I'm doing it, so maybe now perhaps I should be doing it. I mean, even a little walk here and there will probably help." (10)*

For another couple of participants, the website prompted them to do more exercise, on top of what they were already doing.

*"And even when I do water aerobics, I used to come home so tired and then I just wait again for the next Tuesday but now I try and do some every day." (2)*

#### *c) Other Changes to Self-Management*

Several participants spoke about changes they had made to the medical management of their diabetes. These participants reported that the website had prompted them to check their blood sugar levels more frequently.

*"Well, I'm just doing a bit more... being a bit more careful and checking a lot more than I was." (6)*

*"Because the more I thought about it the more I could, for example, take my readings and control my blood sugar." (3)*

Other changes included learning more about managing hypos and how to treat them, as well as being more careful about taking medication with food.

*"Because I did have hypoglycaemia twice, to 3.1 and it was very interesting what they told me, what to do, just in case it happens...I have always with me sugar cubes in my bag, but I did not know how many to eat, for instance" (15)*

## **Negative Experiences of the Website**

### *a) Finding the Information to be Not New or Helpful*

More than half of the participants expressed disappointment in finding that the information on the website did not meet their needs. It was either information they already knew (and did not need refreshing) or that was not helpful to them.

*“It probably didn’t give me so much information as I might have hoped.” (3)*

Several participants spoke of this in relation to the areas of the website that aimed to help people improve their moods. These participants reported that they did not experience difficulties with their moods and therefore did not find this section of the website to be of use to them.

*“I didn’t find it particularly helpful because I just thought... it’s about if you get depressed but it said that people with diabetes are more prone to get depression and I think, maybe because I’m lucky, that hasn’t happened to me.” (12)*

### *b) Not Feeling Able to Relate to the Experiences of Others*

Participants reported feeling frustrated by the views and experiences of others on the website which did not fit with their own. The frustration may have been linked to anxiety regarding whether their approach and attitude towards their diabetes was appropriate or not. The coping styles of people on the website, e.g. being emotionally expressive, may also have opposed the strategies that certain participants had adopted to help them cope with their diabetes, e.g. avoidance.

*“No, they had sort of little stories about people feeling so distraught when they first heard they had diabetes, and I thought, oh, silly people – that’s all I thought.... No, I couldn’t relate to them whinging, no, no.” (4)*

### *c) No Changes to Certain Aspects of Diabetes-Related Behaviour*

Participants spoke of aspects of diabetes self-management that they had not been able to change. They reported intentions to change their behaviour based on the information they had read on the website. However, the difficulty remained in following the intention with action to change their behaviour.



*“Well as I say it hasn’t had a practical impact on me yet because I haven’t organised myself to adopt some of the things I have read and thought were very good to adopt.” (5)*

A few participants expressed shame or guilt in relation to not being able to change their behaviour relating to their diabetes. However, these emotions did not seem to motivate change and therefore may have caught the participants in a vicious cycle of being self-critical and un-motivated and then more self-critical.

*“I ought to do something a bit more than I am doing, made me feel, perhaps, even... I’m very good at feeling guilty these days.” (6)*

A couple of participants expressed that they felt they would need something more than the website to motivate them to change their behaviour, namely diabetes-related complications or more in-depth professional input.

*“I haven’t really changed anything that I should or shouldn’t be doing. Maybe, like I said, when [a complication] happens to me then I might start thinking a bit more about it, but so far, like I said, touch wood, nothing serious yet.” (10)*

#### *d) Technical Frustrations*

The website did cause some participants to feel anger and frustration when using it. This happened mainly in relation to when the website did not work as hoped or did not live up to expectations. This may have therefore led to the participant withdrawing from using the site due to the negative association.

*“Why it didn’t feel intuitive? Well, I intuitively did what I would normally do, and it didn’t give me the answers, and so I just sort of thought, oh well, to hell with it.” (14)*

#### *e) Feeling Guilty About Not Using the Website*

Participants expressed feeling guilt in relation to not using the website in accordance with what was asked of them for the study. This guilt was accentuated by weekly emails and phone calls from the researcher to remind them to use the site and to check in with their progress.

*“I think the only difference I could honestly say it made was that I knew it was there and that I felt guilty about it, really.” (11)*

Occasionally this guilt and frustration towards not being able to use the website seemed to be turned inwards and resulted in self-negative feelings

*“Inadequate feelings, you know. Oh, Christ, you know, I can’t even remember the passwords – that sort of thing.” (17)*

## **Discussion**

This mixed methods study found that within the qualitative interviews, the participants reported a range of perceived emotional benefits from using the HeLP-Diabetes programme. Benefits included feeling better informed and more aware which allowed them to take their diabetes more seriously. These findings were not reflected by the quantitative data and none of the hypotheses were supported.

The quantitative analysis looked at aspects of psychological well-being which previous studies have found to influence diabetes self-management (see introduction). These aspects included: diabetes-related distress (PAID), depression and anxiety (HADS), diabetes specific self-efficacy (DMSES), perceived social support (MOSSSS) and beliefs and representations of diabetes (IPQ-R). The lack of significant findings from these measures indicated that the website did not have a clinically meaningful impact on these aspects of the participant’s psychological well-being. However, the results did show trends indicating a decrease in depression and distress and an increase in self-efficacy. An unexpected finding was a trend towards an increase in anxiety following use of the HeLP-Diabetes website.

Within the post-intervention interviews, the participants’ views supported some of the (non-significant) changes observed in the quantitative data and emphasised some important emotional benefits from the website, that were not captured by the quantitative measures. The positive changes that were described by the participants were divided into ‘behavioural’ and ‘psychological’ domains. In the ‘Positive outcomes: psychological’ domain participants talked about ‘Feeling better-informed and more aware’; ‘Taking diabetes more seriously’; ‘Improved

management of worries and low mood'; 'Help from social comparison and support'; and 'Increased self-efficacy, control and confidence'. Within the 'Positive outcomes: behavioural' domain, participants described 'Changes to eating habits'; 'Changes to exercise' and 'Other changes to self-management'. The quotes and information from the participants, gathered under each of these themes, may help to explain the trend towards significance shown in the PAID, DMSES and depression subscale of the HADS.

The PAID was chosen as the primary outcome measure in this current study as research has highlighted the high prevalence of diabetes-related distress (Nicolucci et al., 2013) and its association with reduced glycaemic control and potential long term health complications (Fisher et al., 2010). Although the quantitative outcomes did not demonstrate a significant difference in the PAID scores from pre- to post-intervention, the themes reported in the post-intervention qualitative interviews reflected many of the areas of distress that the PAID focuses on. Five items in the PAID relate to feeling worried, scared, concerned or overwhelmed (e.g. 'Worrying about low blood sugar reactions'). These items were mirrored in the theme 'Improved management of worries and low mood'. The theme 'Increased self-efficacy, control and confidence' is reflected in the PAID items 'Feeling discouraged with your diabetes treatment plan' and 'Not having clear and concrete goals for your diabetes care'. Additionally, within the theme 'Help from social comparison and support', participants spoke of having their feelings of guilt or worry normalised by comparing with others and feeling less isolated with their diabetes. The PAID captures these ideas within the items 'Feeling alone with your diabetes' and 'Feelings of guilt or anxiety when you get off track with your diabetes management.'

The association between several 'positive outcome' themes from the interviews and the PAID items may explain why the PAID scores showed a (non-

significant) trend towards decreased distress. However, there were additional items on the PAID that were not discussed by the participants in the post-intervention qualitative interviews. These items covered feelings of dissatisfaction relating to diabetes physicians, feeling “burned out” by the constant effort needed to manage diabetes and difficulties around family and social relationships. Participants did not report changes in these areas, which may explain why the PAID did not produce a significant outcome. Additionally, within the qualitative interviews, a particularly salient theme was ‘Feeling better informed and more aware’ and this idea does not seem to be strongly represented in the PAID. One item on the PAID asks the scorer to rate how much of a problem it is ‘Not knowing if your mood or feelings are related to your diabetes’. Other than this item, lack of knowledge or awareness is not captured, which again, may partly explain the non-significant difference in PAID scores.

The quantitative findings are consistent with a recent Cochrane review of computer-based diabetes self-management interventions for adults with type 2 diabetes (Pal et al., 2013). This review also showed mixed findings in relation to the interventions’ impact on psychological well-being. Six studies looking at depression found no significant change in mood (e.g. Glasgow et al., 2006). Furthermore, five intervention studies which measured the impact on health-related-quality of life did not show any significant improvement in scores (Quinn et al., 2011). However, small significant increases were shown in perceived social support in one study (Glasgow, Boles, McKay, Feil & Barrera, 2003) and in self-efficacy in two other studies (Lorig et al., 2010; Quinn et al., 2008). In a separate paper, the effectiveness of web-based CBT for depression in adults with diabetes was evaluated and found a significant reduction in diabetes-related distress, as measured by the PAID (van Bastelaar, Pouwer, Cuijpers, Riper & Snoek, 2011). This is consistent with the trend in the current study showing a reduction in diabetes-related distress.

Contrary to the aims of the website, the anxiety subscale of the HADS showed an upward trend in scores. It is possible that participants' anxiety may have been exacerbated by the information they gathered from website about diabetes-related complications. Within the baseline interviews the participants spoke about their 'Worries about long term complications', which is consistent with other literature which has highlighted this area as a major concern for people with type 2 diabetes (e.g. Snoek, Pouwer, Welch & Polonsky 2000). However, learning more about diabetes-related complications was conveyed as a positive gain by the participants within the post-intervention themes of 'Feeling better informed and more aware' and 'Taking diabetes more seriously'. An increase in anxiety could have been a by-product of increased awareness and acceptance of the possible seriousness of their condition. Copious research has investigated the impact of messages aimed at eliciting anxiety and the consequent changes in behaviour (e.g. Soames, 1988). This research has concluded that fear messages are only successful when coupled with information that conveys what the person has to do to bring about change and increases self-efficacy (Witte & Allen, 2000), as occurred on the HeLP-Diabetes website.

The increase in awareness of the serious consequences of not managing diabetes may have motivated the participants to take steps towards making positive changes to their diabetes-related behaviours. The PRIME theory of motivation (West, 2006) posits that 'the motivational system' is made up of five levels: plans, responses, impulses, motives and evaluations. When faced with a decision to act or not, 'responses' arise from momentary 'impulses' which are created by habit, instinct and 'motives' which are feelings of desire based on anticipation of pleasant or unpleasant experiences. These are all driven by emotional states, imagination, biological drives, memories and sometimes by 'evaluations' or beliefs about whether the action is helpful or unhelpful, good or bad or worthwhile or not. Instead of acting

we will sometimes instead make a 'plan' which involves formulating intentions to undertake actions in the future. The HeLP-Diabetes website may have influenced any of these levels of motivation. For example, the participants' 'motives' may have been affected by a new awareness of potential complications; or their 'evaluations' may have been impacted by listening to other people's stories which may have helped them to feel more capable of acting. However, to change behaviour, Michie, van Stralen and West (2011) propose in their COM-B model of behaviour, that motivation should not be considered alone but in combination with one's 'capability' (physical and psychological) and 'opportunity' (physical and social). Many of the participants in the current study described lacking the 'opportunity' to use the website and change their behaviour due to other demands on their time. The post-intervention data suggests that participants' sense of 'capability' was aided by the website, as they described under the theme of 'Increase in self-efficacy, control and confidence'. Self-efficacy has been found to be associated with improved self-management behaviours such as healthy eating and physical activity (King et al., 2010)

Prior to or during the intervention, participants may have been lacking in motivation to self-manage their diabetes due to a preferred state of avoiding their diabetes-related worries. Within the pre-intervention data, participants described 'Managing by minimising concerns'. Whilst many were able to voice their worries about long-term complications in the interview, it seemed that a coping mechanism adopted by many participants in day-to-day life was to downplay the seriousness of their condition and "push worries to one side". One study concluded that the downplaying of possible diabetes-related complications was a strategy used to dissociate from a diabetic (or 'sick') identity (Lawton, Peel, Parry, Araoz & Douglas, 2005). This strategy could be both negatively reinforced by the resulting reduction in worries and identification as being 'sick'/'diabetic' and positively reinforced by an

increased freedom to live 'normally'. A 'desire for normality' was described by the participants in the pre-intervention data, which was consistent with results from a qualitative study looking at the views of participants towards the DESMOND diabetes self-management programme. This study suggested that the need to maintain a coherent identity and 'normal life' were key challenges to managing diabetes (Ockleford, Shaw, Willars & Dixon-Ward, 2008). Many participants were conscious of the need to make constant decisions between doing what was best for their diabetes and doing what they desired. By minimising their concerns about their diabetes, the result of this decision-making process was more likely to result in something that would give them pleasure (e.g. unhealthy food). One of the most powerful impacts of the website on the participants' psychological well-being may therefore have been bringing diabetes more into the forefront of the participants' minds in everyday life and giving it greater weight in their moment-to-moment behavioural decisions.

One contradiction in the quantitative and qualitative results was the trend towards increased anxiety scores on the HADs and the participants' reporting of 'Improved management of worries and low mood' in the interviews. This sense of improved management may relate to the participants' reports of feeling like they had received 'Help from social comparison and support'. By hearing real-life stories from people with type 2 diabetes and entering into discussions on the forum, participants were able to normalise their feelings and reactions to their condition; they were inspired by the resilience of others and the ability of people with type 2 diabetes to lead a healthy, happy life; and they were able to more firmly establish the stance they wished to take towards their diabetes – which for many was about not letting it take over their lives. This social element of the website, may have allowed participants to feel better able to manage their worries and low mood around certain aspects of their diabetes self-management. This is consistent with research which

has shown a negative correlation between anxiety and amount of perceived social support in adults with type 2 diabetes (Wu et al., 2013).

For several participants, their stance towards their diabetes was strengthened by disagreeing with the reaction of others on the website. The reaction towards the people on the website which they disagreed with, was one of frustration and criticism, which may have related to the dissonance felt between their approaches to coping. One theory of coping suggests that people use problem focused (task-oriented and approach strategies) and emotion-focused (emotional approach as well as avoidant strategies) approaches in coping with stressful events (Lazarus & Folkman, 1984). The people presenting their stories on the website used mainly a problem-focused approach in facing up to their diabetes. This may have created a sense of disconnect for the participants who tend to use emotion-focused coping with their diabetes and consequently it may have hindered their chances of making positive behavioural changes. Studies have found that emotion-focused coping is positively correlated with anxiety in people with type 2 diabetes (Karlsen & Bru, 2002). The experience of these participants may be one reason why the perceived increase in social support, as reported in the post-intervention interviews, was not reflected in the social support quantitative measure.

In the post-intervention interviews, participants expressed 'Feeling guilty about not using the website'. This emotional reaction may link with the 'Anger and self-criticism' they described in the pre-intervention interviews. Within this latter sub-theme, participants described their guilt and self-annoyance in not being able to make the 'correct' decisions in their day-to-day lives or do all the things that were expected of them from their health professionals, e.g. eat food with low sugar content. This finding is consistent with other qualitative research which found that patients self-attributed blame for being unable to achieve treatment goals. Furthermore this study reported that patients frequently expressed frustration and



disappointment inwardly through self-deprecating comments (Beverley et al., 2012). It is possible that these feelings of self-blame and self-criticism around their self-management pervaded to their difficulties in logging on to the website as agreed and thus reinforced their critical self-perception. The likelihood of this emotional impact occurring may be greater for older adults with type 2 diabetes who may find the website technologically challenging or for adults of working age who cannot find the time to dedicate to the website. With the amount of demands that are placed on people with type 2 diabetes to self-manage their condition, it may be for some people, that using a website is one demand too many.

### **Limitations and Strengths of Methodology**

Although generalisations from qualitative research should be made with caution, it is important to consider how the results of the current study may or may not extend to other users of the HeLP-Diabetes website. Aspects of the methodology that may have limited the extent to which the sample was representative of the larger population included: the sample size, the characteristics of the sample, demand characteristics and length of intervention.

In terms of qualitative research, a sample size of 18 is considered to be sufficient. Studies have demonstrated that saturation can often be reached within 12 interviews (Guest, Bunce & Johnson, 2006) and within the current study, themes began to be re-stated after approximately seven to eight interviews. However, with regards to the quantitative aspect of the study, the sample size meant the statistical power was low, making it more difficult to detect changes on the quantitative variables. This may be one of the reasons why the quantitative data did not produce any significant results and why there was a discrepancy between the results of the quantitative and qualitative analyses. The effect sizes that were generated also suggested that a larger sample size was needed. Another important consideration regarding the quantitative analysis was the large amount of measures being used,

therefore increasing the chance of a type 1 error. For this reason it was decided that a conservative approach would be taken and the significance level was lowered to 0.01.

The sample was representative of a good range of ages, ethnic backgrounds, times since diagnosis, attendance at self-management courses and computer skills. However, it was skewed towards male, older and more highly educated individuals. The level of education may have been a reflection of the population of the GP practices from which the participants were recruited. However, this is not necessarily generalisable to other areas. As the participants were self-selected, it might be that partaking in research was of more interest to people with higher education or people who were more motivated and resourceful in accessing a new intervention. This, therefore, means that those who were less motivated in managing their diabetes may not be represented by the current sample. The majority of participants had lived with diabetes for more than 5 years, meaning that newly diagnosed individuals were also under-represented. Baseline characteristics from the measures showed that the participants were not depressed, anxious or particularly distressed about their diabetes. This meant that a floor affect was easily reached with regards to the difference the website could make to these measures. It also means that individuals with more severe psychological difficulties may have a very different experience of the website. The three participants who disclosed during the interviews that they were in therapy during the time of the study did not allude to therapy being influential to their views of HeLP-Diabetes.

Another limitation to the generalisability of the results was the manner in which the intervention was delivered. The participants met with the researcher for one and a half hours initially and then had weekly contact (either by phone or email) for six weeks to prompt them to use the website. In the context of research which has highlighted the high attrition rates in online interventions (Bennett & Glasgow,

2009), it was decided that this amount of contact and support was appropriate. However, the intervention was therefore expanded from independent use of the HeLP-Diabetes website to more of a guided self-help model. Even with this level of support, only 11 participants reported using the website at least once a week. However, a strength of the study was that only one out of the nineteen participants dropped out of the study therefore making the attrition rate unusually low for an online intervention. The disadvantage of the amount of contact offered was that it made the study less ecologically valid as other users may not receive the same amount of support. An implementation study is currently being carried out by the developers of the HeLP-Diabetes website, to investigate the most helpful and cost-effective level of support to be offered to the website users (Ross et al., 2014). It is therefore yet to be established whether the model of guided self-help in the current study will be very different from what will be offered in GP practices.

Due to the level of contact between the researcher and participants, another factor which may have affected the results were demand characteristics. Although it was explained to the participants that the researcher was not part of their health care team, the fact that the interviews were held in their GP practice may have influenced their disclosure of certain feelings or behaviours. For example, they may not have shared discrepancies from the self-management plan agreed with their GP for fear of their health team finding out. Although it was explained that the researcher was not involved in the development of the website, it was conveyed that the researcher was conducting the research in collaboration with the E-Health Unit team. The participants may therefore have felt pressure to give positive feedback regarding the website. They were also aware that the study was looking at the psychological impact of the website and therefore may have over-reported positive emotional reactions to the website in order to benefit the study and please the researcher. The fact that the researcher had type 1 diabetes was not disclosed in

case it may have further affected the participants' ability to share their feelings regarding their condition.

A further limitation was the amount of time offered to participants to use the HeLP-Diabetes programme. Participants were given six weeks to use the website before meeting the researcher for the follow-up interview. This timing was chosen in the context of the limited time the researcher had to conduct the study. Research has also shown that engagement rates in online interventions tend to drop over time (Bennett & Glasgow, 2009). However, this may not have been enough time to bring about substantial changes to the participants' psychological well-being. They may also have struggled to establish a routine of using the website in that time. Conversely, they may have felt most of the benefits of using the website in the first couple of weeks and then been unable to remember or retain those benefits up to the six week follow-up.

### **Clinical Implications**

The findings of the current study further highlight the need for health professionals to consider the psychological impact of living with diabetes and to take steps to help their clients address it. The qualitative data demonstrates that a web-based diabetes self-management programme can improve the psychological well-being of adults with type 2 diabetes. The HeLP-Diabetes website therefore provides a viable option to GPs and Practice Nurses for helping their patients increase their awareness of their condition; appreciate the seriousness of their diabetes whilst increasing their self-efficacy and confidence in managing it; and learn from others with type 2 diabetes so that they feel better able to manage their anxieties and low moods. These improvements in psychological well-being may then lead to improvements in glycaemic control and reduced risk of diabetes-related complications (e.g. Sturt et al., 2010).

This study also highlights some important factors for GPs and Practice Nurses to consider when deciding who the website might be more or less helpful for. The results showed that 47% of participants had not previously received any structured education around their diabetes. For people who do not have the time or ability to attend a face-to-face course, HeLP-Diabetes can provide an accessible alternative to receiving important diabetes-related information. However, patients who are not familiar or comfortable with online resources or patients who are already dealing with many demands in their day-to-day lives, might find it challenging to make best use of the website. If these patients already have a tendency to be self-critical regarding their difficulties with diabetes self-management, then it is possible that this intervention may reinforce their sense of 'failure' if they are unable to use the website. Conversely, it might be that HeLP-Diabetes could be particularly helpful for people who are newly diagnosed. This unfortunately was not established in the current study as there was only one newly diagnosed participant. However, the majority of participants expressed that they felt the website would be most helpful to people who had just received their diagnosis. Research has shown that it is commonly assumed that patients with a new diagnosis have difficulty in retaining information due to the resulting shock and stress (van der Molen, 1999). However, a qualitative study involving 40 newly diagnosed patients with type 2 diabetes, found that most patients wanted more information about diabetes management at the time of diagnosis (Peel, Parry, Douglas & Lawton, 2004).

The results of this study may also have implications for Clinical Health Psychologists working with people with type 2 diabetes. The results from the interviews highlight the types of psychological needs that clients may present to a psychologist. It is important to note that despite the amount of difficulties described by these participants, the majority did not report the levels of diabetes-related

distress, depression or anxiety on the measures, which may usually warrant a referral to a psychologist. This may be due to an avoidance of concerns and responsibilities around their condition. This study highlights the need of health professionals to talk further with patients with diabetes about their experiences, challenges and psychological impacts of living with diabetes in order that they can receive appropriate support. It is possible that patients would be reluctant to receive a referral to a psychologist if they are managing by minimising their diabetes-related concerns, in which case a referral to the HeLP-Diabetes website might be preferable and also of benefit.

### **Recommendations for Further Research**

The UCL E-Health Unit is currently conducting a randomised controlled trial to investigate the efficacy of the HeLP-Diabetes website. As part of the RCT they will be looking at diabetes-related distress. With a larger sample size and greater statistical power, the RCT will provide further information regarding the impact of the website on the users' psychological well-being.

To improve upon the current study, future research could experiment with the amount of time needed for participants to use the website in order to feel some psychological benefits. Some participants in the current study expressed that they felt six weeks had been too short or their time had been compromised by other things going on in their lives. It may therefore be beneficial to look at the amount of time spent on the website compared to the perceived benefits gained.

Further research could also be conducted to look at who is more likely to feel improvements in psychological well-being from using the website. It may be that the website is best aimed at people experiencing low levels of distress or psychological difficulties so that they might be able to better concentrate on and engage with the contents of the website. Alternatively it could be the people who feel most distressed who could find the information on the website particularly helpful. Time

since receiving the diabetes diagnosis may also be a factor that could influence the amount of benefit gained from the website.

Finally, it may be helpful to investigate the psychological impact of specific aspects of the HeLP-Diabetes programme. GPs or Practice Nurses would then be able to recommend sections of the website for particular emotional needs of their patients. The programme includes a module on 'managing moods' but interestingly this part of the website did not seem to have the largest effect on the participants' emotions. Instead, it seemed to be general information provision and the sense of support gained from the website as a whole which the participants found to be most beneficial. By gaining a better understanding of the emotional influence of specific aspects of the website, it may be possible to enhance the positive impact of HeLP-Diabetes on psychological well-being.

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### **Part 3: Critical Appraisal**

The following critical appraisal clarifies the context to the research presented in parts one and two. I will explain how my background affected my approach to the study and will explore the advantages and disadvantages of having experiential knowledge of the research topic. I will also look again at methodological issues mentioned in the discussion, including further consideration of the key decisions. Specifically, I will look at the use of reflexivity and bracketing of pre-conceptions, the decision to use a mixed methods approach, the role of prompts and researcher-participant rapport during the intervention, technical issues with the programme and recruitment. I will conclude with reflections on the personal impact of the research.

### **Background**

Whilst exploring various options for the topic of my major research project, the possibility of doing a piece of work with the HeLP-Diabetes team was presented to me by my internal supervisor. Conducting research on diabetes was not something I had previously considered. However, on learning more about the study, it became apparent that it matched many of my interests – both professionally and personally.

I was diagnosed with type 1 diabetes in 1990, at the age of six. Since then, there have been many significant advances within the understanding of diabetes and the provision of care (Nyenwe, Jerkins, Umpierrez & Kitabchi, 2011). For example, my own self-management regime has advanced from using insulin vials with hypodermic needles, to using pre-loaded insulin 'pens', to wearing a continuous subcutaneous insulin infusion pump. These advances have certainly made aspects of the physical management of diabetes easier. However, an area which I have long felt to be less advanced in diabetes care is the provision of psychological or emotional support.

A pinnacle moment in my psychology career occurred within a Clinical Health Psychology lecture during my undergraduate degree. A Psychologist spoke

to us about the emotional difficulties involved in living with diabetes and the role that health professionals could play in helping to alleviate diabetes-related distress. After 16 years of living with the condition, this was the first time that I had heard a professional acknowledge the existence of a psychological impact of diabetes. This felt like a revelation. It provided comfort to realise that I was not alone in my emotional experience of diabetes. However, it also caused frustration in realising that a large part of my struggle of living with diabetes had been overlooked by my diabetes care team. I consequently became very interested in the psychological impact of health conditions in general and decided to do an MSc in Health Psychology.

Having experiential knowledge of a research topic can offer both advantages and disadvantages to the research process (Barker, Pistrang & Elliott, 2002). One advantage of my knowledge of diabetes was that it gave me a good level of understanding into the self-management challenges described by the participants. This meant that the participants could speak freely during the interviews without being interrupted by requests for explanations about diabetes in general. My experiences also better enabled me to empathise with the participants. This is particularly important for this population, whose self-management efforts are often misunderstood. This theme was included in the findings of the study, where the participants described having to balance their diabetes self-management with wanting to lead a normal life. Whilst loved ones and medical professionals may view a person with diabetes as not doing everything they can to look after themselves, another perspective could be that they are doing all they can whilst maintaining their quality of life. Due to my experiences, I was able to fully empathise with the difficult nature of this dilemma, rather than negatively judging any inability to meet the demands of their self-management regime.

On the other hand, a possible disadvantage of having experiential knowledge of the research area was my potential emotional reaction to the study. When deciding whether to do this piece of research, one major consideration was whether the subject matter might be too close to home. I contemplated whether being continually exposed to information regarding difficulties associated with diabetes, especially health complications, might negatively affect my mood. However, I also realised that learning more about diabetes and hearing from others with similar experiences could be not only very interesting, but potentially helpful to my own diabetes management. Positivist social scientist researchers have argued that a researcher's emotions can negatively impact the research process and contaminate findings (Tillmann-Healy & Kiesinger, 2001). However, within contemporary social science research, it is more commonly accepted that the researcher's emotions and reactions can provide insight and value to a study, particularly in health and illness research (Gough & Madill, 2012).

Another disadvantage of my experiential knowledge was the risk of forming false assumed similarities with the participants. Despite being very aware of the extreme variation in how people can experience their diabetes and self-management, my knowledge of diabetes placed me in a position where I might have over-identified or over-empathised with the participants. This issue was managed through reflecting on and bracketing my assumptions and prior beliefs.

### **Reflexivity and Bracketing**

Qualitative research has its roots in constructivism, which posits that meaning is constructed by human beings as they interact and engage in interpretation (O'Leary, 2004). The researcher and participant are therefore both responsible for constructing meaning throughout the research process. The prior assumptions and beliefs of a researcher will inevitably shape the interpretations and meanings that are formed (Willig, 2008). Through reflexivity, researchers can gain



greater awareness of their preconceptions around the research topic and then attempt to 'bracket' them or set them aside so they have less influence over the research (Gearing, 2004). During the study process, I used supervision with an experienced researcher to reflect on my own biases and assumptions around diabetes. One such assumption was that most of the participants would have experienced or would currently be experiencing some level of emotional distress with regards to their diabetes. This belief was based on my own experiences, the experiences of friends with diabetes who had reported feeling similarly and also my research into health conditions during my MSc. By bringing this view into my awareness, I could attempt to bracket it and remain open-minded to other possibilities, e.g. that an individual's emotional well-being may not necessarily be negatively impacted by living with diabetes.

During the interviews, it was also necessary to reflect upon the distinction between my role as a researcher versus my role as a Trainee Clinical Psychologist. I was conscious of my tendency, as a Trainee Clinical Psychologist, to want to help people gain greater understanding of their difficulties and to challenge unhelpful cognitions and patterns of behaviour. I was also aware of unspoken hypotheses that formed in my mind about the possibility of some patients being avoidant of expressing or being in touch with their difficult emotions around their diabetes. This again seemed to relate to my preconceptions around the emotional experience of people with diabetes. With regards to 'bracketing' my approaches as a Trainee Clinical Psychologist, I tried to achieve this by listening and reflecting without offering interpretation or suggestions. Using a semi-structured interview approach allowed me to move on to my next question if I felt we were getting into a space where I might be tempted to intervene. However, for a couple of participants, speaking about their diabetes and feelings opened up some areas of difficulty, which were not necessarily relevant to the study, but which they felt compelled to

share with me. In these moments I felt the researcher and Trainee Clinical Psychologist parts of me were conflicted. However, rather than quickly cutting the participant off and moving to the next question, I tried to find a compromise of allowing them to talk for a while before steering them back to the topic. I also recommended to these participants that they speak to their GP about opportunities for counselling. This manner of handling the situation seemed to aid the rapport that I was able to establish with the participants.

I think the most difficult role to 'bracket' was that of being a fellow diabetic. As well as attempting to set aside any false assumed similarities, I also had to manage my temptations to offer practical advice around difficulties which I had experienced that were described by the participants. In anticipation of this, I made the decision prior to the interviews, that I would not disclose my diabetes to the participants. Not only did this help to gain some emotional distance, but I felt that disclosure would have interfered with the interview process and possibly the themes that the participants felt willing to talk about. Instead of offering practical advice, if there was a specific aspect of their diabetes self-management that they were finding difficult, I would direct them to a relevant section on the HeLP-Diabetes website or advise them to speak to their GP.

### **Mixed Methods Approach**

During my MSc in Health Psychology I conducted qualitative research into the experiences of people living with Chronic Regional Pain Syndrome (CRPS; Rodham, Boxell, McCabe, Cockburn & Waller, 2012). CRPS is a neuropathic pain syndrome which consists of a wide range of symptoms in the limbs, which are disproportionate to the original insult. With so much attention usually focused on the physical aspects of CRPS, it felt like the qualitative interview process provided a rare and important opportunity for the participants to describe the psychological and

social challenges that they faced with the condition. This experience helped to inform the decision to involve a qualitative approach with the current study.

The decision to expand the study design into a mixed method, quantitative and qualitative approach was based on several considerations. Mixed methods research has been used for several decades, mainly to broaden the scope of research to counter-balance the weakness of either approach alone (Creswell & Plano Clark, 2007; Tashakkori & Teddlie, 2003). The qualitative interviews allowed for exploration of the participants' complex views of their diabetes and the emotional impact of the HeLP-Diabetes programme. The interviews allowed the participants to have more flexibility and give more detail in their responses to questions. It also meant that the information gathered was not constrained by pre-existing hypotheses (Barker, Pistrang & Elliott, 2002). However, in testing the study hypotheses and capturing changes in emotional well-being, it was felt that validated measures could give more precise descriptions. A quantitative approach also had the advantage of allowing a more accurate comparison of responses obtained before and after the intervention. The two methods were therefore used in a complementary fashion to gather both detailed views and more precise, and potentially more subtle, changes in emotional and cognitive constructs. It was also possible to use the qualitative findings to gain greater understanding of specific trends found in the quantitative measures. An example of this occurred with the non-significant trend towards an increase in anxiety on the HADS. From the interviews it was possible to ascertain that an explanation of this slight increase in anxiety may have been an increased awareness of diabetes-related complications.

The quantitative and qualitative data were separately analysed, in order to provide an overall picture of outcome for the group of participants as a whole. Future research could look at each participant's differences in scores on the

quantitative measures and see how they compared to that person's interview data. This could offer greater insight into individual experiences of using the website.

The present analysis yielded discrepant findings from the quantitative and qualitative arms of the study. Whilst there were no statistically significant gains in the quantitative scores, the qualitative interviews clearly demonstrated that the participants had felt many emotional benefits from using HeLP-Diabetes. Two potential reasons for this discrepancy were: 1) the low statistical power of the study, which made it more difficult to achieve a statistically significant result, even though the obtained effect sizes suggested positive trends; and 2) the choice of constructs to be measured may not have accurately captured the aspects of emotional well-being of central concern to the participants.

### **Prompts and Researcher-Participant Rapport**

My approach to this research was also influenced by my previous work experience as a Primary Care Mental Health Worker. As part of this role I facilitated patients' use of a computerised CBT intervention called 'Beating the Blues' (Ultrasis Ltd, 2014). In this capacity I started to understand the issues of engagement that were associated with online interventions and the importance of additional support in aiding usage (Bennett & Glasgow, 2009). It was therefore decided that the participants would be offered weekly prompts. These prompts came in the form of weekly phone calls, texts or emails, depending on the participants preferred method of communication. Prompts have been found to increase positive outcomes in health behaviour interventions (Fry & Neff, 2009). The primary aim of the prompts was to remind the participants to use the website. However, the prompts also provided an opportunity to troubleshoot any technical difficulties and to suggest areas of the website that they might find helpful, based on the information from the pre-intervention interview. I was pleasantly surprised to find that my expectations of the participants' engagement with the online intervention, as based on my previous

experiences, were not accurate. Many of the patients engaged well with the HeLP-Diabetes programme and were able to notice benefits from using it.

Although reports from the post-intervention interviews suggested that participants found prompts to be helpful, they also seemed to have two unintended consequences. The first was that for many participants the prompts caused them to feel guilty or self-critical due to them not using the programme as agreed. The second was that the phone calls (and interviews) created a space in which a participant-researcher rapport was able to develop. The phone call prompts often became quite lengthy; due to discussions around aspects of the site they had been finding useful or technical difficulties. A possible advantage of the rapport was that the attrition rate for the study was unusually low for an online intervention (Bennett & Glasgow, 2009). A disadvantage of the rapport however was its possible influence on demand characteristics (McCambridge, de Bruin & Witton, 2012). The participants may have felt more inclined to try and please me with their responses to the HeLP-Diabetes programme. Another possible effect of the amount of contact and rapport that was built could have been a Hawthorne effect (Adair, 1984), in which the participants benefited from having some space to talk to someone about their diabetes. Future research could use two experimental conditions of high and low levels of support, to compare the impact of support and possible influence of demand characteristics. Lower levels of support could be achieved through keeping prompts to texts and emails, rather than phone calls.

### **Technical Difficulties with the Programme**

The HeLP-Diabetes website was launched in April 2013, with access only granted to users who were involved in research with the UCL E-Health Unit. By the time the participants of my study started using the programme (June 2013), it was still very new and therefore experiencing a few minor technical issues. Also, the programme's 'forum', where users could discuss diabetes-related issues and share

experiences, had very little activity at the start. These aspects of the programme were reported as being off-putting by many of the participants and were likely to have influenced the usage and emotional impact of the website. It would have been advantageous to have conducted the study when HeLP-Diabetes was further along with its development and general usage; however this was not possible due to the constraints of my academic programme.

Another technical aspect of HeLP-Diabetes, which seven participants reported having difficulty with, was logging into the site. In anticipation of this issue I asked them to write down their username and password on a HeLP-Diabetes guide (see Appendix G), for them to take home, so that they wouldn't forget them. I remain unclear why the difficulties with logging in occurred, or why the usernames and passwords did not seem to work. One hypothesis is that the passwords on the website were case sensitive, and despite warning about this, the participants may still have been entering the passwords incorrectly. For one participant, this became such an issue that I invited him to join me for an additional facilitation appointment to show him again how to log-on to the website, following which he was able to log-on at home. Another participant reported having very basic computer skills and could only use the website when his nephew was present to help him to log-in to the programme. Other people, who were able to log-in to the programme, reported finding the log-in process tedious and annoying. Though this appears to be a minor issue, if participants were entering the website feeling frustrated then it may have affected their ability to feel a positive influence from the website.

### **Recruitment**

The sample in the present study was recruited from three GP practices, with 11% from practice one, 68% from practice two and 21% from practice three. There seemed to be three main reasons for the difficulties in recruitment from practices one and three. Firstly, the Practice Nurses who were asked to refer patients

reported that they were extremely busy during the research period. This meant that their focus was not on the study and they talked about having difficulty in keeping it in mind when meeting with patients. I tried to aid this situation by sending regular emails to the Practice Nurses to ask how the referrals were coming along and to see if there was anything I could do to help with recruitment. I also supplied them with leaflets (see Appendix F) about the study to give to patients, in order to reduce the time they would need to spend discussing it. However, these approaches seemed to have little impact.

The second factor which impacted recruitment was inappropriate referrals. Practice one referred eight patients in total, six of whom were inappropriate for various reasons: two were unresponsive to emails and phone calls, despite numerous attempts; one reported that they were too busy to partake in the study; and three reported having mental health difficulties which meant they did not feel able to take part. Three patients that were referred from practice two and practice three declined to take part due to lack of interest. The reason for these referrals may have been because the Practice Nurses were unsure what else to offer these patients and thought that HeLP-Diabetes might be beneficial, without gauging interest or appropriateness. Another possible reason for the inappropriate referrals was a lack of clarity on my part in explaining the inclusion criteria for the study to the Practice Nurses. The inclusion criteria were explained at an initial practice recruitment meeting and then sent to the Practice Nurses via email for their information. However, in hindsight, I should have emphasised the criteria more strongly and sent reminders about them. This may have also prevented the recruitment of three patients who it later emerged were already in therapy.

The third and most evident cause of recruitment differentiation between the practices was the varying recruitment methodologies. Whilst practices one and three utilised the proposed recruitment strategy of identifying patients in routine

practice appointments, practice two requested to implement a different strategy.

This involved the practice sending out study invitation letters to appropriate patients, as identified by a GP from the practice database. The patients then opted-in to the study voluntarily. This manner of recruitment was a lot more effective. However, it may have also led to a sample bias towards more highly educated, middle to upper class individuals and also the type of people who would readily volunteer for research. This therefore reduces the study's generalisability as users outside of the research setting may not be as motivated or have as much free time as these individuals.

### **Reflections on the Personal Impact of the Research Process**

This research process has had a considerable impact on my own conceptualisation of diabetes. From my initial reading of the diabetes literature for my research proposal, I realised how little I knew about the potential serious consequences of poor glycaemic control. Reading the facts about long term health complications and reduced life expectancy did cause some initial shock. In my history of diabetes care, health professionals had always spoken of the 'risk of complications' as a way of highlighting the importance of good diabetes self-management. The finer details of such complications were not discussed however, presumably to prevent generating too much anxiety or psychological distress. I do not feel that the health professionals were mistaken in this approach as using fear as a motivator for behaviour change will not always be successful, especially if it is not coupled with a sufficient amount of support or information on how to change (Witte & Allen, 2000). It did however mean that on starting this study, I was exposed to new information that did cause me some concern. I dealt with this by thinking further about how I might improve my own self-management.

I found the interviews and interactions with the participants to be enjoyable but also sobering. I was moved by the manner in which the participants coped with



their diabetes and the daily challenges it presented them with. I also felt angry that more wasn't being done to support these individuals with their diabetes-related distress. The participants expressed their acknowledgement of the overloaded nature of the NHS and the limited time and resources it could offer to the ever growing number of people with type 2 diabetes. Most of them also spoke in a complimentary manner of the Nurse or GP that offered them annual diabetes reviews. However, my overall sense from my meetings with the participants was that they were largely fighting the diabetes battle alone and often felt like they were losing. I believe that this created emotional difficulties that were predominantly dealt with by downplaying their diabetes, at a detriment to their health.

One of the benefits of HeLP-Diabetes that was described by the participants was the sense of social support and connectedness with other people with type 2 diabetes. This benefit is commonly reported in the support group literature (e.g. Yalom & Leszcz, 2005). I feel my experience of the research process reflected this. By meeting people with diabetes I felt my own struggles with diabetes were normalised and thereby became easier to manage. However, I was also mindful that my experience of living with type 1 diabetes differed in some significant ways from their experiences of type 2 diabetes. One factor that differentiates type 2 diabetes is that it is often caused by lifestyle and obesity. The participants spoke of a sense of self-blame and guilt associated with this, which I could relate to, but had not personally experienced. Also, as type 2 diabetes is most frequently controlled with oral medication, many of the participants also spoke of their strong fear of having to start insulin injections – which I have been using since the age of 6. Despite these differences, I strongly empathised with the participants, without, I hope, over-identifying with them.

One of the personal consequences of this research process was that it brought my own diabetes to the forefront of my conscience. As described by the

participants, I have also tended in the past to push my diabetes to one side in trying to keep up with the demands of the rest of my life. However, learning more about complications and meeting with other people with diabetes provided me with the motivation to address my own self-management. I have subsequently managed to achieve much tighter control of my blood sugar levels and am currently healthier than I have been in a very long time.

### **Conclusion**

The impact of the research process on my own diabetes self-management, and my views on diabetes care in general, has been considerable. With the amount of people with diabetes reaching epidemic proportions, it is more important than ever that the impact of diabetes-related distress on diabetes self-management is acknowledged and addressed. The HeLP-Diabetes programme provides an accessible and cost-effective manner of delivering emotional support, which could compliment the work of GPs, Diabetes Nurses and Consultants and Clinical Health Psychologists. The nature of this online public health intervention means that it could reach a large number of people whose quality of life is being compromised by their condition. By improving their emotional well-being, people living with diabetes may consequently be able to improve their glycaemic control, lower their risk of developing long term health complications and lead happier, healthier lives.

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## Appendices

## **Appendix A: Medline Search Strategy for Literature Review**

Number	Searches
1	Intervention.mp.
2	coach*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
3	train*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
4	education.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
5	treat*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6	program*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
7	self management.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
8	1 or 2 or 3 or 4 or 5 or 6 or 7
9	diabetes related distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
10	diabetes related emotional distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
11	diabetes specific distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
12	diabetes distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
13	diabetes related emotional distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]

14	diabetes specific emotional distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
15	diabetes related psychosocial distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
16	diabetes specific psychosocial distress.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
17	emotional adjustment to diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
18	psychosocial adjustment to diabetes.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
19	(diabet* adj4 distress).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
20	9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21	*Diabetes Mellitus, Type 2/
22	diabet*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
23	limit 22 to yr="2013"
24	21 or 23
25	8 and 20 and 24



## **Appendix B: Screen Shots of the HeLP-Diabetes Programme**

## Diabetes self management programme

As part of a research project, the content of this website is currently available only to invited participants. Even small changes in what you do can make a big difference to your health if you work them in to your daily life. The choices you make have a much bigger effect on your type 2 diabetes than what your healthcare team does. Studies have shown that people who know more about diabetes develop fewer complications and have better control of their blood glucose levels.



- Getting started
- Planning changes
- Staying on track

To understand and self-manage type 2 diabetes, start here.

### Newly diagnosed?

- [Quick guides](#)
- [Common diabetes questions](#)
- [Treating type 2 diabetes](#)
- [Food](#)
- [Lifestyle changes](#)
- [Will diabetes affect my work?](#)
- [How will the NHS help me?](#)
- [HeLP Diabetes Forum](#)

### How to be healthier

- [Looking after yourself](#)
- [Blood pressure](#)
- [Physical activity](#)
- [Taking medicines](#)
- [Eating right](#)
- [Should I lose weight?](#)
- [Cutting down on alcohol](#)
- [Quitting smoking](#)

- Self management**  
What can I do to stay healthy?
- How the NHS can help**  
What care and health checks to expect.
- Easy exercises**  
How to increase my energy and fitness, or lose weight.
- Food and nutrition**  
What should I eat and how does it affect me?

### Latest news

[Giving up smoking improves mental and physical health](#)

[What did this study find?](#)

[Edit this article.](#)

[Home](#)

Search... [Search](#)

## Managing my feelings

### HOME



[Understanding my moods](#)

[My mood tools](#)

- [Understanding my moods](#)
- [My mood tools](#)

### RELATED TOPICS

- [Relationships](#)

Coming to terms with a diagnosis of type 2 diabetes and coping with difficult emotions can be a challenge. Learn more about moods here, and try out some tools to help you manage them.

### Watch the 'Getting the diagnosis' video

You will need audio for these videos. Click the expand button in the bottom right corner of the video to view full screen.

This 2 minute video explores the effects of being given a diagnosis of type 2 diabetes and the feelings that people have to deal with.

[Getting the diagnosis](#)

**Appendix C: Letter of Ethical Approval from the National Research  
Ethics Committee North West - Greater Manchester North**



**Health Research Authority**  
National Research Ethics Service

**NRES Committee North West - Greater Manchester North**

HRA NRES Centre Manchester  
3<sup>rd</sup> Floor, Barlow House  
4 Minshull Street  
Manchester  
M1 3DZ  
Tel: 0161 625 7817  
Fax: 0161 625 7299

Email: [nrescommittee.northwest-gmnorth@nhs.net](mailto:nrescommittee.northwest-gmnorth@nhs.net)

Ms Megan Cockburn  
Researcher  
University College London  
Department of Clinical, Educational & Health Psychology  
e-Health Unit  
Upper 3rd Floor, Royal Free Hospital  
Rowland Hill Street  
NW3 2PF

22 February 2013

Dear Ms Cockburn

**Study title:** The Impact of a Web-Based Self-Management Programme for Adults with Type 2 Diabetes on Emotional Well-Being  
**REC reference:** 13/NW/0076  
**IRAS project ID:** 119409

Thank you for your email dated 04 February 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 28 January 2013

**Documents received**

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	Email	04 February 2013
Participant Consent Form	1.2	04 February 2013
Participant Information Sheet	1.2	04 February 2013
Questionnaire: IPQ-R Diabetes	2	04 February 2013

**Approved documents**

The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Advertisement	1.0	06 December 2012
Covering Letter	Email	04 February 2013
Evidence of insurance or indemnity		02 December 2012
Evidence of insurance or indemnity	Cockburn	06 November 2009
GP/Consultant Information Sheets	1.0	04 December 2012

A Research Ethics Committee established by the Health Research Authority

Interview Schedules/Topic Guides	1.0	03 December 2012
Investigator CV	Murray	
Other: CV Academic Supervisor	Barker	
Other: Student CV	Cockburn	
Other: Data Protection Registration	Cockburn	02 December 2012
Other: GP Letter	1.0	04 December 2012
Other: GP Recruiting Email	1.0	04 December 2012
Other: Letter from Funder	Emails	26 October 2010
Participant Consent Form	1.2	04 February 2013
Participant Information Sheet	1.2	04 February 2013
Protocol	1.0	03 January 2013
Questionnaire: DMSES	Validated	
Questionnaire: HADS	Validated	
Questionnaire: MOSSS	Validated	
Questionnaire: PAID	Validated	
Questionnaire: IPQ-R Diabetes	2	04 February 2013
REC application	3.4	15 January 2013
Referees or other scientific critique report		17 October 2012
Summary/Synopsis	1.0	04 December 2012

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

<b>13/NW/0076</b>	<b>Please quote this number on all correspondence</b>
-------------------	---

Yours sincerely



**Ms Cynthia Carter**  
**Committee Co-ordinator**

This letter has been signed electronically. If you require a wet ink version please request one from the Committee Co-ordinator by email and it will be sent in the post.

Copy to: Dr Elizabeth Murray, Chief Investigator, UCL [elizabeth.murray@ucl.ac.uk](mailto:elizabeth.murray@ucl.ac.uk)

Professor Chris Barker, Academic Supervisor, University College London  
[c.barker@ucl.ac.uk](mailto:c.barker@ucl.ac.uk)

Mr Dave Wilson, Joint Research Office, University College London  
[jro.randd@ucl.ac.uk](mailto:jro.randd@ucl.ac.uk)

Dr Clara Kalu, R&D office for UCLH/Royal Free Hospital  
[clara.kalu@uclh.nhs.uk](mailto:clara.kalu@uclh.nhs.uk)

**Appendix D: Letter of Ethical Approval from the Local R & D**

27 March 2013

Dr Elizabeth Murray  
UCL Research Department of Primary Care and Population Health  
Upper 3rd floor, Royal Free Hospital  
Rowland Hill Street  
London NW3 2PF

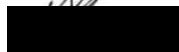
Dear Dr Elizabeth Murray

I am pleased to confirm that the following study has now received R&D approval, and you may now start your research in **the trust(s) identified below**:

<b>Study Title:</b> The Impact of the HeLP-Diabetes Programme on Emotional Well-Being V1.0 <b>R&amp;D reference:</b> 13PC33 <b>REC reference:</b> 13/NW/0076		
This NHS Permission is based on the REC favourable opinion given on <b>28 January 2013</b> .		
Name of the trust	Name of current PI/LC	Date of permission issue(d)
NHS Islington NHS Camden	Dr Elizabeth Murray Dr Elizabeth Murray	27 March 2013 27 March 2013
<b>If any information on this document is altered after the date of issue, this document will be deemed INVALID</b>		

Specific Conditions of Permission (if applicable)
<b>If any information on this document is altered after the date of issue, this document will be deemed INVALID</b>

Yours sincerely,



Emmanuel Rollings-Kamara  
Senior Research Governance Officer

## **Appendix E: Participant Information Sheet**





Participant information sheet date of issue: 27.3.13

Participant information sheet version number: V1.3

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## **PARTICIPANT INFORMATION SHEET**

### **The Impact of the HeLP-Diabetes Programme on Emotional Well-Being**

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You are being invited to take part in a study that is looking at whether a web-based programme can help improve the emotional wellbeing of people with type 2 diabetes.

Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve for you. This information sheet will help you, so please take some time to read carefully it and ask any questions if anything is not clear. Talk to others about the study if you wish.

Part 1 of this information sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

#### **PART 1.**

##### **Why are we doing the study?**

Type 2 diabetes is one of the most common long term health conditions in the UK, affecting over 2 million adults. Many people with type 2 diabetes need help and support to live a healthy, happy life. The NHS recommends that every person with type 2 diabetes should have the opportunity to attend a course on diabetes when first told they have diabetes, and once a year thereafter. But not everybody who needs these courses gets them – either because there are not enough courses locally, or because the courses are hard to get to.

We think one way of helping people with diabetes get the support and information they need to live a healthy, happy life is through the internet. We have developed a web-based programme offering help and support to people with type 2 diabetes, called HeLP-Diabetes. We now want to see if it

helps to increase the emotional well-being of the people who use it. We are asking for your help with this. You can use the programme whether or not you decide to help us with our research.

**Why have I been chosen?**

We are looking for people aged 18 and above with type 2 diabetes who are registered at your general practice and have internet access.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part in the research. Your usual health care from your doctor and general practice team will not be affected by whether you chose to take part or not. Take as long as you need to decide and discuss the study with the practice nurse or the researcher before making a decision. If you do decide to take part, you will be asked to sign a consent form. Even after signing this form you are free to withdraw at any time without giving a reason. However, if you do withdraw after providing the research team with some information about you, that information will be kept as part of the study.

**What will happen to me if I take part?**

You can use the HeLP-Diabetes programme without taking part in the research. However, if you do decide to help us with our study, the first thing you will be asked to do is participate in a brief initial interview about your experiences of living with diabetes.

You will then be asked to complete some online questionnaires at home or wherever you have convenient access to the internet.

You are then free to use the website as much or as little as you like. If you need any help using it, you can ask the researcher. You will be given the option to receive reminder texts and/or emails that will offer help and encouragement in using the programme.

Six weeks after registering on the programme we will ask you to complete some further questionnaires. We will also ask you to participate in a second interview to ask about your experience of using the HeLP-Diabetes programme. This will be with the same researcher and you can do this in person or over the phone.

The HeLP-Diabetes programme includes an online forum for people with type 2 diabetes to communicate with each other. Guidelines for use of the forum are clearly visible on the website. The guidelines ask participants not to post any offensive or personally hurtful remarks and not to use the forum as a replacement for contacting their own health professionals. The research team will be checking the forum and any offensive remarks will be taken down. If misleading or inaccurate information is posted then the research team will add a post directing participants to the part of the website where accurate information on this topic is available.

The programme is designed to help to improve your self-management skills. **It is not designed to provide individual medical help.** There is an "ask the expert" tool in the programme, where you can post requests for more information. This tool is not suitable for individual medical advice and all such queries should be directed toward your own health professional.

**Will I benefit from taking part?**

We have designed the HeLP-Diabetes programme to be useful for people who want to feel better about living with type 2 diabetes. You can use the programme (HeLP-Diabetes) whether or not you decide to take part in the study. However, if you do take part you will know you have helped us to work out if the HeLP-Diabetes programme can help people to increase their emotional well-being.

**Are there any risks involved?**

It is very unlikely that you will come to harm as a result of taking part in the study. The information on the website has been developed by a team of doctors, nurses, dieticians and researchers. It reflects current best practice in the NHS. However, some people may be upset by reading information about their health and potential future problems. If so, we encourage you to talk about any worries or anxieties you have with your doctor or nurse.

The research procedures are also very low risk. You will be asked to complete questionnaires about your health and wellbeing and two interviews about your experience of living with diabetes and using HeLP-Diabetes. It is possible that you may feel upset in talking about difficult aspects of your diabetes. You do not have to answer any interview questions that make you uncomfortable. If you do feel upset in the interviews then we will encourage you to look at areas of the programme that have been developed to help people to cope better with difficult emotions. We would also encourage you to talk to your health professional about the possibility of gaining additional support.

**What happens when the study stops?**

When the research stops you will not be required to do anything further.

The HeLP-Diabetes programme may still be available for you to use, however, this is not guaranteed at this point and will partly depend on how many people use it. Following the research study, amendments may need to be made to the programme, or the site may have to go offline for other reasons. More information on this will be made available on the HeLP-Diabetes programme at the end of the study period.

**What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

**Will my GP and health care team know I am in the study?**

Yes. We will inform your GP that you are in the study. This will not affect the care they give you in any way.

**Will the information I give in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

**Can I withdraw from the study once I'm in it?**

Yes. You can withdraw from the study at any time without giving a reason. However, any information that you have already provided will be kept in the study.

## **PART 2: Detailed information about the conduct of the study.**

### **What will happen to the information I provide?**

All information about you will be treated confidentially and in accordance with the Data Protection Act 1998. We will keep your personal identification data (your name, address) separate from the rest of the information about you in the study, which will only be identified by a unique participant identification number. The data will be stored online on a secure server which has been approved for clinical research. Only authorised persons (the research team and the regulatory bodies that monitor researchers in the UK) will have access to your personal data.

The results of the questionnaires you fill in and the answers you give to interview questions will not be shared with your health care team, unless you or someone else is deemed to be at risk. If the questions make you aware of a problem you should tell your GP or nurse.

### **What if there is a problem?**

Any complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should speak to the study researcher, Megan Cockburn, who will do her best to answer your questions. If she cannot help, your concern will be passed to the Chief Investigator, Dr Elizabeth Murray, who has overall responsibility for the study. The contact details for both Megan Cockburn and Dr Murray are below.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS - [www.pals.nhs.uk](http://www.pals.nhs.uk)).

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. Please make the claim in writing to Dr Elizabeth Murray who is the Chief Investigator for the research and is based at the e-Health Unit (UCL Research Department of Primary Care – full address below). The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this

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

The results of this study will be written up in a report and submitted for publication in academic journals and presented at conferences. We hope they will influence NHS policy and lead to improved provision for patients. You will not be identified in any report or publication. We would be happy to send you a summary of the results – if you would like us to do so please fill in the second page of the consent form.

### **Loss of Capacity**

In the very unlikely and unfortunate event that someone who takes part in the study loses the ability to make informed decisions for him or herself, that person would not continue to take part in the study. Any information that we have received before such an event would be used in the study.

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

The trial is being run by University College London. It is funded by the National Institute of Health Research. It is sponsored by University College London.

The research team are: Dr Elizabeth Murray (General Practitioner and Researcher), Prof Chris Barker (Joint Research Director of the UCL Clinical Psychology doctorate programme); Dr Kingshuk Pal (General Practitioner and Researcher), Dr Charlotte Dack (Psychologist and Researcher), Ms Jamie Ross (Psychologist and Researcher), Ms Orla O'Donnell (Project Coordinator) and Megan Cockburn (Trainee Clinical Psychologist and Researcher).

The content of HeLP Diabetes has been written and developed by a larger team including people with Type 2 Diabetes, Specialist Diabetes Consultants, General Practitioners, Diabetes Specialist Nurses, Practice Nurses, Dieticians, Sociologists, Psychologists, a Web Designer and a Software Company. For more information about the team, please see <http://www.ucl.ac.uk/pcph/research-groups-themes/e-health>

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

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by [NAME ] Research Ethics Committee.

### **Is there an independent contact point where I can get general advice about taking part in research?**

Yes. INVOLVE is a national advisory group that supports greater public involvement in NHS, public health and social care research. They provide advice and information on public involvement in research. You can find out more from their website: [www.invo.org.uk](http://www.invo.org.uk)

You can contact them at: INVOLVE, Wessex House, Upper Market Street, Eastleigh, Hampshire, SO50 9FD or Telephone: 023 8065 1088

### **Is there a contact point where I can find out further details about the research trial?**

Yes. If you have any questions at all about the trial or would like further information, please contact the study researcher, Ms Megan Cockburn or your practice nurse.

### **Who do I contact if I wish to take part?**

If you are interested in taking part, have any questions about the study or would like further information then please contact the study researcher, Ms Megan Cockburn, at the details below:

## **CONTACT DETAILS**

Name	Ms Megan Cockburn	Dr Elizabeth Murray
Role	Study Researcher	Chief Investigator
Tel	[REDACTED]	020 7794 0500 ext 38826
Email	<a href="mailto:megan.cockburn.09@ucl.ac.uk">megan.cockburn.09@ucl.ac.uk</a>	elizabeth.murray@ucl.ac.uk

Address	Research Department of Clinical, Educational and Health Psychology University College London, Gower Street, London WC1E 6BT	eHealth Unit, UCL Research Department of Primary Care & Population Health, Upper 3rd Floor, Royal Free Hospital, Rowland Hill Street, London NW3 2PF
Fax	020 7916 1989	020 7794 1224.
Web	<a href="https://www.ucl.ac.uk/pcph/research-groups/themes/e-health">https://www.ucl.ac.uk/pcph/research-groups/themes/e-health</a>	<a href="https://www.ucl.ac.uk/pcph/research-groups/themes/e-health">https://www.ucl.ac.uk/pcph/research-groups/themes/e-health</a>

## **Appendix F: Informed Consent Form**

**ROYAL FREE AND UNIVERSITY COLLEGE MEDICAL SCHOOL  
UCL DEPARTMENT OF PRIMARY CARE AND POPULATION HEALTH  
E-HEALTH UNIT**

Consent form date of issue: 27.3.13  
Consent form version number: V1.3



Centre Number:  
Study Number:  
Patient Identification Number for this trial:

**CONSENT FORM**

Title of Project: **The Impact of the HeLP-Diabetes Programme on Emotional Well-Being**

Name of Researchers: 1) Dr Elizabeth Murray (Chief Investigator)  
2) Miss Megan Cockburn (Study Researcher)

	<b>Initial here</b>
I confirm that I have read and understand the information sheet dated 27.3.13, V1.3 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that I am volunteering to participate in a research study exploring the psychological impact of the HeLP-Diabetes Programme	
I understand that a researcher will access my HeLP-Diabetes registration data and use this anonymously for research purposes. I agree to my registration data being used.	
I understand that I will be asked to complete questionnaires prior to registration and 6 weeks after registering. I agree to complete these questionnaires.	
I understand that I will be asked to attend two interviews with a researcher to discuss my experiences of living with diabetes and using the HeLP-Diabetes programme. I agree to take part in these interviews.	
I understand that the information I provide will be tape recorded or saved on a computer and used for the purposes of this research study only. I also understand that once the information has been transcribed, names and all other personal data will be destroyed in accordance with the Data Protection Act 1998.	



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. I also understand that any information provided up to the point of withdrawal will be kept in the study.	
I agree to my GP being informed of my participation in the study.	
I understand that all the information I provide will be kept confidential and anonymous	
I understand that relevant sections of my data collected during the study may be looked at by individuals from regulatory authorities and/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.	
I agree to take part in the above study.	

\_\_\_\_\_  
Name of participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of person taking  
consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

If you would like us to send you a summary of the results once the study has been completed, please tick here

Please provide your email address below

Email address: .....

This piece of paper will be stored apart from your consent form, and will not be linked to the data you provide in any way.

## **Appendix G: Study Leaflet**

## Using HeLP-Diabetes

### Useful information

#### Can I get help using the HeLP-Diabetes SMP?

Yes, if you are interested in using the HeLP-Diabetes SMP and would like some help with anything from logging in to deciding what bits of the programme to use then you can make a facilitation appointment with a nurse or researcher. Ask your doctor or nurse to refer you for one of these appointments.

#### Can I use HeLP-Diabetes without attending a facilitation appointment?

No. HeLP-Diabetes is not openly available to everyone. It is a new service that is only being made available to selected practices, diabetes clinics and patients at the moment. In order to use the programme and get the most out of using it you must attend a facilitation appointment with a nurse or researcher.

#### I don't have a home internet access, can I still use HeLP-Diabetes?

Yes, HeLP-Diabetes can be accessed from any computer with an internet connection. Your diabetes nurse or researcher will be able to give you information about local places where you can connect to the internet. HeLP-Diabetes can also be used during your appointment with your diabetes nurse and GP.

#### Having trouble using HeLP-Diabetes?

You can contact the HeLP-Diabetes researcher working in your GP practice or diabetes clinic below:  
Megan Cockburn  
UCL Researcher  
Tel: 020 7794 0500 (Ext: 38826)  
Email: [megan.cockburn.09@ucl.ac.uk](mailto:megan.cockburn.09@ucl.ac.uk)

#### Your login details:

Username:

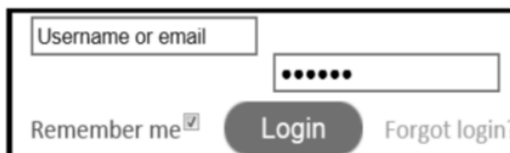
Password:

#### How do I access HeLP-Diabetes?

1. Type in the URL: [www.help-diabetes.org.uk](http://www.help-diabetes.org.uk) into your web browser:



2. When prompted enter your login details that you created in the facilitation appointment:



3. If this is your first login you will need to agree to the terms and conditions of using the site before accessing the content.

#### Forgotten your login details?

Don't worry, if you have forgotten your login details follow step 1. and then click the 'Forgot login?' button and follow the instructions on screen.



Healthy Living for People with  
type 2 Diabetes



[www.HeLP-Diabetes.org.uk](http://www.HeLP-Diabetes.org.uk)

**HeLP-Diabetes**  
an online self-management  
programme for people with  
type 2 diabetes

An information guide



## HeLP-Diabetes.org.uk

an online self-management programme for people with type 2 diabetes

### What is HeLP-Diabetes?

HeLP-Diabetes is an online programme which is designed for people with type 2 diabetes. Having type 2 diabetes means it is really important to lead a healthy lifestyle and look after the body and mind. Self-management is the most important part of diabetes care and can help people lead a healthy, happy life with diabetes whilst reducing the risk of other health problems. HeLP-Diabetes has been created to assist people with type 2 diabetes with the tasks involved in self-management.

### How has HeLP-Diabetes been developed?

HeLP-Diabetes has been developed by a research team at University College London (UCL) made up of GP's, psychologists, researchers, diabetes nurses and consultants, dieticians and most importantly people with type 2 diabetes. HeLP-Diabetes provides information, tools, advice and support to everyone with type 2 diabetes, whether you are newly diagnosed or have had diabetes for many years.

### How can I use HeLP-diabetes?

HeLP-Diabetes is made up of different sections designed to provide something for everyone with type 2 diabetes whether you are newly diagnosed or have been living with diabetes for many years, whether you manage your condition with diet and physical activity or if you take medications or are on insulin we hope you find something useful for you. On the next page you will find a summary of the different parts of HeLP-Diabetes.

**Understanding diabetes** answers commonly asked questions about type 2 diabetes. You will find information on what diabetes is, how diabetes might affect your body and what you can do to look after yourself. **Watch** the 'Explaining diabetes' animation.

**Treating diabetes** gives information on specific medicines, what to do in certain situations like when you are ill and guidance on how to look after the parts of the body that might be affected by diabetes. **Learn** about different tablets used to treat diabetes.

**Living & Working with diabetes** provides practical information on managing relationships, jobs, travel, social life and finances. **Explore** the 'food' section written by dieticians.

**Staying healthy** has tools to help you achieve the best possible outcomes for your health through positive changes in your lifestyle including improving your diet, taking regular physical activity, stopping smoking and taking prescribed medicines. **Take** a health check.

**Managing my feelings** contains information on the range of emotions that are often associated with diabetes and tools to help you feel good and lead a happy life with diabetes. **Try** a feel good technique.

**My health record** provides information to help you understand your medical test results. You can also record your medications, test results and questions you want to ask your diabetes team. **Enter** your appointments and set reminders.

**News and research** related to diabetes is in this section. It included articles from the news, information on important research trials and advice about stories in the news. **Keep** up to date.

**Getting help** offers the chance to hear about other people's experiences of diabetes through the forum or watching 'people's stories'. **Interact** with others.

## Facilitation appointment

### What to expect

#### What is the facilitation appointment?

The facilitation appointment is a half hour session with a researcher from UCL which has been specifically designed to help you use the HeLP-Diabetes programme.

#### What will happen at this appointment?

At this appointment you will have the opportunity to find out more about the programme and ask any questions you may have. The researcher will register you on the programme and help you to login. You will learn how to use the programme and find out which parts of the programme may be most useful and interesting to you.

#### Do I need to bring anything to this appointment?

Yes. In order to be registered on the programme you will need an email address. Please make sure you know your email address or write it down and bring it with you. You should also bring your referral letter for this appointment with you.

#### Do I need to do anything before this appointment?

To get the most out of your appointment you can think about what areas of diabetes self-management you would like help with or to learn more about. This leaflet gives an overview of the different sections of the programme that may be of interest to you. You can also talk to your doctor or nurse about what areas of self management you might want to focus on.

#### I'm not very good with computers!

Don't worry, this session is designed for people with a range of experience with computers. The researcher will help you through every step and you will have plenty of time to ask questions.

**Appendix H: An Extract from the 'Guide to Using HeLP-Diabetes at Home'**

# Guide to using HeLP- Diabetes at home

Use this space to record your login details	
<b>HeLP-Diabetes login details</b>	
Username	
Password hint	

# Introduction

## What are the activities?

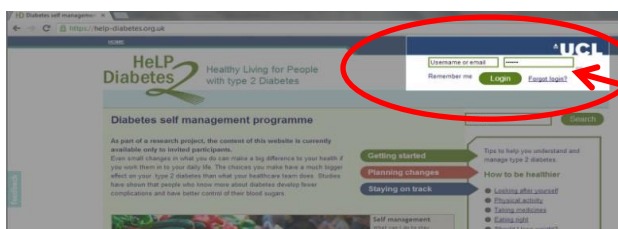
In this booklet you will find activities to help you with your diabetes self-management. They are designed to build on what you did in your HeLP-diabetes training session. You can do activities related to the area of diabetes self-management that you focussed on in your training session and any of the other activities that interest you.

## How do I do the activities?

1. Open your internet browser and go to the HeLP-Diabetes website.

URL: **www.help-diabetes.org.uk**

2. Enter your login details that you created in the training session.



**Tip:** If you've forgotten your username or password click the 'forgot login?' button.

activity there are instructions on how to find the right part of the website in just three or four clicks.

## Example

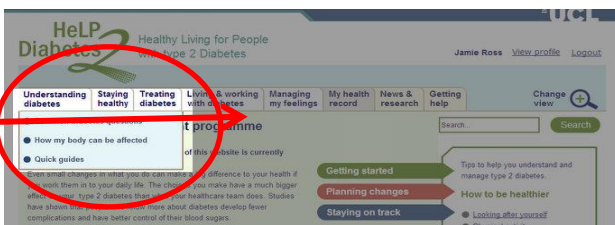
### Click 1

The main section of the website that your activity is in.



### Click 2

The category of the website that your activity is in



## Understanding diabetes

These activities will help you understand what diabetes is and answer some common questions you might have.

Activity 1	What is this activity?	How do I find it?
<b>Watch</b> the 'What is type 2 diabetes?' video	Watch an animation that introduces type 2 diabetes, explains what happens inside the body and what symptoms you might experience.	<b>Click 1:</b> Understanding diabetes <b>Click 2:</b> Common diabetes questions <b>Click 3:</b> What is type 2 diabetes

Activity 2	What is this activity?	How do I find it?
<b>Do</b> the 'About type 2 diabetes' quick guide	Follow this quick guide which will give you essential information about type 2 diabetes in under 15 minutes.	<b>Click 1:</b> Understanding diabetes <b>Click 2:</b> Quick guides <b>Click 3:</b> About type 2 diabetes

Activity 3	What is this activity?	How do I find it?
<b>Watch</b> the 'Getting the diagnosis' video	Watch people with type 2 diabetes talking about their experience of being diagnosed with diabetes and health professionals talking about the importance of self-management.	<b>Click 1:</b> Living & working with diabetes <b>Click 2:</b> Relationships <b>Click 3:</b> The emotional impact of diabetes



**Appendix I: Letter Confirming the Conclusion of a  
Participant's Involvement in the Study**

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ROYAL FREE AND UNIVERSITY COLLEGE MEDICAL SCHOOL  
UCL DEPARTMENT OF PRIMARY CARE AND POPULATION  
HEALTH E-HEALTH UNIT



Lead Clinician  
General Practice Address

Friday, 20<sup>th</sup> December 2013

Dear X,

**Re: [Participant Details]**

Thank you for referring the above named person to the HeLP-Diabetes study. HeLP-Diabetes is a web-based self management programme which aims to help people look after themselves and take control of their diabetes so they can lead healthier and happier lives. The current study asked Mr X to use the HeLP-Diabetes programme for 6 weeks. He was then asked to feed back about his experience of using the programme. Mr X and I met for our follow up appointment on 20<sup>th</sup> December 2013 and he has now completed his involvement in the study.

Kind regards,

Megan Cockburn

Trainee Clinical Psychologist and HeLP-Diabetes Researcher

## **Appendix J: Background Information Questionnaire**

## Section 1 - Background Information

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**What is your identification number?**

*(Your identification number should have been given to you by the UCL researcher during your facilitation appointment. If you have not received the number, or have mislaid it, then please contact [megan.cockburn.09@ucl.ac.uk](mailto:megan.cockburn.09@ucl.ac.uk))*

3

**What is your gender?**

- Male  
 Female

**How old are you?**

**What is your ethnic group?**

Please select ▼

**What is your marital status?**

Please select ▼

**Do you have children?**

- Yes  
 No

**What is your first language?**

**What is the highest level of education you have attained?**

Please select ▼

**Have you previously attended a course or group to learn more about your diabetes? If so, what was it called?**

**How long have you lived with diabetes?**

- 0-6 months
- 6 months to 1 year
- 1 to 2 years
- 2 to 5 years
- 5 to 10 years
- 10 years or more

**Which of the following are included in your current diabetes treatment plan?**

**(Please tick all the boxes that apply)**

- A healthy, balanced diet
- Regular physical activity
- Other lifestyle changes
- Metformin
- Insulin
- Other diabetes related medication
- Blood sugar testing
- Blood pressure monitoring

Please specify any other aspect of your treatment plan not otherwise specified:

**Have you experienced any diabetes related complications affecting the following:**

**(Please tick all the boxes that apply)**

- Eyes
- Heart

- Kidney
- Nerves
- Feet
- None of the above

Please specify any other diabetes related complications:

**Where do you use the internet?  
(Please tick all the boxes that apply)**

- At home
- In public locations (e.g. library or internet cafe)

**How would you describe your current computer skills?**

- Basic
- Intermediate
- Advanced

## **Appendix K: Baseline Interview Schedule**

**Assessment of Current Emotional Impact of Type 2 Diabetes:  
Baseline Interview**

**Semi-Structured Interview Schedule**

*“In this interview I am going to ask you a bit about what it’s like for you, living with type 2 diabetes. I would like to get an idea of how it impacts what you do day to day, your mood, your relationships and life in general. I would also like to find out what you think are the most difficult parts of having diabetes, how you cope with them and what you would like to change about your self-management. Finally, I’m going to ask a couple of questions about what you would like to get out of the HeLP-Diabetes programme.*

1. What is it like for you, living with type 2 diabetes?
2. What do you think are the most difficult parts of having diabetes?

*Note for Interviewer: Prompt for details on the impact of their diabetes on their mood, their day to day life and their relationships*

3. What would you like to change with relation to your diabetes self-management?
4. What would you like to get out of the HeLP-Diabetes programme?



## **Appendix L: Follow-Up Interview Schedule**

**Assessment of the Psychological Impact of a Web-Based Self-  
Management Programme for Adults with Type 2 Diabetes:  
6 Week Follow-Up Interview  
Semi-Structured Interview Schedule**

*“In this interview, I would like to ask you about how you found the HeLP-Diabetes programme and if you think that it has made any difference to you, your day-to-day life or your diabetes self-care. I'd like to get an idea of which bits you thought were good and which were not as good.”*

1. First of all, can you remember what you told me six weeks ago when I asked which parts of having diabetes you were struggling with and what you hoped to get out of the programme?

*Note to interviewer: Remind participant of their answers from the baseline interview if necessary.*

2. What, if any, difference did the HeLP-Diabetes programme make to how you feel about those parts of your diabetes that you find more difficult and your self-management?

*Note to interviewer: Prompt for detail on how it has impacted on their psychological well-being, their day-to-day lives, their confidence in managing their diabetes and their relationships with others.*

3. What did you feel were the good bits and the not so good bits of the programme?

*Note to interviewer: Prompt for detail on why they found certain aspects of the programme helpful or unhelpful.*

4. Would you recommend the HeLP-Diabetes programme to a friend with type 2 diabetes?

## **Appendix M: Example of Thematic Analysis**

Extract from Follow-up Interview	Initial Coding	Themes
<p><i>Researcher:</i> Okay. And just with regards to things like – do you remember what drew your interest in first in terms of the sections on the website?</p> <p><i>Participant:</i> Actually, the one thing that really grabbed me was side-effects – I'd never really thought about side-effects, you know.</p> <p><i>Researcher:</i> For the medications?</p> <p><i>Participant:</i> Of medication, but also for just general side-effects of having diabetes. I'd sort of blanked all that out: oh, I'm tough, I can manage; but then when you read about it, and then you think, no, it's a bit scary – I should pay more attention.</p> <p><i>Researcher:</i> Okay. So, yes, so it was something that you were a bit... that you weren't so aware of with the side-effects?</p> <p><i>Participant:</i> Well, I think I'd put it to, about rest, so something I wasn't aware of is that I really didn't know that being constantly exhausted was part of diabetes; no one ever told me about. Because I've told everybody – when I was at [hospital], when they checked me regularly – I'd say, why do I feel like hell every day, and I...? No one ever told me. Now I see it in black and white, I know there's a reason for it, it's so much better.</p> <p><i>Researcher:</i> I see, okay. So to read that, kind of, can you tell me a bit more about the impression it made on you?</p> <p><i>Participant:</i> Well, now I know why! All this time I was wondering why. When I know why, somehow it seems all right suddenly. I know why I feel like hell every day. I get up in the morning sometimes and I put one foot in front of the other and I say, no, I just can't face this, I go back to bed! I'm that exhausted, and that's after 12 hours' sleep sometimes. So I don't know now... and then the emphasis on exercise - I... that made me... I haven't yet, but that's been various other reasons, because my knee still hurts. But, yes, I will try. It's reminded me that exercise is as important as anything. And I have lost a few pounds.</p>	<p>New information about diabetes</p> <p>Increased awareness of health risks</p> <p>Comforted by new knowledge</p> <p>New awareness around diabetes</p> <p>New attitude to exercise</p> <p>Increase motivation</p>	<p>Better informed and more aware</p> <p>Taking diabetes more seriously</p> <p>Better informed and more aware</p> <p>Better informed and more aware</p> <p>Changes to exercise</p>

## **Appendix N: Respondent Validation E-mail**

Dear X,

I hope this e-mail finds you well.

As I mentioned in our final meeting, I am getting in touch with a brief summary of the findings from my study. I hope you will find these interesting and I also wondered if you would be kind enough to give me some feedback on them. I would very much appreciate it if you could read through the following summary and then send me a quick e-mail in the next week, to let me know if you think it accurately captures your own experience of diabetes and the HeLP-Diabetes programme or not. If it does not capture your experience well, it would be very helpful to know where it seems inaccurate, or what might be missing.

Just as a reminder, the study was primarily interested in whether the HeLP-Diabetes programme had any impact on people's emotions. In our initial meeting, before using the website, you shared your experiences of living with diabetes and your hopes for the website. In our follow-up meeting, after using the website, you told me what you thought of HeLP-Diabetes and whether it had been helpful or not.

The information that each of the participants shared in the interviews was extremely helpful and interesting. The results reflect experiences that were described many times by various participants. They therefore don't intend to represent everyone's individual views but are instead a summary of common experiences.

### **Results from the Initial Interviews**

In our first meeting, I asked you describe some of the main difficulties that you experience in relation to your diabetes. These difficulties were divided into three broad categories: 'Impact on Emotional Well-Being', 'Difficulties with Self-Management' and 'Social Pressures and Impact on Social Roles'.

Within the 'Emotional Well-being' category, difficulties included worrying about long term complications and side effects of medications. Study participants also spoke about experiencing anger due to their diabetes and feeling self-critical about being unable to meet all the demands of their diabetes self-management. Another common theme was the dilemma of wanting to live 'normally' (e.g. eating sugary foods) but realising how this could negatively impact their diabetes.

In the 'Difficulties with Self-Management' category, the challenges that were most commonly described included having battles with weight and eating; having difficulties controlling blood sugar levels; experiencing a lack of control and predictability with regards to the impact of medications and foods; and difficulties in sticking to a healthy regime.

Within the category of 'social pressures and impact on social roles', participants talked about feeling pressure from loved ones to not eat certain foods. Though it was recognised that this pressure was well-intended, it was still a source of irritation. Another common topic was the impact of diabetes on social roles, including roles in people's families, work places and social lives. These roles seemed to be limited or made more challenging in various ways by diabetes.

As well as asking about experiences of diabetes in the initial interview, I also asked about hopes for the HeLP-Diabetes programme. The most common hopes that

were described were as follows: 1) changing diet and losing weight; 2) changing level of exercise; 3) help with moods; 4) learning from other people with diabetes; and 5) wanting to learn more about diabetes.

### **Results from the Follow-Up Interviews**

After approximately six weeks of using the HeLP-Diabetes programmes, we did a follow-up interview to discuss your views of the website. Participants described both positive and negative experiences of using the programme. The positive outcomes were divided into 'Emotional' and 'Behavioural' categories.

In the 'Positive Emotional Outcomes' category, people described feeling better informed and more aware of their diabetes since using the website. They also felt like they were taking their diabetes more seriously and had an increased sense of control and confidence over their condition. Many participants felt that the website had helped them to improve their management of their worries and low mood. An aspect of the website that seemed to be particularly helpful for many people was hearing about other people's experiences of diabetes and gaining a sense of support from the website.

In the 'Positive Behavioural Outcomes' category, participants described noticing improvements in their eating habits, the amount of exercise they were doing and various other aspects of their diabetes self-management.

The most common negative experiences that were described by participants were: 1) feeling guilty about not using the website; 2) experiencing technical frustrations; 3) not perceiving any changes to certain aspects of their diabetes related behaviours; 4) not feeling able to relate to the experiences of others with diabetes on the website; and 5) not finding the information on the website to be new or helpful.

I hope you found the results interesting. It would be really helpful if you could drop me a very quick email me **before Mon 26th May** to let me know if you feel the above summary accurately captured your experiences or not.

Finally, I would like to say another big thank you for taking part in the study. Your time and willingness to share your experiences were greatly appreciated. I will be handing in my thesis in just over a month and then will be writing up my study for publication over the summer.

Thanks also, in advance, for your feedback on the above summary!

Best wishes,

Megan Cockburn

HeLP-Diabetes Researcher